APPENDIX II – Logic Rules

Examples of 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.

This appendix provides a reference list of rules that must be taken into account when configuring the logic rules of the LIMS and developing the supporting standard operating procedures. The rules identified are correct at the time of writing but are subject to change as referenced documents are updated. The list may not be comprehensive, and it is the responsibility of the laboratory manager to ensure that all necessary controls are in place.

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.

Table 1: Age Related

Logic rule	Reference
Irradiated blood and platelets for intrauterine transfusion	BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BSH 2016)[28] Guidelines on the Use of Irradiated Blood Components 2020 (BSH 2020)[36]
CMV seronegative red cell and platelet components for intrauterine transfusions and for neonates (i.e., up to 28 days post expected date of delivery)	BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BCSH 2016)[28] SaBTO cytomegalovirus tested blood components Position Statement March 2012 (SaBTO 2012b)[26]

Abbreviations: BSH, British Society of Haematology; CMV, Cytomegalovirus; SaBTO, Safety of Blood, Tissues and Organs

Table 2: Gender

Logic rule	Reference
K- red cells for females under 50 years of age	BSH Guidelines for Pretransfusion Compatibility Procedures in Blood Transfusion Laboratories (BCSH 2013)[23]
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[38] Blood Transfusion in Obstetrics (RCOG 2015)[38] SaBTO cytomegalovirus tested blood components Position Statement March (SaBTO 2012b)[26]
Red cells negative for c antigen to c negative females of child-bearing potential	Good practice agreed across Wales
Prophylactic anti-D immunoglobulin to non-sensitised pregnant RhD negative women*	RCOG Green-top guideline[22] The Use of Anti-D Immunoglobulin for Rh D Prophylaxis (RCOG 2011)[39] BSH Guidelines for the use of Prophylactic anti-D Immunoglobulin (BCSH 2014)[28]

Abbreviations: BCSH, British Committee for Standards in Haematology; CMV, Cytomegalovirus; RCOG, Royal College of Obstetricians and Gynaecologists; SaBTO, Safety of Blood, Tissues and Organs

*There is a requirement for override for example if D Pos HLA matched platelets are only available for a D negative Haematology Patient.

Table 3: Clinical/Diagnosis Related

Logic rule	Reference
Irradiated products required for: ● Patients with Hodgkin's Disease ● Patients within 7 days of Autologous stem cell collection ● Patients undergoing Stem cell transplantation ● Patients receiving purine analogue drugs ● Patients post intrauterine transfusion whilst in the neonatal period Consideration to length of time irradiated products are required must be taken into account	European Bone Marrow Transplant handbook (EBMT 2019) Chapter 23[40] Guidelines on the Use of Irradiated Blood Components (BSH 2020)[30] BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BCSH 2016)[28]
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 2018) 2nd edition[41] BSH Guidelines on red cell transfusion in sickle cell disease. Part I: principles and laboratory aspects (2017)[42] BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BCSH 2016)[26]
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 (3rd edition 2016)[43]
Rh and K-matched cells for patients on Therapeutic Monoclonal Antibody (TMAb) regimens (anti-CD38 / anti-CD47)	BSH Pre-Compatibility guidelines addendum (2017)[44]

Logic rule	Reference
Red cell units within 7 days of collection for red cell exchange in sickle cell disease or other haemoglobinopathy	Standards for the care of adults with sickle cell disease in the UK (NHS 2018) 2nd edition[45] BSH Guidelines on red cell transfusion in sickle cell disease. Part I: principles and laboratory aspects (2017)[42] BSH Guidelines on red cell transfusion in sickle cell disease Part II: indications for transfusion (2017)[42] Standards for the Clinical Care of Children and Adults with Thalassaemia in the UK (3rd Edition 2016)[45] BSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BSH 2013)[22]
Red Cell units within 5 days of collection for Paediatric Cranio-Facial or Cardiac Surgery requiring a large volume transfusion (LVT)	BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BCSH 2016)[28]
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 2019)[40] SaBTO report of the Cytomegalovirus Steering Group (2012)[26]
SD FFP for patients with TTP and HUS	BSH Guidelines on the diagnosis and management of thrombotic thrombocytopenic purpura and other thrombotic microangiopathies (BSH 2012)[46]
Platelets in PAS for those flagged	-
Washed red cells for those flagged	-

Abbreviations: BSH, British Society of Haematology, BSCH, British Committee for Standards in Haematology; CMV, Cytomegalovirus; EBMT, European Society for Blood & Marrow Transplantation; FFP, fresh frozen plasma; HbS, sickle cell haemoglobin; HUS, haemolytic uremic syndrome; LVT, large volume transfusion; PAS, Patient Administration Systems; SD, standard deviation; TMAb, therapeutic monoclonal antibody; TTP, thrombotic thrombocytopenic purpura; UK, United Kingdom

Table 4: Antigen Matching Criteria

Logic rule	Reference
Antigen negative for red cell antibodies of potential clinically significant antibodies	BSH Guidelines for Pre-transfusion Compatibility Procedures in Blood Transfusion Laboratories (BSH 2013)[22]
HLA or platelet specific antigen-negative selected platelets for patients with HLA or HPA antibodies	BSH Guidelines for the use of Platelet Transfusions (BSH 2016)[47] BSH Transfusion Guidelines for Foetuses, Neonates and Older Children 2016 (BSH 2016)[28]
IgA deficient products (or equivalent) for those with anti-IgA antibodies	-

Abbreviations: BSH, British Society of Haematology; HLA, human leukocyte antigen; HPA, Human platelet antigen; IgA, Immunoglobulin-A

Reflex testing/Product issue

The following are examples of good practice. Using automatically requested reflex testing will ensure additional required testing is completed.

Table 5: Examples of Automatically Requested Additional Tests

Additional Test	Triggered by
Antiglobulin profile	Positive direct antiglobulin test
Kleihauer	On D negative maternal samples with a D positive cord result
Antibody Identification	Positive antibody screen
Timing of next antenatal sample	Antenatal samples with a negative antibody screen / referral of samples for cffDNA testing / confirmation
Routine anti-D prophylaxis	Antenatal D negative patients
Reduced expiry time/date on Frozen/Thawed products.	Issue of a Thawed product

Abbreviations: cffDNA, cell-free fetal DNA