# Irish Blood Transfusion Service
## Seirbhís Fuilaistriúcháin na hÉireann

## *Document Detail*

**Type:** PMF IBTS SPEC
**Document No.:** IBTS/PMF/SPEC/0201[5]
**Title:** **PRODUCT MASTER FILE - GENERAL REQUIREMENTS**
**Owner:** QA DOC CON QA DOC CONTROL
**Status** CURRENT
**Effective Date:** 19-Feb-2024
**Expiration Date:** 19-Feb-2026

### *Review*

**Review:** IBTS PMF REVIEW

| Level | Owner Role | Actor | Sign-off By |
|---|---|---|---|
| 1 | DOCUMENT CONTROLLER | REBECCA WALDEN | REBECCA WALDEN |
| 2 | LABS HEAD OF TESTING IBTS | PADRAIG WILLIAMS | PADRAIG WILLIAMS |
| 3 | LABS PHS DIR IBTS | BARRY DOYLE | BARRY DOYLE |
| 3 | NATIONAL MEDICAL DIRECTOR | TOR HERVIG | TOR HERVIG |
| 3 | SSCD HEAD OF DEPT IBTS | AILEEN FARRELLY | AILEEN FARRELLY |
| 3 | COMPONENTS HEAD OF DEPT MRTC | AINE FITZPATRICK | AINE FITZPATRICK |
| 4 | QUALITY ASSURANCE REVIEWER IBTS | COLIN JOHNS | COLIN JOHNS |

### *Change Orders*

| Changes as described on Change Order: | Change Order No. |
|---|---|

### *Change Orders - Incorporated*

| Changes as described on Change Order: | Change Order No. |
|---|---|
| | IBTS/CO/0031/24 |



**Valid on Day of Printing, Verify Current Version**
**Printed By:** **Date:**

# IRISH BLOOD TRANSFUSION SERVICE

# PRODUCT MASTER FILE GENERAL REQUIREMENTS

**Change Description:**

1. In the General Testing Specification table: Add update to HTLV 1+2 Antibody and add HEV NAT to table
2. Section 8.1 – Add Malaria antibody testing, retrospectively update PMF for the introduction of HEV testing
3. Update PMF for the introduction of Malaria antibody testing

**Reason for Change:**

1. Currently PMF states "All units" are tested and selective testing for HTLV is to be introduced in Feb 2024Donors considered to be regular donors if they have donated in the last five years. Ref CC 155/16/IBTS & 299/23/IBTS.
2. PMF was not updated when HEV testing was introduced. Ref CC 555/15
3. Malaria testing was introduced in 2023 and needs to be added to section 8.1. Ref CC 24/20

**Change Order No.:**

IBTS/CO/0031/24

**Referenced Documents**

IBTS/EXT/DOC/0006
IBTS/MED/GDE/0001
IBTS/QA/SS/0460

**SmartSolve Roles**

N/A

**Training Type**

N/A

**SmartSolve Document Category**

| Category | Mobile | Cryobiology | Website | GDP |
|---|---|---|---|---|
| Yes / No | No | No | Yes | No |

## Title; Product Master File General Requirements

**Name of Products:** **Blood and Blood Components**

**General Description:** This specification applies to single donor and small pool components prepared from units of whole blood or collected by apheresis appliances.



**Secure and effective procedures shall ensure that:**

**1. Donor Selection**

1.1 Donors of blood or cellular components for homologous use are voluntary and non-remunerated.

1.2 Donors are provided with educational materials.

1.3 Donors undergo an individual medical assessment to determine eligibility to donate.

1.4 Suitable donors are selected at the time of donation, in accordance with the EU Directive, following the IBTS Donor Selection Guidelines IBTS/MED/GDE/0001 and in accordance with written standard operating procedures. Face to face interviews are conducted with all donors and records retained. Interviews with first time, lapsed or deferred donors are conducted by a Medical Officer or Registered General Nurse.

1.5 Donors are temporarily or permanently deferred in accordance with written standard operating procedures.

1.6 Donors of blood for autologous transfusion are selected, in compliance with EU Directive and in accordance with written standard operating procedures.

**2. Donation Collection**

2.1 Donation collection is performed according to written standard operating procedures by manual procedure or using automated apheresis appliance.

2.2 The first 30ml of the donation is diverted. This diverted volume is the source of the blood sample for mandatory testing of the donation.

2.3 Donations, components, their laboratory samples and corresponding Donor Questionnaires are correctly identified by ISBT-128 barcoded and eye-readable identification numbers. Professional/Hospital users are advised to take appropriate action to ensure good inventory management with an intact audit trail.

2.4 Donations can be traced to their donor.

2.5 Batch numbers of blood collection sets, identity of manufacture and the serial number of equipment used to collect every donation are traceable.

2.6 Equipment used in donor testing and donation collection is validated, calibrated and maintained and records of these activities made and retained.

2.7 Donations are transported, from the collection site, stored in containers and appliances validated for the purpose within the specified temperature range according to written standard operating procedures.

2.8 Donor samples are suitably stored to preserve the properties for which they will be tested.

2.9 Adverse reactions in donors are documented and reported in compliance with the EU Directive and in accordance with written standard operating procedures and communicated to the Health Products Regulatory Authority (HPRA) by the Donor Consultant.



## 3. Donation Testing

3.1 Tests are appropriately performed and controlled using validated procedures and the results recorded.

3.2 All testing, both mandatory and additional, is performed according to written standard operating procedures.

3.3 Batch numbers of kits and reagents, identity of manufactures and the serial number of equipment used to test every donation are traceable.

3.4 Test equipment is validated, calibrated and maintained and records of these activities made and retained.

3.5 Appropriate reactivity with control samples is demonstrated with every series of tests.

3.6 The laboratory report indicates the result of each and every test. Individual results are recorded either by computer interfaced to a test reader or manually.

3.7 Test results and other relevant test information are archived.

3.8 Donors' NAT plasma sample tubes are archived

## 4. Donation Processing

4.1 Component Processing areas satisfy the air quality requirements defined in the current *Rules Governing Medicinal Products in the European community Volume IV, Good Manufacturing Practice for Medicinal Products.*

4.2 Whole blood is maintained at ambient temperature before processing in accordance with written standard operating procedures for a minimum of 6 hours and not exceeding 24 hours

4.3 Components are prepared in a closed system using validated procedures and in accordance with written standard operating procedures.

Cellular components and plasma for clinical use are leucodepleted within 24 hours of donation and before storage at 4 C, 22 C or freezing.

4.4 When components are transferred into a pack that was not part of the original pack assembly, a secure system is in place to ensure the correct identification labelling of the final pack.

4.5 Component sampling procedures are designed and validated to ensure when test samples are removed from a component to be issued for infusion, the essential properties of the component is not adversely affected and the sample truly reflects the contents of the component pack

4.6 Male donors are selected for the preparation of plasma components

4.7 Components can be traced to their donor.

4.8 Components are labelled in accordance with written standard operating procedures.

4.9 Components are stored in appliances validated for the purpose within the specified temperature range according to written standard operating procedures.

4.10 Autologous blood and blood imports are stored separately.

4.11 Components are inspected visually for defects, leakage, abnormal colour or visible clots.

4.12 All platelet components are irradiated prior to release for use

## 5. Component Release

5.1 Blood and Blood Components are not released for issue until all the General Quality Requirements (Section 7 mandatory laboratory tests), have been completed, documented, acceptable test results achieved and approved for release for issue. Platelet Components are stored for a minimum of 36 hours after collection before bacterial testing and are released with bacterial 'culture negative to date' result after 12 hour post testing hold.

5.2 Swirling phenomenon is demonstrated in Platelet Components.

5.3 Components are inspected visually for defects, leakage, abnormal colour or visible clots before issue to hospitals.

5.4 Components are transported in containers and appliances validated for the purpose within specified temperature range according to written standard operating procedures.

5.5 Autologous blood components are distributed and transported separately.

5.6 Components issued can be traced to the receiving hospital or institution. Hospitals are responsible for ensuring traceability to the recipient.



## 6 General labeling requirements (refer to Appendix I- attachment 6.2 extracted from IBTS/QA/SS/0460)

6.1 The following shall be included on the labels:

- Component Name in Eye Readable format only
- Component ISBT-128 Code in Eye Readable and Barcoded format (will reflect irradiation if applicable)
- Component Codabar Code in Eye Readable and barcoded format.
- Donation Number in ISBT Eye Readable and Barcoded format (14 digits, consisting of R0001= Republic of Ireland, next 2 digits= year, 6 digit donation number and a final check character).
- Donation Number label (50 mm x 19mm) placed in top left corner of the Full Face Label in the area marked Cut away section.
- Short Form Donation Number, 6 digit donation number embedded in the ISBT 128 Donation Number above.
- ABO Group as an Eye Readable image and in Barcoded format

- Codabar ABO Barcode in Eye Readable and Barcoded format.
- Rh D positive or negative as an Eye Readable image and in Barcoded format
- ABO barcode also contains C,c,E,e,K values in position 3 as per Data Structure 002 in the ICCBBA Technical Standard. The 4 digit code is also in eye readable format underneath the ABO barcode. (Reference; Appendix II ).
- Date of donation as Drawn Date in Eye Readable and Barcoded (Julian date) format.
- ISBT-128 Expiry date and Time in Eye Readable and Barcoded (Julian Date) format
- Codabar Expiry Date in Eye Readable and barcoded (Julian date) format
- The identification of the Manufacturing Centre /Blood Collection Establishment and Version No.
- Storage Temperature in Eye Readable format only
- Component Volume or Nominal Volume in Eye Readable format only.
- Warnings not to use if there are visible signs of deterioration (abnormal colour, haemolysis etc.) and that this component may transmit infection in Eye Readable format.
- Instructions that the component should be administered through a 170–200 mm filter in Eye Readable format only.
- The Name, Composition and Volume of anticoagulant (e.g. CPD) and / or additive solution (e.g. SAGM) in Eye Readable format.
- Antigens in Eye Readable and Barcoded format encoded in accordance with Data Structure 012 in the ICCBBA Technical Standard. ( Ref. Appendix III). This additional information will not be applicable to the labels for Platelets, Leucocytes and Frozen Products.
- The ISBT red cell antigen barcode is located over the eye readable extended phenotype on the unit label. This barcode consists of 18 digits. Digits 1-16 encode for commonly tested antigens.

**Additional component information (if appropriate)**

**Modifiers**

CMV Antibody Negative in Eye Readable format
Confirmed Group in Eye Readable format

Irradiated – component barcode will reflect irradiation of product if applicable.

**Autologous Blood and Blood Components**

- Additional instruction For Autologous transfusion only in Eye Readable format.

- Additional Tag containing the following data:

| **Side 1** | **Side 2** |
|---|---|
| Donor's name | Unit Number |
| Address | Name of admitting hospital |
| Date of Birth | Donor's Signature |
| Medical Officer's Signature | |



## 7. Components suitable for use in intrauterine transfusion, neonates and infants under one year

**General requirements are**

7.1 Components are prepared from donors who fulfil the following criteria:

- have given at least one donation in the previous five years and have tested negative in microbiology tests that were designated as mandatory at that time
- CMV antibody negative
- C and E antigen negative if Rh D negative
- K antigen negative (red cell components only)
- free from clinically significant irregular blood group antibodies
- free from high titre Anti A and Anti B (components suspended in plasma only)
- Sickle Cell trait negative ( red cell components only)
- have not received a blood transfusion or organ transplant
- have not taken aspirin in the last five days

7.2 Components for neonates are split into pedipacks thereby providing the potential to reduce donor exposure.

- Components are mixed prior to splitting to ensure the contents are homogenous in accordance with written standard operating procedures
- A Split component is identified by a unique number, e.g. Donation

number and Component Code, to ensure all sub batches are accounted for.

- An un-split ISBT-128 component code will end in 00
- The ISBT-128 component code of Splits 1/2/3 will end in A0, B0, C0. If the splits are further split into aliquots they become Aa, Ba or Ca.

## 8. Additional Tests or Procedures

8.1 Additional tests / procedures of selected donations may be undertaken in special circumstances to increase the safety of transfusion for susceptible patients or clinical efficacy of specific transfusions e.g.

- West Nile Virus (WNV) RNA NAT testing.
- CMV antibody negative component
- Malaria antibody testing
- HLA matched platelets
- Irradiated components
- Extended Antigen Typing
- Washed Component

8.2 Components are exposed to more than 25Gray and less than 50Gray ionising radiation in accordance with written standard operating procedure. Where irradiation is mandatory, the word 'IRRADIATED' will be in the name of the component. In certain circumstances, e.g. irradiated to order, the word 'IRRADIATED' will be in eye readable format in the modifier part of the label.

8.3 When these tests / procedures are performed to meet a specific need the results are an essential part of the criteria for release for issue of that component.



## 9. Specific Component Quality Requirements

9.1 Component and process monitoring tests are performed on at least 1% of each component type and are subjected to statistical analysis. It is acceptable, due to biological variability, that a minimum of 75% of components tested should achieve the specified quality requirements excluding leucocytes where 95% should achieve the specified quality requirement. Tests of this type are not part of the criteria for component release for issue. The specific quality requirement for each component release is detailed in written standard operating procedures.

## 10. Serious Adverse Reactions

10.1 Serious Adverse Reaction (SAR) in a recipient notified to the IBTS which may be attributable to the quality and safety of blood or blood components is documented and investigated according to written standard operating procedures by the Quality Assurance and the Medical Departments and is notified to the National Haemovigilance Office.

10.2 Serious Adverse Reaction in a recipient notified to the IBTS which may be attributable to the quality and safety of blood or blood components is communicated to the HPRA through the NHO by the Director of Quality and Compliance as soon as all relevant information about the reaction is known.

**Serious Adverse Events**

10.3 Serious Adverse Event (SAE) in the Blood Establishment which may affect the quality and safety of blood and blood components is documented and investigated according to written standard operating procedures by the Quality Assurance Department

10.4 In the event that a Serious Adverse Event is confirmed, the HPRA will be notified by Director of Quality and Compliance as soon as relevant information about the event is known. (Refer to 10.3 above.)

## 11. References

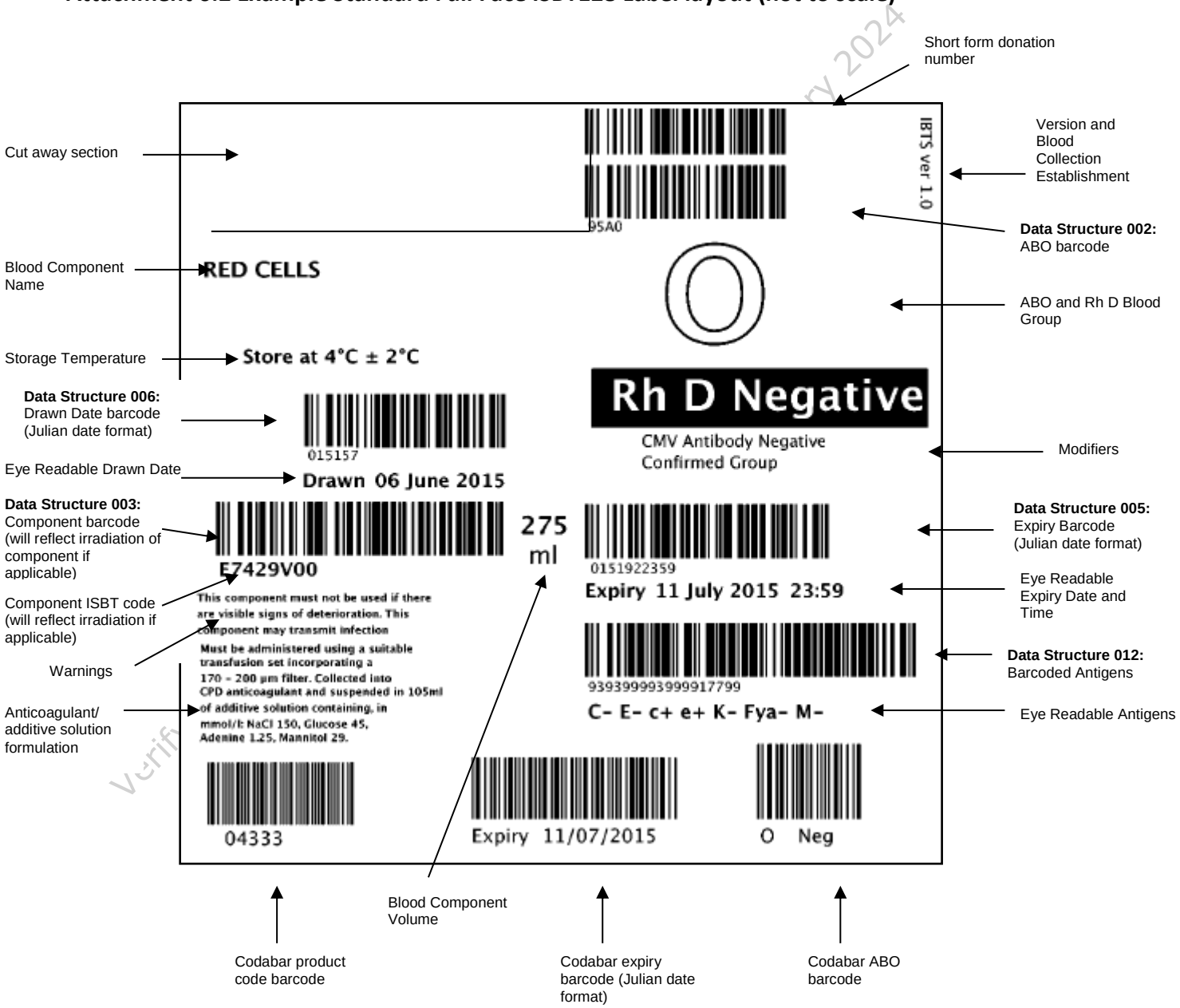
1.1 Rules Governing Medicinal Products in the European community Volume IV, Good Manufacturing Practice for Medicinal Products. (IBTS/EXT/DOC/0006)

**General Testing Specification:**

| Parameter | Quality Requirement | Frequency of Control |
|---|---|---|
| ABO, RhD | ABO RhD Group | All Units |
| HBs Antigen | Negative | All Units |
| HIV 1+ 2 Antibody | Negative | All Units |
| HCV Antibody | Negative | All Units |
| HTLV 1+2 Antibody | Negative | First time donors only, donors not previously tested for HTLV (i.e. donated prior to 1997) and products that are not Leucodepleted e.g. granulocytes<br>All donors will be screened at least once for HTLV antibodies |
| Syphilis | Negative | All Units |
| HBc antibody | Negative | All Units |
| HIV NAT | Negative | All Units |
| HCV NAT | Negative | All Units |
| HBV NAT | Negative | All Units |
| HEV NAT | Negative | All Units |
| Bacterial Screen | Culture Negative to Date, (Sampling after minimum 36 hours hold post collection and further minimum 12 hour hold post testing) | Platelet Units Only |
| Sickle Cell Trait | Negative | Neonatal Red Cell / Whole Blood Units only |
| Ionizing Irradiation | Exposure 25-50 Gray | All Platelet Units<br>Red Cell units as specified or clinically requested/required. |

# Appendix I

## Attachment 6.2 Example Standard Full Face ISBT128 Label layout (not to scale)




N.B. ISBT128 barcodes are displayed with the barcode value underneath

# Appendix II

## ICCBBA Technical Standard Document Table 6 Data Structure 002 Position 3



Table 6 Data Structure 002: Rh, Kell, and Mia/Mur Phenotypes [RT007]

| Results with Anti-Kell: | | | Phenotype: | | | |
|---|---|---|---|---|---|---|
| Not tested | Negative | Positive | C | c | E | e |
| 0 | S | T | not tested | not tested | not tested | not tested |
| 1 | A | J | negative | positive | negative | positive |
| 2 | B | K | positive | positive | negative | positive |
| 3 | C | L | positive | positive | positive | positive |
| 4 | D | M | positive | positive | positive | negative |
| 5 | E | N | negative | positive | positive | positive |
| 6 | F | O | negative | positive | positive | negative |
| 7 | G | P | positive | negative | negative | positive |
| 8 | H | Q | positive | negative | positive | positive |
| 9 | I | R | positive | negative | positive | negative |
| X | Y | Z | negative | not tested | negative | not tested |
| U | | | Mi$^3$/Mur negative | | | |
| V | | | Mi$^3$/Mur positive | | | |
| W | | | Special Testing bar code present and must be scanned and interpreted | | | |

Values of **r** {0–9, A–T, X–Z} are used to encode the results of testing for K, C, c, E, and e as shown in this table. (For example, if the value of **r** is **E**, then the red blood cells are K-negative, C-negative, c-positive, E-positive and e-positive). Values U and V encode Mi$^3$/Mur antigen test results.

# Appendix II

**Example of Data Structure 002 ABO variations**

The ISBT ABO barcode consists of 4 characters, the first two are the base ABO value, the third (position 3) is encoded in accordance with Table 6 and the fourth character will always be 0.

| ABO | Base Value |
|---|---|
| A Positive | 6200 |
| A Negative | 0600 |
| O Positive | 5100 |
| O Negative | 9500 |
| B Positive | 7300 |
| B Negative | 1700 |
| AB Positive | 8400 |
| AB Negative | 2800 |
| Bombay Positive | H600 |
| Bombay Negative | G600 |



**Example 1: A Negative (0600)**

| Results with Anti Kell: | | | Phenotype: | | | |
|---|---|---|---|---|---|---|
| **Not Tested** | **Neg** | **Pos** | **C** | **c** | **E** | **e** |
| 0600 | 06S0 | 06T0 | not tested | not tested | not tested | not tested |
| 0610 | 06A0 | 06J0 | neg | pos | neg | pos |
| 0620 | 06B0 | 06K0 | pos | pos | neg | pos |
| 0630 | 06C0 | 06L0 | pos | pos | pos | pos |
| 0640 | 06D0 | 06M0 | pos | pos | pos | neg |
| 0650 | 06E0 | 06N0 | neg | pos | pos | pos |
| 0660 | 06F0 | 06O0 | neg | pos | pos | neg |
| 0670 | 06G0 | 06P0 | pos | neg | neg | pos |
| 0680 | 06H0 | 06Q0 | pos | neg | pos | pos |
| 0690 | 06I0 | 06R0 | pos | neg | pos | neg |
| 06X0 | 06Y0 | 06Z0 | neg | not tested | neg | not tested |

# Appendix II

**Example 2: O Negative (9500)**

| Results with Anti Kell: | | | Phenotype: | | | |
|---|---|---|---|---|---|---|
| **Not Tested** | **Neg** | **Pos** | **C** | **c** | **E** | **e** |
| 9500 | 95S0 | 95T0 | not tested | not tested | not tested | not tested |
| 9510 | 95A0 | 95J0 | neg | pos | neg | pos |
| 9520 | 95B0 | 95K0 | pos | pos | neg | pos |
| 9530 | 95C0 | 95L0 | pos | pos | pos | pos |
| 9540 | 95D0 | 95M0 | pos | pos | pos | neg |
| 9550 | 95E0 | 95N0 | neg | pos | pos | pos |
| 9560 | 95F0 | 95O0 | neg | pos | pos | neg |
| 9570 | 95G0 | 95P0 | pos | neg | neg | pos |
| 9580 | 95H0 | 95Q0 | pos | neg | pos | pos |
| 9590 | 95I0 | 95R0 | pos | neg | pos | neg |
| 95X0 | 95Y0 | 95Z0 | neg | not tested | neg | not tested |

## Appendix III

**IBTS Configuration of ISBT128 Data Structure 012 Special Testing Red Cell antigens Barcode**

The ISBT red cell antigen barcode is located over the eye readable extended phenotype on the unit label. This barcode consists of 18 digits. Digits 1-16 encode for commonly tested antigens.

Data Structure 012 allows the option of using Position 1 or Position 14-16 for coding of RHCE status. Positions 14-16 will be used for C/cE/e by the IBTS therefore position 1 will always be shown as a '9'.

Data Structure 012 allows the use of the digits at Positions 17 & 18 to indicate antigen negative status of a number of different mostly rare antigens. However, this position is also used to indicate whether the unit is HbS negative. To reduce ambiguity when a unit may be antigen negative for a high frequency antigen and HbS negative, only two values will be configured for Positions 17 & 18 - namely "96" to indicate the unit is labelled as HbS negative (this will also be eye-readable) or the default, "99" if no information provided.

If the unit has been found to be negative for an antigen not listed in positions 1 through 16, then this will be visible in eye-readable format* on the label but will not be encoded in the barcode (e.g. if a unit is $Kp^b$ negative, this information will be on the label in eye-readable format but not contained within the barcode). This may require an individual Transfusion Laboratory to enter this status manually or as decided locally.

*In rare cases of very rare antigen types, it may not be printed on the label. The status of the units will in this case be identified by other means.

# Appendix III

## ICCBBA Technical Standard Document Table 9 Data Structure 012 Special Testing Red Blood Cell Antigens Positions 1 – 9



Table 9 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 1 through 9 [RT009]

| Position | 1 | 2 | | 3 | | 4 | | 5 | | 6 | | 7 | | 8 | | 9 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antibody | | | | | | | | | | | | | | | | | |
| Antigen / Value | Rh* | K | k | $C^w$ | $Mi^a$† | M | N | S | s | U | P1 | $Lu^a$ | $Kp^a$ | $Le^a$ | $Le^b$ | $Fy^a$ | $Fy^b$ |
| 0 | C+c-E+e- | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt |
| 1 | C+c+E+e- | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg |
| 2 | C-c+E+e- | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos |
| 3 | C+c-E+e+ | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt |
| 4 | C+c+E+e+ | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg |
| 5 | C-c+E+e+ | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos |
| 6 | C+c-E-e+ | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt |
| 7 | C+c+E-e+ | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg |
| 8 | C-c+E-e+ | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos |
| 9 | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni |

Key: † most commonly associated with GP.Mur (Mi.III); nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

*Common Rh antigens may be encoded together as a phenotype (Rh column 1) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column one shall be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens shall all be set to ni or nt.

# Appendix III

## ICCBBA Technical Standard Document Table 9 Data Structure 012 Special Testing Red Blood Cell Antigens Positions 10 – 16



Table 9 (continued) Data Structure 012: Special Testing: Red Blood Cell Antigens — Table General, Positions 10 through 16

| Position | 10 | | 11 | | 12 | | 13 | | 14 | | 15 | | 16 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Antibody | | | | | | | | | | | | | | CMV |
| Antigen / Value | Jk$^a$ | Jk$^b$ | Do$^a$ | Do$^b$ | In$^a$ | Co$^b$ | Di$^a$ | VS/V | Js$^a$ | C* | c* | E* | e* | |
| 0 | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt | nt |
| 1 | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg |
| 2 | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos |
| 3 | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt | neg | nt |
| 4 | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg | neg |
| 5 | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos |
| 6 | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt | pos | nt |
| 7 | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg | pos | neg |
| 8 | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos | pos |
| 9 | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni | ni |

Key: res — reserved; nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

*Common Rh antigens may be encoded together as a phenotype (Rh column 1) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column one should be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens must all be set to ni or nt.

# Appendix III

**ICCBBA Technical Standard Document Table 12 Data Structure 12 Special Testing Red Blood Cell Antigens Positions 17 -18**



Table 12 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT011]

| Value | Antigen | Value | Antigen | Value | Antigen | Value | Antigen |
|---|---|---|---|---|---|---|---|
| 00 | information elsewhere | 25 | $Kp^b$ | 50 | $Au^a$ | 75 | $An^a$ |
| 01 | $En^a$ | 26 | $Kp^c$ | 51 | $Au^b$ | 76 | $Dh^a$ |
| 02 | 'N' | 27 | $Js^b$ | 52 | Fy4 | 77 | $Cr^a$ |
| 03 | $V^w$ | 28 | $Ul^a$ | 53 | Fy5 | 78 | IFC |
| 04 | $Mur^a$ | 29 | K11 | 54 | Fy6 | 79 | $Kn^a$ |
| 05 | Hut | 30 | K12 | 55 | $Di^b$ | 80 | $In^b$ |
| 06 | Hil | 31 | K13 | 56 | $Sd^a$ | 81 | $Cs^a$ |
| 07 | P | 32 | K14 | 57 | $Wr^b$ | 82 | I |
| 08 | $PP_1P^k$ | 33 | K17 | 58 | $Yt^b$ | 83 | $Er^a$ |
| 09 | $hr^S$ | 34 | K18 | 59 | $Xg^a$ | 84 | Vel |
| 10 | $hr^B$ | 35 | K19 | 60 | Sc1 | 85 | Lan |
| 11 | f | 36 | K22 | 61 | Sc2 | 86 | $At^a$ |
| 12 | Ce | 37 | K23 | 62 | Sc3 | 87 | $Jr^a$ |
| 13 | G | 38 | K24 | 63 | $Jo^a$ | 88 | $Ok^a$ |
| 14 | $Hr_0$ | 39 | $Lu^b$ | 64 | removed | 89 | $Wr^a$ |
| 15 | CE | 40 | Lu3 | 65 | Hy | 90 | reserved for future use |
| 16 | cE | 41 | Lu4 | 66 | $Gy^a$ | 91 | reserved for future use |
| 17 | $C^x$ | 42 | Lu5 | 67 | Co3 | 92 | reserved for future use |
| 18 | $E^w$ | 43 | Lu6 | 68 | $LW^a$ | 93 | reserved for future use |
| 19 | $D^w$ | 44 | Lu7 | 69 | $LW^b$ | 94 | reserved for future use |
| 20 | $hr^H$ | 45 | Lu8 | 70 | Kx | 95 | reserved for future use |
| 21 | $Go^a$ | 46 | Lu11 | 71 | Ge2 | 96 | Hemoglobin S negative |
| 22 | Rh32 | 47 | Lu12 | 72 | Ge3 | 97 | parvovirus B19 antibody present |
| 23 | Rh33 | 48 | Lu13 | 73 | Wb | 98 | IgA deficient |
| 24 | Tar | 49 | Lu20 | 74 | $Ls^a$ | 99 | no information provided |