

Blood Transfusion LIMS

LIMS

VALIDATION

PLAN

Validation/Verification Plan Prepared by:

Date:

I recommend approval of this validation/verification plan:

***Name:***

***Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Date****\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Blood Sciences Laboratory Manager/Quality Manager/Deputy*

# Purpose and scope

## 1.1 Introduction

This document details the validation requirements for the Blood Transfusion LIMS procured as part of the EPR system. The current LIMS has been in use at the Trust for over X years and has had multiple upgrades to produce a robust and safe system for the control and issue of blood components and products. The LIMS is being replaced as part of the EPR installation process and the purpose of the validation is to ensure that the LIMS is fit for purpose.

EPR provides a total electronic system for patient records and a LIMS for pathology, but does not provide a LIMS solution for blood transfusion. EPR offers a restricted selection of transfusion LIMS that can be interfaced to the EPR system. In addition, the Trust has implemented an electronic blood tracking system for control and administration of blood components and products, the transfusion LIMS must also interface to this system.

The Trust has selected the LIMS following a closed tender process.

All validation will be performed in the test LIMS system interfaced to the test systems provided by the EPR and Electronic blood tracking system.

Data from the legacy system will be transferred to the LIMS system by a third party, using legacy LIMS extracts created by the third party company. The information transferred will include all data relating to living patients. Data pertaining to deceased patients will be retained in the legacy system, access to this system will be available in perpetuity and the system will be maintained by the Trust IMT department.

To support blood ordering and sample taking in the EPR system, an electronic blood tracking system upgrade is required, from the current version, X.0 to X.1 validation of these upgrades will be performed in parallel with the LIMS validation using Electronic blood tracking revalidation scripts

## 1.2 Goals

Confirmation that the blood transfusion LIMS performs in accordance with the specification requirements (see appendix A)

Confirmation that the interfaces function in accordance with the specification requirements:

Electronic blood tracking

EPR

NPeX

GP Order Comms

Analyser and middleware

PAS feed

Confirmation that data cleansing and transfer of information from the legacy system has been successful

* All patient demographics
* All patient history records
* All testing and component/product issue/transfusion information
* All antigen negative flags
* All antibody positive results and antibody specificity, where relevant
* All special interest notes (irradiated, bone marrow transplant, solid organ transplant, antigen negative requirements, IVIg requirements, neonatal not requiring compatibility testing, exclusion from 72 hour rule)
* Patient on DARA/genotyping information

## 1.3 Scope

The scope of the validation applies to all aspects of transfusion test requesting, examination procedures, blood component/product issue, blood component/product selection and traceability.

## 1.4 Specific procedures and processes covered

The following SOPs cover the use of the LIMS in transfusion and will be updated as part of the implementation process:

1. X Requesting and request amendment for transfusion tests on IPS
2. X Sample checking and labelling
3. X Validating and authorizing sample results and storage
4. X Input special interest notes and e-issues rules
5. X Blood grouping and antibody testing during pregnancy
6. X Foetal leak investigations
7. X Quantitation of antibodies
8. X ABO and Rh grouping tube technique with centrifugation
9. X ABO & D grouping cards
10. X Rhesus phenotyping cards
11. X gel card antibody screen
12. X Direct antiglobulin test card method
13. X Antibody identification – methods and guidance on interpreting the results
14. X Investigation of suspected transfusion reaction
15. X Weak partial D confirmatory test
16. X Clinical significant blood group antibodies
17. X Referral of samples to the NHSBT
18. X Manual additional red cell phenotyping
19. X Special blood requirements
20. X Procedures for computer failure
21. X Non-emergency red cell issue
22. X Emergency crossmatch
23. X Neonatal blood transfusion
24. X The use of intraosseous samples in emergency situations
25. X Blood transfusion MTO duties
26. X Blood donation traceability
27. X Major incident procedure for blood transfusion
28. X Issuing fresh frozen plasma, cryoprecipitate and Octaplas
29. X Batch products issuing, returning and disposal
30. X Platelet concentrate ordering, issuing and dereservation
31. X Blood components from NHSBT, ordering, stock control, receipt
32. X Dereserving, return and disposal of blood components including NHS credits
33. X Telephone results procedures
34. X Stock entry of batched products, clotting factors and ordering
35. X Blood product recall
36. X Collection of blood from blood issue fridge and delivery
37. X Blood Sciences amended report policy
38. X Reporting Incidents and serious adverse blood reactions and events (SABRE)
39. X Transfusion statistics procedures
40. X NBS blood figures and wastage reporting
41. X Use of Electronic blood tracking
42. X HP-Patch release validation

## 1.5 Assumptions

* Test environments contain identical functionality to the live environments
* For the purposes of this implementation the test environment will become the live environment
* All data relating to validation performed in the test environment will be retained and will be accessible if required.

# Background References

## References to legal documents

Blood Safety and Quality Regulations 2005 (as amended)

Good Practice Guidelines for Blood Establishment Required to Comply with Directive 2005/62/EC (15/02/2018)

## 2.2 References to Guidelines

British Committee for Standards in Haematology (BCSH) Specification, Implementation and Management of Information Technology (IT) Systems in Hospital Transfusion Laboratories <https://b-s-h.org.uk/media/15774/transfusion-jones-specification-implementation-and-management-of-information-technology-systems-in-hospital-transfusion-laboratories.pdf>

MHRA guidance on electronic issue 2010 - <https://www.gov.uk/government/publications/electronic-issue-of-blood-components>

BCSH Guidelines for pre‐transfusion compatibility procedures in blood transfusion laboratories 2013 <https://b-s-h.org.uk/guidelines/guidelines/pre-transfusion-compatibility-procedures-in-blood-transfusion-laboratories/>

BCSH Guideline for blood grouping and red cell antibody testing in

Pregnancy 2013 <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-3148.2012.01199.x>

BCSH Guidelines for validation and qualification, including change control, for hospital transfusion laboratories 2012 <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-3148.2011.01124.x>

MHRA GXP Data Integrity Guidance and Definitions; Revision 1: March 2018

BCSH Administration of blood components 2017 <https://b-s-h.org.uk/guidelines/guidelines/administration-of-blood-components/>

*BCSH Use of platelet transfusions 2016* [*https://b-s-h.org.uk/guidelines/guidelines/use-of-platelet-transfusions/*](https://b-s-h.org.uk/guidelines/guidelines/use-of-platelet-transfusions/)

*BCSH Red cell transfusion in sickle cell disease (part I and part ii)* [*https://b-s-h.org.uk/guidelines/guidelines/red-cell-transfusion-in-sickle-cell-disease-part-ii/*](https://b-s-h.org.uk/guidelines/guidelines/red-cell-transfusion-in-sickle-cell-disease-part-ii/) *and* [*https://b-s-h.org.uk/guidelines/guidelines/red-cell-transfusion-in-sickle-cell-disease-part-l/*](https://b-s-h.org.uk/guidelines/guidelines/red-cell-transfusion-in-sickle-cell-disease-part-l/)

*BCSH Transfusion of foetuses, neonates and older children 2016* [*https://b-s-h.org.uk/guidelines/guidelines/transfusion-for-fetuses-neonates-and-older-children/*](https://b-s-h.org.uk/guidelines/guidelines/transfusion-for-fetuses-neonates-and-older-children/)

*BCSH Blood grouping and antibody testing in pregnancy 2016* [*https://b-s-h.org.uk/guidelines/guidelines/blood-grouping-and-antibody-testing-in-pregnancy/*](https://b-s-h.org.uk/guidelines/guidelines/blood-grouping-and-antibody-testing-in-pregnancy/)

*BCSH Haematological management of major haemorrhage 2015* [*https://b-s-h.org.uk/guidelines/guidelines/haematological-management-of-major-haemorrhage/*](https://b-s-h.org.uk/guidelines/guidelines/haematological-management-of-major-haemorrhage/)

*BCSH Spectrum of fresh frozen plasma and cryoprecipitate products 2018* [*https://b-s-h.org.uk/guidelines/guidelines/spectrum-of-fresh-frozen-plasma-and-cryoprecipitate-products/*](https://b-s-h.org.uk/guidelines/guidelines/spectrum-of-fresh-frozen-plasma-and-cryoprecipitate-products/)

*BCSH Use of anti-D for the prevention of haemolytic disease of the fetus and newborn 2014* [*https://b-s-h.org.uk/guidelines/guidelines/use-of-anti-d-immunoglobin-for-the-prevention-of-haemolytic-disease-of-the-fetus-and-newborn/*](https://b-s-h.org.uk/guidelines/guidelines/use-of-anti-d-immunoglobin-for-the-prevention-of-haemolytic-disease-of-the-fetus-and-newborn/)

*BCSH Management of anaemia and red cell transfusion in adult critically ill patients 2012* [*https://b-s-h.org.uk/guidelines/guidelines/management-of-anaemia-and-red-cell-transfusion-in-adult-critically-ill-patients/*](https://b-s-h.org.uk/guidelines/guidelines/management-of-anaemia-and-red-cell-transfusion-in-adult-critically-ill-patients/)

*BCSH Investigation and management of acute transfusion reactions 2012* [*https://b-s-h.org.uk/guidelines/guidelines/investigation-and-management-of-acute-transfusion-reactions/*](https://b-s-h.org.uk/guidelines/guidelines/investigation-and-management-of-acute-transfusion-reactions/)

*BCSH Use of irradiated blood components 2010* [*https://b-s-h.org.uk/guidelines/guidelines/use-of-irradiated-blood-components/*](https://b-s-h.org.uk/guidelines/guidelines/use-of-irradiated-blood-components/)

*BCSH Estimation of fetomaternal haemorrhage 2009* [*https://b-s-h.org.uk/guidelines/guidelines/the-estimation-of-fetomaternal-haemorrhage/*](https://b-s-h.org.uk/guidelines/guidelines/the-estimation-of-fetomaternal-haemorrhage/)

*NICE Guidance Routine antenatal anti-D prophylaxis for women who are rhesus D negative 2008* [*https://www.nice.org.uk/guidance/ta156/chapter/1-Guidance*](https://www.nice.org.uk/guidance/ta156/chapter/1-Guidance)

*NICE Guidance Blood Transfusion 2015* [*https://www.nice.org.uk/guidance/ng24*](https://www.nice.org.uk/guidance/ng24)

*JPAC Guidelines for the blood transfusion services in the UK* [*https://www.transfusionguidelines.org/red-book*](https://www.transfusionguidelines.org/red-book)

## 2.3 References to other documents

2.3.1 BSI standards publication - Medical laboratories —Requirements for quality and competence (ISO 15189:2012)

2.3.2 TRUST Transfusion LIMS specification document (stored in HITREQVAL0132 on Q-Pulse)

2.3.3 TRUST change control document BTCC0132

2.3.4 SLA for management of the transfusion LIMS - between TRUST IMT department and TRUST blood transfusion department.

2.3.5 Supplier user guides

2.3.6 Electronic blood tracking user guides

2.3.7 HITREQVAL0139 HIT-FORM- Electronic blood tracking re-validation – this document will cover the validation of the interface between the LIMS and Electronic blood tracking system. All evidence pertaining to this phase of the validation will be retained within HITREQVAL0139. Electronic blood tracking system will be released into the live environment at the same time as the LIMS system. If either systems encounter issues during the validation period which result in delays in go-live then both systems will be delayed. Electronic blood tracking system upgrade will not be validated against the legacy LIMS interface and can, therefore not be released whilst IPS is still in operation.

2.3.8 Analyser and middleware user guides

2.3.9 Legacy LIMS user guides and data migration information

# Definitions and acronyms

LIMS – laboratory information management system

EPR – electronic patient record

SOP – standard operating procedure

BSQR – blood safety and quality regulations

MHRA – medicines and healthcare products regulatory agency

UKAS – United Kingdom accreditation service

BCSH – British committee for standards in haematology

ISO – international organization for standardization

GP order comms – general practitioner order communication system

IMT – information, management and technology

SLA – service level agreement

PC – personal computer

KPI – key performance indicator

SME – subject matter expert

NHSBT – National Health Service Blood and Transplant

CMV – Cytomegalovirus

EQA – external quality assurance

IQC – internal quality control

# System definition and description

The system to be validated is a laboratory information management system designed for use in a hospital blood transfusion laboratory.

The system includes all management of transfusion information required from request in the EPR or GP order comms system through to release of test results and/or fating of blood components/products for traceability processes. Detailed aspects of the information entered and retained in the system are documented in appendix A, the validation requirements and evidence documents and in the transfusion LIMS specification document.

The system includes software to be hosted on the TRUST servers allocated for this purpose by the TRUST IMT services department, as included in the EPR implementation project.

The system includes hardware in the form of PCs and printers to be installed and tested in the transfusion laboratory by the TRUST IMT department.

# System maintenance and support strategy

The system software will be maintained via a service contract with the supplier, this will include:

Fault resolution

Upgrades, including patches for identified critical issues and regular planned upgrades

Release notes for all upgrades

Access to helpdesk for fault reporting, tracking and resolution

Disaster recovery

Business continuity

The host servers and hardware (PCs and printers) will be supported by the TRUST IMT department in accordance with the SLA.

The performance of the system will be monitored via agreed key performance indicators monitored by the supplier and the TRUST transfusion management team. The KPIs will be defined in the contract drawn up by the TRUST procurement and purchasing department.

# Validation/verification approach

## 6.1 Schedule

August 2019 – test system to be installed on the TRUST host servers

November 2019 – validation of test system to be commenced by TRUST transfusion management team

November 2019 – February 2020 – validation of system, identification and resolution of non-any identified compliances

March 2020 – live system to be installed on the TRUST host servers

May 2020 - planned go-live of system for live testing and use prior to EPR implementation, linked to test EPR system

June 2020 – live LIMS system to be linked with live EPR system, critical functions to be re-validated at go-live

Update 28/04/2020: Live LIMS planned for July 2020

## 6.2 Resource summary

Costs for installation of the system and interface to EPR test and live systems will be met by the EPR project funding stream.

Costs for interface between LIMS and transfusion analysers will be met by the EPR project.

Costs for interface between LIMS and GP order comms will be met by the GP order comm project funding stream.

Costs for interface between LIMS and NPeX will be met by the Blood Sciences budget.

Costs for reagents and consumables will be minimal as test results will be entered into the system manually with no testing wherever possible. For interface testing results from live testing will be used and transferred into the test LIMS system. When this is not possible the funding for any testing will be met by the transfusion budget.

Staff costs will be met by the EPR SME funding stream, as agreed by the Diagnostics Directorate. Staff time required for testing and validation purposes will be backfilled via this funding stream.

Costs for any development work required for the system to meet the specification requirements, within the scope of the contract, will be met by the supplier.

## 6.3 Responsibilities

Blood Sciences Laboratory Manager – responsible for approval of validation plan and confirmation of completion of change control actions.

IMT project manager for EPR implementation – responsible for project management of IMT and EPR related aspects of the validation.

Blood Sciences Quality Manager – responsible for project management of the validation process and liaising with supplier throughout the validation period.

Transfusion Manager– responsible for performing aspects of validation and producing the validation summary report.

Blood Sciences Laboratory Manager – responsible for review and approval of the validation summary report

## 6.4 Method of validation/verification

The number of samples, requests, blood component/product issues to be tested is detailed in the validation requirements in appendices and is dependent on the task under validation. The numbers chosen are considered to be representative of the quantity required for assurance that the system can successfully complete the task.

Where appropriate the system will be challenged with relevant scenarios as detailed in the appendices. This is particularly relevant to critical functions including, but not limited to:

* prevention of issue of ABO incompatible red cells via laboratory, e-issue or remote allocation
* management of issue of blood components to patients with special requirements, such as irradiated and CMV negative
* management of the issue of blood components based on; age, gender, antigen negative requirements, ABO group and RhD group
* interpretation of blood groups and antibody screens from raw data transferred from the transfusion analyser system
* interpretation of blood groups and antibody screens input from manual tests
* transfer of blood component information via the NHSBT electronic delivery note
* management of blood component and product stocks
* compatibility with the Electronic blood tracking system
* functionality of interfaces; Electronic blood tracking system, EPR, GP order comms and NPeX

Any discrepancies identified during the validation testing period will be escalated to the supplier for investigation and resolution. In the event that a resolution cannot be achieved prior to go-live a workaround may be agreed between the supplier and the TRUST. This will be subject to acceptable risk assessment and dependent on the criticality of the deficiency/discrepancy, this will be reviewed on an individual basis.

The testing detailed in the scripts is the minimum requirement for testing, wherever possible additional testing should be performed. The scripts can be expanded to include the details of additional testing undertaken, evidence of additional testing must be documented in the scripts.

Where scripts have been created but are no longer relevant to the scope of the LIMS, this must be clearly marked on the scripts, including the reason why testing is no longer relevant. Scripts must not be deleted and no sections of the scripts can be left blank.

Whenever discrepancies or problems arise, these must be escalated immediately to the blood sciences quality manager for investigation.

## 6.5 Validation/verification of IT systems

The interfaces will be tested in relation to their functionality. The interface between the transfusion analyser and the LIMS will be tested using every test permutation currently sent from the analyser. The number of permutations of test requests and blood component/issues that are transmitted through other interfaces, EPR, GP order comms and NPex, are too large to be tested exhaustively, therefore assumptions may be made based on the type of test or type of component/product. Where assumptions are made this will be clearly noted in the validation summary.

The following computer systems will be checked as part of the validation to ensure that correct requests, tests, components/products and results have been transmitted:

EPR

Transfusion analyser middleware

GP order comms

NPeX

Electronic blood tracking

PAS feed

# Implementation strategy

* 1. The intention is to implement the LIMS prior to the EPR implementation to allow for live testing in a controlled environment with skilled and knowledgeable laboratory staff able to feedback on any deficiencies or discrepancies that may not have been identified during the validation period. This will provide an opportunity to resolve issues prior to EPR implementation. It is accepted that the LIMS will not be linked to live EPR for test requesting or component/ordering purposes at this time and these functions will be performed manually by the laboratory staff during this interim period.
  2. Training for laboratory advanced users, named individuals, will be performed by the supplier. Training for all other laboratory staff who will interact with the system will be provided by the supplier and/or the laboratory advanced users. All laboratory staff will be provided with full training prior to using the system and prior to lone working with the system. All laboratory staff will be given relevant training on the linked aspects of the LIMS; EPR, NPeX and GP order comms. Competency assessments will be created by the transfusion laboratory management team in conjunction with the supplier. All laboratory staff will be competency assessed in using the system and the interfaces. The laboratory management team and the supplier will provide 24/7 help and support for a defined period after go-live until all staff are competent and confident in using the system.
  3. Contingency plans will be provided during the initial go-live period to ensure that urgent transfusions are not delayed due to laboratory staff unfamiliarity with the new system. The clinical users will be made aware that a new system is being implemented but there is no requirement for clinical users to have training or access to the system.
  4. During this implementation period the clinical users will not have access to transfusion results on IPS. It is accepted that this is a low risk, currently users do not regularly access IPS for transfusion results but are reliant on Electronic blood tracking and paper reports for information relating to transfusion results. During the interim period, when results are unavailable a printed copy of the results will be produced from the LIMS.

# Training requirements related to responsibilities

* 1. List of staff to be trained will be compiled prior to training, a copy of the signed staff training record will be retained with the validation records on Q-Pulse
  2. Use of the LIMS will be included in the blood transfusion competency assessment scheme and assessment will be completed on an annual basis in accordance with laboratory practice.

# Appendices

* 1. Appendix A: Validation requirements and scripts
  2. Appendix B: Supplier installation and operational qualification documents
  3. Appendix C: Supplier installation and implementation plan
  4. Appendix D: Supplier training plan

N.B. 9.2-9.4 ARE not provided in this document, but required for your own validation

# APPENDIX A: VALIDATION OF TRANSFUSION LIMS SOLUTION FOR X NHS FOUNDTION TRUST

Note to supplier:

This validation plan is a living document and may be subject to change during the validation period in the event of changes to national standards or recommendations. Any changes will be discussed and agreed with the supplier.

It is accepted that the LIMS may not comply with all aspects of the validation plan upon installation. Where aspects of non-compliance are identified the criticality of the non-compliance will be determined by the TRUST laboratory management. The supplier will be expected to work with the laboratory to resolve the non-compliance(s) in a time frame that is reasonable with respect to the criticality and agreed between both parties.

In the event that the LIMS must be approved into use with outstanding non-compliances, workarounds must be implemented and agreed by both parties. The workarounds must be risk assessed by TRUST and the resolution(s) time frames must be reasonable with respect to the criticality and agreed between both parties. The resolution actions must be recorded on DATIX as part of the risk assessment to allow transparency for Trust senior management.

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| --- | --- | --- | --- | --- |
| **Number** | Requirement | **Evidence requirement** | **Validation passed** | **Date and initials of tester** |
| **1** | Essential System Requirements |  |  |  |
| 1.1 | There must be a bidirectional interface between the LIMS and any analytical system within the transfusion laboratory. | Interface visible in LIMS  Status of interface visible in LIMS (active or inactive)  Transfer of normal and abnormal results  Transfer of result edited in the analyser system is transferred to LIMS and visible as edited (excluded from e-issue) |  |  |
| 1.2 | There must be a bidirectional interface between the LIMS and the Electronic blood tracking system | Interface visible in the LIMS  All products:  Transfer of blood component/product from LIMS to Electronic blood tracking  Storage location is mirrored in LIMS and Electronic blood tracking  Move out status is mirrored in LIMS and Electronic blood tracking  In transit status mirrored in LIMS and Electronic blood tracking  Arrival status is mirrored in LIMS and Electronic blood tracking  Transfused status (from begin or end transfusion) is mirrored in the LIMS and Electronic blood tracking  Return to storage is mirrored in LIMS and Electronic blood tracking  Return to stock is mirrored in LIMS and Electronic blood tracking  Audit trail of all transactions are mirrored in LIMS and Electronic blood tracking |  |  |
| 1.3 | There must be a bidirectional interface between the LIMS and the electronic ordering system/electronic patient record. | Interface visible in LIMS  Status of interface visible in LIMS (active or inactive)  Orders transmitted from EPR to LIMS for:  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Praxbind (or equivalent)  Urgency of order transmitted to LIMS, as specified in EPR  Date/time component/product required is transmitted to LIMS, as specified in EPR  Patient details transmitted to LIMS, as specified in EPR:  Surname/forename  DoB  Hospital number  NHS number  Gender  Location for transfusion  Reason for request transmitted to LIMS, as specified in EPR and in accordance with national request codes (specified in appendix 1)  Volume of product required, dependent on component/product transmitted to LIMS:  Number of whole units  Numbers of mls (for paediatric/neonatal)  Volume in IU  Volume in grams  Identification of requestor transmitted to LIMS  Date/Time of request transmitted to LIMS  Reason for request override, if applicable, transmitted to LIMS  Availability of components/products once issued by the lab is visible on EPR associated with patient record:  Type of component/product  Volume IU/grams  Dereservation date  Location of component/product  Alert generated by EPR to ward/location that component/product is ready |  |  |
| 1.4 | There must be a bidirectional interface between the LIMS and the referral system (NPEx) | Interface visible in LIMS  Status of interface visible in LIMS (active or inactive)  Request transmitted to NPEx:  Patient details  Test details  Urgency  Identification of referral centre  Results/report received from referral centre via NPEx and transmitted to LIMS:  Patient record updated  Test results/report input to patient record  Date/Time results received  Report identified as processed by referral centre |  |  |
| 1.5 | The LIMS will need to be able to communicate with the PAS, Electronic Request Systems (Order Comms- EPR), Electronic Blood Administration (tracking) Systems (Electronic blood tracking ), Electronic Delivery Note (EDN NHSBT) and other hospital systems. Electronic Data Interchange (EDI) is the term used to describe the structured messages and protocols used for such communications in a way that the receiving system can correctly interpret the value, meaning and context of the information sent from the transmitting system. Required EDI functionality should be identified, and EDI standards that are used within the national and local healthcare IT environment should be specified. | LIMS interfaced to all appropriate external systems:  EPR  NPEx  Electronic blood tracking  Beaker |  |  |
| 1.6 | Interfaces between computer systems, in particular between the PAS and LIMS must be configured and validated to ensure compatibility between the information formats used by each system. (NCA 2011) | As demonstrated by above requirements |  |  |
| 1.7 | To ensure running security and performance, supplier must state:   * number of concurrent users allowed on system at any one time; * maximum transaction rate to be supported; * resilience to single point of failure. | Must support minimum number of concurrent users – 30  Maximum transaction rate achieved as detailed by supplier  Test resilience to single point of failure:  Access to supplier for fault resolution  Contingency for Electronic blood tracking downtimes  Contingency for EPR downtime  Back up servers available and functioning |  |  |
| 1.8 | The system must support multiple environments with a minimum of two environments to allow a separation of live and validation/training environments.  Each environment must be completely independent and must be kept fully updated in parallel with the live system.  The supplier must specify the number and type of environments supplied | Live system available and functioning  Test system available and functioning  Confirmation of requirement and provision for updates to both systems to allow mirroring  Confirmation of server requirements for both systems to function concurrently |  |  |
| 1.9 | Data migration is the transfer of essential information (data) from an existing to a replacement system. It will be necessary to migrate the following data to the new system:  ● legal requirement (e.g. traceability as defined by the BSQR 2005 (as amended) in terms of the final fate of all components, including transfused, disposed);  ● operational requirements e.g. historic group, antibody information, special requirements  The supplier must confirm that migration of data is possible and detail how this will be achieved  Retaining operational data on a legacy system that is not electronically linked to the operational system (i.e. interrogating a separate database which is a manual step), is not acceptable for maintaining patient safety within the transfusion laboratory. | Confirmation that the IPS LIMS has been searched for duplicate records and these resolved before legacy data is transferred.  Data migration must include at a minimum:  Most recent group and screen results (going back to 1995)  Date of most recent group and screen result  Details of any positive antibody screens since 1995  Identification of any antibody specificities  cffDNA RhD result relating to any current on-going pregnancy  Any special requirements linked to patient:  Irradiated  CMV neg  HLA matched  HPA matched  Any antigen negative requirements attached to patient record  Any phenotype results attached to patient record  Any special notes attached to patient record:  IVIg type and dose  Bone marrow transplant information  Maternal information for neonatal transfusion purposes  Genotypes from IBGRL |  |  |
| 1.10 | Supplier must state how non-essential data will be retained and must be searchable, state how this will be achieved  The same data security controls must be applied to the archived data | Confirm access to legacy system for data not captured above  Confirmation of password access:  Current password  Process for accessing the data once the current password has expired |  |  |
| 1.11 | In order to effectively maintain the legacy system the following requirements will need to be met:  ● adequate backup of the legacy database;  ● ongoing system maintenance contract and licensing;  ● regular start up and running of system;  ● maintenance of staff access to and skills in the use of the system;  ● regular “lookback” validation exercises;  ● regular review to ensure ongoing hardware and software support;  ● planning for ongoing migration or archiving when system can be no longer supported.  Supplier must confirm that all these requirements are met | Confirmation of process for maintaining the database on the servers  Agreement on look back exercises  Agreement with IMT for supporting the legacy system |  |  |
| 1.12 | The maintenance requirements of the new system must include:  ● clear definition of services to be provided;  ● responsibilities and duties of the hospital transfusion laboratory (customer);  ● responsibilities and duties of the hospital IT department;  ● responsibilities and duties of the system supplier;  ● key Performance Indicators (KPIs);  ● problem management procedures;  ● disaster recovery.  ● definition of service period and termination of agreement;  ● warranties;  ● review periods.  Supplier must confirm that requirements are met and provide details of these arrangements | SLA review and agreement with IMT (see separate SLA document) |  |  |
| 1.13 | The supplier must provide change management procedures; release notes must be supplied in a timely manner to allow for validation of the changes in the test system prior to release into the live system | Confirmation for supply of release notes and time frame:  3 month time frame for validation purposes  Date that upgrade will be applied to the test system  Agreement that upgrade will not be applied to the live system until validation passed and approved by RDE |  |  |
| 1.14 | All upgrades to the system must be supplied free of charge | Confirmation only required |  |  |
| **2** | Stock Management |  |  |  |
| 2.1 | It is a requirement of the Blood Safety and Quality Regulations (as  amended) (BSQR 2005) and the EU Directive 2001/83/EC (EU 2001) that records are retained allowing tracing of all components and products from source to recipient or final fate and vice versa.  The system must support fating of units electronically via the Electronic blood tracking system | Fate of all component/product received from Electronic blood tracking to LIMS:  Patient identification correct  Fate correct:  Returned to stock  Transfused  Disposed out of temp control  Disposed expired  Disposed broken  Disposed for NHSBT credit  Disposed transferred to another hospital  No fate – test patient  Date/time component/product fated  Fated status of component product visible in audit trail:  Patient enquiry  Component/product enquiry  All transactions, storage locations visible in audit trail from receipt in lab to final fate:  Component/product enquiry  Patient enquiry  Identification of any cold chain excursions visible in audit trail:  Component/product enquiry  Patient enquiry  Including any actions taken/comments  For components/products that have been returned to stock for re-use the audit trail must clearly show that component/product not fated for the patient involved in the return to stock transaction  For transfused components/products the fate must only be attached to the transfused patient record and not show as transfused for any other patients that may have previously been assigned the component/product |  |  |
| 2.2 | The system must hold a local reference table of blood components and batch products in which label barcodes are associated with descriptions and internal codes. | Reference table matches that provided by:  NHSBT for all blood components  Lyoplas  Octaplas  Albumin suppliers  IVIg suppliers  Anti-D suppliers  Factor concentrate suppliers  Others (state or evidence in validation file) |  |  |
| 2.3 | There must be the facility to update this table to allow for new components and products to be added by appropriately authorised personnel. | Confirmation that the table can be updated:  Update applied and visible  Current components/products can be updated with audit trail of update:  Previous data accessed  Identification of user applying update  Date/time of update  Confirmation that updates can only be applied by authorised personnel with appropriate access rights  Confirmation that updates cannot be applied by authorised personnel with inappropriate access rights |  |  |
| 2.4 | The system must be able to receive blood components labelled from any of the UK Blood Establishments and other products as defined by the users. | Confirmation of components/products supplied by:  NHSBT  CSL Behring  Baxter  BPL  Grifols  Bayer  Pfizer  Octapharma  Biotest  Alloga  Healthcare at Home  DRK Blutspendedienst  Sobi  Praxbind |  |  |
| 2.5 | For cells and tissues imported from outside the UK there should be a procedure on entering information into the LIMS to ensure the donor/patient traceability chain is maintained | Confirmation that autologous stem cell harvests can be entered into the LIMS:  ISBT128 compliant label (unique product number, product code, product split number and expiry date)  Date/time entered into LIMS  Identification of individual entering product to LIMS  Issue of stem cells to patient:  Patient details (surname, forename, DoB, hospital number, NHS number  Audit trail of all transactions and storage locations from Electronic blood tracking :  Issue by lab  Move out  Arrival  Transfused (begin and end transfusion)  Returned to stock  Disposed  Ability to enter the above details manually if not performed in Electronic blood tracking  Ability to access audit trail:  Component enquiry  Patient enquiry |  |  |
| 2.6 | It must be possible to configure the LIMS to take specific actions, based on user defined stock levels, for each blood component and batch product.  Actions may include: providing warnings when stock falls below minimum  levels; generating advisory reorders; or initiating automatic reordering.  The supplier must detail how this is achieved | Confirmation that minimum stock levels can be set for components/products  Confirmation that warnings are generated when stock level hits minimum level  Generation of product order form  Ability to interface with VMI to re-order with NHSBT |  |  |
| 2.7 | The system must support the NHSBT Electronic Delivery Note (EDN) system through the Electronic blood tracking system. | Confirmation that LIMS will accept EDN via Electronic blood tracking  Confirmation of successful transfer of all information from EDN to LIMS for at least:  20 red cell units  20 FFP units  10 cryo units  10 platelet units  Confirmation that component details on EDN match in LIMS:  Antigen negative  Antigen positive  Volume  Component type (including irradiated, neonatal)  Expiry date  Special testing (CMV neg, HbS neg)  Date bled (draw date)  Cost |  |  |
| 2.8 | The system stock inventory and ordering system must be configurable to support stock levels of different antigenic phenotypes (e.g. stock target of 6 group O R1R1, 4 group O R1r, 2 group O R2r etc).  Please state how this is achieved | Confirmation that inventory matches:  6 group O R1R1 (cEK neg)  4 group O R1r (EK neg)  2 group O R2r (CK neg)  2 group O R2R2 (CeK neg)  6 group A R1R1 (cEK neg)  4 group A R1r (EK neg)  2 group A R2r (CK neg)  2 group A R2R2 (CeK neg)  4 group O irradiated R1R1 (cEK neg)  4 group A irradiated R1R1 (cEK neg)  2 AB Pos  2 AB Neg  2 B Pos  2 B Neg  Confirmation of alert when stock reaches set lower limit for all above targets |  |  |
| 2.9 | A secure method of input is required to ensure the correct information regarding each component and batch product is held within the LIMS.  The LIMS must allow for storage of the following minimum information for  each unit:  · donation number;  · ABO and D group (where supplied);  · component/product code, including division numbers, as provided by the supplier;  · expiry date;  · expiry time (where appropriate);  · date and time of receipt into the laboratory and /or time booked into the  LIMS;  · source of component (from a Blood Establishment, external supplier or transferred from another hospital). | Confirmation of each information status:  · donation number;  · ABO and D group (where supplied);  · component/product code, including division numbers, as provided by the supplier;  · expiry date;  · expiry time (where appropriate);  · date and time of receipt into the laboratory and /or time booked into the  LIMS;  · source of component (from a Blood Establishment, external supplier or transferred from another hospital)  Component type:   * Pooled * Apheresis * Additive solution * Methylene blue treated * Solvent detergency treated |  |  |
| 2.10 | The LIMS must also allow for the following component characteristics to  be retained against the component (all attributes as detailed in the EDN):  · antigen typing;  · Cytomegalovirus (CMV) antibody status;  · gamma/Xray Irradiation;  · Hb S status;  · high titre flags;  · volume;  · comment field. | Confirmation that following information is retained in the LIMS assigned to the individual unit (for at least 20 units of red cells, FFP, cryo and platelets) :  · antigen typing;  · Cytomegalovirus (CMV) antibody status;  · gamma/Xray Irradiation;  · Hb S status;  · high titre flags;  · volume (test 10 adult units and 5 neonatal units);  · comment field. |  |  |
| 2.11 | The system must record if the above information was received electronically or entered manually. | Confirmation that audit trail on the unit identifies fields that are input manually (test at least 10 red cells, FFP, cryo and platelets):  donation number;  · ABO and D group (where supplied);  · component/product code, including division numbers, as provided by the supplier;  · expiry date;  · expiry time (where appropriate);  · date and time of receipt into the laboratory and /or time booked into the  LIMS;  · source of component (from a Blood Establishment, external supplier or transferred from another hospital)  Component type:   * Pooled * Apheresis * Additive solution * Methylene blue treated * Solvent detergency treated   · antigen typing;  · Cytomegalovirus (CMV) antibody status;  · gamma/Xray Irradiation;  · Hb S status;  · high titre flags;  · volume (test 10 adult units and 5 neonatal units;  · comment field. |  |  |
| 2.12 | The LIMS must support the current UK combinations of ISBT 128 and codabar labelling systems and be future proofed for potential full implementation of ISBT128 and the introduction of two-dimensional Data Matrix codes. | Confirmation using Lyoplas and Octaplas barcodes (ISBT128):  Unique product number  Unique product code  Blood group  Expiry date  Confirmation using Autologous Stem Cell Harvest units (if available)  Unique product number  Unique product code  Blood group  Expiry date  Confirmation from supplier for two-dimensional Data Matrix codes. |  |  |
| 2.13 | Electronic dispatch notes (EDN) meeting the standardised specification written by Standing Advisory Committee for Information Technology (SACIT)(MacLennan 2013) are available from UK Blood Services. The LIMS must be capable of supporting the EDN | Confirmation that LIMS has met item 2.7 |  |  |
| 2.14 | When the delivery is received at the hospital each component received must be reconciled to the information captured from the EDN. This can be achieved by scanning the relevant pack barcodes, e.g. donation number and component type. Other information may be transferred electronically, including additional information such as red cell typing, which may not be barcoded on the label.  Please state how this is achieved | Confirmation that all information from the EDN and the component pack has been reconciled in the LIMS and Electronic blood tracking (see item 2.7) |  |  |
| 2.15 | The LIMS must be able to store this additional information in a manner that can be searched to support selection of appropriate antigen negative units. The search function must support search by:  • Location  • ABO group  • RhD group  • Antigen negative attribute (when searching for units that are negative for multiple antigens the search must be based on “and”, not “or”)  • Status (free or allocated to patient) | Confirmation that the search function supports search by (test at least 20 components, red cells, FFP, cryo, platelets):  • Location  • ABO group  • RhD group  • Antigen negative attribute (when searching for units that are negative for multiple antigens the search must be based on “and”, not “or”)  • Status (free or allocated to patient) |  |  |
| 2.16 | For batch products the system must store the following details of the product:  ● date and time of receipt;  ● manufacturer;  ● name of product;  ● batch number (including provision for unique batch number for administration and fating through the Electronic blood tracking system);  ● expiry date;  ● quantity of units received;  ● batch comments, including volume and amount of product/bottle (e.g. IU/mL  or bottle), where appropriate.  •Cost of the product  ● supplier if different to manufacturer;  ● type of product;  ● ABO group (if applicable). | Confirmation that the following information can be input and retained by the LIMS:  ● date and time of receipt;  ● manufacturer;  ● name of product;  ● batch number (including provision for unique batch number for administration and fating through the Electronic blood tracking system);  ● expiry date;  ● quantity of units received;  ● batch comments, including volume and amount of product/bottle (e.g. IU/mL  or bottle), where appropriate.  •Cost of the product  ● supplier if different to manufacturer;  ● type of product;  ● ABO group (if applicable). |  |  |
| 2.17 | In general batch products are only identified by the manufacturer down to the level of batch number. The RDE require allocation of local serial numbers to individual items within the batch to allow full traceability of each item  The unique numbers must be transferrable to the Electronic blood tracking system  Please state how this will be achieved | Confirmation that stock entry of batch products generates a unique number for each bottle  Confirmation that the unique number and product code can be transmitted to Electronic blood tracking  Confirmation that the unique number and product code is searchable on the LIMS:  Free  Allocated to a patient  Returned to stock  Confirmation that the unique number and product code are visible on stock control functions  Confirmation that the unique number and product code transactions are updated on LIMS when transactions and movements occur in Electronic blood tracking |  |  |
| 2.18 | There is an international move towards standard bar coding of plasma derivatives/batch products. Information on this is available from the  supply chain standards organisation GS1.  <http://www.gs1.org/sites/default/files/docs/barcodes/BD_Implementation_Guide_v1_0_24_aug_2010.pdf>  Please state if the solution supports this | Confirmation from the supplier that the LIMS supports this |  |  |
| **3** | Stock Tracking |  |  |  |
| 3.1 | The system must allow the location of stock to be recorded and must support transfer of stock between multiple locations with appropriate audit trails. | Confirmation for following components/products:  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Praxbind (or equivalent)   * stock locations are recorded in the LIMS * stock transfer between stock fridge and batch issue fridge * stock location movements in Electronic blood tracking are mirrored in the LIMS * stock location mirrored in Electronic blood tracking and LIMS post return to stock * audit trail correctly identifies all stock locations during product search (at least 20 products tested using all stock locations in Electronic blood tracking ) * stock for home delivery does not appear in Electronic blood tracking but LIMS must retain home delivery as a location and be visible in audit trail |  |  |
| 3.2 | The LIMS must be able to support electronic  de-reservation of blood components/products and the production of a list of units which are beyond their reservation period.  The dereservation date/time should default to:   * 24 hours from the time that the blood component is required * The date/time that the sample validity ends * Date/time specified by the NHSBT on the product label * A configurable date/time for batch products | Confirmation that the dereservation date/time is set by the LIMS:   * 24 hours from the time that the blood component is required * The date/time that the sample validity ends * Date/time specified by the NHSBT on the product label * A configurable date/time for batch products   Confirmation that the LIMS identifies components/products that are past de-reservation date/time:  Red cells (24 hours)  FFP(24 hours)  Platelets(24 hours)  Cryo(24 hours)  PCC (72 hours)  Albumin (72 hours)  IVIg(72 hours)  Factor concentrate(72 hours)  C1 esterase (72 hours)  Fib concentrate(72 hours)  Granulocyte(72 hours)  Anti-D(72 hours)  Praxbind (or equivalent) (72 hours) |  |  |
| 3.3 | The system must support the recall of units and maintain records of the reason and any incidents related to the component/product.  Please state how this is achieved | Confirmation that components/products can be flagged as recalled  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Praxbind (or equivalent)  Confirmation that LIMS retains all recall information as required by HITFORMH  Confirmation that LIMS can generate reports detailing recalls based on:  Date period recall initiated  Component/product involved  Fate of component/product (transfused or retrieved)  Reason for recall  Initiator of recall  DATIX reference number  Confirmation that a recall initiated in the LIMS for a component/product in a remote storage locations results in a quarantine/unusable status in Electronic blood tracking  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Confirmation that batch products involved in recall can be searched on LIMS using the supplier product number (without sequential identifier):  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Anti-D |  |  |
| 3.4 | The system must allow units to be retrieved from being issued/allocated to a patient and returned to the stock of unallocated units. | Confirmation that return to stock function in Electronic blood tracking is transmitted for following products and dissociates component/product from the patient record :  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Confirmation that component/product is returned to correct storage location in LIMS:  Red cells – stock fridge  FFP – stock fridge  Platelets – platelet agitator  Cryo – lab room temp  PCC – stock fridge  Albumin - stock fridge  IVIg- stock fridge  Factor concentrate- stock fridge  C1 esterase - stock fridge  Fib concentrate- stock fridge  Granulocyte lab room temp  Anti-D- stock fridge |  |  |
| 3.5 | Units which are no longer suitable for use (e.g. past their expiry date or out of temperature control) must be blocked from being returned to stock. | Confirmation that following components/products blocked from return to stock if expired or unusable:  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Confirmation that final fate of units is visible in the audit trail |  |  |
| 3.6 | There must be the facility to record the fate of discarded and transferred units. The fate codes should cover (at a minimum):  • Out of temp control  • Expired  • Transferred to another hospital  • Broken by ward  • Broken by lab  • Recall – for re-charge  • NHSBT re-charge | Confirmation that fate codes can be applied to the following components/products:  Red cells  FFP  Platelets  Cryo  PCC  Albumin  IVIg  Factor concentrate  C1 esterase  Fib concentrate  Granulocyte  Anti-D  Confirmation that disposal fate usable for products that are allocated and unallocated to patients  Confirmation that LIMS can generate reports for fated components/products based on :  Ward/location  Final fate  Wastage reason |  |  |
|  |  |  |  |  |
| **4** | Managing the patient record |  |  |  |
| 4.1 | Correct patient demographics are a key feature of any IT system involved in the transfusion process. This applies to the Patient Administration System (PAS), the LIMS, Electronic Blood Administration (tracking) Systems (Electronic blood tracking ) and any electronic communication system (e.g. Order Comms) used to make requests of the transfusion laboratory.  Please state how data integrity is maintained during transfer of information across the systems | Confirmation that correct patient information is transferred to the LIMS from EPR blood ordering system for at least 20 patients:  Surname  Forename  DoB  NHS number  TRUST number  Address (if applicable)  Patient location  Consultant  Special requirements  Gestation age for antenatal patients  Test(s) required  Date/time for transfusion requests  Location for transfusion  Type of component/product required  Number/volume of component/product required  Urgency of request  Confirmation that correct patient information is transferred to the LIMS from Electronic blood tracking system for at least 20 patients:  Surname  Forename  DoB  NHS number  TRUST number  Patient location  Unit number involved in transaction  Component/product type involved in transaction  Date/time of transaction  Confirmation that correct patient information is transferred to the LIMS from GP order comm system for at least 20 patients:  Surname  Forename  DoB  NHS number  TRUST number  Gestation age for antenatal patients  Test(s) required  Date/time for transfusion requests  Location for transfusion  Type of component/product required  Number/volume of component/product required  Special requirements  Identification of GP requestor |  |  |
| 4.2 | When the patient demographic details are amended/updated, the previous patient details must be retained against relevant samples. | Confirmation that amendment of the following items can be traced in the audit trail (for at least 10 patients):  Surname  Forename  DoB  NHS number  TRUST number  Address (if applicable)  Patient location  Consultant  Special requirements  Gestation age for antenatal patients  Test(s) required  Date/time for transfusion requests  Location for transfusion  Type of component/product required  Number/volume of component/product required  Urgency of request  Identification of the user making the amendment  Date/time of amendment  Reason for amendment |  |  |
| 4.3 | The LIMS system must support the use of the NHS number (or equivalent) (NPSA 2007) in addition to other numbering systems as required by the user,  e.g. A&E or temporary numbers. | Confirmation that patient search can be made using the NHS number  Confirmation that manual entry can be made using the NHS number  Confirmation that A&E temporary numbers can be used:  Manual entry  Electronic entry via EPR blood ordering  Confirmation that EPR electronic entry/manual entry includes at a minimum:  Unique identification number  Gender  Approximate age (confirm that LIMS flags this as approximate/temporary or some other indicator to denote that this is not confirmed but is used in algorithms for appropriate blood component selection):  Confirmation that following merge to correct patient record that audit trail contains details of emergency number, details and any components/products issued against that record.  Confirmation that audit trail of components/products issued shows the emergency details for that transaction and not the correct patient details (as merged) |  |  |
| 4.4 | The NHS number must be the main identifier within the system | Confirmation that the NHS number is on each screen in the LIMS:  Request entry  Patient enquiry  Result entry  Result reporting  Crossmatch  Component/product enquiry  Component/product issue |  |  |
| 4.5 | The system must be capable of holding the following essential information:  · basic patient demographic information including first and last name, DOB,  gender, address and postcode;  · all relevant transfusion related patient data;  · all previous transfusion/grouping records relating to a patient;  · historic blood group information;  · special requirements;  · patient antibodies and antigens (should be coded to the international coding structure for antibodies/antigens) (ISBTa)  · previous names and addresses if applicable;  · patient diagnoses/clinical details/reason (justification) for transfusion. | Confirmation that essential information retained in patient record (confirm for at least 5 patient records):  · basic patient demographic information including first and last name, DOB,  gender, address and postcode;  · all relevant transfusion related patient data;  · all previous transfusion/grouping records relating to a patient;  · historic blood group information;  · special requirements;  · patient antibodies and antigens (should be coded to the international coding structure for antibodies/antigens) (ISBTa)  · previous names and addresses if applicable;  · patient diagnoses/clinical details/reason (justification) for transfusion. |  |  |
| 4.6 | Requests may be received associated with patients who have not yet been fully identified. The system needs to support entry of partial patient records and to allow patient details to be updated as they become available in accordance with local risk management policy | Confirmation that patient records can be created via EPR or manual input with A&E emergency numbers  Confirmation that the record can be updated with correct patient details on the same TRUST number:  Surname  Forename  DoB  NHS number  Confirmation that amendments can be identified on audit trail:  Date/time of amendment  User making amendment  Reason for amendment  Confirmation that following records remain with updated patient record:  Special requirements  Antigen negative requirements  Antibody positive results  Antibody specificities  Compliance with e-issue rules  Transfusion history  Transfusion test history (including cffDNA for RhD)  Any linked records (see 4.7) |  |  |
| 4.7 | There will be occasions when records from one individual will need to be associated with another individual’s record and the LIMS system must support this. e.g. mother with infant and partner association in pregnancy associated testing. | Confirmation of capability of linking records:  Maternal and infant for post-delivery samples  Maternal and partner for antenatal cases with positive antibody result  Confirmation that records can be un-linked if required:  Maternal and partner if not relevant for current pregnancy  Audit trail retains:  Date/time of un-linking  User performing un-linking  Reason for un-linking  PID of both records |  |  |
| 4.8 | Duplicate patient records within a healthcare database have the potential to create a serious risk to patient safety by increasing the risk of incorrect or inappropriate actions from a lack of recognition of previous results. There must be a method available to merge/link duplicate records in a way which ensures the integrity of the transfusion record. | Confirmation that patient records can be merged  Confirmation that LIMS alerts during merge if there is a mis-match between:  Surname  Forename  DoB  NHS number  TRUST number  Confirmation that LIMS allows override for merge with mismatch:  Date/time of override  User confirming override  Reason for override  Confirmation of ability to un-merge if required:  Audit trail of un-merge – date/time, user, reason |  |  |
| 4.9 | Locally defined rules for merging records must be in place and must address  the following:  ● only nominated staff with appropriate password privileges can use the  merge function;  ● the retention of all historic grouping and screening information, special requirements (e.g. irradiation) and any specific antibody investigation information plus the identity of the person undertaking the merge must be retained following the merge  ● the system must maintain Traceability requirements (as listed in the Blood Safety and Quality Regulations 2005) met, and provide an audit trail of the individual records merged to form the single record. | Confirmation of following:  ● only nominated staff with appropriate password privileges can use the merge function;  ● Staff without appropriate password privileges cannot use the merge function;  ● the retention of all the following must be retained following the merge:  Blood group  Antibody screen information  Antibody specificity  Special requirements  Antigen negative requirements  Compliance with e-issue rules  cffDNA for current pregnancy  Previous transfusion history  Previous test history  Previous linked records  Audit trails of any previous overrides :  amendments for test results,  Amendments to patient demographics,  Previous linked records,  Previous un-merges  ● Confirmation of an audit trail of the merged to form the single record:  Date/time of merge  User performing merge  Reason for merge (if required) |  |  |
| 4.10 | The system must identify and alert the user in the event that the records to be merged have:  ● different ABO and/or D blood groups;  ● different antibody and/or antigen profiles;  ● different special transfusion requirements | Confirmation of alert in the event of:  ● different ABO and/or D blood groups;  ● different antibody and/or antigen profiles;  ● different special transfusion requirements |  |  |
| 4.11 | Differences must be resolved or accepted by an appropriately qualified person before the merge can proceed. Password control must be in place in order to override routine control criteria. | Confirmation of ability to resolve alerts based on user access rights:  User with appropriate access rights can accept a merge in the event of differences  User without appropriate access rights cannot accept merge in the event of differences  Audit trail of acceptance of merge with differences:  Date/time of acceptance  User details  Reason for accepting merge with differences |  |  |
| 4.12 | The audit trail must include  ● the full patient details of both records prior to the merge;  ● the date/time of the merge;  ● the relevant details of the individual who performed the merge | Confirmation that audit trail includes:  ● the full patient details of both records prior to the merge;  ● the date/time of the merge;  ● the relevant details of the individual who performed the merge  Details of any overrides |  |  |
| 4.13 | It should be recognised that undoing a merge is a high risk process which has the potential to compromise mandated traceability. A system must be in place to ensure that all information prior to the time of the merge reverts to the original state, and that subsequent information is correctly assigned to the appropriate record.  An audit trail must be maintained | Confirmation that when using patient enquiry any transfusion records are assigned to the patient details present at the time of the transaction  Confirmation that when using component/product enquiry any transfusion records are assigned to the patient details present at the time of the transaction  Confirmation that when using test enquiry any transfusion records are assigned to the patient details present at the time of the transaction  Audit trail present for un-merge:  Date/time of un-merge  User performing un-merge  Reason for un-merge |  |  |
| 5 | Generating Transfusion Requests |  |  |  |
| 5.1 | The system must be capable of accepting transfusion requests generated in the following ways:   * Manually input by authorised staff * Electronically via an order comms system within the Trust * Electronically via an order comms system outside of the Trust (eg. NPeX or GP order comms) | Confirmation that the following tests can be generated manually:  Group and save  Neonatal blood group  Antibody identification  Prophylax screen (or equivalent)  Emergency blood group and antibody screen  Direct antiglobulin test  Extended direct antiglobulin test  Feto-maternal haemorrhage test  Serological crossmatch  Electronic crossmatch  Emergency crossmatch  NHSBT crossmatch  Transfusion of emergency uncrossmatched group O blood  Serological phenotype (Rh and K)  Serological phenotype (Fy, Jk, MNSs and k)  Antibody titration  Weak D testing  Genotype from IBGRL  Report from referral centre (NHSBT RCI):  Group and screen  DAT  Antibody specificity  H&I tests  Confirmation that the following tests can be generated from EPR request:  Group and save  Neonatal blood group  Antibody identification  Emergency blood group and antibody screen  Direct antiglobulin test  Extended direct antiglobulin test  Feto-maternal haemorrhage test  Serological crossmatch  Electronic crossmatch  Emergency crossmatch  NHSBT crossmatch  Transfusion of emergency uncrossmatched group O blood  Serological phenotype (Rh and K)  Serological phenotype (Fy, Jk, MNSs and k)  Antibody titration  Confirmation that the following tests can be generated from GP order comms system:  Group and save  Neonatal blood group  Antibody identification  Direct antiglobulin test  Extended direct antiglobulin test  Feto-maternal haemorrhage test  Serological crossmatch  Electronic crossmatch  Emergency crossmatch  NHSBT crossmatch  Serological phenotype (Rh and K)  Serological phenotype (Fy, Jk, MNSs and k)  Antibody titration  Confirmation that a test request generated electronically can have additional tests added to the same sample number:  Group and save  Neonatal blood group  Antibody identification  Prophylax screen (or equivalent)  Emergency blood group and antibody screen  Direct antiglobulin test  Extended direct antiglobulin test  Feto-maternal haemorrhage test  Serological crossmatch  Electronic crossmatch  Emergency crossmatch  NHSBT crossmatch  Transfusion of emergency uncrossmatched group O blood  Serological phenotype (Rh and K)  Serological phenotype (Fy, Jk, MNSs and k)  Antibody titration  Weak D testing  Confirmation that tests can be deleted from the patient record with audit trail of deletion:  Date/time deleted  User deleting test  Reason for deletion  Confirmation that manual testing information entered into the LIMS includes:  Reagent lot number  Reagent expiry date  Consumable lot number  Consumable expiry date  Confirmation that wherever possible the entry of the above information can be achieved via barcode scanning of the reagent/ consumable  Confirmation that reagent and consumable lot number and expiry date can be entered manually |  |  |
| 5.2 | Receipt of samples and the matching of the request to the appropriate sample is a critical point in the system and correct association of sample and request is essential. Processes and controls must be clearly specified and interfaces between Order Comms, LIMS and manual actions well defined.  Please state how this is achieved | Confirmation that receipt of sample with EPR request is correctly assigned within the LIMS:  Surname  Forename  DoB  NHS number  TRUST number  Test requested  Blood component/product required  Date/time required  Location of transfusion  Requestor/consultant  Special requirements  Confirmation of sample receipt transmitted in EPR:  Date/time receipted  Confirmation of additional tests added to sample record:  Date/time added  Test added  User adding test (LIMS only)  Confirmation of results authorised (LIMS only):  Date/time authorised  User authorising record  Notes/comments added to record |  |  |
| 5.3 | Laboratory staff must be appropriately alerted to all requests especially where there are no accompanying samples.  Ideally there should be automated request and activity monitoring that will alert management in the event that activity is not performed in a timely manner. | Confirmation that requests can be made in EPR with no requirement for sample:  DAT  Red cells:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  FFP:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  Platelets:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  Cryo:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  Anti-D:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  Octaplas:  if valid sample in lab and being processed  if valid sample fully processed and authorised  not if no valid sample in lab  Batch products:  HAS  IVIg  Factor concentrates  Fib Conc  Anti-tetanus  Praxbind  Lyoplas  PCC  if valid sample in lab and being processed  if valid sample fully processed and authorised  if no valid sample in lab |  |  |
| 5.4 | When patient demographics are entered onto the LIMS manually from the request form, the LIMS must be able to identify if the patient is already known and provide options to match to a record in the system.  If no match is found a new patient record must be created. If during this process it is identified by the LIMS that a potential duplicate record is being created (i.e. same/similar details but different unique patient identifier entered) the user should be alerted. | Confirmation that the LIMS will identify patient record during manual input from following starting parameters:  TRUST number  NHS number  Surname  Forename  DoB  Confirmation if no match is noted the patient information can be entered manually  Confirmation that LIMS will alert during the patient detail input if it is noted that a patient record exists with similar:  TRUST number  NHS number  Surname, forename combination  Surname and DoB combination  Forename and DoB combination |  |  |
| 5.5 | Once all patient identification checks are complete the request together with the accompanying samples must be allocated a unique barcoded laboratory number.  Please state how this is achieved | Confirmation that for requests received that have not been generated in EPR the manual input of patient details and tests:  Generates and prints a unique barcode number for sample identification  Or  Allows for input of externally produced unique barcode number for sample identification  Confirmation that either/both of the above options results in a unique sample barcode that can be :  Processed through the laboratory analyser system  Transmitted to EPR and associated to the correct patient record  Confirmation that the unique barcode cannot be replicated in the future and mis-associated with an incorrect patient  Confirmation that unique sample number barcodes created by EPR can be processed through the laboratory analyser system |  |  |
| 5.6 | When the patient record has been identified or created the unique laboratory number should be scanned and the request details, the collection date and time and any relevant additional information (e.g. special requirements) entered.  Any necessary record association (e.g. mother, infant) should be made at this point. | Confirmation that the following are associated correctly:  Patient record  Unique sample barcode  Test requests  Component/product requests  Special requirements  Sample collection date and time  Component/product required date/time  Linked records:  maternal/cord  maternal/partner |  |  |
| 5.7 | Where there is an electronic transfer of information from Order Comms to LIMS. The request must always be identified with a unique request number. | Confirmation that a unique request number is associated with all orders from:  EPR  GP order comms  Confirmation that the request number cannot be replicated and associated with an incorrect patient record  Confirmation that manually entered requests are assigned a request number once the request is registered on EPR |  |  |
| 5.8 | The matching of the request to the appropriate LIMS patient record is a critical point in the system. Date and time the sample is collected must be electronically entered into the LIMS. | Confirmation that the date/time sample collected in EPR is transmitted to the LIMS  Confirmation that date/time sample taken matches exactly in LIMS and EPR – test for at least 10 requests  Confirmation that sample collected before midnight but request receipted in LIMS after midnight that the correct sample collection date/time is recorded in the LIMS |  |  |
| 5.9 | Any special requirements noted in the order comms system must be transmitted to the LIMS | Confirmation that the following special requirements in EPR are transmitted and retained in the LIMS:  Irradiated  CMV negative  Washed  IgA deficient |  |  |
| 5.10 | Any necessary record association (e.g. mother, infant) must be transmitted to the LIMS | Confirmation that records linked in EPR are transmitted and linked in LIMS:  Maternal and cord  Maternal and partner |  |  |
| 5.11 | The system must include an alert system to inform laboratory staff when an order has been added to the system. | Confirmation that an order generated in EPR creates an alert in the LIMS  Confirmation that alerts in LIMS can be acknowledged :  Acknowledge accepted by user with appropriate access rights  Alert cannot be acknowledged by user with no appropriate access rights  Audit trail retained on alert acknowledgement:  Date/time acknowledged  User acknowledging alert |  |  |
| 5.12 | The system must include a process to identify urgent requests from routine requests. | Confirmation of triage process in LIMS:  Urgent request identification process  Request list is presented in order of component/product required date/time  Request list for red cells is separate to that for other components and products  Request list is updated on receipt of a new urgent request  Request are removed from the list once they have been completed |  |  |
| 5.13 | Manual systems must be in place to support transfusion activity when Order Comms is unavailable. When the systems are available again appropriate mechanisms must be in place to update them.  Please state how this is achieved | Confirmation that requests which have been generated manually are then updated on EPR  Create at least 10 patient requests and complete with suspended EPR interface for following and confirm that EPR is updated when interface switched back on :  Group and save  Crossmatch for red cells  Component issue  Product issue  cffDNA test  Antibody identification  DAT  Neonatal blood group  Weak D test  Prophylax test  Antibody titration  Serological phenotype (Rh and K) |  |  |
| **6** | Analytical Processes |  |  |  |
| 6.1 | Automated links between laboratory equipment and the LIMS must be in place | Confirmation that interfaces exist:  BT analysers and LIMS  LIMS and EPR  LIMS and GP order comms  LIMS and NPeX  Confirmation that following tests can be transmitted via the above interfaces:  Blood group  Antibody screen  Antibody identification  DAT  Extended DAT  Serological phenotype  Antibody titration  Prophylax  Weak D  FMH test  cffDNA test  Confirmation that reaction strengths for test results are transmitted via the analyser interface:  0 (negative)  4 (strongly positive)  3 (positive)  2 (positive)  1 (weakly positive)  ND (not determined)  Confirmation that transmitted results can be interpreted into results (use appendix 19):  Blood Group:  O A B AB  A subgroup  B subgroup  AB subgroup  RhD positive  RhD negative  Weak D (requiring confirmation)  Antibody screen:  Positive (from a screen containing a single positive result and a screen containing multiple positive results)  Negative (from a screen containing all negative results) |  |  |
| 6.2 | Where interpreted results are sent from the analyser to the LIMS results which have been edited on the analyser must be flagged. This is important for the algorithm for electronic issue (EI). | If results are to be edited on the analyser system the functionality of e-issue must be confirmed in accordance with item 8.12 and (appendices 2 and 3)  If laboratory policy states that no results are to be edited on the analyser state that no validation is required but how this will be controlled. |  |  |
| 6.3 | It must be possible to identify testing undertaken against a specific request at a specified time, as the immunological status of the patient can change. | Confirmation that when performing a patient enquiry the historic requests display the date/time:  sample collection  sample receipt  results authorised |  |  |
| 6.4 | The LIMS should have a role in the determination of tests required for a specific request in accordance with predefined test profiles.  These tests should be allocated directly to test equipment through electronic communication | Confirmation that order sets configured in EPR are correctly transmitted to LIMS:  Group and screen = blood group + antibody screen  Group, screen and crossmatch = blood group + antibody screen + crossmatch  FMH screen = blood group + antibody screen + kleihauer  Neonatal DAT = neonatal blood group + DAT  Confirmation that test codes are correctly transmitted to the analyser system:  Blood group  Antibody screen  Phenotype  Crossmatch  DAT  Antibody identification  Antibody titration  Weak D screen  Prophylax screen |  |  |
| 6.5 | The LIMS should be able to respond to test results that trigger further laboratory investigation by allocating follow up tests (reflex testing) the following are examples of good practice:    Antiglobulin profile reflexed from Positive direct antiglobulin test    FMH estimation reflexed from D positive result for cord associated with a D negative mother    Antibody Identification reflexed from Positive antibody screen | Confirmation of reflex testing rules:  Antiglobulin profile reflexed from Positive direct antiglobulin test    FMH estimation reflexed from D positive result for cord associated with a D negative mother    Antibody Identification reflexed from Positive antibody screen |  |  |
| 6.6 | The system must be capable of reflex testing based on patient location and clinical reason for request (eg phenotype request for patient on the haematology ward or patient with clinical details aligned with haematological malignancy) | Confirmation that phenotype (R/K) can be reflexed by location:  Yarty ward  Yarty Day case  Cherrybrook  Yeo  Bramble (any ward)  Sid  Creedy  Heavitree HD  South Devon Kidney Unit  East Devon Kidney Unit  North Devon Kidney Unit  Confirmation that phenotype (R/K) can be reflexed by clinical details:  Renal-CRF  Renal-ARF  Haem-Aplastic anaemia  Haem-AML  Haem-ALL  Haem-MDS  Haem-MPD  Haem-Chronic leukaemia  Haem-Lymphoma  Haem-Myeloma  Haem-Iron deficiency  Haem-B12/folate  Deficiency  Haem-Anaemia of chronic disorders  Haem-Haemolysis acquired  Haem-Haemolysis congenital  Haem-Sickle cell disease  Haem-Thalassaemia  Haem-ITP  Haem-Congenital platelet disorder  Haem-DIC  Haem-TTP  Haem- single factor deficiency  Onc-Chemo  Onco-Anaemia of malignancy  Onco-Radiotherapy  Confirmation that reflex of Rh/K phenotype can be blocked if historic results available |  |  |
| 6.7 | Reflex testing rules must be user configurable, some tests need only be reflexed once whereas others may be reflexed on every occasion. | Confirmation of reflex test rules:  Antibody identification from positive antibody screen = every occasion  Antiglobulin profile reflexed from Positive direct antiglobulin test = once    FMH estimation reflexed from D positive result for cord associated with a D negative mother = every occasion  Rh/K phenotype = once only |  |  |
| 6.8 | The system should be able to produce worksheets, configured to user requirements, for recording laboratory results and/or checking specimen identity. | Confirmation of worklists required:  cffDNA tests for molecular genetics |  |  |
| 6.9 | It should be possible to view and update worksheets on screen, or print copies for manual completion | Confirmation that worklist is visible on screen and can be printed |  |  |
| 6.10 | The system must support electronic data transfer from the laboratory automated equipment.  As part of the result information for each test the LIMS should hold the following administrative information:  ● whether results have been entered by automatic links or manually;  ● whether the result has been edited;  ● date (and time) of testing;  ● audit trail of activities. | Confirmation of functionality of interface from transfusion analyser system  Confirmation of information held for each request:  whether results have been entered by automatic links or manually;    whether the result has been edited;    date (and time) of testing;    audit trail of activities |  |  |
| 6.11 | Where manual interpretation and/or entry are required procedures must be in place to reduce the risk of a manual error remaining undetected (e.g. use of double blind interpretation and entry.) A full audit trail of these activities must be retained by the LIMS. | Confirmation that manual entry of results mandates second check by authorised user (BMS):  Kleihauer  Manual crossmatch  Manual blood group  Manual antibody screen  Manual phenotype  Manual antibody identification  Manual DAT  Manual antibody titration  Manual weak D test  Manual Prophylax screen  Manual extended DAT  Report from NHSBT referral lab  Confirmation that second check includes:  User identity  Date/time of second check  Any result amendments made with reason included  Confirmation that patient result enquiry allows access to second check audit trail  Confirmation that non-authorised personnel cannot perform second check |  |  |
| 6.12 | Where results are entered manually into the LIMS the historic results must not be displayed on screen. | Confirmation that during manual entry of result the historic results are not displayed on the result entry screen:  Blood group  Neonatal blood group  Antibody screen  DAT |  |  |
| 6.13 | Results entered into the system as double blind entry/second check must be verified by a second operator. A full audit trail of these activities must be retained by the LIMS. | Confirmation of item 6.11 |  |  |
| 6.14 | Robust ABO and D typing, and storage of results are essential for safe transfusion practice. Any discrepancies between current ABO/D results and historic results must be flagged by the system | Confirmation that LIMS generates an alert as a result of ABO/D discrepancy:  Historic A – current O  Historic A – current B  Historic A – current AB  Historic B – current O  Historic B – current A  Historic B – current AB  Historic O – current A  Historic O – current B  Historic O – current AB  Historic AB – current A  Historic AB – current B  Historic AB – current O  Historic D Pos – current D Neg  Historic D Neg – current D Pos  Historic DU Pos – current D Neg  Historic D Neg – current DU Pos  Historic D Pos – current DU Pos |  |  |
| 6.15 | Antibody screening results must be stored as individual results against each cell by each technique and as a composite result.  Positive antibody screening results must alert the user and should automatically trigger a request for antibody identification.  The LIMS must display any previously detected antibodies | Confirmation that antibody results are received from the analyser and retained as individual result against each cell:  Cell 1+ cell 2- cell 3-  Cell 1- cell 2+ cell 3-  Cell 1- cell 2- cell 3+  Cell 1+ cell 2+ cell 3-  Cell 1+ cell 2- cell 3+  Cell 1- cell 2+ cell 3-  Cell 1- cell 2+ cell 3+  Cell 1+ cell 2+ cell 3+  Confirmation that any combination of positive results reflexes an antibody identification  Confirmation that the LIMS displays previously detected antibody specificities:  Patient enquiry screen  Result entry screen  Blood component/product issue screen  Crossmatch screen |  |  |
| 6.16 | Antibody identification results must be stored as individual results against each cell by each technique and as a composite result | Confirmation that results (item 6.15) is also displayed as a composite result – antibody screen positive:  Cell 1+ cell 2- cell 3-  Cell 1- cell 2+ cell 3-  Cell 1- cell 2- cell 3+  Cell 1+ cell 2+ cell 3-  Cell 1+ cell 2- cell 3+  Cell 1- cell 2+ cell 3-  Cell 1- cell 2+ cell 3+  Cell 1+ cell 2+ cell 3+ |  |  |
| 6.17 | Antibody identification interpretation must be entered as separate specificities, using drop down (coded) lists or equivalent. There should be controls in place to minimise the risk of manual error. There must be a facility for free text entry if required.  Please state how this is achieved | Confirmation that the following antibody specificities can be selected as individual or any combination:  Anti-D  Anti-C  Anti-E  Anti-c  Anti-e  Anti-Cw  Anti-f  Anti-V  Anti-VS  Anti-G  Anti-Vel  Anti-P1  Anti-M  Anti-N  Anti-S  Anti-s  Anti-U  Anti-Jka  Anti-Jkb  Anti-Fya  Anti-Fyb  Anti-Lea  Anti-Leb  Anti-K  Anti-k  Anti-Kpa  Anti-Kpb  Anti-Lua  Anti-Lub  Anti-Jsa  Anti-Jsb  Anti-Dia  Anti-Dib  Anti-Coa  Anti-Cob  Anti-Wra  Anti-LWa  Anti-LWb  Anti-Mia  Anti-Yta  Anti-Ytb  Anti-Doa  Anti-Dob  Anti-Xga  Anti-Chido Rogers  Anti Kna-McCa  Enzyme only no specificity  AHG no specificity  Prophylactic anti-D  HPA-1a platelet antibody  HPA-1b platelet antibody  HPA-5a platelet antibody  Confirmation that the following antibody specificities can be selected as individual or any combination (at a minimum):  Auto anti-D  Auto anti-C  Auto anti-E  Auto anti-c  Auto anti-e  Auto anti-Cw  Auto anti-f  Auto anti-V  Auto anti-VS  Auto anti-G  Auto anti-M  Auto anti-N  Auto anti-S  Auto anti-s  Auto anti-U  Auto anti-Jka  Auto anti-Jkb  Auto anti-Fya  Auto anti-Fyb  Auto anti-Lea  Auto anti-Leb  Auto anti-K  Auto anti-k  Auto anti-Kpa  Auto anti-Kpb  Auto anti-Lua  Auto anti-Lub  Auto anti-Wra  Auto anti-LWa  Auto anti-LWb  Warm autoantibody no specificity  Cold autoantibody no specificity |  |  |
| 6.18 | The system should have the ability to categorise antibody specificities according to their clinical significance and use this information to support the generation of reports using standard comments (e.g. possible delay in provision of red cells). The system should allow adjustment of these comments in specific cases.  Please state how this is achieved | Confirmation that the system can categorise antibodies into clinical significance according to the NHSBT table in appendix 5  Confirmation that report comment is transmitted to EPR if antibody screen is positive:  “This may cause a delay in the provision of blood – please contact the laboratory for advice if transfusion required”  This function must be tested for at least 10 antibodies, including at least 4 combination specificities |  |  |
| 6.19 | Crossmatch results for each unit tested must be stored as individual results by technique and as a composite conclusion. These results must be transferrable electronically from an analyser or entered manually.  Whatever the method of entry the following information must be stored:  ● patient identifier;  ● donation number;  ● test conclusion or results of individual test by technique and reaction grade;  ● date, time and identity of personnel/analyser for all actions.  If the results are entered manually the second check (independent verification) step should be prompted with full audit trail | Confirmation that crossmatch results are stored as individual results for manual testing:  Donor cell – positive control + = unit is compatible; unit released for labelling via authorisation  Donor cell + positive control + = unit is incompatible; unit is not released for labelling, cannot be authorised  Donor cell - positive control - = QC failed -unit is incompatible/unusable; cannot be authorised  Donor cell + positive control - = QC failed -unit is incompatible/unusable; cannot be authorised  Confirmation that crossmatch results are stored as individual results for automated testing:  Donor cell –= unit is compatible; unit released for labelling via authorisation  Donor cell + = unit is incompatible; unit is not released for labelling, cannot be authorised  Confirmation that the following information must be stored for manual and automated crossmatch:  ● patient identifier;  ● donation number;  ● test conclusion or results of individual test by technique and reaction grade;  ● date, time and identity of personnel/analyser for all actions.  Confirmation that If the results are entered manually the second check (independent verification) step should be prompted with full audit trail |  |  |
| 6.20 | Antenatal testing: The IT system must store the following additional information to that identified above:  ● number of weeks gestation and EDD (where EDD only has been supplied the LIMS should automatically calculate and display the weeks of gestation);  ● partner phenotype (where relevant);  ● Free fetal DNA results where relevant  ● titre/quantitation results where clinically significant antibodies are present;  ● date anti-D prophylaxis administered and dose | Confirmation that the following occurs for requests identified in the LIMS as antenatal:  EDD can be entered into the LIMS and this generates a gestation week displayed on the patient enquiry screen  Gestation week is displayed on the patient enquiry screen related to the request date (eg booking sample history shows gestation as 12 weeks, subsequent results display 28 weeks, 34 week etc)  Subsequent sample requirements for antenatal patient with no positive antibody:  RhD positive = 28 weeks  RhD negative = 28 weeks and delivery  Process for cancelling antenatal screening requests:  At delivery  Post fetal loss  Sample received after 8 weeks post EDD  Confirmation of following information linked to antenatal request :  partner phenotype for antenatal patient with clinically significant antibody  Free text comment for significance of partner phenotype result  Free text/coded comment for subsequent testing requirements based on antibody specificity (see appendix 6)  cffDNA test reflexed from antenatal booking sample and RhD result is negative  cffDNA cannot be reflexed if gestation age <12 weeks  cffDNA test is not reflexed from antenatal booking sample and RhD result is positive  cffDNA results where antenatal patient is RhD negative  titre/quantitation results where clinically significant antibodies are present;  date anti-D prophylaxis administered and dose (result from Electronic blood tracking ) |  |  |
| 6.21 | Antenatal testing: On the basis of patient information and the results entered the LIMS should be able to:  ● provide recall testing information against a user defined algorithm with reference to the Guidelines for Blood Grouping and Antibody Testing in Pregnancy (BCSH 2016).  ● indicate requirements for Routine Antenatal anti-D Prophylaxis (RAADP). | Confirmation that antenatal screening process includes:  recall testing information against a user defined algorithm with reference to the Guidelines for Blood Grouping and Antibody Testing in Pregnancy (see appendix 6)  Confirmed using the following examples (at a minimum):  Anti-D present at booking  Anti-D present at 28 weeks  Anti-K present at booking and partner K positive  Anti-K present at booking and partner K negative  Anti-c present at booking  Anti-c present at 28 weeks  Anti-E present at booking  Anti-E present at 28 weeks  Confirmation that guidance given for RAADP:  Patient RhD negative + cffDNA positive = Anti-D recommended at 28 weeks and post any sensitising events  Patient RhD negative + cffDNA negative = Anti-D not recommended for this pregnancy  Patient RhD negative + cffDNA not determined = Anti-D recommended at 28 weeks and post any sensitising events  Confirmation that disclaimer regarding accuracy of the cffDNA test is included in the report generated by the LIMS |  |  |
| 6.22 | The system must be able to accept test results for automated extended phenotyping including at least the following antigens:  Rh CcEe  Kk  Fy a and b  Jk a and b  Ss  MN | Confirmation that the phenotyping results can be transmitted via the analyser interface to the LIMS:  Rh CcEeCw  Kk  Fy a and b  Jk a and b  Ss  MN  Confirmation that the phenotyping results can be manually entered into the LIMS:  Rh CcEeCw  Kk  Fy a and b  Jk a and b  Ss  MN  Confirmation that the LIMS is able to differentiate between result entered manually and those received via the interface:  Date/time of result entry  Identification of user (ie individual or the identity of the interface)  Amendment of results including reason for amendment  Confirmation that phenotyping results for RhCcEe and K are automatically added to the patient record as antigen negative requirements by the LIMS  Confirmation that any antigen negative requirements can be added to the patient record manually:  Single antigen negative requirement  Multiple antigen negative requirements  Date/time antigen negative requirement added  Identity of user adding requirement  Confirm for all following as individual and at least 10 combinations:  Rh CcEe  Kk  Fy a and b  Jk a and b  Ss  MN |  |  |
| 6.23 | The LIMS must be able to support automated authorisation (“auto validation”) when results are transferred from a fully automated analyser; there has been no editing of results; and where there are no discrepancies identified from previous results. | Confirmation of automated authorisation rules:  Results transferred from analyser + no edit + no discrepancies from previous results + antibody screen negative = autoauthorised  Results transferred from analyser + no edit + no discrepancies from previous results + positive antibody screen= no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit + no discrepancies from previous results + outstanding test results= no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit +discrepancy from previous ABO test results = no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit +discrepancy from previous RhD test results = no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit +discrepancy from previous antibody screen test results = no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit +discrepancy from previous phenotype test results = no autoauthorise, results retained for BMS review  Results transferred from analyser + no edit +discrepancy from previous DAT test results = no autoauthorise, results retained for BMS review |  |  |
| 6.24 | All results which do not fulfil the above criteria, manual and automated, must be reviewed and approved by authorised staff. Staff performing the review must have access to all information associated with the results. | Confirmation that results not eligible for autoauthorise;  Can only be authorised ay staff with appropriate access rights (BMS)  Cannot be authorised by staff with inappropriate access rights (MTO)  Audit trail retained and accessible:  Date/time authorised  Identity of individual authorising results  Confirmation that edit result function for ABO group changes (eg post bone marrow transplant):  Can only be performed by staff with appropriate access rights (BMS)  Cannot be performed by staff with inappropriate access rights (MTO)  Alert is generated by the LIMS that the blood group is being changed and confirmation required to continue  LIMS mandates entry of reason for change (at least 3 letters entry)  Audit trail of change maintained by LIMS:  Date/time of change  Identity of user making change  Reason for change  Confirmation that in the event of inability to assign an ABO or RhD group red cells can still be issued:  ABO group undetermined = group O issue allowed  ABO group undetermined = group A red cell issue excluded by LIMS  ABO group undetermined = group B red cell issue excluded by LIMS  ABO group undetermined = group AB red cell issue excluded by LIMS  RhD group undetermined = RhD neg red cell issue only  RhD group undetermined = RhD pos red cell issue excluded by LIMS  Confirmation that in the event of inability to assign an ABO or RhD group FFP, platelets and cryo can still be issued:  ABO group undetermined = group A FFP, platelets and cryo issue allowed  ABO group undetermined = group AB FFP, platelets and cryo issue allowed  ABO group undetermined = group B FFP, platelets and cryo issue only  ABO group undetermined = group O FFP, platelets and cryo issue excluded by LIMS |  |  |
| **7** | Quality Assurance of Analytical Processes |  |  |  |
| 7.1 | The method of recording and storing IQC data might depend on whether the data is generated on automation linked to the LIMS, or in manual systems. However this is handled, it must be possible to associate all tests in the LIMS with valid IQC. | Confirmation that details of valid IQC associated with an individual test is retained by the LIMS:  Automated testing  Manual testing  Date/time of IQC test  IQC validity period dependent on test:  Automated tests = 15 hours  Manual tests:  ABO/D and antibody screen = 24 hours  DAT = 24 hours  Phenotype = reagent batch change  Prophylax = reagent batch change  Weak D test = reagent batch change  Extended DAT = reagent batch change  IQC status for manual tests= pass/fail  LIMS mandates actions taken for manual IQC failure  In the event of IQC failure/IQC not tested for set period (eg 24 hours) the LIMS generates a flag when test results are entered (manual tests)  Confirmation that when a new batch of IQC is recorded that all tests relating to the previous batch numbers retain the original IQC lot number and expiry details – test at least 3 IQC batch lot changes |  |  |
| 7.2 | For automated testing, where IQC data is generated but not used by the instrument to control result interpretation and transfer, IQC data must be sent to the LIMS and the LIMS must verify IQC data before accepting the test results | IQC will be controlled by the analyser system, confirmation only required from supplier that LIMS has potential to control IQC if required in the future |  |  |
| 7.3 | For automated testing, where the automated system validates IQC data prior to transfer of test results, IQC data should still be retained by the LIMS | Confirmation that valid IQC information is transmitted to the LIMS from the analyser system;  IQC validity accessible via patient enquiry for all automated tests:  Group and screen  Neonatal group  Antibody identification  Crossmatch  Antibody titration  Weak D screen  Prophylax  Phenotyping |  |  |
| 7.4 | The LIMS must facilitate processing of EQA samples, and be able to interpret and store results of EQA samples in the same way as clinical samples. | Confirmation that LIMS can process EQA samples;  Request entry using EQA “patient demographics”;  EQA supplier identification  EQA exercise reference number  Date EQA exercise received  Test entry  Result entry (automated and manual)  ABO/RhD changes from previous subject to authorisation rules 6.24  Antibody identification/specificity changes subject to audit trail (user, reason, date/time)  Phenotype information can be entered against patient request, if provided by EQA scheme  EQA donor cells can be entered into blood stocks for crossmatch purposes – EQA blood stock with minimal donor information (eg donor cell 1 group A)  Crossmatch for EQA patient subject to blood issue rules  Patient enquiry for EQA samples displays the relevant EQA information provided for each exercise  Note: solution may include a separate EQ “patient” for each exercise and so changing blood groups etc may not be relevant |  |  |
| 7.5 | It must be possible to flag EQA samples so that they are easily identifiable, and can be excluded from laboratory workload statistics if required | Confirmation that EQA samples are distinguishable from patient samples  Confirmation that workload reports can be generated for patient samples separately to EQA samples  Confirmation that EQA reports can be generated based on:  Date exercise received  Tests requested |  |  |
|  |  |  |  |  |
| 8 | Component selection |  |  |  |
| 8.1 | The LIMS must ensure that components selected meet all necessary requirements to ensure their suitability (e.g. antigen negative units, neonatal requirements etc.)  Please state how this is achieved | Confirmation that the LIMS controls selection of red cells in accordance with remote allocation and e-issue specification (appendices 7 and 8):  As demonstrated in appendices 2 and 3  Confirmation of blood selection via baby crossmatch:  Meets acceptance criteria in appendix 9  Confirmation that the LIMS controls selection of red cells for other blood issue methods (serological crossmatch and emergency issue in accordance with appendix 10):  Patient female <50 and RhD pos =ABO/D compatible cEK negative  Patient female <50 and RhD neg = ABO compatible CDEK negative  Patient female <50 with antigen negative requirements = ABO compatible antigen negative (CcEe K negative, as appropriate)  Patient female <50, RhD positive with antigen negative requirements (non CcEeK) = ABO compatible cEK + antigen negative  Patient female <50, RhD negative with antigen negative requirements (non CcEeK) = ABO compatible CEK + antigen negative  Patient male with antigen negative requirements = ABO/D compatible + antigen negative  Patient male with no antigen negative requirements = ABO/D compatible  Patient female >50 with no antigen negative requirements = ABO/D compatible  Patient with CMV negative requirements = ABO/D compatible (antigen neg based on age/gender and antigen neg requirements )+ CMV negative  Patient with irradiated requirement = ABO/D compatible (antigen neg based on age/gender and antigen neg requirements ) + irradiated  Patient <1 year old = ABO/D compatible (antigen neg based on age/gender and antigen neg requirements ) + CMV negative  Confirmation that the LIMS controls selection of FFP, Cryo and platelets:  Use appendix 11  See appendices 12 and 13 for plasma compatibility truth tables  Confirmation that the LIMS controls selection of Octaplas in accordance with criteria defined in appendix 14 |  |  |
| 8.2 | In clinical emergencies some requirements may need to be overridden in accordance with pre-agreed protocols and any concessions must be documented and retained in a full audit trail on the LIMS | Confirmation that incompatible plasma components can be issued in an emergency:  Using appendices 12, 13 and 14 to document evidence of override facility  Override function contains:  Date/time of override  User performing override  Reason for override, >3 characters allows override  Reason for override <3 characters block override  Alert generated by override for acknowledged by staff with appropriate access rights (band 7 and above)  Alert generated by override for cannot be acknowledged by staff with inappropriate access rights (band 6 and below)  Report can be generated in LIMS for override based on:  Date period  Reason for override  Staff performing override |  |  |
| 8.3 | It is important to take into account the special requirements flagged for the individual patient. Patient special requirements may be known from previous transfusion history/testing; specified on the sample request; identified through current testing; or determined by the application of predefined demographic/clinical rules  Please state how this is achieved | Confirmation that requirement for special requirement can be generated:  Via EPR blood request  Input manually by laboratory staff  Manual input includes:  Date/time special requirement entered  User entering requirement  Reason for requirements (from drop down list) including:  Irradiated red cells/platelets  CMV negative red cells/platelets  Washed red cells/platelets  HLA Matched platelets  Patient starting daratumumab (send sample to transfusion for extended phenotyping)  Planned allogeneic BM/PBSC transplant  Excluded from BCSH guidelines for sample timing validity  Confirmation that special requirement remain assigned to patient record during subsequent requests:  Single request  Multiple requests  Merge of duplicate records |  |  |
| 8.4 | The system must support selection of red cells along one of the following paths:  ● serological crossmatch (manual or automated);  ● electronic Issue (EI) without serological crossmatch;  • Remote Issue (RA) at a blood fridge without serological crossmatch  ● emergency issue of red cells. | Confirmation that red cells can be selected appropriately and issued to patient via:  Full serological crossmatch  Laboratory electronic issue  Remote allocation using Electronic blood tracking  Emergency ABO compatible issue  Emergency uncrossmatched issue  NBS issue (via referral lab testing)  Neonatal issue with no sample required  Blood received from another hospital with patient transfer  Note: appropriate selection of red cells already tested but this section requires confirmation that all crossmatch routes can be used to issue red cells |  |  |
| 8.5 | In all cases the LIMS must ensure that the controls and rules expressed in the Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories (BCSH 2013) are followed. Guidance below addresses the management of some of these requirements by the LIMS.  The following requirements apply:  • the LIMS must not allow selection of ABO incompatible red cell units;  • the LIMS must prevent use of results from an invalid sample;  • the LIMS must not allow issue of units where pre transfusion tests remain outstanding, except in emergency situations, where a controlled override should be possible, with a full audit trail.  • The LIMS must be capable of selecting red cells based on age and gender rules, configurable by the laboratory | Confirmation that LIMS controls:  LIMS does not allow selection of ABO incompatible red cell units, in accordance with truth table in appendix 15a;  LIMS prevents use of results from an invalid sample >72 hours old;  E-issue  Serological crossmatch  Emergency crossmatch  LIMS allows use of a sample >72 hours but < 7days with override  Override includes:  Date/time  User performing override  Reason for override (> 3 characters)  LIMS does not allow issue of units where pre transfusion tests remain outstanding, except in emergency situations, where a controlled override should be possible, with a full audit trail:  Date/time of override  User performing override  Reason for override (> 3 characters)  LIMS allows identification of patients who have had a bone marrow or peripheral blood stem cell transplant  LIMS allows input of donor details including:  ABO group  RhD group  Rh/K phenotype  Date of transplant  Transplant centre  LIMS controls selection of red cells, FFP and platelets for patients identified as received a bone marrow or peripheral blood stem cell transplant in accordance with the truth tables in appendices 15b, c and d.  LIMS controls selection of RhD type of red cells and platelets post bone marrow or peripheral blood stem cell transplant in accordance with:  LIMS allows reservation and issue of RhD negative red cells and platelets  LIMS blocks reservation and issue of RhD positive red cells and platelets  Reservation and issue of RhD positive red cells and platelets allowed with override and audit trail:  Date/time of override  User details  Reason for override  If recipient RhD type is negative and red cells/platelets reserved are RhD positive, LIMS generates a comment stating “check if anti-D prophylaxis required”  Confirmation that LIMS can generate reports for override based on:  Time period  User  Reason for override |  |  |
| 8.6 | Controls in the LIMS must prevent the following unless appropriate override has been authorised:  ● selection of D positive blood for a D negative patient;  ● selection of incompatible units for a patient with known antibodies.  • Selection of components that do not comply with any special requirements or antigen negative flags on the patient record | Confirmation that LIMS controls:  selection of D positive blood for a D negative patient;  selection of incompatible units for a patient with known antibodies.  Selection of components that do not comply with any special requirements or antigen negative flags on the patient record  Confirmation of the above rules has already been covered in previous section, confirmation required that tests have been performed using all available crossmatch routes:  E-issue  Remote allocation  Serological crossmatch  NBS issue  Neonatal issue  Emergency ABO compatible issue |  |  |
| 8.7 | Units for serological crossmatch must be reserved on the LIMS using barcoded entry of selected donations. | Confirmation that units reserved using barcode entry:  Red cells entered using barcode entry are reserved  Red cells entered manually cannot be reserved  FFP entered using barcode entry are reserved  FFP entered manually cannot be reserved  Platelets entered using barcode entry are reserved  Platelets entered manually cannot be reserved  Cryo entered using barcode entry are reserved  Cryo entered manually cannot be reserved |  |  |
| 8.8 | The system must be capable of accepting serological crossmatch results via the analyser interface or by manual entry. | Confirmation that results for serological crossmatch can be entered:  Manually  Via analyser interface  Confirmation of audit trail:  Date/time results entered  User entering results |  |  |
| 8.9 | The system must have a process of identification of results that have been transferred automatically or entered manually. | Confirmation that results entered manually can be distinguished from those transferred electronically |  |  |
| 8.10 | The system must not issue or print compatibility labels for any units that are resulted as incompatible. | Confirmation that units resulted as incompatible (positive crossmatch result):  Cannot be authorised for issue  Do not transmit to Electronic blood tracking for label printing  Do not print labels from LIMS  Can be returned to stock for re-use for another patient  Will generate alert on LIMS if reserve is attempted for the same patient during a subsequent crossmatch request |  |  |
| 8.11 | The LIMS must perform checks to ensure that all the requirements for EI/RI have been met including all criteria identified in the Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). The Medicines and Healthcare products Regulatory Agency (MHRA) have published guidance on EI and this should be referred to (MHRA 2010). | EI/RI rules have been tested in previous sections, confirmation required here that this conforms to BCSH and MHRA guidance |  |  |
| 8.12 | EI must not be used:  ● in the event of LIMS downtime;  ● where the patient group or antibody screening results have not been transferred electronically from automation to the LIMS;  ● with units that have not been entered into blood bank stock electronically;  ● where automated results have been manually edited. | Confirmation required:  LIMS downtime – no process for accessing any previous LIMS database and using for blood issue  Confirmation that the SOP for procedures in the event of LIMS downtime has been updated and staff understand contents  Confirmation that EI/RI cannot be used where the patient group or antibody screening results have not been transferred electronically from automation to the LIMS;  Confirmation that EI/RI cannot be used with units that have not been entered into blood bank stock electronically;  Confirmation that EI/RI cannot be used where automated results have been manually edited.  Note: validation of above has been performed in previous sections, confirmation only required here that the validation has been successful |  |  |
| 8.13 | The LIMS must support RI including electronic selection of suitable blood (special requirements, antigen negative) according to:   * Age and gender * Antigen negative requirements * Special requirements (eg irradiated, CMV negative) | Confirmation that RI includes selection of suitable blood according to:  Age and gender  Antigen negative requirements  Special requirements (eg irradiated, CMV negative)  Note: validation of above has been performed in previous sections, confirmation only required here that the validation has been successful |  |  |
| 8.14 | There will be occasions where it is necessary to release blood for transfusion without performing/completing pre transfusion testing or crossmatching. In these circumstances the LIMS must allow emergency issue as identified in the Guidelines for Pre Transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). | Confirmation that emergency group O blood can be released via the LIMS:  O Neg can be issued with emergency compatibility tag containing no patient details  Emergency tag is compatible with Electronic blood tracking manager and Electronic blood tracking Tx  O Pos can be issued with emergency compatibility tag containing no patient details  Emergency tag is compatible with Electronic blood tracking manager and Electronic blood tracking Tx  LIMS allows selection of O Neg CEK neg blood for emergency use  LIMS block selection of O Neg that is not CEK neg:  C+E-K- units are blocked from issue  C-E+K- units are blocked from issue  C-E-K+ units are blocked from issue  LIMS allows selection of O Pos cEK neg blood for emergency use  LIMS block selection of O Pos that is not cEK neg:  c+E-K- units are blocked from issue  c-E+K- units are blocked from issue  c-E-K+ units are blocked from issue  LIMS allows selection of O Neg CEK neg neonatal blood for emergency use  LIMS block selection of O Neg that is not CEK CMV neg:  C+E-K- CMV- units are blocked from issue  C-E+K- CMV- units are blocked from issue  C-E-K+ CMV- units are blocked from issue  CMV + units are blocked from issue  Confirmation that LIMS can support Electronic blood tracking Courier to release emergency group O red cells for patients based on RhD type:  Release O Pos if patient known to be RhD Pos  Release O Neg if patient known to be RhD neg  Release O Neg if patient RhD type is unknown  Release O Pos if patient RhD type is known to be weak D  Release O Neg if patient RhD type is known to be partial D |  |  |
| 8.15 | In all cases entry of retrospective testing e.g. compatibility results, must be possible with full audit trail of entries and amendments available | Confirmation that retrospective testing results can be entered into the LIMS:  Red cells issued as ABO compatible that require a retrospective serological crossmatch can have results entered:  Results of room temp/immediate spin issue  Results of retrospective serological crossmatch  Audit trail includes:  Date/time results entered  Identity of user entering results |  |  |
| 8.16 | If patient information is not available at the time of issue later reconciliation must be possible once the full patient record has been established. The LIMS must retain the information associated with the initial issue of the blood components. | Confirmation that records for uncrossmatched blood can be updated in the LIMS:  Assignment of patient details to the emergency unit via manual entry  Assignment of patient details to the emergency unit via electronic record transmitted by Electronic blood tracking Tx  Confirmation that the unit was given uncrossmatched is clear in the LIMS  Reason for use is retained in the LIMS based on drop down list including:  Obstetric bleed  Trauma  AAA  GIB  Intra-op bleed  Post-op bleed  Other (free text)  Reports can be generated in the LIMS for emergency group O use based on:  Date period  Location of patient  Reason for request  Confirmation that, if patient demographics are subsequently altered the initial issue is associated with the original patient details:  Via patient enquiry  Via unit enquiry |  |  |
| 8.17 | The LIMS must be capable of accepting patient information transmitted from the Electronic blood tracking system associated with emergency blood issue and reconciling the unit details with the patient details within the LIMS system | Confirmation that the LIMS can accept patient information transmitted electronically by Electronic blood tracking Tx following transfusion of an uncrossmatched emergency group O unit:  Unit assigned to known patient in the LIMS  Patient record created by the LIMS if no known patient in the system  Unit can be assigned to the patient in the absence of a valid sample  Unit can be assigned to patient in the absence of an historic blood group |  |  |
| 8.18 | The LIMS must enable selection of fractionated blood products based on clinical algorithms.  These must utilise user configurable flags or logic rules to prompt accurate and/or timely selection of the right product (e.g. management of anti-D immunoglobulin, issue of IVIg in accordance with ideal body weight dosing). | Confirmation that the LIMS controls selection of blood products:  Anti-D:  Reason for anti-D request:  Allows manual entry from drop down list  Allows electronic entry from EPR  Reasons for anti-D match in EPR and LIMS:  RAADP  Potentially sensitising events:   * Amniocentesis * Cordocentesis * Other in-utero therapeutic intervention/surgery (e.g. intrauterine, shunting) * Ante partum haemorrhage * Chorionic villus sampling * Ectopic pregnancy * External cephalic version * Fall/abdominal trauma * Intrauterine death * Miscarriage * Termination of pregnancy * Abdominal pain with reasonable suspicion of abruption * Post-delivery of RhD positive infant   Allows reservation and issue for patients with RhD negative result  Blocks reservation and issue for patients with RhD positive result  Blocks reservation and issue for patients with RhD weak positive result  Alerts on reservation and issue for patient with RhD partial result – “check anti-D appropriate for this patient”  Alerts on reservation and issue for patient with known allo-anti-D result – “check anti-D appropriate for this patient”  Allows reservation and issue of 1500iu anti-D when reason entered is 28 week routine anti-D prophylaxis  Alerts on reservation and issue of 500iu anti-D when reason entered is 28 week routine anti-D prophylaxis  Allows reservation and issue of 1500iu and 500iu anti-D when reason entered is potentially sensitising event  Alerts on reservation and issue of anti-D if cffDNA result within 40 weeks has negative result – “check anti-D appropriate for this patient”  Allows reservation and issue of anti-D post-delivery if cord sample result is RhD positive  Blocks reservation and issue of anti-D post-delivery if cord sample is RhD negative  Alerts on reservation and issue of anti-D post-delivery if cord sample result is unavailable - “check anti-D appropriate for this patient”  Block issue of 500iu anti-D post-delivery if record of cell salvage re-infusion present within 72 hours prior to request  Allows issue of 1500iu anti-D post-delivery if record of cell salvage re-infusion present within 72 hours prior to request  IVIg management in accordance with criteria defined in appendix 16  Confirmation from supplier that criteria are configurable to allow for changes to national demand management  Reason for IVIg request drop down list matches in LIMS and EPR:  Alloimmune Thrombocytopenia (foeto-maternal/neonatal)  Chronic inflammatory demyelinating polyradiculoneuropathy  Gullian-Barre Syndrome  Haemolytic disease of the newborn  HSCT in primary immunodeficiencies  Immune thrombocytopenic purpura (acute and persistent, excluding chronic)  Kawaski disease  Paraprotein –associated demyelinating neuropathy (IgM, IgG or IgA)  Primary immunodeficiencies  Specific antibody deficiency  Thymoma with immunodeficiency  Toxic epidermal necrolysis, stevens Johnson syndrome  Acquired red cell apla  sia  Autoimmune congenital heart block  Autoimmune haemolytic anaemia  Autoimmune uveitis  Coagulation factor inhibitors (alloantibodies and autoantibodies)  Haemophagocytic syndrome  Immunobullous disease  Inflammatory myopathy  Multifocal motor neuropathy  Myasthenia gravis (including Lambert-Eaton myasthenic syndrome)  Necrotising (PVL-associated) staphylococcal sepsis  Post-transfusion purpura  Rasmussen syndrome  Secondary antibody deficiency (any cause)  Severe or recurrent clostridium difficile colitis  Staphylococcalor Streptococcal toxic shock syndrome  Stiff person syndrome  Transplantation (solid organ)  Confirmation that LIMS allows selection of treatment option depending on reason selected (in accordance with table in appendix 16:  Short term  Long term  Override in place for non-commissioned option with alert and full audit trail  Reservation screen for IVIg displays confirmation of IVIg registration form and ideal body weight dose calculator  Confirmation of ideal body weight dose calculator includes:  Dose calculated according to calculator  Calculator not appropriate for this patient – reason must be included (>3 characters) with audit trail (date/time added, user details)  Ideal body weight dose calculator accessed via the LIMS (appendix 17)  Reservation screen for IVIg displays confirmation of patient requirements for:  Product type suitable for patient  Dose  Frequency  Review date  Reason for IVIg treatment  Alerts on reservation and issue if no confirmation of registration form and ideal body weight dose calculator – “check IVIg appropriate for this patient”  Alert for above visible to user and generates email to [rde-tr.HTT@nhs.net](mailto:rde-tr.HTT@nhs.net)  Allows reservation and issue for IVIg product confirmed suitable for patient  Alerts on reservation and issue of product not confirmed suitable for patient - “check IVIg appropriate for this patient”  All alerts and overrides retain audit trails:  Date/time override  User performing override  Reason for override (>3 characters) |  |  |
| 8.19 | The LIMS system must include a user configurable flags or logic rules to prevent inappropriate issue of batch products, eg issue of anti-D to an RhD positive patient | Confirmation of logic rules:  Confirmation of logic rules as detailed in appendix 18  Confirmation from supplier that blood product management table is configurable to allow for amendments/additions to product list and rules  Confirmation that product request drop down list matches in LIMS and EPR  Confirmation that product requested can be entered:  Manually  Electronically from EPR  Confirmation that fate of blood product can be entered:  Manually in the LIMS  Electronically from Electronic blood tracking Tx  Confirmation that reports can be generated from the LIMS based on:  Date period of product request  Date period of product usage  Reason for request  Location of patient  Product type  Override for product |  |  |
| 8.20 | The LIMS must provide an outstanding requests/orders list for blood components and batch products, including:   * Urgency * Location * Component/product type * Number required * Sample status (eg, no sample required, sample in lab, sample to be taken) * Patient details * Date/time required   List generated in chronological order | Confirma |  |  |
| 8.21 | The LIMS must provide an outstanding requests/orders list for tests, including:   * Test type * Patient details * Urgency * Sample status (eg, sample in lab, sample to be taken) * Sample accession number * Sample date/time |  |  |  |
|  |  |  |  |  |
| **9** | Component labelling and Issue |  |  |  |
| 9.1 | Units should be authorised and the labels printed and attached, one patient at a time, at a single workstation location. The system must include a label printer for each crossmatch work station | Confirmation that blood component and product labels can be printed by LIMS  Confirmation that each workstation used for component/product issue has a printer  Confirmation that labels printed from single workstation to printer attached to workstation  Confirmation that labels can be printer to printer not attached to workstation in the event of printer failure  Confirmation that labels can be printed from Electronic blood tracking in the event of LIMS downtime |  |  |
| 9.2 | All labels when attached to components should not cover or obscure donation or manufacturer information on the unit base labels. The system should provide a process to verify that the correct label has been attached to the correct unit | Confirmation that LIMS can print on current label used – BrenmoorBBL007 and BBL012-LC  Confirmation that LIMS can print to other labels styles compatible with Electronic blood tracking Manager/Courier/Tx - state labels confirmed by supplier (note – validation of all labels not possible within this validation)  Confirmation that label validation can be achieved within the LIMS  Confirmation that LIMS label validation:  Checks component details against label details;  Unit number  Product code  Expiry date  Blood group  Checks batch product details against label details;  Unit number  Product code  Demonstrates successful validation when label matches component details  Demonstrates successful validation when label matches product details  LIMS generates alert when label does not match component details  LIMS generates alert when label does not match product details  Alert generated visible to user  Reports can be generated within the LIMS for label verification based on:  Date period  Successful and unsuccessful verification  Users  Component/product type  Confirmation that red cell cannot be scanned into Electronic blood tracking Courier without successful label verification  Confirmation that FFP cannot be scanned into Electronic blood tracking Courier without successful label verification  Confirmation that the following components/products cannot be moved in or moved out of storage locations on Electronic blood tracking Manager without successful label verification;  Cryo  Octaplas  Lyoplas  Platelets  Anti-D  Human albumin solution  C1 esterase inhibitor  Factor concentrates  IVIg  Anti-tetanus  Prothrombin complex concentrate  DOAC reversal agent  Label verification is currently performed in Electronic blood tracking manager system, if LIMS unable to provide function then validation requires confirmation that label verification can be performed in Electronic blood tracking using labels generated in LIMS:  Red cells  FFP  Cryo  Octaplas  Lyoplas  Platelets  Anti-D  Human albumin solution  C1 esterase inhibitor  Factor concentrates  IVIg  Anti-tetanus  Prothrombin complex concentrate  DOAC reversal agent |  |  |
| 9.3 | The compatibility tag must be printed out once the units have been authorised as compatible or suitable for issue. The information required to be printed onto each label is identified in Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013). The system must include the following information on the compatibility tag when available:  i. last name;  ii. first name;  iii. date of birth;  iv. unique patient identification number  v. patient ABO and D group;  vi. donation number (ideally in both eye-readable and barcode format);  vii. component type;  vii. statement indicating whether the component is compatible or suitable;  ix. (should include) date by which the component must be transfused or de-reserved (taking into account the change in expiry date and time when thawing frozen plasma component/products). | Confirmation that label only printed from LIMS when component/product authorised/issued as suitable  Confirmation that label not printed from LIMS when component/product has not been authorised/issued as suitable;  Reservation stage reached  Unit marked on LIMS as incompatible  Confirmation that label generated by LIMS includes the following information:  i. last name;  ii. first name;  iii. date of birth;  iv. unique patient identification number  v. patient ABO and D group;  vi. donation number (ideally in both eye-readable and barcode format);  vii. component type;  vii. statement indicating whether the component is compatible or suitable; |  |  |
| 9.4 | It should be possible to print a comment on the compatibility tag, e.g. to highlight where the blood group of the unit and the patient are compatible but not identical. | Confirmation that LIMS prints comment on component labels when there is a discrepancy between ABO or RhD types:  Red cells:  Patient A – donor O  Patient B – donor O  Patient AB – donor O  Patient AB – donor A  Patient AB – donor B  Patient RhD pos – donor RhD neg  Patient RhD neg – donor RhD pos  FFP:  Patient O – donor A  Patient O – donor B  Patient O – donor AB  Patient A – donor AB  Patient A – donor B  Patient A – donor O  Patient B – donor AB  Patient B – donor A  Patient B – donor O  Patient AB – donor O  Patient AB – donor A  Patient AB – donor B  Patient RhD pos – donor RhD neg  Cryo:  Patient RhD neg – donor RhD pos  Patient O – donor A  Patient O – donor B  Patient O – donor AB  Patient A – donor AB  Patient A – donor B  Patient A – donor O  Patient B – donor AB  Patient B – donor A  Patient B – donor O  Patient AB – donor O  Patient AB – donor A  Patient AB – donor B  Patient RhD pos – donor RhD neg  Platelets:  Patient O – donor A  Patient O – donor B  Patient O – donor AB  Patient A – donor AB  Patient A – donor B  Patient A – donor O  Patient B – donor AB  Patient B – donor A  Patient B – donor O  Patient AB – donor O  Patient AB – donor A  Patient AB – donor B  Patient RhD pos – donor RhD neg |  |  |
| 9.5 | Where a blood tracking system is to be used in conjunction with the IT system the system must support any requirements for additional barcodes | Confirmation that component/product label generated by LIMS:  Includes 2D barcode compatible with Electronic blood tracking manager and Tx  Includes peel off sticky labels (these may be required for anti-D given in community for patient hand held paper notes – confirm with EPR project) |  |  |
| 9.6 | There must be a specific process step to ensure the correct label has been attached to the correct component. Ideally this verification should be by automated means using electronically readable information (this process may be provided by the Electronic blood tracking system, but the LIMS must support label printing via the Electronic blood tracking system).  This verification step must include:  ● check to ensure donation number on component is identical to the donation number on the compatibility tag;  ● check to ensure the component type on the compatibility tag is correct | As confirmed in section 9.2 for correct label attached to bag  Confirmation required that where different component types have the same unit number label verification in the LIMS is able to generate alert:  Neonatal split packs red cells  FFP – Red cells  Platelet – red cells  Platelet split packs |  |  |
| 9.7 | Where automated support for verification of the donation number is employed this will require printing of the barcoded donation number on the compatibility tag. The automated system must be designed to ensure that the donation numbers from both the component and the compatibility tag have been compared, (i.e. duplicate entry of one barcode would be detected as an error). | Confirmation that LIMS generates alert when:  Unit number on component is scanned twice in label verification  Barcode on label is scanned twice in label verification  Confirmed for:  Red cells  FFP  Cryo  Octaplas  Lyoplas  Platelets  Anti-D  Human albumin solution  C1 esterase inhibitor  Factor concentrates  IVIg  Anti-tetanus  Prothrombin complex concentrate  DOAC reversal agent |  |  |
| 9.8 | Remote Electronic Issue: Components in remote issue locations must be managed by the transfusion laboratory and procedures in place to ensure that at all times only suitable components are available. The current location of all blood and components, including thawed FFP, should be available in the laboratory LIMS. Records must be kept in the LIMS of all movements of components | Confirmation that location of components/products is mirrored in real time for:  Red cells  FFP  Cryo  Octaplas  Lyoplas  Platelets  Anti-D  Human albumin solution  C1 esterase inhibitor  Factor concentrates  IVIg  Anti-tetanus  Prothrombin complex concentrate  DOAC reversal agent  Evidence required documented in appendix 18 |  |  |
| 9.9 | Remote issue of red cells must only be used for patients who have been determined as eligible for EI. The LIMS must be capable of controlling all aspects of EI | EI and RI validation in confirmed in appendices 2 and 3  Confirmation required in this section that the LIMS is controlling all aspects of EI and RI  If any workarounds have been agreed confirm that these have been risk assessed – state risk assessment number  Confirmation that supplier is aware of any deficiencies  Confirmation of resolution date for any deficiencies as agreed with supplier  Confirmation and reference number of development items agreed with supplier  Confirmation that any actions required by the supplier have been added to the risk assessment on DATIX with agreed and reasonable target dates |  |  |
| 9.10 | Remote electronic issue must be rigorously controlled through use of standard operating procedures, trained and competent staff and validation of the system in use. The following controls within the LIMS must apply to all remote electronic issue systems:  ● the user must be positively identified by the system and verified to ensure they are authorised for the procedure;  ● procedures must be in place to ensure all stock is suitable for issue and appropriate stock rotation is in place to ensure units are removed prior to expiry;  ● the identification of the patient and the request for components must follow the same rules as identified in section 2.3 and the Guidelines on Administration of Components (BCSH 2009)  ● request information must be transferred to the LIMS either through electronic requesting or direct input to the remote issue system.  ● the LIMS must verify the patient request and authorise the issue of group compatible components;  ● the LIMS must take into account any special requirements (including irradiated, CMV negative, antigen negative) that apply to the patient and ensure that these are met;  ● selected units must be scanned into the remote issue system and a label produced;  ● there must be a system for label verification to ensure that the label attached to the component matches exactly in terms of donation number;  ● the system must generate local and remote alarms if a user scans the wrong unit, and give a prompt to return the unit and take out the correct one | Confirmation of control of rules:  ● the user must be positively identified by the system and verified to ensure they are authorised for the procedure;  ● procedures must be in place to ensure all stock is suitable for issue and appropriate stock rotation is in place to ensure units are removed prior to expiry;  ● the identification of the patient and the request for components must follow the same rules as identified in section 2.3 and the Guidelines on Administration of Components (BCSH 2009)  ● request information must be transferred to the LIMS either through electronic requesting or direct input to the remote issue system.  ● the LIMS must verify the patient request and authorise the issue of group compatible components;  ● the LIMS must take into account any special requirements (including irradiated, CMV negative, antigen negative) that apply to the patient and ensure that these are met;  ● selected units must be scanned into the remote issue system and a label produced;  ● there must be a system for label verification to ensure that the label attached to the component matches exactly in terms of donation number;  ● the system must generate local and remote alarms if a user scans the wrong unit, and give a prompt to return the unit and take out the correct one  Note: above requirements are currently controlled within the Electronic blood tracking system, confirmation only required from supplier that LIMS complies if required in the future  Confirmation required in this section that validation process have successfully confirmed LIMS control of:  Antigen matching via RI  E-issue eligibility via RI  Special requirement matching via RI  Sample validity compliance via RI  Details of red cell unit issued at fridge retained in LIMS assigned to valid sample  Details of red cell unit transfused at Tx retained in LIMS assigned to valid sample  Details of red cell unit not transfused but returned to stock for re-use retained in LIMS assigned to valid sample  Details of red cell unit not transfused but disposed retained in LIMS assigned to valid sample  Confirmation that RI reports can be generated by LIMS based on:  Date period  Location of RI (fridge name)  User details  Fate of unit |  |  |
| **10** | Records |  |  |  |
| 10 | Records stored must include:  ● identity of individuals undertaking any step in the process;  ● identification of the patient;  ● donation numbers of the units placed into stock or issued;  ● component type(s);  ● date and time of placement and issue | Confirmation that LIMS records for blood component/product handling include:  ● identity of individuals undertaking any step in the process;  Note: identity of users involved in collection and administration may be held only in Electronic blood tracking and not in LIMS – state here if this is the case  Confirmation that LIMS can include details of users involved in collection and administration if required in the future  Confirmation of the following has been covered in previous sections, confirm here that validation has been successful  ● identification of the patient;  ● donation numbers of the units placed into stock or issued;  ● component type(s);  ● date and time of placement and issue |  |  |
| 10.1 | There should be an alarmed electronic override feature as this is essential for use in emergencies i.e. release of emergency group O blood. All events should be logged and investigated retrospectively | Confirmation that alarmed electronic override is available during release of uncrossmatched emergency group O blood  Note: this is currently controlled by Electronic blood tracking , confirmation only required that LIMS has this capability if required in the future:  Alert generated at collection of emergency red cells, PCC  Acknowledgement and resolution of alert required  Acknowledgement and resolution of alert by authorised personnel only based on access rights |  |  |
| 10.2 | There must be a process to reconcile units issued as emergency (eg O RhD negative red cells, PCC) to unnamed patients with the patient record once the transfusion has occurred. This process must be automated within the LIMS, taking the patient information from the electronic blood tracking system | Confirmation that validation successful for reconciliation of emergency red cell and PCC patient details in LIMS via Electronic blood tracking Tx  If LIMS does not have this capability then confirmation:  Development agreed with supplier  Target date for resolution agreed with supplier  Actions added to risk assessment on DATIX |  |  |
| 10.3 | All blood that has been recalled or removed from the remote issue system for longer than the specified time (depending on user configurable storage conditions) must be quarantined so that it cannot be dispensed | Confirmation that LIMS can identify all components/products in quarantine in remote fridges and set component/product to “unusable” including:  Date/time quarantined  User details  Reason for quarantine  Component/product can only be removed from remote storage location by authorised personnel:  Can be removed by staff with laboratory access rights  Cannot be removed by personnel with non-laboratory access rights:  Tx  Courier  Doctor  Remote allocation  Note: Electronic blood tracking manager system currently used to set components/products in remote storage locations to unusable – state if LIMS does not have this capability  Confirmation that if unusable status is set using Electronic blood tracking manager this message is transmitted to LIMS  If LIMS does not have this capability then confirmation:  Development agreed with supplier  Target date for resolution agreed with supplier  Actions added to risk assessment on DATIX |  |  |
| 10.4 | Remote issue systems must not be used if the interface to the LIMS or any element of the remote issue system fails | Confirmation that RI cannot be used in LIMS interface downtime  Confirmation of procedure for using Electronic blood tracking RI in LIMS interface downtime  Confirmation that authorised user in the laboratory can suspend RI in the event of a planned or unexpected LIMS interface downtime  Confirmation that blood component/product issue can continue in the event of a planned or unexpected interface downtime |  |  |
| **11** | Post Analytical Reporting |  |  |  |
| 11.1 | The system must support both printed reports and electronic reports available on-line | Confirmation that LIMS generates reports:  Results transmitted electronically to EPR:  Group and screen  Antibody identification and associated comments  cffDNA and associated comments  FHM test and associated comments  Antenatal testing results and associated comments  DAT results and associated comments  NHSBT results and associated comments  No test - associated comment that request and sample received but not tested  Results transmitted electronically to GP systems:  Group and screen  Antibody identification and associated comments  cffDNA and associated comments  FHM test and associated comments  Antenatal testing results and associated comments  DAT results and associated comments  No test - associated comment that request and sample received but not tested  Generation of specific printed reports according to:  Location  Requestor  Ad hoc on demand |  |  |
| 11.2 | It must be possible to format reports so that they are clearly presented and contain terminology that is clear and unambiguous. Where possible comments added to reports should conform to those identified in BCSH guidelines. | Confirmation that reports are configured so that information is clear to the clinical users;  Approved by clinical users (state name of clinician and date approved):  Haematology clinician  Obstetric clinician |  |  |
| 11.3 | Reports must be designed to give all information required for full identification of the patient and essential user information as laid down by UKAS ISO15189 standards. | Confirmation that patient information included in the report:  Surname  Forename  DoB  TRUST number  NHS number  Confirmation of compliance with ISO15189:  a) comments on sample quality that might compromise examination results;  b) comments regarding sample suitability with respect to acceptance/rejection criteria;  c) critical results, where applicable;  d) interpretive comments on results, where applicable, which may include the verification of the interpretation  of automatically selected and reported results in the final report.  The report includes the following:  a) a clear, unambiguous identification of the examination including, where appropriate, the examination procedure;  b) the identification of the laboratory that issued the report;  c) identification of all examinations that have been performed by a referral laboratory;  d) patient identification and patient location on each page;  e) name or other unique identifier of the requester and the requester’s contact details;  f) date of primary sample collection (and time, when available and relevant to patient care);  g) type of primary sample;  h) examination results reported in SI units, units traceable to SI units, or other applicable units;  i) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision  values, where applicable;  j) interpretation of results, where appropriate;  k) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary  sample which may have compromised the result, results/interpretations from referral laboratories, use of  developmental procedure);  l) identification of examinations undertaken as part of a research or development programme and for which  no specific claims on measurement performance are available;  m) identification of the person(s) reviewing the results and authorizing the release of the report (if not contained  in the report, readily available when needed);  n) date of the report, and time of release (if not contained in the report, readily available when needed); |  |  |
| 11.4 | The report must state the number of pages containing the full report (eg page 1 of 2) | Confirmation that printed reports with more than one page;  page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.). |  |  |
| 11.5 | The report must draw the users attention to the date of final authorisation and advise the user to take this into consideration when interpreting the information e.g. report may state that the patient is suitable for electronic issue but this may no longer apply depending on the sample date | Confirmation that comments relating to date related factors are clearly marked:  Sample validity for red cell issue depends on sample date  Request for repeat FMH screening related to initial FMH sample date  cffDNA test result related to current pregnancy  Repeat antenatal testing for patient with positive antibody screen related only to current pregnancy  For patients who have received transfusion of blood component/product report includes comment that patient must be informed they can no longer received blood |  |  |
| 11.6 | There should be options to have reports by:  ● type of test;  ● consultant/requestor;  ● location;  ● blood component/product;  ● others as defined by local specification. | Confirmation of report generation within LIMS by:  ● type of test;  ● consultant/requestor;  ● location;  ●blood component/product;  ● printed or electronic.   * For patients who have received transfusion of blood component/product report includes comment that patient must be informed they can no longer received blood - only to GP location following discharge from hospital |  |  |
| 11.7 | Test reports must either be:  ● final - released following authorisation;  ● interim - released prior to authorisation but clearly marked as unauthorised or incomplete.  ● turnaround times from request receipt to final authorisation  ● turnaround times based on test type  ● turnaround times based on location of request | Confirmation that reports clearly identifiable as:  ● final - released following authorisation;  ● interim - released prior to authorisation but clearly marked as unauthorised or incomplete.  Confirmation that LIMS can generate report designed to monitor turnaround times based on:  ● turnaround times from request receipt to final authorisation  ● turnaround times based on test type  ● turnaround times based on location of request |  |  |
| 11.8 | An audit trail must be in place to show when the electronic report was viewed and by whom | Confirmation that this function is provided by EPR EPR  Confirmation that this function can be provided by the LIMS if required:  Date/time results viewed  Identification of user |  |  |
| 11.9 | The system must support transfer of information to other IT systems, including GP systems, NPEx. Such transfer should comply with applicable healthcare communication standards applied within the organisation. Dispatch of the reports must be to a recognised system and must meet the security and information governance recommendations | Confirmation that results can be transferred electronically from the LIMS to;  NPeX  GP links/GP order comms  EPR |  |  |
| 11.10 | The system must provide an option to send a report of any transfusions to the patient GP location. | Confirmation from item 11.6:  Report only generated to GP on report on patient discharge summary  Report only generated to EPR on report on patient discharge summary  Report not generated on each component/product request, issue or fate |  |  |
| 11.11 | Correction to issued reports must be treated as a quality incident with appropriate investigation, corrective and preventive actions including:  ● withdraw all copies of the report;  ● inform the relevant users that the report has been changed  ● follow through of actions that other electronic systems have taken on the basis of the original report e.g. Order Comms  ● monitor, track and trend the number of incidents where this occurs  The LIMS should support this activity by:  • providing lists of users who have viewed on line reports  • issue of an updated report which clearly indicates its revised status | Confirmation of LIMS compliance with amended reports:  ● withdraw all copies of the report from clinical user view  ● inform the relevant users that the report has been changed - alert generated that report has been withdrawn  ● follow through of actions that other electronic systems have taken on the basis of the original report e.g. order placed on EPR following report release   * Retain all information contained in the original report in an accessible audit trail * Automatic generation of place holder/test code in LIMS for DATIX reference code (>3 characters) or comment that DATIX not required with reason * Full audit trail of all activities associated with amended report including date/time of amendment, user details, reason for amendment   Confirmation of LIMS report generation for monitoring, tracking and trending the number of incidents where this occurs, based on:  Date period  User identification  Reason for amendment |  |  |
| **12** | Cold Chain |  |  |  |
| 12.1 | The system must support compliance with the cold chain as detailed in the Blood Safety and Quality Regulations (2005) and the BCSH The administration of blood components (2017). | Confirmation that LIMS contains rules for cold chain:  Red cells:   * If 30 min out of temperature controlled storage is exceeded the LIMS prevents the unit from return to stock * Up to 60 min out of controlled temperature is acceptable, LIMS allows unit to be quarantined, by placing in a secure refrigerator for at least 6 h, to allow the unit to return to 2–6 °C * LIMS only releases unit for re-issue after 6 hours in controlled storage   If LIMS unable to comply with above guidance the following must be confirmed:  red cells that have been out of temperature controlled storage for >30 minutes must not be returned to stock for re-use |  |  |
| 12.2 | The system must prevent issue of blood components and batch products that do not have a compliant cold chain audit trail, as defined by the laboratory. | Confirmation of following requirements for blood components other than red cells:  **Standard FFP**  LIMS allows re-issue of FFP up to 24 h post thaw if stored at 2–6 °C  LIMS does not allow re-issue of FFP up to 24 h post thaw if not stored at 2–6 °C  LIMS allows thawed FFP that is out of a temperature‐controlled environment (2–6 °C) to be accepted back into temperature‐controlled storage (2–6 °C), if this occurs on one occasion only of less than 30 min.  LIMS does not allow thawed FFP that is out of a temperature‐controlled environment (2–6 °C) to be accepted back into temperature‐controlled storage (2–6 °C), if this occurs on more than one occasion only of less than 30 min.  LIMS does not allow thawed FFP that is out of a temperature‐controlled environment (2–6 °C) to be accepted back into temperature‐controlled storage (2–6 °C), if this occurs for more than than 30 min.  **Methylene blue‐FFP**  LIMS allows thawed MB FFP component to be issued for up to 24 h if stored at 2–6 °C  LIMS does not allow thawed MB FFP component to be issued if more than 24 h of storage at 2–6 °C  LIMS does not allow return to stock and re-issue of MB FFP following release from controlled storage  **Solvent detergent‐FFP**  At present, Octapharma is the only supplier of SD‐FFP in the UK.  LIMS allows that after thawing, Octaplas® can be stored for up to 24 h at 2–8 °C  LIMS allows storage of Octaplas for up to 8 h at room temperature (20–25 °C), before collection  LIMS does not allow return to stock and re-issue of MB FFP following release from controlled storage  **Cryoprecipitate**  LIMS does not allow refrigerated storage of cryo  LIMS allows return to stock and reissue for transfusion within 4‐h period from thawing.  LIMS does not allow return to stock and reissue for transfusion if greater than 4‐h period from thawing  Note: for frozen products the LIMS must include date/time that the component is thawed to allow calculation of storage and re-issue times  **Platelets**  LIMS allows storage at 20–24 °C with constant gentle agitation.  LIMS allows return to stock and re-issue of components that have not left storage  LIMS allows return to stock and re-issue of platelets that have been out of temperature controlled storage for up to 8 hours on a single excursion  LIMS does not allow return to stock and re-issue of platelets that have been out of temperature controlled storage for more than 8 hours on a single excursion  LIMS does not allow return to stock and re-issue of platelets that have been out of temperature controlled storage for more than 24 hours (combined) on multiple excursions  **White cells (or granulocytes)**  LIMS allows storage at room temperature (20–24 °C) without agitation  LIMS allows return to stock and re-issue (to that named patient only) within the lifespan of that unit.  LIMS does not allow return to stock and re-issue to a different patient  LIMS does not allow issues of granulocytes via e-issue rules  Note: storage location temperatures are currently controlled by the Electronic blood tracking system, this section requires that the LIMS system contains the same storage rules as Electronic blood tracking |  |  |
| 12.3 | The system must support user configurable cold chain rules that are specific for each component/product | Confirmation that the LIMS controls storage conditions for batch products:  Lyoplas  Anti-D  Human albumin solution  C1 esterase inhibitor  Factor concentrates  IVIg  Anti-tetanus  Prothrombin complex concentrate  DOAC reversal agent  LIMS allows return to stock and re-issue of above products if outside storage for up to 72 hours  LIMS does not allow return to stock and re-issue of above products if outside storage for more than 72 hours |  |  |
| **13** | Training |  |  |  |
| 13.1 | The supplier MUST detail the training requirements for the system including duration of any training courses normally included in the supply of the system. | Confirmation that the supplier has detailed the training requirements for the system |  |  |
| 13.2 | The supplier MUST provide advanced training for at least two members of staff for the system | Confirmation that at least two members of staff have attended the advanced training for the system:  State names of staff |  |  |
| 13.3 | The supplier MUST provide on-site training for all system operators | Confirmation that the supplier has a training package and intends to train all operators on-site  Confirmation that a list of operators to be trained has been generated for the supplier  Confirmation that a timetable has been generated for supplier training on-site |  |  |
| 13.4 | The supplier MUST give details of any user groups.  If a cost is attached to attendance of these meetings it SHOULD be shown here. | Confirmation that supplier has provided details of user group meetings  Confirmation of any cost associated with the meetings  Note: this is for information only |  |  |
| 13.5 | On-going training MUST be provided as required following significant changes to software or hardware or laboratory staff. | Confirmation that on-going training will be provided following significant changes to:  Software  Hardware  Laboratory staff  Confirmation that release notes for software changes will be provided in adequate time for validation |  |  |
| **14** | Installation & Operation Qualification |  |  |  |
| 14.1 | The supplier MUST provide a detailed implementation and installation project plan with timescales. | Confirmation that an implementation and installation plan was provided and agreed by the Trust  Confirmation that the installation complied with agreed timescales |  |  |
| 14.2 | The supplier MUST perform the installation and operational qualification validation steps for the system | Confirmation that the supplier performed the installation and operational qualification steps  Confirmation that system passed installation and operational qualification  Confirmation that documentation for installation and operational qualification has been retained by the TRUST |  |  |
| 14.3 | The supplier MUST support the laboratory performance qualification/verification as defined by the laboratory, including all costs, to meet the standards required by ISO 15189, BCSH and MHRA | Confirmation that the supplier has supported the laboratory during the validation steps identified in this document |  |  |
| 14.4 | The system MUST operate for its lifetime in accordance with ISO 15189 BCSH and MHRA standards | Confirmation that the supplier will support any changes to the system required for it to operate in the event of any changes to ISO 15189 BCSH and MHRA standards |  |  |
| 14.5 | The supplier MUST provide an installation and an operational risk assessment for the use of their system. | Confirmation that the supplier provided an installation and an operational risk assessment for the use of their system.  Confirmation that the installation and an operational risk assessment has been retained by the TRUST |  |  |
| 14.6 | The supplier MUST ensure full service provision is maintained during implementation/works.  Details of how this will be achieved MUST be included in the tender response | Confirmation of no disruption to service during installation and validation |  |  |
| 14.7 | A fully competent company representative MUST be available on site until the installation is complete and system is functioning satisfactorily. | Confirmation that the supplier provided a competency company representative for the installation and validation purposes |  |  |
| 14.8 | All software upgrades and their subsequent validation/verification to meet ISO 15189, BCSH and MHRA MUST be fully supported by the supplier and be free of charge | Confirmation that supplier supports software upgrades and their subsequent validation/verification to meet ISO 15189, BCSH and MHRA and is free of charge |  |  |
| **15** | Operation and Maintenance |  |  |  |
| 15.1 | Supplier MUST guarantee a maximum response time by an engineer/ application specialist of 30 minutes from reporting a fault during 9 to 5.30 (core hours). | Confirmation that supplier guarantees a maximum response time by an engineer/ application specialist of 30 minutes from reporting a fault during 9 to 5.30 (core hours).  Included in KPI |  |  |
| 15.2 | Supplier MUST guarantee a maximum response time from fault reporting to engineer visit/escalation of 8 working hours | Confirmation that the supplier guarantees a maximum response time from fault reporting to engineer visit/escalation of 8 working hours  Included in KPI |  |  |
| 15.3 | Supplier SHOULD provide 24/7 support for breakdowns. | Confirmation that supplier provides 24/7 support for breakdowns. |  |  |
| 15.4 | System must have an uptime of no less than 99.8% of operational time | Confirmation that supplier guarantees an uptime of no less than 99.8% of operational time  Included in KPI |  |  |

# Appendix 1: Logic Rules

Regulation and guidelines require that many rules are applied when determining the suitability of components for transfusion. Wherever possible it is advisable to embed these rules into the operating logic of the LIMS. However the LIMS can only apply rules on the basis of information known to the system. In practice the correct application of rules will rely on a combination of logic rules applied by the LIMS and procedural rules applied by laboratory staff. These may be combined in a situation where a member of laboratory staff follows procedural rules to apply a ‘flag’ to a patient record, and the LIMS then applies logic rules specific to the flag to control issue of components. This applies in particular to the clinical/diagnosis section below.

Logic rules specify the way in which the LIMS operates and should be configured to ensure the system meets all necessary legislation and guidelines. LIMS logic rules are established to control component release under normal circumstances, however there will sometimes be occasions when there is a need to override a specific logic rule (e.g. in a clinical emergency) and the system must allow this in a controlled manner and by appropriately authorised staff. Override actions must be defined and controlled through standard operating procedures. There must be an audit trail of all overrides capturing the reason and the operator.

The following rules that have been split into age, gender, clinical/diagnosis and antigen matching related sections.

|  |  |  |  |
| --- | --- | --- | --- |
| **Logic rule** | **Reference/evidence of compliance** | **Validation passed/failed** | **Date and initials of tester** |
| **Age-related** |  |  |  |
| Imported (non-UK) MB FFP (or SD FFP) for patients born after 1st Jan 1996 | SaBTO Updated Risk Assessment and reissued guidance 2012 (SaBTO 2012a) |  |  |
| Irradiated blood and platelets for intrauterine transfusion | BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)  Guidelines on the Use of Irradiated Blood Components 2011 (BCSH 2011) |  |  |
| CMV seronegative red cell and platelet components for intrauterine transfusions and for neonates (i.e. up to 28 days post expected date of delivery). | BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)  SaBTO cytomegalovirus tested blood components Position Statement March 2012 (SaBTO 2012b) |  |  |
| **Gender-related** |  |  |  |
| CDEK- red cells for females under 50 years of age and RhD neg | BCSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013) |  |  |
| cEK negative red cells for females under 50 years of age and RhD Pos | TRUST best practice SOP |  |  |
| CMV seronegative red cell and platelet components for transfusions during pregnancy | The guideline indicates this is not required for transfusion during delivery however, the LIMS may not have the necessary information to include this in the logic rule.  RCOG Green-top guideline (47) Blood Transfusion in Obstetrics (RCOG 2007)  SaBTO cytomegalovirus tested blood components Position Statement March (SaBTO 2012b) |  |  |
| Prophylactic anti-D immunoglobulin to non-sensitised pregnant RhD negative women | RCOG Green-top guideline (22): The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis (RCOG 2011)  BCSH Guidelines for the use of Prophylactic anti-D Immunoglobulin (BCSH 2006) Clinical/Diagnosis-related |  |  |
| **Irradiated products required for:** |  |  |  |
| Patients with Hodgkin’s Disease | Confirmation that LIMS attaches irradiated flag to all requests for blood components where the clinical indication is Hodgkin’s lymphoma  Where is the LIMS going to get this information? Not included in the national codes – will we still need to retain special requirements letter or reliant on EPR to pass on this information? |  |  |
| Patients within 7 days of autologous haemopoietic stem cell collection | Where is the LIMS going to get this information? Not included in the national codes – will we still need to retain special requirements letter or reliant on EPR to pass on this information? |  |  |
| Patients undergoing haemopoietic stem cell transplantation | Where is the LIMS going to get this information? Not included in the national codes – will we still need to retain special requirements letter or reliant on EPR to pass on this information? |  |  |
| Patients receiving purine analogue drugs | Where is the LIMS going to get this information? Not included in the national codes – will we still need to retain special requirements letter or reliant on EPR to pass on this information? |  |  |
| Patients post intrauterine transfusion whilst in the neonatal period | Where is the LIMS going to get this information? Not included in the national codes – will we still need to retain special requirements letter or reliant on EPR to pass on this information? |  |  |
| Consideration to length of time irradiated products are required for must be considered | Guidelines on the Use of Irradiated Blood Components (BCSH 2011)  BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004) |  |  |
| Rh and K-matched and HbS negative red cells for patients with Sickle Cell Disease | Standards for the care of adults with sickle cell disease in the UK (NHS 2008)  Sickle cell disease in childhood: standards and guidelines for clinical care (NHS 2010)  BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004) |  |  |
| Rh and K-matched red cells for patients with β-Thalassaemia major | Standards for the Clinical Care of Children and Adults with Thalassaemia in the UK (NHS 2008)  Thalassaemia International Federation Guidelines 2nd edition (Thal 2008) |  |  |
| Red cell units within 14 days of collection for red cell exchange in sickle cell disease or other haemoglobinopathy | Standards for the clinical care of adults with sickle cell disease in the UK (NHS 2008)  Sickle cell disease in childhood: standards and guidelines for clinical care (NHS 2010) |  |  |
| CMV seronegative red cell and platelet components according to local policy and if flagged e.g. haemopoietic stem cell transplantation, solid organ transplantation | European Bone Marrow Transplant handbook (EBMT 2012) |  |  |
| SD FFP for patients with TTP and HUS | BCSH Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies (BCSH 2012)  Confirmation that request for FFP for patient with HUS or TTP transmits requirement for Octaplas to LIMS |  |  |
| Platelets in PAS for those flagged | Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| Washed red cells for those flagged | Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| Antigen Matching Criteria | Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| Antigen negative for red cell antibodies of potentially clinically significant antibodies | BCSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013)  Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| HLA or platelet specific antigen-negative selected platelets for patients with HLA or HPA antibodies | BCSH Guidelines for the use of Platelet Transfusions (BCSH 2003)  BCSH Transfusion Guidelines for Neonates and Older Children 2004 (BCSH 2004)  Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| IgA deficient products (or equivalent) for those with anti-IgA antibodies | Confirmation that flag can be set in LIMS  Confirmation that the flag is transmitted to EPR for patient record – not attendance record |  |  |
| **Clinical data sets for transfusion – to be configured in the LIMS and EPR system** |  |  |  |
| Gastrointestinal  GI-Oesophageal  GI-Gastric  GI-Pancreatic  GI-Liver surgery  GI-Colorectal  GI-Other surgery  GI-Upper GI bleed (non-variceal)  GI-Upper GI bleed (variceal)  GI-Lower GI bleed  GI-Liver failure  GI-Pancreatitis | Confirmation that codes exist in LIMS |  |  |
| Genitourinary  GU-Cystectomy  GU-Nephrectomy  GU-Prostatectomy  GU-Other surgery | Confirmation that codes exist in LIMS |  |  |
| Gynaecology  Gyn-Surgical malignancy  Gyn-Surgical non-malignant  Gyn-Non surgical | Confirmation that codes exist in LIMS |  |  |
| Maxillo-facial Surgery  Plastic Surgery | Confirmation that codes exist in LIMS |  |  |
| Neurosurgery  Neuro-Intracranial bleeding  Neuro -Malignancy  Neuro -Spinal  Neuro -Other surgery | Confirmation that codes exist in LIMS |  |  |
| Obstetrics  Obs-APH  Obs-PPH  Obs-Placenta praevia  Obs-DIC  Obs-Caesarean section  Obs-Other surgery | Confirmation that codes exist in LIMS |  |  |
| Orthopaedics  Ortho-Primary Hip  Ortho-Redo Hip  Ortho-Primary Knee  Ortho- redo Knee  Ortho-Spinal  Ortho-Other surgery  Ortho-RTA  Ortho-# femur  Trauma-  Burns | Confirmation that codes exist in LIMS |  |  |
| Renal  Renal-CRF  Renal-ARF  Renal-HUS | Confirmation that codes exist in LIMS |  |  |
| Vascular  Vasc-Elective AAA  Vasc-Emergency AAA  Vasc-Leg artery grafts | Confirmation that codes exist in LIMS |  |  |
| Haematology  Haem-Aplastic anaemia  Haem-AML  Haem-ALL  Haem-MDS  Haem-MPD  Haem-Chronic leukaemia  Haem-Lymphoma  Haem-Myeloma  Haem-Iron deficiency  Haem-B12/folate deficiency  Haem-Anaemia of chronic disorders  Haem-Haemolysis acquired  Haem-Haemolysis congenital  Haem-Sickle cell disease  Haem-Thalassaemia  Haem-ITP  Haem-Congenital platelet disorder  Haem-DIC  Haem-TTP  Haem-Reversal of warfarin  Haem- single factor deficiency  Infection-Malaria | Confirmation that codes exist in LIMS |  |  |
| Oncology  Onc-Chemo  Onco-Anaemia of malignancy  Onco-Radiotherapy | Confirmation that codes exist in LIMS |  |  |
| Paediatics  Paed- exchange transfusion  Paed- top up transfusion  Paed-Neonatal alloimmune thrombocytopenia  Paed-Sepsis | Confirmation that codes exist in LIMS |  |  |
| Procedure  Pro-Ascitic tap  Pro-Chest drain  Pro-Endoscopy  Pro-ERCP  Pro-Laparoscopy  Pro-Line Insertion  Pro-Liver biopsy  Pro-Lumbar puncture | Confirmation that codes exist in LIMS |  |  |
| **Clinical Transfusion Dataset**  **Data item Source of data Mandatory (M) or desirable (D)?** |  |  |  |
| **Group and screen** |  |  |  |
| Patient identifier  Transfusion request into LIMS  M | Confirm that patient identifiers are transmitted from EPR to LIMS;  Surname  Forename  NHS number  RDE number |  |  |
| Consultant responsible for care  Transfusion request into LIMS  D | Confirm that consultant name/code is transmitted from EPR into LIMS system  Confirm actions taken by EPR and LIMS for non-consultant requests, including;  Clinical nurse specialists  Pre-operative assessment nurses  Midwives |  |  |
| Clinical Specialty  Transfusion request into LIMS  M | Confirm that clinical speciality is transmitted from EPR into LIMS system |  |  |
| Year of birth  Transfusion request into LIMS  M | Confirm that full date of birth (DD/MM/YYYY) is transmitted correctly from EPR to LIMS for at least 20 patients, including:  Patient born in 19…..  Patient born in 20….. |  |  |
| Gender  Transfusion request into LIMS  M | Confirm that gender transmitted from EPR  Male  Female  Unknown |  |  |
| Previous transfusion history  Transfusion request into LIMS  D | Confirm that LIMS retains legacy data for patient history including pregnancy  Confirm for at least 20 patients with known pregnancy history |  |  |
| Previous obstetric history  Transfusion request into LIMS  D | Confirm that information is transmitted from EPR  Note: acceptable if this information is in EPR only |  |  |
| **Blood component order** | Confirm that patient identifiers are transmitted from EPR to LIMS;  Surname  Forename  NHS number  RDE number |  |  |
| Patient identifier  Transfusion request into LIMS  M | Confirm that patient identifiers are transmitted from EPR to LIMS;  Surname  Forename  NHS number  RDE number |  |  |
| Consultant responsible for care  Transfusion request into LIMS  D | Confirm that consultant name/code is transmitted from EPR into LIMS system  Confirm actions taken by EPR and LIMS for non-consultant requests, including;  Clinical nurse specialists  Pre-operative assessment nurses  Midwives |  |  |
| Clinical Speciality  Transfusion request into LIMS  M | Confirm that clinical speciality is transmitted from EPR into LIMS system |  |  |
| Year of birth  Transfusion request into LIMS  M | Confirm that full date of birth (DD/MM/YYYY) is transmitted correctly from EPR to LIMS for at least 20 patients, including:  Patient born in 19…..  Patient born in 20….. |  |  |
| Gender  Transfusion request into LIMS  M | Confirm that gender transmitted from EPR  Male  Female  Unknown |  |  |
| Previous transfusion history  Transfusion request into LIMS  D | Confirm that LIMS retains legacy data for patient history including pregnancy  Confirm for at least 20 patients with known pregnancy history |  |  |
| Previous obstetric history  Transfusion request into LIMS  D | Confirm that information is transmitted from EPR  Note: acceptable if this information is in EPR only |  |  |
| Number of units (mL) required  Transfusion request into LIMS  M | Confirmation that number of units ordered within the EPR system is transferred to LIMS, for at least:  Red cell request  FFP request  Platelet request  Octaplas request  HAS request  Anti-D request  PCC request  IVIg request |  |  |
| Coded clinical reason for use  Transfusion request (selected by the requester)  M | Test for following request reason transmitted from EPR blood order:  R 1  Acute bleeding with BP instability  Massive haemorrhage  Trauma code red  R 2  Hb ≤ 70 g/L in stable ICU patient  R 3  Hb ≤ 80 g/L non-ICU patient with signs/symptoms of anaemia  R 4  Hb ≤ 100 g/L with acute cardiac ischaemia  R 5  Surgical blood loss anticipated  R 6  Other (free text)  Fresh frozen plasma  Information transmitted from EPR  F 1  Massive bleeding  F 2  INR ≥ 1.6 with bleeding  F 3  INR ≥ 1.6 and pre-procedure  F 4  Therapeutic exchange  F 5  Other (free text)  Cryoprecipitate  Information transmitted from EPR  C 1  Active bleeding  C 2  Fibrinogen ≤ 1.0g/l & pre-procedure  C 3  Other (free text)  Platelets  Information transmitted from EPR  P 1  PLT count ≤ 10 x 109/l stable patient  P 2  PLT count ≤ 20 x 109/l with platelet consumption  P 3  PLT count ≤ 50 x 109/l pre-procedure  P 4  Bleeding on anti-PLT medication  P 5  Massive bleeding  P 6  Other (free text) |  |  |
| Truncated National Indication Code  Transfusion request (selected by the requester)  M | Information transmitted from EPR and visible in LIMS  Test for following codes;  GIB  Nephrectomy  Cystectomy  Prostatectomy  Gynaecology–non-malignant surgery  Gynaecology–malignant surgery  Gynae - TOP  Maxillo-facial surgery  Obs-APH  Obs-APH  Obs-Placenta praevia  Obs-LSCS  Ortho-TKR  Ortho-THR  Ortho-rev TKR  Ortho- rev THR  Ortho-#NOF  Ortho-spinal  Renal-CRF  Renal – ARF  Renal –ESRF  Haem- Aplastic Anaemia  Haem- AML  Haem – ALL  Haem – MDS  Haem – MPD  Haem – CLL  Haem – Lymphoma  Haem – Myeloma  Haem – IDA  Haem – AIHA  Haem-SCD  Haem – Thalassaemia  Haem- ITP  Haem-Congenital platelet disorder  Haem- DIC  Haem- TTP  Haem- reversal of warfarin  Haem- reversal of DOAC  Haem- single factor deficiency  Onc –chemo  Onc- anaemia of malignancy  Onc-radiotherapy  Paed – exchange transfusion  Paed – top up transfusion  Paed – neonatal alloimmune thrombocytopaenia  Paed – sepsis  Pro – ascetic tap  Pro-chest drain  Pro-endoscopy  Pro-ERCP  Pro-laparoscopy  Pro-line insertion  Pro-liver biopsy  Pro-lumbar puncture  Vasc-Elective AAA  Vasc-Emergency AAA  Vasc-Leg artery grafts |  |  |
| Has consent been documented?  Transfusion request into LIMS  M | EPR only – no requirement for LIMS to retain this information |  |  |
| Was the patient transfused? Yes / No  LIMS  M | Transfusion fate visible in LIMS on patient history – attached to individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Octaplas  HAS  Anti-D  Confirm that LIMS clearly defined between fates:  Transfused  Returned to stock  Disposed |  |  |
| Date of transfusion  LIMS  M | Date of transfusion visible in LIMS on patient history – attached to individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Octaplas  HAS  Anti-D |  |  |
| Time of transfusion  LIMS  M | Time of transfusion visible in LIMS on patient history – attached to individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Octaplas  HAS  Anti-D |  |  |
| **Transfused component (ISBT)**  **LIMS**  **M** |  |  |  |
| Blood group of transfused component  LIMS  M | Blood group visible in LIMS on patient history – attached to individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Octaplas  Lyoplas |  |  |
| Blood group of patient  LIMS  M | Blood group of patient visible in LIMS on patient history – visible against individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Anti-D |  |  |
| Expiry date of component  LIMS  M | Expiry date visible in LIMS on patient history – attached to individual unit for components and products  Test minimum of 10 patients, including:  Red cell unit  FFP  Platelet  Cryo  Octaplas  Anti-D  HAS  IVIg  Factor concentrate |  |  |
| Pre transfusion lab test result (coag, Hb, plts)  LIMS - Haematology  M | Acceptable for EPR only |  |  |
| Post transfusion lab test result (coag,Hb, Plts)  LIMS - Haematology  M | Acceptable for EPR only |  |  |
| Hb 14-42 days pre op (if date of procedure known) | Acceptable for EPR only |  |  |
| **LIMS - Haematology**  M |  |  |  |
| Immediate Pre op Hb (if date / time of procedure known)  LIMS - Haematology  M | Acceptable for EPR only |  |  |
| Discharge Hb (if date of discharge known)  LIMS - Haematology  M | Acceptable for EPR only |  |  |
| Date of admission  PAS  M | Acceptable for EPR only |  |  |
| Date of discharge / death  PAS  M | Acceptable for EPR only |  |  |
| Did patient die in this admission?  PAS  M | Acceptable for EPR only |  |  |
| ICD10 code (diagnostic code)  PAS  M | Acceptable for EPR only |  |  |
| OPCS4 code (procedure code)  PAS  M | Acceptable for EPR only |  |  |
| HRG code  PAS  M | Acceptable for EPR only |  |  |
| Date and time of procedure  PAS  M | Acceptable for EPR only |  |  |
| Adverse event?  Not currently collected  D | Acceptable for EPR only |  |  |
| Near patient test result: Hb, coag, TEG/ROTEM, plt function test  LIMS – Haematology Beaker/Electronic blood tracking  D | Information obtained from EPR – visible in LIMS or via LIMS  Note: may be acceptable to access this information in Beaker/EPR only |  |  |
| Was cell salvage used?  Theatre record/Electronic blood tracking  D | Information obtained from Electronic blood tracking manager – visible in LIMS |  |  |
| Volume of salvaged red cells returned  Theatre record/Electronic blood tracking  D | Information obtained from Electronic blood tracking manager – visible in LIMS |  |  |
| Was tranexamic acid prescribed?  Paper prescription / electronic prescription  D | Information obtained from Electronic blood tracking manager – visible in LIMS |  |  |
| Was the prescriber trained in blood ordering?  Collected as part of transfusion request by EPR  D | NA – EPR will retain this information |  |  |
| **Categories of Justification for Transfusion to Support Appropriate Use**  **Red cell concentrates**  **Information transmitted from EPR** |  |  |  |
| R 1  Acute bleeding with BP instability | Information obtained from EPR – visible in LIMS |  |  |
| R 2  Hb ≤ 70 g/L in stable ICU patient | Information obtained from EPR – visible in LIMS |  |  |
| R 3  Hb ≤ 80 g/L non-ICU patient with signs/symptoms of anaemia | Information obtained from EPR – visible in LIMS |  |  |
| R 4  Hb ≤ 100 g/L with acute cardiac ischaemia | Information obtained from EPR – visible in LIMS |  |  |
| R 5  Surgical blood loss anticipated | Information obtained from EPR – visible in LIMS |  |  |
| R 6  Other (free text) | Information obtained from EPR – visible in LIMS |  |  |
| **Fresh frozen plasma**  **Information transmitted from EPR** |  |  |  |
| F 1  Massive bleeding | Information obtained from EPR – visible in LIMS |  |  |
| F 2  INR ≥ 1.6 with bleeding | Information obtained from EPR – visible in LIMS |  |  |
| F 3  INR ≥ 1.6 and pre-procedure | Information obtained from EPR – visible in LIMS |  |  |
| F 4  Therapeutic exchange | Information obtained from EPR – visible in LIMS |  |  |
| F 5  Other (free text) | Information obtained from EPR – visible in LIMS |  |  |
| **Cryoprecipitate**  **Information transmitted from EPR** |  |  |  |
| C 1  Active bleeding | Information obtained from EPR – visible in LIMS |  |  |
| C 2  Fibrinogen ≤ 1.0g/l & pre-procedure | Information obtained from EPR – visible in LIMS |  |  |
| C 3  Other (free text) | Information obtained from EPR – visible in LIMS |  |  |
| **Platelets**  **Information transmitted from EPR** |  |  |  |
| P 1  PLT count ≤ 10 x 109/l stable patient | Information obtained from EPR – visible in LIMS |  |  |
| P 2  PLT count ≤ 20 x 109/l with platelet consumption | Information obtained from EPR – visible in LIMS |  |  |
| P 3  PLT count ≤ 50 x 109/l pre-procedure | Information obtained from EPR – visible in LIMS |  |  |
| P 4  Bleeding on anti-PLT medication | Information obtained from EPR – visible in LIMS |  |  |
| P 5  Massive bleeding | Information obtained from EPR – visible in LIMS |  |  |
| P 6  Other (free text) | Information obtained from EPR – visible in LIMS |  |  |
| **Backdate rules** |  |  |  |
| Confirm that Backdate session requires entry of a reset date and time | Screenshot from LIMS |  |  |
| Confirm that the backdate date/time are displayed in red on the login screen | Screenshot from LIMS |  |  |
| Confirm that results can be added to a patient record in backdate mode | Confirmation that following tests can be added:  GGS2  KLE  Manual G&S  Phenotype  Extended phenotype  Antibody identification  DAT  MDAT |  |  |
| Confirm that components/batch products can be added to the patient record in backdate mode | Confirmation that following components/products can be added:  Red cells  FFP  CRYO  Platelets  HAS  PCC  IVIg |  |  |
| Return to current mode and review the history of the tests and component/product issues above | Screenshot confirm that:  LIMS identifies the records as being added in backdate mode  Dates/times are accurate as input |  |  |

# Appendix 2: E-issue and remote allocation rules

**RULE 1 No historic group excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 2 Historic blood group present accepted for e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue allowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue allowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue allowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue allowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE (same day) | E-issue allowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 3 Sample valid for 72 hours post transfusion**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue allowed |  |
| Date | Patient name | Accession no | ID no | 71 hours | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | E-ISSUE | E-issue allowed |  |
| Date | Patient name | Accession no | ID no | 72 hours | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | E-ISSUE | E-issue disallowed |  |
| Date | Patient name | Accession no | ID no | 72 hours | Tests requested | Expected result | Validation  Pass/Fail |
| Test rule with valid 72 hr sample but with new sample (unresulted in process) |  |  |  |  |  | Allows e-issue |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 4 Patients with positive antibody screen excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab pos cell 1 | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab pos cell 2 | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab pos cell 3 | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |
|  | Test patient with positive DAT but negative antibody screen |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 5 Patient with blood group discrepancy in historical records excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ABO discrepancy | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – RhD discrepancy | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 6 Patient with bone marrow transplant/solid organ transplant excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – bone marrow | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – solid organ | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 7 Patient with edited blood group excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – anti-A edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – anti-B edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – anti-AB edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – anti-D1 edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – anti-D2 edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – A cell result edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – B cell result edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – auto control result edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab screen cell 1 result edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab screen cell 2 result edited | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – ab screen cell 3 result edited | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 8 Blood units with manual entry excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – unit number manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – product code manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – expiry date manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – blood group manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – unit number and expiry date manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – unit number and product code date manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – product code and expiry date manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – unit number and blood group manual entry | E-issue disallowed |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – blood group and expiry date manual entry | E-issue disallowed |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

**RULE 9 ABO incompatible units excluded from e-issue**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Date | Patient name | Accession no | ID no | Sample collected date/time | Tests requested | Expected result | Validation  Pass/Fail |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor A patient O |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor B patient O |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor AB patient O |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor A patient B |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor B patient A |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor AB patient A |  |  |
|  |  |  |  |  | GROUP AND SCREEN  E-ISSUE – Donor AB patient B |  |  |

Validation accepted as passed

Name ……………………………. Signature…………………………. Date……………………………..

# Appendix 3: Remote allocation rules

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
|  |  |  |  | No special requirements, ABO/D compatible units offered |  |
| Manual edit testing |  |  |  | Not eligible for remote allocation |  |
|  |  | Blood unit manually edited |  | Not eligible for remote allocation |  |
|  |  | manually entered into stock |  | Not eligible for remote allocation |  |
| Special requirement testing |  | CMV negative requirement added |  | Only issues ABO/D compatible, CMV negative units |  |
|  |  | CMV negative requirement added |  | Only issues ABO/D compatible, CMV negative units |  |
|  |  | HbS negative requirement added |  | Only issues ABO/D compatible, HbS negative units |  |
|  |  | HbS negative requirement added |  | Only issues ABO/D compatible, HbS negative units |  |
|  |  | HEV negative requirement added |  | Only issues ABO/D HEV negative units |  |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
|  |  | Irradiated requirement added |  | Only issues ABO/D compatible, Irradiated units |  |
|  |  | Irradiated requirement added |  | Only issues ABO/D compatible, Irradiated units |  |
| Female <50 testing |  | cEK neg required |  | Only issues ABO/D compatible cEK- units |  |
|  |  | CEK- requirement |  | Only issues ABO CDEK- units |  |
|  |  | cEK- requirement |  | Only issues ABO/D compatible cEK- units |  |
|  |  | cEK neg required |  | Only issues ABO/D compatible cEK- units |  |
|  |  | cEK neg required |  | Only issues ABO/D compatible cEK- units |  |
|  |  | cEK neg required (patient DoB altered) |  | Only issues ABO/D compatible cEK- units |  |
|  |  | CEK- requirement |  | Only issues ABO CDEK- units |  |
|  |  | cEK neg required |  | Only issues ABO/D compatible cEK- units |  |
|  |  | C neg K neg required |  | None issued as no suitable in HB80 |  |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
| Antigen negative testing |  | CEK- required, added S- |  | Only issues ABO CDEK- units, S- |  |
|  |  | CEK- required, added M- |  | Only issues ABO CDEK- units, M- |  |
|  |  | Jkb negative required |  | Only issues ABO/D compatible Jkb – units |  |
|  |  | E- required |  | Only issues ABO/D compatible E – units |  |
|  |  | K- required |  | Only issues ABO/D compatible K – units |  |
|  |  | Jka negative requirement |  | Only issues ABO/D compatible Jka – units |  |
|  |  | s negative requirement |  | Only issues ABO/D compatible s – units |  |
|  |  | Fyb negative requirement |  | Only issues ABO/D compatible cEK Fyb – units |  |
|  |  | Fya negative requirement |  | Only issues ABO/D compatible Fya – units |  |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
|  |  | CEK Jka negative requirement |  | Only issues CEK Jka negative |  |
| Single sample testing |  |  |  | Not eligible for remote allocation |  |
|  |  |  |  | Not eligible for remote allocation |  |
|  |  |  |  | Not eligible for remote allocation |  |
| Blood group discrepancy testing |  |  |  | Not eligible for remote allocation until has 2 consecutive identical blood groups |  |
| End to end testing |  |  |  | Units allocated correctly, fated correctly on IPS and Electronic blood tracking |  |
|  |  |  |  | Units allocated correctly, fated correctly on IPS and Electronic blood tracking |  |
|  |  |  |  | Units allocated correctly, fated correctly on IPS and Electronic blood tracking |  |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
| Sample available testing |  |  | 4474473 | NO TEST added to patient record – IPS and Electronic blood tracking do not count as valid sample |  |
| Return of remote allocated unit |  |  |  | Unit allocated at HB80 then returned to stock, remains in the inventory list |  |
| Alerts testing |  |  |  | Incorrect tag scanned at kiosk during remote allocation process – alert at kiosk and manager |  |
|  |  |  |  | Disconnect from LIS errors – alerts at BT manager |  |
|  |  |  |  | * 30 minute rule testing – unit returned to HB80 but created an alert and quarantined unit |  |
|  |  |  |  | Unit transfused to wrong patient on Tx begin transfusion – created alert on PDA and on BT manager |  |
| **Rule tested** | **Date tested** | **Patient number** | **Lab number (if relevant)** | **Expected result** | **Date and initials of tester** |
|  |  |  |  | Unit scanned against a different patient compatibility tag – label does not match unit and removed without scanning alerts |  |
|  |  |  |  | Incorrect tag scanned at kiosk – alert at kiosk and BT manager |  |

# Appendix 4: Remote allocation truth table

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Donor blood group | | | | | | | |
| Patient | O Pos | O Neg | A Pos | A Neg | B Pos | B Neg | AB Pos | AB Neg |
| O Pos | 1 | 99 | 99 | 99 | 99 | 99 | 99 | 99 |
| O Neg | 99 | 1 | 99 | 99 | 99 | 99 | 99 | 99 |
| A Pos | 99 | 99 | 1 | 99 | 99 | 99 | 99 | 99 |
| A Neg | 99 | 99 | 99 | 1 | 99 | 99 | 99 | 99 |
| B Pos | 99 | 99 | 99 | 99 | 1 | 99 | 99 | 99 |
| B Neg | 99 | 99 | 99 | 99 | 99 | 1 | 99 | 99 |
| AB Pos | 99 | 99 | 2 | 99 | 99 | 99 | 1 | 99 |
| AB Neg | 99 | 99 | 99 | 2 | 99 | 99 | 99 | 1 |

Key:

1= red cell issue allowed

99= red cell issue prevented

# Appendix 5: Antibody specificities and their clinical significance

|  |  |  |
| --- | --- | --- |
| **System** | **Antibody** | **Recommendation[[1]](#footnote-1)** |
| ABO | Anti-A1 | IAT crossmatch compatible |
| *H* | *Anti-H (in A1 and A1B patients)* | IAT crossmatch compatible |
| Prophylactic anti-D | Prophylactic Anti-D | IAT crossmatch compatible |
| Rh | Anti-D,-C,-c,-E,-e | Antigen negative |
| Rh | Cw | IAT crossmatch compatible 2 |
| Kell | Anti-K,-k,- Kpb,-Jsb | Antigen negative |
| *Kell* | *Anti-Kpa* | IAT crossmatch compatible 2 |
| Kidd | Anti-Jka,-Jkb | Antigen negative |
| MNS | Anti-M (active at 37oC) | Antigen negative |
| *MNS* | *Anti-M (not active at 37oC)* | IAT crossmatch compatible |
| *MNS* | *Anti-N* | IAT crossmatch compatible |
| MNS | Anti-S,-s,-U | Antigen negative |
| Duffy | Anti-Fya,-Fyb | Antigen negative |
| *P* | *Anti-P1* | IAT crossmatch compatible |
| *Lewis* | *Anti-Lea,-Leb,-Le-a+b* | IAT crossmatch compatible |
| *Lutheran* | *Anti-Lua* | IAT crossmatch compatible |
| Lutheran | Anti-Lub | Antigen negative |
| Diego | Anti-Wra | *IAT Crossmatch compatible* |
| *Chido/Rodgers* | *Chido/Rodgers antibodies* | *Use plasma neutralized with AB serum and issue ABO & D matched blood compatible by 37ºC IAT\** |
| *Knops system* | *Anti Kna-McCa* | *Not clinically significant. Issue least incompatible to reduce the risk of masking other, clinically significant, antibodies* |
| Others | All others active by IAT at 37oC | Seek advice from Blood Centre |
| Auto Antibodies | Autoantibodies | If a new case seek advice from Blood Centre, Test & perform IAT crossmatch if RCI report indicates. |

IAT crossmatch compatible: *Select blood of the same (or compatible) ABO and D type as the patient and crossmatch in IAT (Diamed BioRad) at 37oC, override the antigen matching alert and type* IAT XM compatible required*.*

2 These recommendations apply when the antibody is present as a sole specificity. If present in combination, antigen negative blood may be provided by the blood centre, to prevent wastage of phenotyped units.

# Appendix 6: Antenatal testing requirements

Rh D Positive

No Antibodies

Rh D Negative

No Antibodies

BLOOD GROUP AND ANTIBODY SCREEN AT 28 WEEKS

Rh D Positive

No Antibodies

NO FURTHER TESTING

Rh D Negative

No Antibodies

CORD AND MATERNAL SAMPLES AT DELIVERY

Rh D Negative

Antibodies

Rh D Positive

Antibodies

IDENTIFY ANTIBODY

Clinically significant antibodies  
(Non D, c or K)

Anti-D, c or K

Titre

Partner/fetus antigen status unknown or positive

Partner/ Fetus antigen  
negative

Titre/Quantify

Partner testing / fetal typing  
from maternal blood.

Repeat Antibody Titre / Quantification at 2 weekly intervals until delivery

**ABO, Rh D typing and antibody screening at Booking**

Non clinically significant /   
non-specific antibodies

Partner testing / fetal typing from maternal blood

# Appendix 7: Blood selection via remote allocation



# Appendix 8: Blood Selection via e-issue



# Appendix 9: Baby crossmatch rules



# Appendix 10: Antigen matching rules



# Appendix 11: Plasma component selection rules

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Post 1 Jan 1996 | Patient ABO group  **A** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | N | |  | |  | |
| FFP HT- | O |  | N | |  | |  | |
| FFP HT- | A |  | N | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | N | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | N | |  | |  | |
| CRYO HT- POOL | O |  | N | |  | |  | |
| CRYO HT- POOL | A |  | N | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | N | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | Y | |  | |  | |
| MB FFP | B |  | N | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | Y | |  | |  | |
| MB CRYO POOL | B |  | N | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | N | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | Y | |  | |  | |
| PLTLD | B+ |  | N | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | N | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | Y | |  | |  | |
| PLTIR | A+ |  | Y | |  | |  | |
| PLTIR | B+ |  | N | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | N | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | Y | |  | |  | |
| PLTP | B+ |  | N | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | N | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Post 1 Jan 1996 | Patient ABO group  **O** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | N | |  | |  | |
| FFP HT- | O |  | N | |  | |  | |
| FFP HT- | A |  | N | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | N | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | N | |  | |  | |
| CRYO HT- POOL | O |  | N | |  | |  | |
| CRYO HT- POOL | A |  | N | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | N | |  | |  | |
| MB FFP  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP | A |  | Y | |  | |  | |
| MB FFP | B |  | Y | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | Y | |  | |  | |
| MB CRYO POOL | A |  | Y | |  | |  | |
| MB CRYO POOL | B |  | Y | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | Y | |  | |  | |
| PLTLD | A+ |  | Y | |  | |  | |
| PLTLD | B+ |  | Y | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | Y | |  | |  | |
| PLTLD | A- |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | Y | |  | |  | |
| PLTIR | A+ |  | Y | |  | |  | |
| PLTIR | B+ |  | Y | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | Y | |  | |  | |
| PLTIR | A- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | Y | |  | |  | |
| PLTP | A+ |  | Y | |  | |  | |
| PLTP | B+ |  | Y | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | Y | |  | |  | |
| PLTP | A- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Post 1 Jan 1996 | Patient ABO group  **B** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | N | |  | |  | |
| FFP HT- | O |  | N | |  | |  | |
| FFP HT- | A |  | N | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | N | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | N | |  | |  | |
| CRYO HT- POOL | O |  | N | |  | |  | |
| CRYO HT- POOL | A |  | N | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | N | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | N | |  | |  | |
| MB FFP | B |  | Y | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | N | |  | |  | |
| MB CRYO POOL | B |  | Y | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | N | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | N | |  | |  | |
| PLTLD | B+ |  | Y | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | N | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | N | |  | |  | |
| PLTIR | A+ |  | N | |  | |  | |
| PLTIR | B+ |  | Y | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | N | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | N | |  | |  | |
| PLTP | B+ |  | Y | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | N | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

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| Hosp No | DoB  Post 1 Jan 1996 | Patient ABO group  **AB** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | N | |  | |  | |
| FFP HT- | O |  | N | |  | |  | |
| FFP HT- | A |  | N | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | N | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | N | |  | |  | |
| CRYO HT- POOL | O |  | N | |  | |  | |
| CRYO HT- POOL | A |  | N | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | N | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | Y | |  | |  | |
| MB FFP | B |  | N | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | Y | |  | |  | |
| MB CRYO POOL | B |  | N | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | Y | |  | |  | |
| PLTLD | B+ |  | N | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | N | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | N | |  | |  | |
| PLTIR | A+ |  | Y | |  | |  | |
| PLTIR | B+ |  | N | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | N | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | Y | |  | |  | |
| PLTP | B+ |  | N | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | N | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | N | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  PRE 1 Jan 1996 | Patient ABO group  **A** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | Y | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | Y | |  | |  | |
| FFP HT- | O |  | Y | |  | |  | |
| FFP HT- | A |  | Y | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | Y | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | Y | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | Y | |  | |  | |
| CRYO HT- POOL | O |  | Y | |  | |  | |
| CRYO HT- POOL | A |  | Y | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | Y | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | Y | |  | |  | |
| MB FFP | B |  | N | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | Y | |  | |  | |
| MB CRYO POOL | B |  | N | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | Y | |  | |  | |
| PLTLD | B+ |  | N | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | N | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | N | |  | |  | |
| PLTIR | A+ |  | Y | |  | |  | |
| PLTIR | B+ |  | N | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | N | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | Y | |  | |  | |
| PLTP | B+ |  | N | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | N | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Pre 1 Jan 1996 | Patient ABO group  **O** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | Y | |  | |  | |
| FFP | A |  | Y | |  | |  | |
| FFP | B |  | Y | |  | |  | |
| FFP | AB |  | Y | |  | |  | |
| FFP HT- | O |  | Y | |  | |  | |
| FFP HT- | A |  | Y | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | Y | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | Y | |  | |  | |
| CRYO POOLED | A |  | Y | |  | |  | |
| CRYO POOLED | B |  | Y | |  | |  | |
| CRYO POOLED | AB |  | Y | |  | |  | |
| CRYO HT- POOL | O |  | Y | |  | |  | |
| CRYO HT- POOL | A |  | Y | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | Y | |  | |  | |
| MB FFP  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP | A |  | Y | |  | |  | |
| MB FFP | B |  | Y | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | Y | |  | |  | |
| MB CRYO POOL | A |  | Y | |  | |  | |
| MB CRYO POOL | B |  | Y | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | Y | |  | |  | |
| PLTLD | A+ |  | Y | |  | |  | |
| PLTLD | B+ |  | Y | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | Y | |  | |  | |
| PLTLD | A- |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | Y | |  | |  | |
| PLTIR | A+ |  | Y | |  | |  | |
| PLTIR | B+ |  | Y | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | Y | |  | |  | |
| PLTIR | A- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | Y | |  | |  | |
| PLTP | A+ |  | Y | |  | |  | |
| PLTP | B+ |  | Y | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | Y | |  | |  | |
| PLTP | A- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Pre 1 Jan 1996 | Patient ABO group  **B** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | Y | |  | |  | |
| FFP | AB |  | Y | |  | |  | |
| FFP HT- | O |  | Y | |  | |  | |
| FFP HT- | A |  | Y | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | Y | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | Y | |  | |  | |
| CRYO POOLED | AB |  | Y | |  | |  | |
| CRYO HT- POOL | O |  | Y | |  | |  | |
| CRYO HT- POOL | A |  | Y | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | Y | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | N | |  | |  | |
| MB FFP | B |  | Y | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | N | |  | |  | |
| MB CRYO POOL | B |  | Y | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | N | |  | |  | |
| PLTLD | B+ |  | Y | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | N | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | N | |  | |  | |
| PLTIR | A+ |  | N | |  | |  | |
| PLTIR | B+ |  | Y | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | N | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | N | |  | |  | |
| PLTP | B+ |  | Y | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | N | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | Y | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB  Pre 1 Jan 1996 | Patient ABO group  **AB** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 FFP/CRYO ABO Truth table prevents issue of incorrect types**  **RULE 2 PLATELET Truth table prevents issue of incorrect types (Al=Alert)**  **RULE 3 Platelet check alert for Female <50yr** | | | FFP  **FFP LD** | O |  | N | |  | |  | |
| FFP | A |  | N | |  | |  | |
| FFP | B |  | N | |  | |  | |
| FFP | AB |  | Y | |  | |  | |
| FFP HT- | O |  | Y | |  | |  | |
| FFP HT- | A |  | Y | |  | |  | |
|  | | | FFP HT-  **FFP LD** | B |  | Y | |  | |  | |
| CRYO POOLED  **CRYOPP** | O |  | N | |  | |  | |
| CRYO POOLED | A |  | N | |  | |  | |
| CRYO POOLED | B |  | N | |  | |  | |
| CRYO POOLED | AB |  | Y | |  | |  | |
| CRYO HT- POOL | O |  | Y | |  | |  | |
| CRYO HT- POOL | A |  | Y | |  | |  | |
|  | | | CRYO HT- POOL  **CRYOPP** | B |  | Y | |  | |  | |
| MB FFP  **FFPMB1** | O |  | N | |  | |  | |
| MB FFP | A |  | N | |  | |  | |
| MB FFP | B |  | N | |  | |  | |
| MB FFP  **FFPMB -P** | AB |  | Y | |  | |  | |
| MB FFP HT-  **FFPMB1** | O |  | Y | |  | |  | |
| MB FFP HT- | A |  | Y | |  | |  | |
| MB FFP HT- | B |  | Y | |  | |  | |
| MB CRYO POOL  **CRYPMBP** | O |  | N | |  | |  | |
| MB CRYO POOL | A |  | N | |  | |  | |
| MB CRYO POOL | B |  | N | |  | |  | |
| MB CRYO POOL | AB |  | Y | |  | |  | |
| MB CRYO POOL HT- | O |  | Y | |  | |  | |
| MB CRYO POOL HT- | A |  | Y | |  | |  | |
| MB CRYO POOL HT-  **CRYPMBP** | B |  | Y | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | O + |  | N | |  | |  | |
| PLTLD | A+ |  | N | |  | |  | |
| PLTLD | B+ |  | N | |  | |  | |
| PLTLD | AB+ |  | Y | |  | |  | |
| PLTLD | O- |  | N | |  | |  | |
| PLTLD | A- |  | N | |  | |  | |
|  | | | PLTLD  **PLTLDAS1** | B- |  | N | |  | |  | |
| PLTLD | AB- |  | Y | |  | |  | |
| PLTLD HT- | O+ |  | Y | |  | |  | |
| PLTLD HT- | A+ |  | Y | |  | |  | |
| PLTLD HT- | B+ |  | Y | |  | |  | |
| PLTLD HT- | O- |  | Y | |  | |  | |
| PLTLD HT- | A- |  | Y | |  | |  | |
| PLTLD HT-  **PLTLDAS1** | B- |  | Y | |  | |  | |
| PLTIR  **PLTAIRAS1** | O+ |  | N | |  | |  | |
| PLTIR | A+ |  | N | |  | |  | |
| PLTIR | B+ |  | N | |  | |  | |
| PLTIR | AB+ |  | Y | |  | |  | |
| PLTIR | O- |  | N | |  | |  | |
| PLTIR | A- |  | N | |  | |  | |
| PLTIR  **PLTAIRAS1** | B- |  | N | |  | |  | |
| PLTIR | AB- |  | Y | |  | |  | |
| PLTIR HT- | O+ |  | Y | |  | |  | |
| PLTIR HT- | A+ |  | Y | |  | |  | |
| PLTIR HT- | B+ |  | Y | |  | |  | |
| PLTIR HT- | O- |  | Y | |  | |  | |
| PLTIR HT- | A- |  | Y | |  | |  | |
| PLTIR HT-  **PLTAIRAS1** | B- |  | Y | |  | |  | |
| PLTP  **IRR-PLTP-1** | O+ |  | N | |  | |  | |
| PLTP | A+ |  | N | |  | |  | |
| PLTP | B+ |  | N | |  | |  | |
| PLTP | AB+ |  | Y | |  | |  | |
| PLTP | O- |  | N | |  | |  | |
| PLTP | A- |  | N | |  | |  | |
| PLTP  **IRR-PLTP-1** | B- |  | N | |  | |  | |
| PLTP | AB- |  | Y | |  | |  | |
| PLTP HT- | O+ |  | Y | |  | |  | |
| PLTP HT- | A+ |  | Y | |  | |  | |
| PLTP HT- | B+ |  | Y | |  | |  | |
| PLTP HT- | O- |  | Y | |  | |  | |
| PLTP HT- | A- |  | Y | |  | |  | |
| PLTP HT-  **IRR-PLTP-1** | B- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | O+ |  | N | |  | |  | |
| PLTLHCI HT- | A+ |  | Y | |  | |  | |
| PLTLHCI HT- | B+ |  | Y | |  | |  | |
| PLTLHCI | AB+ |  | Y | |  | |  | |
| PLTLHCI HT- | O- |  | Y | |  | |  | |
| PLTLHCI HT- | A- |  | Y | |  | |  | |
| PLTLHCI HT-  **IRRA-PLTHC** | B- |  | Y | |  | |  | |
| PLTLHCI | AB- |  | Y | |  | |  | |
|  | | |  |  |  |  | |  | |  | |

# Appendix 12: Selection of FFP for adults – truth table

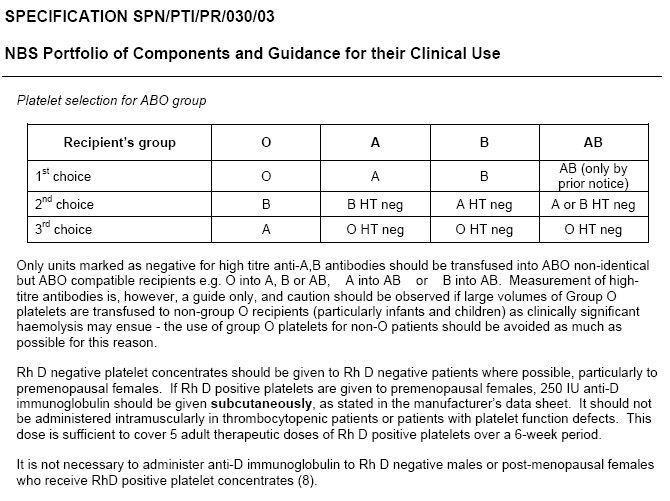
**Adults receiving high titre positive or untested units**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Recipient group** | | **O** | **A** | **B** | **AB** |
| **1st** | **Choice** | **O** | **A** | **B** | **AB** |
| **2nd** | **Choice** | **A** | **AB** | **AB** | **A\*\*** |
| **3rd** | **Choice** | **B** | **B\*\*** | **A\*\*** | **B\*\*** |
| **4th** | **Choice** | **AB** | **-** | **-** | **-** |

**Adults receiving high titre negative units**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Recipient group** | | **O** | **A** | **B** | **AB** |
| **1st** | **Choice** | **O** | **A** | **B** | **AB** |
| **2nd** | **Choice** | **A** | **B** | **A** | **A** |
| **3rd** | **Choice** | **B** | **AB** | **AB** | **B** |
| **4th** | **Choice** | **AB** | **-** | **-** | **-** |

# Appendix 13: Platelet selection truth table



# Appendix 14: Octaplas selection

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Product type | Product ABO Group | Donation No | Hosp No | Patient ABO RhD group |  | Expected result | Validation date  Pass/Fail & initials | Notes |

**RULE A OCTAPLAS TRUTH TABLE FOR GROUP A OCTAPLAS (Barcode =%6600)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OCTAPLAS | A+ | X00216477804 | HH14329 | A- |  | Accept |  |  |
| OCTAPLAS | A+ | “ | HH14303 | B- |  | REJECT |  |  |
| OCTAPLAS | A+ | “ | HJ35689 | AB- |  | REJECT |  |  |
| OCTAPLAS | A+ | “ | HH14282 | O- |  | Accept |  |  |
| OCTAPLAS | A+ | “ | HH11970 | A+ |  | Accept |  |  |
| OCTAPLAS | A+ | “ | HJ35700 | B+ |  | REJECT |  |  |
| OCTAPLAS | A+ | “ | HH14311 | AB+ |  | REJECT |  |  |
| OCTAPLAS | A+ | “ | HJ05413 | O+ |  | Accept |  |  |

**RULE B OCTAPLAS TRUTH TABLE FOR GROUP AB OCTAPLAS (Barcode=%8800)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| OCTAPLAS | AB+ | X00216230149 | HH14329 | A- |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HH14303 | B- |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HJ35689 | AB- |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HH14282 | O- |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HH11970 | A+ |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HJ35700 | B+ |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HH14311 | AB+ |  | Accept |  |  |
| OCTAPLAS | AB+ | “ | HJ05413 | O+ |  | Accept |  |  |

# Appendix 15a: ABO/D compatibility truth table (as extracted from current LIMS)

**Product Type: RCLD - Leucodepleted Red Cells, Red Cells Irradiated**

Table ID: RC

A+  - A+ (1)  A- (41) O+ (41) O- (41)

A-  - A+ (43) A- (1)  O+ (45) O- (41)

AB+ - A+ (25) A- (41) AB+(1)  AB-(41) B+ (41) B- (41) O+ (41) O- (43)

AB- - A+ (47) A- (41) AB+(43) AB-(1)  B+ (45) B- (41) O+ (49) O- (41)

B+  - B+ (1)  B- (41) O+ (41) O- (41)

B-  - B+ (43) B- (1)  O+ (45) O- (41)

O+  - O+ (1)  O- (41)

O-  - O+ (41) O- (1)

Red cell selection truthtable:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Donor blood group | | | | | | | |
| Patient | O Pos | O Neg | A Pos | A Neg | B Pos | B Neg | AB Pos | AB Neg |
| O Pos | 1 | 2 | 99 | 99 | 99 | 99 | 99 | 99 |
| O Neg | 2 | 1 | 99 | 99 | 99 | 99 | 99 | 99 |
| A Pos | 2 | 2 | 1 | 2 | 99 | 99 | 99 | 99 |
| A Neg | 2 | 2 | 2 | 1 | 99 | 99 | 99 | 99 |
| B Pos | 2 | 2 | 99 | 99 | 1 | 2 | 99 | 99 |
| B Neg | 2 | 2 | 99 | 99 | 2 | 1 | 99 | 99 |
| AB Pos | 2 | 2 | 2 | 2 | 2 | 2 | 1 | 2 |
| AB Neg | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 1 |
|  |  |  |  |  |  |  |  |  |

Key:

1,2 = acceptable

99= not acceptable (prevented by LIMS)**Appendix 15b: Red cell selection for marrow or PBSC transplant patients**

Input patient MRN and unit number in the table to demonstrate validation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = O | | | |
|  | Red cell ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | N | N | N | Y |
| B | N | N | N | Y |
| AB | N | N | N | Y |
| O | N | N | N | Y |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = A | | | |
|  | Red cell ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | Y |
| B | N | N | N | Y |
| AB | Y | N | N | Y |
| O | N | N | N | Y |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = B | | | |
|  | Red cell ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | N | N | N | Y |
| B | N | Y | N | Y |
| AB | N | Y | N | Y |
| O | N | N | N | Y |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = AB | | | |
|  | Red cell ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | Y |
| B | N | Y | N | Y |
| AB | Y | Y | Y | Y |
| O | N | N | N | Y |

Y = LIMS allows reservation and issue

N = LIMS blocks reservation and issue (override allowed with full audit trail)

# Appendix 15c: Platelet selection for marrow or PBSC transplant patients

Input patient MRN and unit number in the table to demonstrate validation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = O | | | |
|  | Platelet ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | N |
| B | N | Y | N | N |
| AB | Y | N | N | N |
| O | Y | Y | Y | Y |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = A | | | |
|  | Platelet ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | Y | N |
| B | Y | N | N | N |
| AB | Y | N | N | N |
| O | Y | N | N | N |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = B | | | |
|  | Platelet ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | N | Y | N | N |
| B | N | Y | Y | N |
| AB | N | Y | N | N |
| O | N | Y | N | N |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = AB | | | |
|  | Platelet ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | N |
| B | N | Y | N | N |
| AB | N | N | Y | N |
| O | Y | N | N | N |

Y = LIMS allows reservation and issue

N = LIMS blocks reservation and issue (override allowed with full audit trail)

# Appendix 15d: FFP selection for marrow or PBSC transplant patients

Input patient MRN and unit number in the table to demonstrate validation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = O | | | |
|  | FFP ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | N |
| B | N | Y | N | N |
| AB | N | N | Y | N |
| O | N | N | N | Y |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = A | | | |
|  | FFP ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | Y | N | N | N |
| B | N | N | Y | N |
| AB | N | N | Y | N |
| O | Y | N | N | N |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = B | | | |
|  | FFP ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | N | N | Y | N |
| B | N | Y | N | N |
| AB | N | N | Y | N |
| O | N | Y | N | N |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Recipient ABO group = AB | | | |
|  | FFP ABO group for transfusion | | | |
| Marrow/PBCS donor ABO group | A | B | AB | O |
| A | N | N | Y | N |
| B | N | N | Y | N |
| AB | N | N | Y | N |
| O | N | N | Y | N |

Y = LIMS allows reservation and issue

N = LIMS blocks reservation and issue (override allowed with full audit trail)

# Appendix 16: IVIg request management

|  |  |  |
| --- | --- | --- |
| **Conditions** | **Short term** | **Long term** |
| Alloimmune Thrombocytopenia (foeto-maternal/neonatal) | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Chronic inflammatory demyelinating polyradiculoneuropathy | C | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Gullian-Barre Syndrome | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Haemolytic disease of the newborn | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| HSCT in primary immunodeficiencies | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Immune thrombocytopenic purpura (acute and persistent, excluding chronic) | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Kawaski disease | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Paraprotein –associated demyelinating neuropathy (IgM, IgG or IgA) | C | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Primary immunodeficiencies | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Specific antibody deficiency | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Thymoma with immunodeficiency | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Toxic epidermal necrolysis, stevens Johnson syndrome | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Acquired red cell aplasia | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Autoimmune congenital heart block | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Autoimmune haemolytic anaemia | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Autoimmune uveitis | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Coagulation factor inhibitors (alloantibodies and autoantibodies) | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Haemophagocytic syndrome | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Immunobullous disease | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Inflammatory myopathy | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Multifocal motor neuropathy | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Myasthenia gravis (including Lambert-Eaton myasthenic syndrome) | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Necrotising (PVL-associated) staphylococcal sepsis | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Post-transfusion purpura | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Rasmussen syndrome | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Secondary antibody deficiency (any cause) | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Severe or recurrent clostridium difficile colitis | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Staphylococcalor Streptococcal toxic shock syndrome | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Stiff person syndrome | NC | C |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |
| Transplantation (solid organ) | C | NC |
| Validation evidence – patient number/product number |  |  |
| Validation passed |  |  |

C=commissioned (product issue allowed by LIMS with no recorded IVIg registration form)

NC = not commissioned (product issue allowed by LIMS only with recorded IVIg registration form)

# Appendix 17: IVIg ideal body weight dose calculator



# Appendix 18: Blood component/product movement

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Storage location - movements** | | | | | | | | | | | | | | | | |
| **Component/Product** | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Red cells | Y | Y | N | n | Y | N | Y | Y | Y | N | Y | N | Y | N | Y | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **Storage location - movements** | | | | | | | | | | | | | | | | |
| **Component/Product** | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Red cells | Y | Y | N | n | Y | N | Y | Y | Y | N | Y | N | Y | N | Y | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Storage location - movements** | | | | | | | | | | | | | | | | |
| **Component/Product** | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Red cells | Y | Y | N | n | Y | N | Y | Y | Y | N | Y | N | Y | N | Y | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| FFP | Y | Y | N | n | N | N | Y | Y | Y | N | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Cryo | N | N | N | Y | N | N | N | N | N | N | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Platelets | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | Y |
|  | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Lyoplas | Y | N | Y | N | N | Y | N | N | N | N | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Octaplas | Y | Y | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Anti-D | Y | Y | Y | N | Y | N | Y | N | N | N | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Human albumin 5% or 4.5% | Y | N | Y | N | Y | N | N | N | N | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Human albumin 20% | Y | N | Y | N | N | N | N | N | N | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| C1 esterase inhibitor | Y | N | Y | N | N | N | N | N | N | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Factor concentrate | Y | N | Y | N | N | N | N | N | N | N | N | Y | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Intravenous immunoglobulin | Y | N | Y | N | N | N | Y | N | N | N | N | Y | N | Y | N | Y | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Prothrombin complex concentrate | Y | N | Y | N | N | N | N | N | N | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Anti-tetanus | Y | N | Y | N | N | N | N | N | Y | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | Stock fridge | Issue HB80 | Batch Issue location | BT lab | Community | Air ambulance | Labour Ward HB20 | PEOC HB20 | Main Theatres HB20 | Main theatre batch fridge | Yarty HB20 | Yarty batch fridge | Sidmouth HB20 | Sidmouth batch fridge | Tiverton HB20 | Tiverton batch fridge | Platelet agitator |
| Direct oral anticoagulant reversal agent | Y | N | Y | N | N | N | N | N | N | Y | N | N | N | N | N | N | N |
| Validation evidence – patient number/product number |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**Date and initials of tester:....................................**

Key:

Y = reservation/issue allowed

N = reservation/issue blocked

A = reservation/issue allowed with alert and override (audit trail required)

# Appendix 19: Blood group interpretation tables for component selection

First column is the patient’s ABO/Rh what follows after the “-“ are the compatible ABO/Rh units with a priority, if any, in brackets. Lower value is a closer match and is used when presenting a list of stock to use (along with expiry date).

Red cell selection testing and acceptance criteria:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **O** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | O |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | A |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | B |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | AB |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | O |  | Allow | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **A** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | A |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | B |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | AB |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **B** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | A |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | B |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | AB |  | Prevent | |  | |  | |
| RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **AB** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | A |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | B |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | AB |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | O |  | Alert | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **RhD Positive** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | RhD positive |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | RhD Negative |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | RhD positive |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | RhD Negative |  | Alert | |  | |  | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Patient ABO group  **RhD Negative** | Component type | Donor Group | Donation Number | | Expected result | | Pass/Fail & initials | | **Date and initials of tester** |
| **RULE 1 RCLD ABO Truth table prevents issue of incorrect types**  **RULE 2 RC Irradiated Truth table prevents issue of incorrect types**  **RULE 3 selection of non-identical but compatible types (Al=Alert)** | | | RCLD  **RC Irradiated** | RhD positive |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | RhD Negative |  | Allow | |  | |  | |
| RCLD  **RC Irradiated** | RhD positive |  | Alert | |  | |  | |
| RCLD  **RC Irradiated** | RhD Negative |  | Allow | |  | |  | |

Appendix 18: Blood product management table

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | | **Product reserved/issued** | | | | | | | |  | **Date and initials of tester** |
| **Product requested** | Anti-D | Human albumin 5% or 4.5% | | Human albumin 20% | C1 esterase inhibitor | Factor concentrate | Intravenous immunoglobulin | Prothrombin complex concentrate | Anti-tetanus | Direct oral anticoagulant reversal agent | Lyoplas |  |
| Anti-D | Y | N | | N | N | N | N | N | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Human albumin 5% or 4.5% | N | Y | | A | N | N | N | N | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Human albumin 20% | N | A | | Y | N | N | N | N | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| C1 esterase inhibitor | N | N | | N | Y | N | N | N | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Factor concentrate | N | N | | N | N | Y | N | N | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Intravenous immunoglobulin | N | N | | N | N | N | Y | N | A | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Prothrombin complex concentrate | N | N | | N | N | N | N | Y | N | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Anti-tetanus | N | N | | N | N | N | N | N | Y | N | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Direct oral anticoagulant reversal agent | N | N | | N | N | N | N | N | N | Y | N |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |
| Lyoplas | N | N | | N | N | N | N | N | N | N | Y |  |
| Validation evidence – patient number/product number |  |  | |  |  |  |  |  |  |  |  |  |
| Validation passed |  |  | |  |  |  |  |  |  |  |  |  |

Key:

Y = reservation/issue allowed

N = reservation/issue blocked

A = reservation/issue allowed with alert and override (audit trail required)

# Appendix 20: Blood Group interpretation from manual assays

1. BioRad adult card

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Blood group | Reagents used in assay | Expected blood group results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | A RhD pos  Correct group | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  A Cells+  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control + |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | B RhD pos | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells +  Control + |  |  |  |
|  |  | O RhD pos | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells +  B Cells +  Control + |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | AB RhD Pos | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control + |  |  |  |
|  |  | A RhD neg | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells+  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells +  Control + |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A+  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control + |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | O RhD neg | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  A Cells +  B Cells +  Control + |  |  |  |
|  |  | AB RhD neg | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A +  Anti-B -  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  A Cells -  B Cells -  Control + |  |  |  |

1. Tube Group

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Blood group | Reagents used in assay | Expected blood group results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | A RhD pos  Correct group | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD pos  Incorrect group | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | B RhD pos | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | B RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control+ |  |  |  |
|  |  | O RhD pos | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control + |  |  |  |
|  |  | O RhD pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | AB RhD Pos | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells -  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | AB RhD Pos | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control+ |  |  |  |
|  |  | AB RhD Pos  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D +  Anti-D +  A Cells -  B Cells -  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D +  A Cells -  B Cells -  Control - |  |  |  |
|  |  | A RhD neg | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D +  Anti-D +  A Cells -  B Cells +  Control - |  |  |  |
|  |  | A RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control + |  |  |  |
|  |  | B RhD neg | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D +  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control + |  |  |  |
|  |  | B RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - | Anti-A -  Anti-B +  Anti-D +  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D +  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D +  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | O RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control + |  |  |  |
|  |  | AB RhD neg | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells -  B Cells +  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells -  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A -  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B -  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - |  |  |  |
|  |  | AB RhD neg  (incorrect result entered) | Anti-A  Anti-B  Anti-D  Anti-D  A Cells  B Cells  Control | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control - | Anti-A +  Anti-B +  Anti-D -  Anti-D -  A Cells +  B Cells +  Control + |  |  |  |

# Appendix 21: Antibody screening results and interpretation from manual assays

1. Manual BioRad with NHSBT 2 cell screen

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Antibody screen | Reagents used in assay | Expected antibody screen results | Entered result | LIMS accepts | Pass/Fail & initials | Date and initials of tester |
|  |  | Negative | Cell 1  Cell 2 | Cell 1 -  Cell 2 - | Cell 1 -  Cell 2 - |  |  |  |
|  |  | Negative  (incorrect result entered) | Cell 1  Cell 2 | Cell 1 -  Cell 2 - | Cell 1 +  Cell 2 - |  |  |  |
|  |  | Negative  (incorrect result entered) | Cell 1  Cell 2 | Cell 1 -  Cell 2 - | Cell 1 -  Cell 2 + |  |  |  |
|  |  | Negative  (incorrect result entered) | Cell 1  Cell 2 | Cell 1 +  Cell 2 + | Cell 1 -  Cell 2 - |  |  |  |
|  |  | Positive | Cell 1  Cell 2 | Cell 1 +  Cell 2 + | Cell 1 +  Cell 2 + |  |  |  |
|  |  | Positive | Cell 1  Cell 2 | Cell 1 -  Cell 2 + | Cell 1 -  Cell 2 + |  |  |  |
|  |  | Positive | Cell 1  Cell 2 | Cell 1 +  Cell 2 - | Cell 1 +  Cell 2 - |  |  |  |
|  |  | Positive  (Incorrect result entered) | Cell 1  Cell 2 | Cell 1 +  Cell 2 + | Cell 1 -  Cell 2 - |  |  |  |

# Appendix 22: Crossmatch result entry and interpretation from manual assays

1. Serological crossmatch (result (neg/pos) plus positive control)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Crossmatch result | Reagents used in assay | Expected crossmatch results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | Compatible | Donor/patient  Pos control | Donor/patient -  Pos control + | Donor/patient -  Pos control + |  |  |  |
|  |  | Compatible  (incorrect result entered) | Donor/patient -  Pos control + | Donor/patient -  Pos control + | Donor/patient -  Pos control - |  |  |  |
|  |  | Compatible  (incorrect result entered) | Donor/patient  Pos control | Donor/patient -  Pos control + | Donor/patient +  Pos control - |  |  |  |
|  |  | Incompatible | Donor/patient  Pos control | Donor/patient +  Pos control + | Donor/patient +  Pos control + |  |  |  |
|  |  | Incompatible  (incorrect result entered) | Donor/patient  Pos control | Donor/patient +  Pos control + | Donor/patient +  Pos control - |  |  |  |
|  |  | Incompatible  (incorrect result entered) | Donor/patient  Pos control | Donor/patient +  Pos control + | Donor/patient -  Pos control - |  |  |  |
|  |  | Incompatible  (incorrect result entered) | Donor/patient  Pos control | Donor/patient +  Pos control + | Donor/patient -  Pos control + |  |  |  |

1. Immediate spin (result only – neg/pos)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Crossmatch result | Reagents used in assay | Expected crossmatch results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | Compatible | Donor/patient | Donor/patient - | Donor/patient - |  |  |  |
|  |  | Compatible  (incorrect result entered) | Donor/patient | Donor/patient - | Donor/patient + |  |  |  |
|  |  | Incompatible | Donor/patient | Donor/patient + | Donor/patient + |  |  |  |
|  |  | Incompatible  (incorrect result entered) | Donor/patient | Donor/patient + | Donor/patient - |  |  |  |

1. Neonatal crossmatch (e-issue if maternal ab screen neg and baby DAT neg)
2. Exchange transfusion for baby not yet born (xmat against mother sample but labelled with baby details)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Crossmatch result | Reagents used in assay | Expected crossmatch results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | Compatible | None | NT | NT |  |  |  |

1. NHSBT crossmatch (no result)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Crossmatch result | Reagents used in assay | Expected crossmatch results | Entered result | LIMS accepts | Pass/Fail & initials | **Date and initials of tester** |
|  |  | Compatible | None | NT | NT |  |  |  |

# Appendix 23: Result input for manual assays

1. Antibody identification (scan and attach antigram – attach to “NOTES” – then input the “order number” then can attach the document)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Antibody identification result | Reagents used in assay | Expected antibody identification results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | No antibodies detected | Supplier IAT  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Auto  Control Pos | Supplier IAT  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Auto -  Control Pos + | Supplier IAT  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Auto -  Control Pos + |  |  |
|  |  | Antibodies identified | Supplier IAT  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Auto  Control Pos | Supplier IAT  Cell 1 -/+  Cell 2 - /+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Auto -/+  Control Pos + | Suplier IAT  Cell 1 -/+  Cell 2 - /+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Auto -/+  Control Pos + |  |  |
|  |  | No antibodies detected | Supplier ENZ  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Control Pos  Control Neg | Supplier ENZ  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Control Pos +  Control Neg - | Supplier ENZ  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Control Pos +  Control Neg - |  |  |
|  |  | Antibodies identified | Supplier ENZ  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Control Pos  Control Neg | Supplier ENZ  Cell 1 -/+  Cell 2 - /+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Auto -/+  Control Pos + | Suplier ENZ  Cell 1 -/+  Cell 2 - /+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Auto -/+  Control Pos + |  |  |
|  |  | No antibodies detected | Supplier ID  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Cell 11  Cell 12  Control Pos  Control Neg | Supplier ID  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Cell 11 -  Cell 12 -  Control Pos +  Control Neg - | Suppler ID  Cell 1 -  Cell 2 -  Cell 3 -  Cell 4 -  Cell 5 -  Cell 6 -  Cell 7 -  Cell 8 -  Cell 9 -  Cell 10 -  Cell 11 -  Cell 12 -  Control Pos +  Control Neg - |  |  |
|  |  | Antibodies identified | Supplier ID  Cell 1  Cell 2  Cell 3  Cell 4  Cell 5  Cell 6  Cell 7  Cell 8  Cell 9  Cell 10  Cell 11  Cell 12  Control Pos  Control Neg | Supplier ID  Cell 1 -/+  Cell 2 -/+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Cell 11 -/+  Cell 12 -/+  Control Pos +  Control Neg - | Supplier ID  Cell 1 -/+  Cell 2 -/+  Cell 3 -/+  Cell 4 -/+  Cell 5 -/+  Cell 6 -/+  Cell 7 -/+  Cell 8 -/+  Cell 9 -/+  Cell 10 -/+  Cell 11 -/+  Cell 12 -/+  Control Pos +  Control Neg - |  |  |

1. DAT

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | DAT result | Reagents used in assay | Expected DAT results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | Positive | IgG/C3d card | Wk  1  2  3  4 | Wk  1  2  3  4 |  |  |
|  |  | Positive (incorrect result) | IgG/C3d card | Wk  1  2  3  4 | 0 |  |  |
|  |  | Negative | IgG/C3d card | 0 | 0 |  |  |
|  |  | Negative (incorrect result) | IgG/C3d card | 0 | Wk  1  2  3  4 |  |  |

1. MDAT

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Crossmatch MDAT result | Reagents used in assay | Expected MDAT results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | Positive - IgG |  | IgG +  IgM -  IgA -  C3c -  C3d -  Control - | IgG +  IgM -  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive - IgM |  | IgG -  IgM +  IgA -  C3c -  C3d -  Control - | IgG -  IgM +  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive – IgA |  | IgG -  IgM -  IgA +  C3c -  C3d -  Control - | IgG -  IgM -  IgA +  C3c -  C3d -  Control - |  |  |
|  |  | Positive – C3c |  | IgG -  IgM -  IgA -  C3c +  C3d -  Control - | IgG -  IgM -  IgA -  C3c +  C3d -  Control - |  |  |
|  |  | Positive – C3d |  | IgG -  IgM -  IgA -  C3c -  C3d +  Control - | IgG -  IgM -  IgA -  C3c -  C3d +  Control - |  |  |
|  |  | Negative |  | IgG -  IgM -  IgA -  C3c -  C3d -  Control - | IgG -  IgM -  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive – IgG (incorrect result) | BioRad | IgG +  IgM -  IgA -  C3c -  C3d -  Control - | IgG +  IgM -  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive – IgM (incorrect result) |  | IgG -  IgM +  IgA -  C3c -  C3d -  Control - | IgG -  IgM -  IgA +  C3c -  C3d -  Control + |  |  |
|  |  | Positive – IgA (incorrect result) |  | IgG -  IgM -  IgA +  C3c -  C3d -  Control - | IgG +  IgM -  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive – C3c (incorrect result) |  | IgG -  IgM -  IgA -  C3c +  C3d -  Control - | IgG -  IgM -  IgA -  C3c -  C3d -  Control - |  |  |
|  |  | Positive – C3d (incorrect result) |  | IgG -  IgM -  IgA -  C3c -  C3d +  Control - | IgG -  IgM -  IgA +  C3c -  C3d -  Control - |  |  |
|  |  | Negative (incorrect result) |  | IgG -  IgM -  IgA -  C3c -  C3d -  Control - | IgG -  IgM -  IgA -  C3c -  C3d -  Control + |  |  |

1. Kleihauer

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | KLE result | Reagents used in assay | Expected KLE results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | <2mL bleed | KLE result  Positive Control  Negative Control | KLE result - Neg  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Neg  Positive Ctl - Pos  Negative Ctl –Neg |  |  |
|  |  | <2mL bleed (invalid result) |  | KLE result - Neg  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Neg  Positive Ctl – Neg  Negative Ctl –Neg |  |  |
|  |  | <2mL bleed (invalid result) |  | KLE result - Neg  Positive Ctl - Pos  Negative Ctl - Neg | KLE result – Pos  Positive Ctl – Neg  Negative Ctl –Neg |  |  |
|  |  | <2mL bleed (invalid result) |  | KLE result - Neg  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Neg  Positive Ctl – Pos  Negative Ctl –Pos |  |  |
|  |  | >2mL bleed |  | KLE result - Pos  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Pos  Positive Ctl - Pos  Negative Ctl –Neg |  |  |
|  |  | >2mL bleed (invalid result) |  | KLE result - Pos  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Pos  Positive Ctl – Neg  Negative Ctl –Neg |  |  |
|  |  | >2mL bleed (invalid result) |  | KLE result - Pos  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Pos  Positive Ctl - Pos  Negative Ctl –Pos |  |  |
|  |  | >2mL bleed (invalid result) |  | KLE result - Pos  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Pos  Positive Ctl - Neg  Negative Ctl –Pos |  |  |
|  |  | >2mL bleed (invalid result) |  | KLE result - Pos  Positive Ctl - Pos  Negative Ctl - Neg | KLE result - Neg  Positive Ctl - Pos  Negative Ctl –Neg |  |  |

1. Antibody Titration – no validation of results applied to this test other than NIBSc control, therefore no requirement to test all scenarios

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Titration result | Reagents used in assay | Expected Titration results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | Neat Only | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - weak pos  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - weak pos  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |
|  |  | Neat only (invalid result) | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - weak pos  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - weak pos  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -Neg |  |  |
|  |  | Neat Only | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - 1+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - 1+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |
|  |  | Neat Only | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - 2+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - 2+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |
|  |  | Neat Only | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - 3+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - 3+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |
|  |  | Neat Only | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - 4+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - 4+  1:2 - 0  1:4 - 0  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |
|  |  | 1:4 | 1:1  1:2  1:4  1:8  1:16  1:32  1:64  1:128  1:512  1:1024  1:2048  NIBSc control | 1:1 - 2+  1:2 – 1+  1:4 – weak pos  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 | 1:1 - 2+  1:2 – 1+  1:4 – weak pos  1:8- 0  1:16- 0  1:32- 0  1:64 -NT  1:128-NT  1:512-NT  1:1024-NT  1:2048-NT  NIBSc control -1:8 |  |  |

1. Weak D test– no validation of subtests

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Weak D result | Reagents used in assay | Expected Weak D result results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | RhD negative | Anti-D1  Anti-D2  Anti-D3  Anti-D4  Anti-D5  Anti-D6 | Anti-D1 - 0  Anti-D2- 0  Anti-D3- 0  Anti-D4- 0  Anti-D5- 0  Anti-D6- 0 | Anti-D1 - 0  Anti-D2- 0  Anti-D3- 0  Anti-D4- 0  Anti-D5- 0  Anti-D6- 0 |  |  |
|  |  | Weak D/Partial D positive | Anti-D1  Anti-D2  Anti-D3  Anti-D4  Anti-D5  Anti-D6 | Anti-D1 – weak pos  Anti-D2- 0  Anti-D3- 0  Anti-D4- 0  Anti-D5- 0  Anti-D6- 0 | Anti-D1 – weak pos  Anti-D2- 0  Anti-D3- 0  Anti-D4- 0  Anti-D5- 0  Anti-D6- 0 |  |  |
|  |  | Weak D/Partial D positive | Anti-D1  Anti-D2  Anti-D3  Anti-D4  Anti-D5  Anti-D6 | Anti-D1 – 1+  Anti-D2- 1+  Anti-D3- 0  Anti-D4- 2+  Anti-D5- 2+  Anti-D6- 2+ | Anti-D1 – 1+  Anti-D2- 1+  Anti-D3- 0  Anti-D4- 2+  Anti-D5- 2+  Anti-D6- 2+ |  |  |
|  |  | Weak D/Partial D positive | Anti-D1  Anti-D2  Anti-D3  Anti-D4  Anti-D5  Anti-D6 | Anti-D1 – 2+  Anti-D2- 0  Anti-D3- 3+  Anti-D4- 3+  Anti-D5- 2+  Anti-D6- 0 | Anti-D1 – 2+  Anti-D2- 0  Anti-D3- 3+  Anti-D4- 3+  Anti-D5- 2+  Anti-D6- 0 |  |  |
|  |  | Weak D/Partial D positive | Anti-D1  Anti-D2  Anti-D3  Anti-D4  Anti-D5  Anti-D6 | Anti-D1 – weak pos  Anti-D2- 2+  Anti-D3- 2+  Anti-D4- 2+  Anti-D5- 2+  Anti-D6- 2+ | Anti-D1 –weak pos  Anti-D2- 2+  Anti-D3- 2+  Anti-D4- 2+  Anti-D5- 2+  Anti-D6- 2+ |  |  |
|  |  | Weak D test includes Pheno test | Pheno (Rh/K) – test added to patient tests |  |  |  |  |
|  |  | Weak D test includes DAT test | DAT – test added to patient tests |  |  |  |  |
|  |  | Scan of paper copy can be added to patient file |  |  |  |  |  |

1. Phenotyping – Rh/K (no subtest validation, no requirement to test all possible combinations of antigen types)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Phenotype result | Reagents used in assay | Expected phenotype results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K neg  M Pos | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 |  |  |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K pos  M Pos | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 3+  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 3+  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 |  |  |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K neg  M Neg | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 0  Rh Ctl 0 | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 0  Rh Ctl 0 |  |  |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K neg  M Pos  Invalid result | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 | Anti-C 1+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 |  |  |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K neg  M Pos  Invalid result | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 | Anti-C 2+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 |  |  |
|  |  | C pos  c Neg  E Pos  e Neg  Cw Neg  K neg  M Pos  Invalid result | Anti-C  Anti-c  Anti-E  Anti-e  Anti-K  Anti-Cw  Anti-M  Rh Ctl | Anti-C 3+  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 | Anti-C weak pos  Anti-c 0  Anti-E 4+  Anti-e 0  Anti-K 0  Anti-Cw 0  Anti-M 3+  Rh Ctl 0 |  |  |
|  |  | LIMS allows antigen negative results to be added to patient “extended typings” |  |  |  |  |  |
|  |  | Other antigen types tested – please state and include evidence in the folder |  |  |  |  |  |

1. Phenotyping –Jk (a and b) Fy (a and b) S s k (no subtest validation, no requirement to test all possible combinations of antigen types)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | PhenoXT result | Reagents used in assay | Expected PhenoXT results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | Fya Pos  Fyb Pos  Jka Neg  Jkb Pos  S Pos  s Neg  k Neg | Anti-Fya  Anti-Fyb  Anti-Jka  Anti-Jkb  Anti-S  Anti-s  Anti-k  Neg Ctl | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 |  |  |
|  |  | Fya Pos  Fyb Pos  Jka Neg  Jkb Pos  S Pos  s Neg  k Neg  Invalid result | Anti-Fya  Anti-Fyb  Anti-Jka  Anti-Jkb  Anti-S  Anti-s  Anti-k  Neg Ctl | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 2+ | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 2+ |  |  |
|  |  | Fya Pos  Fyb Pos  Jka Neg  Jkb Pos  S Pos  s Neg  k Neg  Invalid result | Anti-Fya  Anti-Fyb  Anti-Jka  Anti-Jkb  Anti-S  Anti-s  Anti-k  Neg Ctl | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 | Anti-Fya 2+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 |  |  |
|  |  | Fya Pos  Fyb Pos  Jka Neg  Jkb Pos  S Pos  s Neg  k Neg  Invalid result | Anti-Fya  Anti-Fyb  Anti-Jka  Anti-Jkb  Anti-S  Anti-s  Anti-k  Neg Ctl | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 | Anti-Fya 1+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 |  |  |
|  |  | Fya Pos  Fyb Pos  Jka Neg  Jkb Pos  S Pos  s Neg  k Neg  Invalid result | Anti-Fya  Anti-Fyb  Anti-Jka  Anti-Jkb  Anti-S  Anti-s  Anti-k  Neg Ctl | Anti-Fya 3+  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 | Anti-Fya weak pos  Anti-Fyb 4+  Anti-Jka 0  Anti-Jkb 3+  Anti-S 3+  Anti-s 0  Anti-k 0  Neg Ctl 0 |  |  |
|  |  | LIMS allows antigen negative results to be added to patient “extended typings” |  |  |  |  |  |
|  |  | Other antigen types tested – please state and include evidence in the folder |  |  |  |  |  |

1. Prophylax – (no subtest validation, no requirement to test all possible combinations of reaction results)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Prophylax result | Reagents used in assay | Expected Prophylax results | Entered result | LIMS accepts | Pass/Fail & initials/date |
|  |  | No antibodies identified | AB ID cell 1  AB ID Cell 2  AB ID Cell 3  AB ID Cell 4  AB ID Cell 5  AB ID Cell 6 | AB ID cell 1 0  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 | AB ID cell 1 0  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 |  |  |
|  |  | Antibodies identified | AB ID cell 1  AB ID Cell 2  AB ID Cell 3  AB ID Cell 4  AB ID Cell 5  AB ID Cell 6 | AB ID cell 1 weak pos  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 | AB ID cell 1 weak pos  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 |  |  |
|  |  | Antibodies identified | AB ID cell 1  AB ID Cell 2  AB ID Cell 3  AB ID Cell 4  AB ID Cell 5  AB ID Cell 6 | AB ID cell 1 1+  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 | AB ID cell 1 1+  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 |  |  |
|  |  | Antibodies identified | AB ID cell 1  AB ID Cell 2  AB ID Cell 3  AB ID Cell 4  AB ID Cell 5  AB ID Cell 6 | AB ID cell 1 2+  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 | AB ID cell 1 2+  AB ID Cell 2 0  AB ID Cell 3 0  AB ID Cell 4 0  AB ID Cell 5 0  AB ID Cell 6 0 |  |  |
|  |  | Other combination of results entered – please state and add evidence to the file |  |  |  |  |  |

# Appendix 24: Validation of LIMS result reaction strength interpretation

This script covers every manual assay in LIMS (with the exception of the Kleihauer test)

May be possible - :

ABO/D, ab screen, phenotyping

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | DoB | Assay used | Result reaction entered | LIMS expected | Accepts or invalidates | LIMS accepts | Pass/Fail & initials/date |
|  |  | ABO/D | Weak Pos | Positive | Accept |  |  |
|  |  | ABO/D | 1+ | Positive | Accept |  |  |
|  |  | ABO/D | 2+ | Positive | Accept |  |  |
|  |  | ABO/D | 3+ | Positive | Accept |  |  |
|  |  | ABO/D | 4+ | Positive | Accept |  |  |
|  |  | Ab Screen | Weak Pos | Positive | Accept |  |  |
|  |  | Ab Screen | 1+ | Positive | Accept |  |  |
|  |  | Ab Screen | 2+ | Positive | Accept |  |  |
|  |  | Ab Screen | 3+ | Positive | Accept |  |  |
|  |  | Ab Screen | 4+ | Positive | Accept |  |  |
|  |  | Pheno | Weak Positive | Invalid | Invalid |  |  |
|  |  | Pheno | 1+ | Invalid | Invalid |  |  |
|  |  | Pheno | 2+ | Invalid | Invalid |  |  |
|  |  | Pheno | 3+ | Positive | Accept |  |  |
|  |  | Pheno | 4+ | Positive | Accept |  |  |
|  |  | Pheno | NT | Not tested | Accept |  |  |
|  |  | AB IDEN | Weak Pos | Positive | Accept |  |  |
|  |  | AB IDEN | 1+ | Positive | Accept |  |  |
|  |  | AB IDEN | 2+ | Positive | Accept |  |  |
|  |  | AB IDEN | 3+ | Positive | Accept |  |  |
|  |  | AB IDEN | 4+ | Positive | Accept |  |  |
|  |  | AB Titration | Weak Positive | Invalid | Invalid |  |  |
|  |  | AB Titration | 1+ | Invalid | Invalid |  |  |
|  |  | AB Titration | 2+ | Invalid | Invalid |  |  |
|  |  | AB Titration | 3+ | Positive | Accept |  |  |
|  |  | AB Titration | 4+ | Positive | Accept |  |  |
|  |  | AB Titration | NT | Not tested | Accept |  |  |

# Appendix 25: Result input from analyser

LIMS – receives the test interpretation and the raw data from the analyser, needs verification that both are correct. Need to set up all the raw data fields in LIMS and validate the interpretation.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | Sample number | Automated assay used | NEO result | LIMS result | Result identical? | LIMS accepts result | Pass/Fail & initials/date |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

# Appendix 26: Validation of fating units

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | Unit type (RBC, FFP, Cryo etc) | Unit number | Fate on Electronic blood tracking | Fate received on LIMS | Fate identical on LIMS and Electronic blood tracking | LIMS audit trail acceptable | Pass/Fail & initials/date |
|  |  |  | Transfused |  |  |  |  |
|  |  |  | Returned to stock |  |  |  |  |
|  |  |  | Transferred to another hospital |  |  |  |  |
|  |  |  | Return to NHSBT – credit |  |  |  |  |
|  |  |  | Return to NHSBT – recall |  |  |  |  |
|  |  |  | Quarantine |  |  |  |  |
|  |  |  | Disposed – Time Expired |  |  |  |  |
|  |  |  | Disposed – out of temp control |  |  |  |  |
|  |  |  | Disposed – storage failure |  |  |  |  |
|  |  |  | Disposed – product wasted |  |  |  |  |
|  |  |  |  |  |  |  |  |

# Appendix 27: Validation of the coded comments

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Hosp No | Sample number | Assay type | Coded Comment | Comment on LIMS | Comment identical on LIMS and EPR | LIMS audit trail acceptable | Pass/Fail & initials/date |
|  |  | G&S | Delay in provision of blood ( for antibody screen positive and edited results) |  |  |  |  |
|  |  | KLE | <2ml bleed, minimum of 500iu anti-D issued |  |  |  |  |
|  |  | KLE | >2mL bleed, …….iu anti-D issued, repeat KLE in 72 hours |  |  |  |  |
|  |  | Antenatal G&S | Antibody identified, repeat required at 28 weeks, take cord bloods at delivery |  |  |  |  |
|  |  | Antenatal G&S | Antibody identified, repeat required every 4 weeks to 28 weeks, every 2 weeks from 28 weeks, take cord bloods at delivery |  |  |  |  |
|  |  | G&S | Irregular antibody ............... previously detected, but not on this occasion. |  |  |  |  |
|  |  | G&S | Sample rejected – Insufficient sample |  |  |  |  |
|  |  | G&S | Sample rejected – mislabeled form or sample (details free text) |  |  |  |  |
|  |  | G&S | Sample rejected – Haemolysed |  |  |  |  |
|  |  | cffDNA | cffDNA = Negative  Mother RhD Negative  Fetus RhD Negative  Anti-D NOT RECOMMENDED in this pregnancy  Discuss with midwife/GP at 16 weeks  (The test methodology does not measure fetal fraction which means that there is a very small possibility of a false negative result due to low fetal DNA). |  |  |  |  |
|  |  | cffDNA | cffDNA = Positive  Mother RhD Negative  Fetus RhD Positive  Anti-D RECOMMENDED in this pregnancy  Discuss with midwife/GP at 16 weeks |  |  |  |  |
|  |  | cffDNA | cffDNA = NT  Insufficient blood sample received. Please send repeat samples (minimum 2 x 7.5mls EDTA blood) directly to the Molecular Genetics Laboratory, Royal Devon and Exeter  Hospital. Provide Anti-D until cffDNA test states otherwise. |  |  |  |  |

# Appendix 28: Validation of reagents and reagent racks

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| LIMS Rack | Activity tested | Acceptance criteria | LIMS Rack acceptable (Y/N) | Comments | Pass/Fail and initials/date |
| Crossmatch D Pos rack | Rack set up | Rack includes:  Diluent 2  BioRad IgG cards  Titre Cell  NHSBT Weak anti-D |  |  |  |
| Prophylax rack | Rack set up | Rack Includes:  BioRad Prophylax screen  BioRad IgG cards |  |  |  |
| NHSBT AHG and ENZ racks | Rack set up | Rack Includes:  Diluent 2  BioRad IgG cards  NHSBT Weak anti-D  NHSBT AHG and ENZ panel cells |  |  |  |
| Weak D rack | Rack set up | Rack Includes:  Diluent 2  BioRad IgG cards  BioRad Weak D screen |  |  |  |
| ABO/D and AB screen rack (Manual Rack) | Rack set up | Rack Includes:  Diluent 2  BioRad IgG cards  NHSBT Weak anti-D  NHSBT Screening Cell 1  NHSBT Screening Cell 2  Anti-A  Anti-B  Anti-D1  Anti-D2  A Cells  B Cells |  |  |  |
| Titre rack | Rack set up | NHSBT Titration Cell 1  NHSBT Titration Cell 2 |  |  |  |
| Kleihauer rack | Rack set up | KLE Fixative  KLE Elution  KLE counter stain |  |  |  |
| DAT rack | Rack set up | Diluent 2  BioRad IgG/C3d cards  IgG QC |  |  |  |
| A1DB testing rack | Rack set up | Anti-A1  A1 Cells  A2 Cells |  |  |  |
| MDAT Rack | Rack set up | Diluent 2  BioRad ID –Screen 1 |  |  |  |
|  | Supplier entry | Accepts manual reagent supplier |  |  |  |
|  | Reagent expiry entry | Accepts manual reagent expiry dates |  |  |  |
|  | Rack version control | Accepts reagent changes and updates the rack version number |  |  |  |
|  | Automated rack expiry | Allows automatic 24 expiry date to be added to specific rack |  |  |  |
|  | Rack version control in use | Does not allow use of the rack after expiry |  |  |  |
|  | Barcode scanning of rack into LIMS | Rack barcodes (identifying racks) can be scanned into LIMS from a barcode on the rack |  |  |  |
|  | Retention of the QC document | QC document can be scanned to LIMS and retained against rack version |  |  |  |

# Appendix 29: Confirmation that the LIMS-Electronic blood tracking systems are aligned

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Unit number and Type | Electronic blood tracking Location | LIMS Location | Activity | Acceptance criteria | Pass/Fail and initials/date |
|  | Stock Fridge | Stock Fridge | Stock entry | BT and LIMS locations match following activity |  |
|  | Issue Fridge (HB80) | Issue Fridge | Move in | BT and LIMS locations match following activity |  |
|  | Yarty HB20 | Yarty HB20 | Move in | BT and LIMS locations match following activity |  |
|  | Yarty Batch Fridge | Yarty Batch Fridge | Move in | BT and LIMS locations match following activity |  |
|  | Labour Ward HB20 | Labour Ward HB20 | Move in | BT and LIMS locations match following activity |  |
|  | Main theatres HB20 | Main theatres HB20 | Move in | BT and LIMS locations match following activity |  |
|  | Main Theatres batch fridge | Main Theatres batch fridge | Move in | BT and LIMS locations match following activity |  |
|  | PEOC HB20 | PEOC HB20 | Move in | BT and LIMS locations match following activity |  |
|  | Platelet agitator | Platelet agitator | Move in | BT and LIMS locations match following activity |  |
|  | Plasma Freezer | Plasma Freezer | Move in | BT and LIMS locations match following activity |  |
|  | Blood Transfusion location | Blood Transfusion location | Move in | BT and LIMS locations match following activity |  |
|  | Quarantine Location | Quarantine Location | Move in | BT and LIMS locations match following activity |  |
|  | Community Location | Community Location | Move in | BT and LIMS locations match following activity |  |
|  | Batch Issue | Batch Issue | Move in | BT and LIMS locations match following activity |  |
|  | Air Ambulance | Air Ambulance | Move in | BT and LIMS locations match following activity |  |
|  | XXX | XXX | Move in | BT and LIMS locations match following activity |  |
|  | XXX batch fridge | XXX batch fridge | Move in | BT and LIMS locations match following activity |  |
|  | XXX HB20 | XXX HB20 | Move in | BT and LIMS locations match following activity |  |
|  | XXX batch fridge | XXX batch fridge | Move in | BT and LIMS locations match following activity |  |
|  | Multiple location moves – state those tested |  | Move out- move in | Audit trail of all locations retained in BT and LIMS, audit trail matches exactly for location and time of transaction |  |
|  | Multiple location moves – state those tested |  | Activate out- move in | Audit trail of all locations retained in BT and LIMS, audit trail matches exactly for location and time of transaction |  |
|  | Multiple location moves – state those tested |  | Emergency blood | Audit trail of all locations retained in BT and LIMS, audit trail matches exactly for location and time of transaction |  |
|  | Multiple location moves – state those tested |  | Emergency PCC | Audit trail of all locations retained in BT and LIMS, audit trail matches exactly for location and time of transaction |  |

# Appendix 30: Confirmation of printed reports

Print 20 reports including the following:

|  |  |  |  |
| --- | --- | --- | --- |
| Report type | UKAS requirements | Confirmation that report contains all relevant information | Pass/Fail and initials/date |
| Group and save – no antibodies | * 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure   2. the identification of the laboratory that issued the report   3. identification of all examinations that have been performed by a referral laboratory   4. patient identification and patient location on each page   5. name or other unique identifier of the requester and the requesters contact details   6. date of primary sample collection (and time, when available and relevant to clinical care)   7. type of primary sample   8. measurement procedure, where appropriate   9. examination results reported in SI units, units traceable to SI units or other applicable units   10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable   11. interpretation of results, where appropriate   12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure)   13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available   14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed)   15. date of the report, time of release (if not contained in the report readily available when needed)   16. page number to total page numbers (eg page 1 of 4) |  |  |
| Group and save – antibodies detected | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |
| Antenatal group and save – antibodies detected | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |
| cffDNA:  RhD Positive  Rh D Negative | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |
| NHSBT report for antibody identification | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |
| DAT and MDAT report | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |
| Kleihauer report | 1. a clear, unambiguous identification of the examination including, where appropriate, the examination procedure 2. the identification of the laboratory that issued the report 3. identification of all examinations that have been performed by a referral laboratory 4. patient identification and patient location on each page 5. name or other unique identifier of the requester and the requesters contact details 6. date of primary sample collection (and time, when available and relevant to clinical care) 7. type of primary sample 8. measurement procedure, where appropriate 9. examination results reported in SI units, units traceable to SI units or other applicable units 10. biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable 11. interpretation of results, where appropriate 12. other comments such as cautionary or explanatory notes (eg quality or adequacy of the primary sample which may have compromised the result, result/interpretation from referral laboratories, use of developmental procedure) 13. identification of examinations undertaken as part of a research or developmental programme and for which no specific claims on measurement performance are available 14. identification of the person(s) reviewing the results and authorising the release of the report (if not contained in the report, readily available if needed) 15. date of the report, time of release (if not contained in the report readily available when needed) 16. page number to total page numbers (eg page 1 of 4) |  |  |

# Appendix 31: SafeTrace Tx implementation before EPR

This document details the risks and potential mitigations associated with implementation of LIMS ahead of EPR.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Item | Risk | Mitigation | Comments | Risk severity |
| PAS feed to LIMS | PAS feed uses different location codes to EPR, this will result in duplication of location codes once EPR is introduced. At this point manual entry of requests by laboratory staff may result in the wrong location code being select, which may cause interface problems | Possible that Haemonetics can remove the old PAS locations from LIMS |  | Medium |
| PAS feed to LIMS | Current PAS feed patients have MRNs that do not match with current PAS patients in IPS |  | This may be because fake patients are being used for testing – JD to follow up with John Sellick | High – needs to be resolved before go-live |
| PAS feed to LIMS | LIMS is not recording the NHS number because this is sent in a different field |  | Haemonetics looking into resolution for this. We would not be able to implement LIMS without NHS numbers | High – needs to be resolved before go-live |
| Manual entry of requests into LIMS does not allow for advance orders for transfusion | Orders may be missed with the proposed mitigation | Group and save orders can be processed but the transfusion order will need to be entered on the day that the transfusion is required. Lab will need to store request forms and action them on the day. |  | Medium with mitigation in place |
| Access to transfusion results for clinical teams | Clinical teams will not have access to LIMS for transfusion test results, there is limited access to results on Electronic blood tracking enquiry | LIMS provides a print module that could be used to generate printed reports for filing in the patient notes | Haemonetics are working on provision of a UKAS compliant report format | Medium with mitigation in place |
| Wristband/Tx compatibility issue | When Tx interacts with a patient ID band there will be a mismatch because the location is not present, this will prevent administration of components/products | Update to Haemocommunicator required – this is work in progress with target date 30 April 2020 |  | High – needs to be resolved before go-live |
| Suspension of remote allocation | This has already been identified as a risk and will not be resolved until LIMS version 4.4 | Version 4.4 anticipated to be ready in Autumn 2020 | Temporary suspension of remote allocation | Low – known risk |
| Validation work required by laboratory team | Validation is being delayed whilst waiting for LIMS to be available on the new servers. |  | This may delay go-live, currently no target date for new servers | Low – known risk |

1. The clinical significance of blood group antibodies. Transfusion Medicine, vol 12, issue 5, page 287.Blood Matters May 2002 issue 10. [↑](#footnote-ref-1)