United Kingdom Blood Transfusion Services

Specification for the Future Labelling of Blood Components Prepared in the United Kingdom

Version 3.4 September 2021
Contributors to this and previous versions:

Sharon Baker	Zoe Wilder
Angela Brazier	Ian Millar
Tony Coates	Colin Johnston
Arthur Corrigan	Mark Whelan
Pauline Gowdy	Belinda Pelle
Linda Lodge	Ryan Evans
Kerry McArthur	David Mason Hawes
Mark Nightingale	John Muircroft
Sue Rabett	Rhys Bell
Graham Rowe	Emyr Adlam

Contents

Page

REFERENCING

0.1 Document history

Revision	Date	Status	Comment
01.1	August 2014	Committee draft	Incomplete first draft circulated
01.2	December 2014	Committee draft	Complete draft circulated
01.3	January 2015	Committee draft	Additions from TC
01.4	February 2015	Committee draft	Amendments from LL
01.5	February 2015	Committee draft	Additions from AB and MN
01.6	March 2015	Committee draft	Amendments from LL
02.1	November 2017	Committee draft	Amendments from AB
02.2	November 2017	Committee draft	Amendments from LL
2.3	December 2017	Committee draft	Amendments agreed at SACIT review meeting 14/12/2017
2.4	January 2018	Committee draft	Europack specification amendments from BP, General Textual Amendments LL
2.5	April 2018	Committee draft	Changes to make labels possible
2.6	April 2018	Committee draft	Further changes to make label designs possible
2.7	June 2018	Committee draft	Minor editorial amendments
2.8	June 2018	Committee draft	Label wording changes in line with guideline updates
3.1	Jan 2020	Committee draft	Change to data structure 023 use and addition of date of collection data structure 007. Further clarification on the conveyance of CMV test information. Other minor amendments from AB
3.2	Feb 2020	Committee draft	Generic statement added to reference section, dates removed Contributor name update Removal of document links
3.3	September 2021	Committee draft	Updates to font text following service capability checks. Reset of intended roll out dates. Removal of reference to QR codes.`
3.4	September 2021	Committee draft	Editorial tidy up – removal of highlighting, minor format of text and punctuation.

0.2 Normative references and guidelines

References in this section are to the current published edition and associated amendments unless otherwise stated.

Blood Safety and Quality Regulations. UK Acts of Parliament. Statutory Instrument 2005/50 (ISBN 0110516222).

Commission of European Communities. Directive 2002/98/EC of The European Parliament and Council and daughter directives. Setting standards of safety and quality for collecting, processing, testing, storage and distribution of human blood and blood components.

Council of Europe. Guide to the preparation, use and quality assurance of blood components – 17th Edition, EDQM.

EN ISO 3826-1:: Plastics collapsible containers for human blood and blood components Part 1: Conventional containers.

EN ISO 3826-2:: Plastics collapsible containers for human blood and blood components Part 2: Graphic symbols for use on labels and instruction leaflets.

EN/ISO 15223-1: Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.

ISO 10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.

ISO 10993-3: Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.

ISO 10993-4: Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood.

ISO 10993-5: Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity.

ISO 10993-17: Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances.

ISO 10993-18: Biological evaluation of medical devices Part 18: Chemical characterization of materials.

European Pharmacopoeia . European Directorate for the Quality of Medicines of the Council of Europe (EDQM).

International Council for Commonality in Blood Banking Automation (ICCBBA). ISBT 128 Standard Technical Specification.

MacLennan S. Guidelines for the Blood Transfusion Services in the United Kingdom.

MHRA. Best practice guidance on labelling and packaging of medicines.

0.3 Informative references

Gunson HH (1992). Re-labelling blood. British Medical Journal, **304**, 226 – 227.

Hyare J. The User Perspective. Proceeding of a UK Blood Transfusion Services ISBT 128 Workshop.

Jones J, (2009) Whole Blood and Component Labelling.

Nightingale MJ, De Korte D, Chabenel A, Hughes W, Rowe GP, Nicholson G. Eurobloodpack: a common European design for blood bag systems with integral leucodepletion filters. Vox Sanguinis, 2011, **101**, 250 – 254.

Nightingale M, Brazier A, McArthur K, Cardigan R, Lodge L, MacLennan S. UK blood component labelling, room for improvement? Transfusion Medicine, 2013, **23**, Suppl. 2, 34.

Nightingale M, Brazier A, McArthur K, Cardigan R, Lodge L, MacLennan S. The development and evaluation of options for improving future UK blood component labelling - outcome of the 2013 UK hospital survey. Transfusion Medicine, 2014, **24**, 89 - 98.

Serious hazards of Transfusion (SHOT) United Kingdom haemovigilance scheme. Annual Reports and Summaries 1996 to 2010.

Whitaker D (2012) Blood Component Labelling - An Anaesthetist's Perspective. Proceeding of a UK Blood Transfusion Services ISBT 128 Workshop.

0.4 Background

In 1998 the Department of Health issued a letter requiring all Trusts to be able to utilise ISBT 128 Donation numbers (DIN) for blood components and by April 2001 all UK Blood Services had implemented the change from dual labelling (ISBT 128 plus Codabar) of the DIN to ISBT 128 alone. While the patient safety aspect of the dual DIN was addressed the issue of component labels containing two separate coding systems for significant safety related data items was not. It was considered acceptable that extension of the use of ISBT 128 to component and other codes would follow at some time in the future as a second phase.

In 2004 the Joint Professional Advisory Committee (JPAC) endorsed the recommendations in the Standing Advisory Committee Information Technology (SACIT) paper JPAC 04/36 'Recommendations on the further use of ISBT 128 standard in the labelling of blood and blood components' which advocated the use of a single coding system by replacing the remaining CODABAR codes with ISBT128 equivalents.

In 2006 SACIT set up a project in conjunction with the Standing Advisory Committee Blood Components (SACBC) to standardise blood component labels in response to increasing issues surrounding label layout and content. The working group suggested the introduction of additional ISBT 128 barcodes should be looked at in tandem with a full component label review. The rationale being, that while more radical change would incorporate greater project management complexity it would reduce the overall disruption to service and customers of repeated phased change, e.g. introduction of additional ISBT128 linear barcodes, move to 2D barcode, extended phenotyping, all of which would require some degree of label redesign.

Summary of changes

The changes are:

1. Barcodes – complete the move to the ISBT 128 coding system by encoding the donation number, component code (incorporates the move from CODABAR to ISBT Component Codes), expiry date, ABO/Rh D and extended phenotypes into a single ISBT128 2D barcode.
2. Label format – move to full face labels incorporating redesign of the component label to address concerns raised by SHOT, the recent UKBTS hospital labelling survey and best practice guidance from the MHRA.
3. Facilitating the availability of space for potential future change.
4. Further changes to this specification may be necessitated by changes to current guidelines and associated blood bag specifications. System developers should check currency of such before final deployment of change.

The changes will be implemented in a two-stage process deploying a transition state label before moving to the future state label. The transition state label will support both the linear CODABAR system presentation and the ISBT128 coding system introducing the 2D barcode.

1.0 PURPOSE, SCOPE AND TIMESCALE

The specification is intended to provide the requirements for materials and print layout for blood services, hospitals and suppliers of systems and consumables wishing to implement and/or support the improved blood component labelling within this specification.

This specification applies to the finished product labelling of therapeutic blood components produced by Blood Transfusion Services within the United Kingdom. The labelling of intermediate products will depend on the IT system and process in use by each blood service but must be compatible with finished product labelling specified herewith. This specification does not include tissues or cellular and molecular therapy products.

Introduction of Transition State Labels will depend on individual blood service implementation plans. Transition State labels will be retained until hospital systems can accommodate the Future State full face label and ISBT128 component coding. The aim is that introduction will begin mid 2022 and it may take up to 2 years for all new components produced to carry the Transition State label. The target is that by the end of 2024 all hospital systems will be using the ISBT128 component codes and be capable of reading the 2D data matrix where necessary, at this time the UK Blood Services will switch to producing the Future State full face label only and the Transition State label will be retired.

2.0 BASIC LABELLING CONCEPT

Existing blood component labelling is a mix of text, ABC Codabar and ISBT128 barcodes. The label format is laid out in ICCBBA quadrant style but lacks a clear separation of critical, clinical and laboratory information. The improved labelling described in this specification seeks to separate and better present these categories of information based on MHRA best practice guidance on the labelling of medicinal products, feedback received from UK hospitals [Nightingale et al 2014] and SHOT and benchmarking against the component labelling of non-UK Countries.

A **‘future state’** label is specified which represents the goal of this improvement initiative. The future state label standardises on ISBT Code 128 for all barcodes. Apart from the donation number, applied to the blood bag at session, all other barcodes (including the component code, expiry date and ABO/Rh D) are condensed into a single ISBT128 2D barcode that also reproduces the donation number and extended phenotypes. The future state label is printed ‘full face’ onto a single 100 x 100 mm demand printed label which has a cut out to allow placement of the linear barcode containing the donation identification number applied at donation collection.

A full face **‘transition’** label that has basically the same content and layout as the future state is also specified but additionally includes the current Codabar barcodes to enable hospitals and blood services to make a phased transition to the future state label.

The extra space made available on the future state and transition label enables additional text to be accommodated. All other warning messages are identical to

present. Anticoagulant formulation has been removed from the label in line with other EU countries and will be made available to users separately.

It should be noted that to provide clarity in the text for reading smaller fonts, 300 dpi printers would be the preferred printer option.

3.0 BLOOD PACK / BAG BASE LABEL DIMENSIONS / LAYOUT

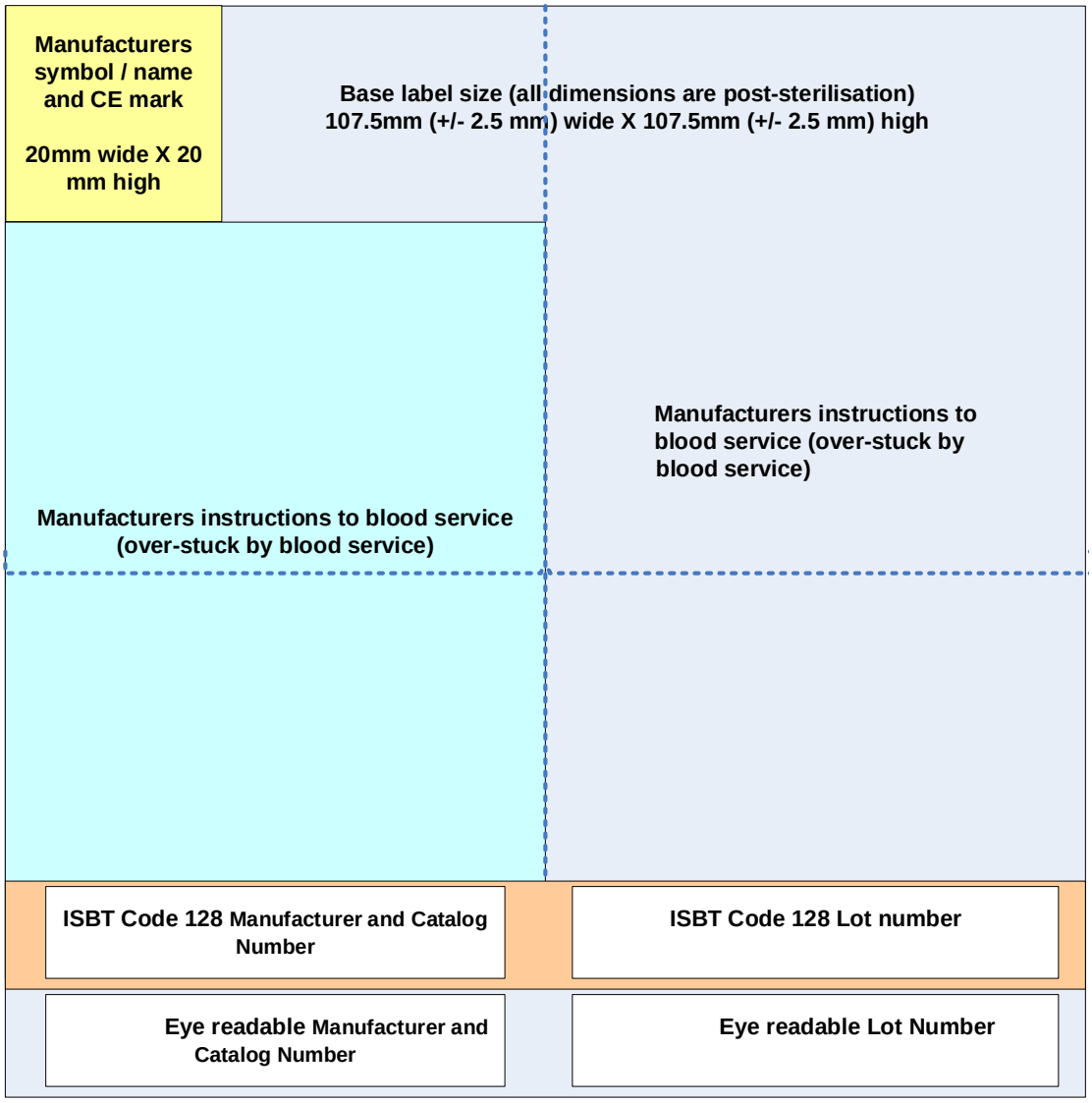
3.1 General

This UK Blood Component Labelling Specification has been written to ensure compatibility with blood packs specified within International Standard ISO 3826 parts 1 and 2 and the EBA Eurobloodpack specification. The dimensions and content of the base label applied by manufacturers are as specified below. Note that two schematics are provided due to recent changes in requirements.

3.2 Base label dimensions/ layout

Base label specification, Eurobloodpack, version 4.5.1. Schematic diagram, not to scale.

For further details see Eurobloodpack specification v4.5.1.



4.0 OVER-STICK LABEL PHYSICAL PROPERTIES, MATERIAL / DIMENSIONS

4.1 Label materials

The donation number label and full face label applied to the manufacturer's base label must exhibit the properties as described in the current version of Guidelines for the Blood Transfusion Services in the United Kingdom.

4.2 Full face label stock dimensions

The dimensions of the full face label (with 'cut out' for the donation identification number) are shown in the figure below, dimensions are in mm.

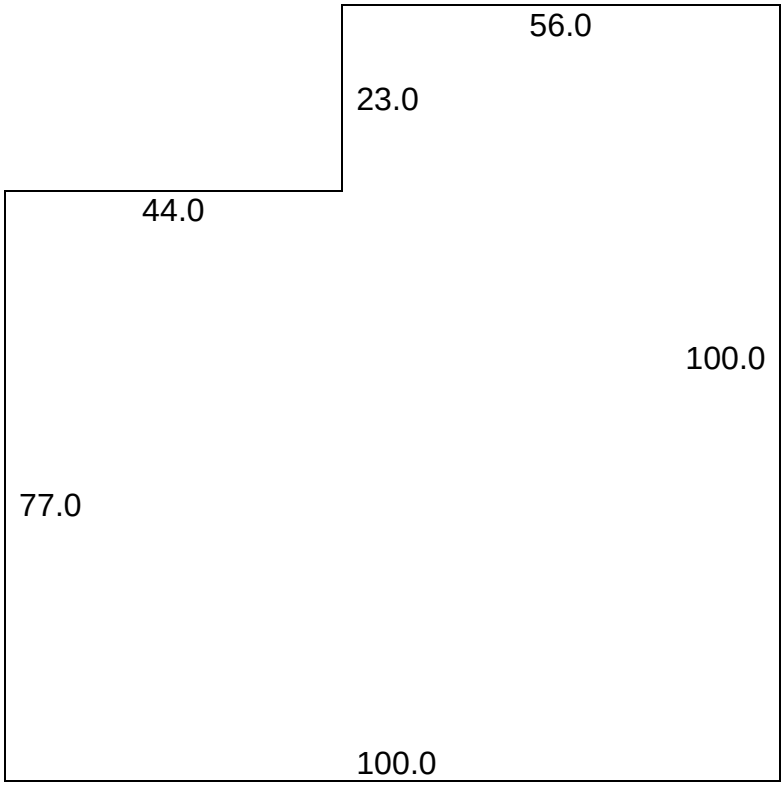


Figure 4.1 – Full face label dimensions (schematic diagram not to scale)

4.3 Donation number label

The ISBT 128 donation identification number (DIN) will continue to be applied to the blood pack at the donor session to provide the unique identification number which cross references blood components and samples taken at the time of donation. The figure below shows the dimensions, content and layout of the DIN label that must be applied to blood bags at collection. The barcode structure for the UKBTS DIN is specified in

Chapter 23 of Guidelines for the Blood Transfusion Services in the United Kingdom. Barcode density information is provided in the ICCBBA ISBT128 Standard Technical Specification.

Figure 4.2 – DIN label (schematic diagram not to scale)

The precise alignment of the DIN on the base label is vital to avoid wastage of blood components and its top and left-hand leading edges must be parallel to and within +/- 1 mm of the corresponding top and left-hand edges of the base label as shown below.

During the transition phase this DIN needs to be able to be concatenated with the donation identification number and the blood group barcodes on the transition state label. This means that the barcodes must be within 3mm – 13mm inclusive of each other.

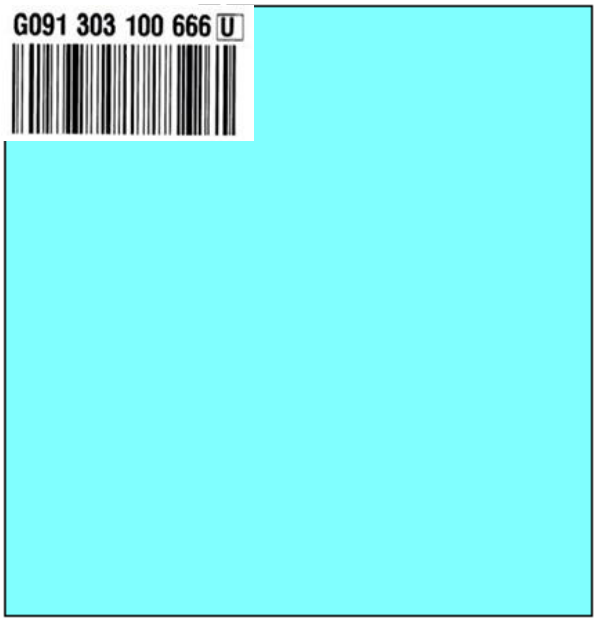


Figure 4.3 – Alignment of DIN on base label (schematic diagram not to scale)

5.0 TRANSITION 'FULL FACE' LABEL LAYOUT / CONTENT

5.1 Transition label layout

The transition label is divided into four zones as shown in Figure 5.1.

- Zone 1 is for critical information
- Zone 2 is for additional clinical information / warnings
- Zone 3 is for component selection / laboratory information
- Zone 4 is for ABC Codabar barcodes.

The blood bag reference and lot numbers shown below Zone 4 are on the blood bag base label and still visible.

The content type and format of each zone for each of the main blood component types is specified in the table below.

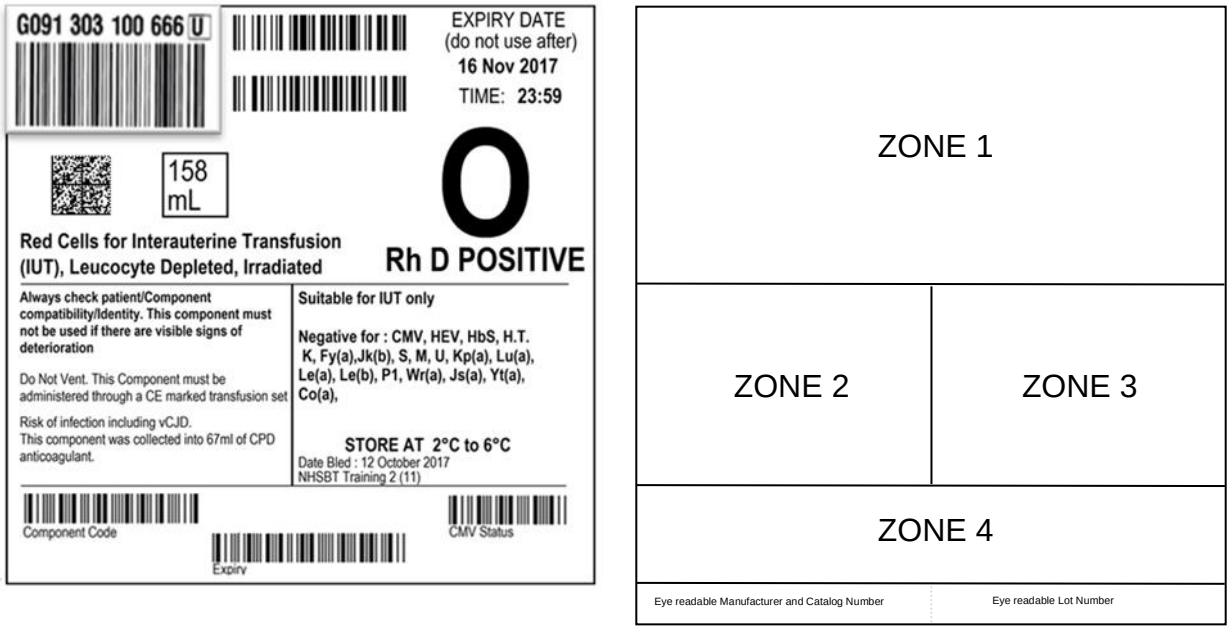


Figure 5.1 – Transition label layout and position of barcodes and text (not to scale)

Text and barcodes in this figure are for illustration only– refer to Table 5.1 for guidance

5.2 Transition label content / format

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 1					
Minimal and/or relative character sizes where 1 denotes the largest size	Variable text is in blue. Characters in bold font are to be reproduced in bold on the label. Content columns are merged when text is common to all component types. Refer to Figure 5.1 for the position of barcodes and text.				
ISBT 128 DIN barcode / eye readable text - see 4.3 The barcode will be type 128 with a density set to x dimension 0.25. The barcode should use subset C character set as far as possible to reduce the length of the barcode (i.e. from character 3 to 16 of this code)	Xnnn nnn nnn nnn n  Eye readable code should be displayed in the 4,3,3,3,1 layout currently used in the UK blood authorities with the eye readable modulus 37,2 check character displayed in a box. i.e. G091 303 100 666 U				
Abbreviated 3-character month text Relative size 4.	EXPIRY DATE (do not use after) **dd MMM yyyy** TIME: **hh:mm**				

<table>
<tr><th rowspan="2"></th><th colspan="5">Content for each blood component type</th></tr>
<tr><th>Red cells</th><th>Platelets</th><th>Fresh frozen plasma</th><th>Cryoprecipitate</th><th>Other</th></tr>
<tr><td>Short form donation identification number barcode for concatenation.
Sited above next item.</td><td colspan="5">See Guidelines for the Blood Transfusion Services in the UK Section 23.3.1.3: National ISBT 128 definitions
Version 1 or 2.</td></tr>
<tr><td>ABO/Rh D
ISBT 128 Data Structure [002]
Barcode type 128 with density set at x dimension 0.25 and barcode height of 6mm
No eye readable text</td><td colspan="5"> 
The barcode MUST be the same density as the DIN barcode used to provide concatenation.</td></tr>
<tr><td>2D barcode – see 7.0
Data Matrix Barcode density 0.34 and symbol type ECC200, follow ISO 8859-1 and be represented as square</td><td colspan="5">  </td></tr>
<tr><td>Blood component volume.
Relative size 3.
Text framed in a quadrangle with line 0.5 mm thick</td><td colspan="5">xxx mL or xxx mL</td></tr>
<tr><td>Blood component name - see 7.5
Relative size 4.
Title case</td><td colspan="5">Xxxxxxxxx
Number of text lines can vary between components.</td></tr>
</table>

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ABO group Bold. Relative size 1. For Rhesus D Negative labels, the font should be in outline with the outline set at a thickness no less than 1 pt. (1 point used in image above)	A / B / AB /O				
Rh D Bold. Relative size 2. White text on black when the Text reads “Rh D NEGATIVE” 1mm must be maintained between the product title and this text.	**Rh D POSITIVE / NEGATIVE**				
ZONE 2 ensure actual content is compliant with current guidelines at time of printing the label					
Major clinical warnings / advice Bold Relative size 6.	**Always check patient /component compatibility /identity.** **This component must not be used if there are visible signs of deterioration.**				
Other clinical warnings / advice Relative size 6	Do not vent. This component must be administered through a CE transfusion set. Risk of infection including vCJD. This component was collected into 67ml of CPD anticoagulant.				

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 3 – Space for up to 7 lines of text available to cover items a, b and c					
a. Component suitability (e.g. for IUT only) Bold. Relative size 5.	**Xxxxxxxx**				
b. Additional storage instructions Bold. Relative size 5.	N/A	Continuous gentle agitation throughout storage is recommended	Use within 4 hours if held at 20-24ºC or up to 120 hours if held at 2-6ºC depending on indication Date and Time Thawed: ___/___/____ ___ : ___ hrs	Use within 4 hours if held at 20-24ºC Date and Time Thawed: ___/___/____ ___ : ___ hrs	*As applicable*
c: Negative for: Bold. Relative size 5. Line 1 reserved for CMV, HEV, HbS and H.T. Line 2 and 3 reserved for blood group antigens	<line 1> <line 2> <line 3>				*(e.g. for autologous)* Donor Name DOB: DD October YYYY Donor number
Storage temperature Relative size 4.	**Store at 2ºC to 6ºC**	**Store at 20ºC to 24ºC**	**Store at -25°C or below**	**Store at -25°C or below**	*As applicable*
Date bled. Relative size 6 The month is not abbreviated.	dd Month yyyy				

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
Blood establishment name Relative size 6. *('NHSBT Training 2 (11)' in example)*	xxxxxxxx				
ZONE 4. The following barcodes are positioned top left to bottom right in the following order.					
Component ABC Codabar barcode, density set at 0.25 and minimum height of 5 mm. The text is below the barcode	Component code				
Expiry ABC Codabar barcode, density set at 0.25 and minimum height of 5 mm. The text is below the barcode	Expiry date				
CMV negative ABC Codabar barcode, density set at 0.25 and minimum height of 5 mm. is below the barcode	CMV Status				

NOTE: - Zone separation lines that are printed across the label should be 0.5 pt (at most) and should not be carried the full width of the label this is to reduce the chance of the ribbon used in the print process being cut while printing this line.

6.0 FUTURE STATE 'FULL FACE' LABEL LAYOUT / CONTENT

6.1 Future state label layout

The future state label is divided into three zones as shown in Figure 6.1.

- Zone 1 is for critical information
- Zone 2 is for additional clinical information / warnings
- Zone 3 is for blood component selection / laboratory information.

The blood bag reference and lot numbers shown below Zone 3 are on the blood bag base label and still visible.

The content type of each zone for each of the main blood component types is specified in the table below.

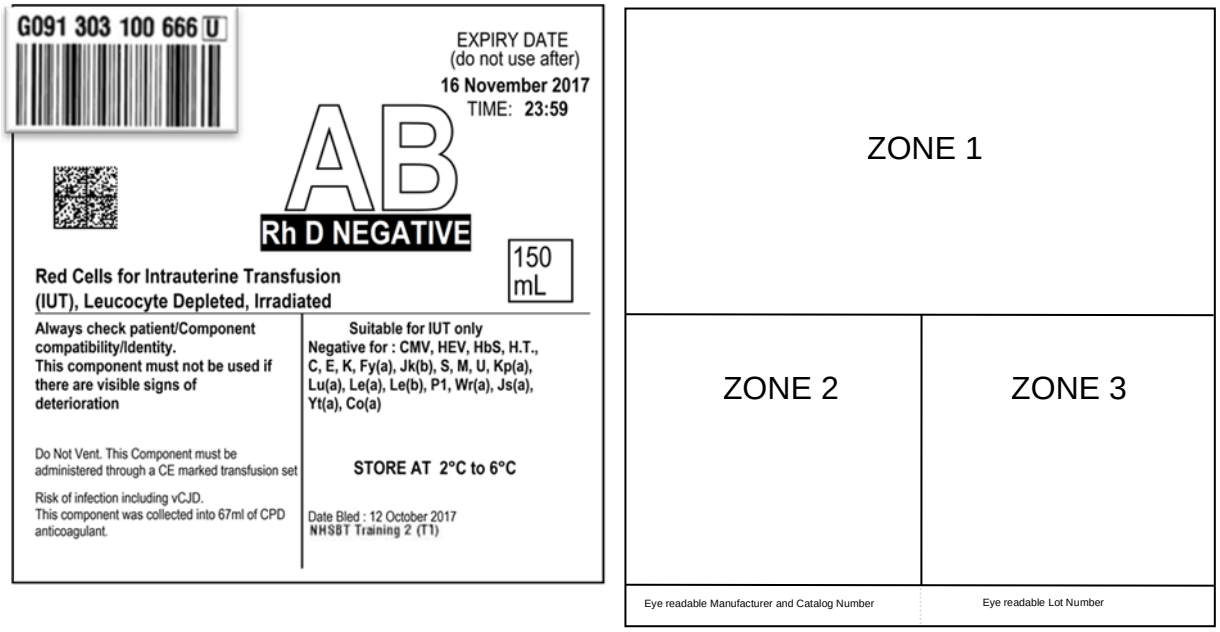


Figure 6.1 – Future state label layout and position of barcodes and text (not to scale)

Text and barcodes in this figure are for illustration only – refer to Table 6.1 for guidance

6.2 Future state label content / format

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 1					
ISBT 128 DIN barcode / eye readable text - see 4.3 The barcode will be type 128 with a density set to x dimension 0.25. The barcode should use subset C character set as far as possible to reduce the length of the barcode (i.e. from character 3 to 16 of this code)	Xnnnnnnnnnnnnn  Eye readable code should be displayed in the 4,3,3,3,1 layout currently used in the UK blood authorities with the eye readable modulus 37,2 check character displayed in a box. i.e. G091 303 100 666 U				
The month is not abbreviated. Relative size 4.	EXPIRY DATE (do not use after) **dd Month yyyy** TIME: **hh:mm**				
2D barcode – see 7.0 Data Matrix Barcode density 0.34 and symbol type ECC200, follow ISO 8859-1 and be represented as square					
Blood component volume. Relative size 3. Text framed in a quadrangle with line 0.5 mm thick	**xxx mL** or xxx mL				

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
Blood component name - see 7.5 Relative size 4. Title case.	**Xxxxxxxxxx** Number of text lines can vary between components				
ABO group Bold. Relative size 1. For Rhesus D Negative labels, the font should be in outline with the outline set at a thickness no less than 1 pt. (1 point used in image above)	A / B / AB /O				
Rh D Bold. Relative size 2. White text on black when the Text reads “Rh D NEGATIVE” 1mm must be maintained between the product title and this text.	**Rh D POSITIVE / NEGATIVE**				
ZONE 2 – ensure actual content is compliant with current guidelines at time of printing the label					
Major clinical warnings / advice Bold Relative size 6.	**Always check patient /component compatibility /identity.** **This component must not be used if there are visible signs of deterioration.**				
Other clinical warnings / advice Relative size 6	Do not vent. This component must be administered through a CE marked transfusion. Risk of infection including vCJD. This component was collected into 67ml of CPD anticoagulant.				

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
ZONE 3 – Space for up to 7 lines of text available to cover items a, b and c					
c. Component suitability (e.g. for IUT only) Bold. Relative size 5.	**Xxxxxxxx**				
b. Additional storage instructions Bold Relative size 5	N/A	Continuous gentle agitation throughout storage is recommended	Use within 4 hours if held at 20-24ºC or up to 120 hours if held at 2-6ºC depending on indication Date and Time Thawed: ___/___/____ ___ : ___ hrs	Use within 4 hours if held at 20-24ºC Date and Time Thawed: ___/___/____ ___ : ___ hrs	*As applicable*
c: Negative for: Bold. Relative size 5 Line 1 reserved for CMV, HEV, HbS and H.T. Line 2 and 3 reserved for blood group antigens	<line 1> <line 2> <line 3>				*(e.g. for autologous)* Donor Name DOB: DD October YYYY Donor number
Storage temperature Relative size 4	**Store at 2ºC to 6ºC**	**Store at 20ºC to 24ºC**	**Store at -25°C or below**	**Store at -25°C or below**	*As applicable*

	Content for each blood component type				
	Red cells	**Platelets**	**Fresh frozen plasma**	**Cryoprecipitate**	**Other**
Date bled Relative size 6 The month is not abbreviated.	dd Month yyyy				
Blood establishment name Relative size 6. *('NHSBT Training 2 (11)' in example)*	xxxxxxxx				

NOTE: - Zone separation lines that are printed across the label should be 0.5 pt (at most) and should not be carried the full width of the label this is to reduce the chance of the ribbon used in the print process being cut while printing this line.

7.0 TECHNICAL SPECIFICATION FOR THE 2-D BARCODES IN THE PROPOSED UK TRANSITION AND FUTURE STATE LABELS

7.1 Background

This specification supports the UK designs for the transition (see 5.0) and future state (see 6.0) labels. The use of two dimensional (2-D) barcodes will convey more blood component information and enable amalgamation of multiple data elements to release space for clearer presentation of the textural information.

2-D symbology is proven for blood, cell, tissue, and organ products by ICCBBA. It is the only adopted international standard to address this challenge. ISBT 128 standard states that 'Data Matrix (ECC 200) shall be used as the 2-D symbology for ISBT 128 container labels. The ISO/IEC 16022 Information technology—International Symbology Specification—Data Matrix shall be followed'.

ECC 200 uses error and erasure recovery that allows the routine reconstruction of the entire encoded data string when the symbol has sustained 30% damage. Data Matrix has an error rate of less than 1 in 10 million characters scanned however, 'readers' need to accurately locate the position of the symbol (printed matrix) in order that reading can occur. The symbol will be square with an even number of rows and columns. Utilisation of the ECC 200 error correction is by the upper right corner module being the same as the background colour (Binary 0).

ICCBBA have an implementation guide – 'Use of Data Matrix Symbols with ISBT 128'. Currently for blood, the 2-D barcode is only advocated as a supplementary information source, other ISBT 128 linear barcodes are required to attain full observance to the standard. To enable a phased transition to the future state label by UK blood services and hospitals the 2-D barcode will be supplemented by the existing ABC Codabar barcodes for product code, blood group, expiry date and CMV negative status (in addition to the DIN in long and short form ISBT 128).

It is important to note that the use of a data structure for data derived from component testing does not compel blood services to do all the tests. There are 'ni' - no information and 'nt' - not tested values that may be used. Care must be taken with information regarding CMV testing as there is an overlap in [Data Structures 012] and [Data Structure 027] in the ISBT128 Standard Technical Specification - version 5.10.0, for the conveyance of this information. Where CMV test information is being conveyed, then both data structures must be populated with the test information.

7.2 ICCBBA data structures and their appropriate use

The following data structures are relevant to UKBTS component labelling:

1. Donation Identification Number [Data Structure 001] – Use, already adopted.
2. Blood Groups [ABO and RhD] [Data Structure 002] – Use, already adopted for ABO and RhD group information. UK Guidelines currently specifies a limited application of the 'gg' values for this data structure.
3. Product Code [Data Structure 003] – Use. Will require a translation table of component codes through the period of transition and for continued historical component code mapping. (Note that bacterial monitoring is covered under the component code definitions).
4. Expiration Date and Time [Data Structure 005] – Use. Will give greater clarity on expiration of short shelf life components. Defined in the ISBT 128 Standard Technical Specification - version 5.10.0; 'A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of 2359 shall be encoded in the data structure'.
5. Special Testing: General [Data Structure 010] – Use. Will include the conveyance of; red cell antibodies, IgA deficient, Haemoglobin S status, that product meets additional nationally specified requirements for paediatric use and some immune plasma antibodies (e.g. Tetanus, Varicella Zoster).
6. Special Testing: Red Blood Cell Antigens – General [Data Structure 012] – Use. Will cover the red cell antigenic expressions (be they detected through phenotyping or genotyping) that are important in the provision of matched components. Note that Rh antigens must be encoded individually using positions 14, 15, and/or 16. In compliance to the ISBT128 Standard Technical Specification - version 5.10.0; Column one shall always be set to 9.
   It is considered that this information is relevant to granulocyte, platelet and red cell components and will be included with all components whether or not testing has been carried out for each antigen/allele. This will ensure that the size of the data matrix is consistent when printed on the label.
7. Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]. There are no clear current benefits for the use of this data structure (blood services provide best matched HLA and HPA components for the hospitals and providing the hospitals with actual type data may provide no direct benefit). Its inclusion for all components again enables the size of the data matrix to be consistent pending a more appropriate structure being identified in future. The HLA coding element does not currently cover the D locus.
8. Infectious Markers: [Data Structure 027] –Use will cover Hepatitis E Virus, CMV and other infectious markers where deemed necessary.
9. Collection Date and Time [Data Structure 007] – Will convey the date and time the donation was bled. Defined in the ISBT 128 Standard Technical Specification - version 5.10.0; 'A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of 2359 shall be encoded in the data structure'.
   This data structure will not be used for components derived from more than one donation. (Consideration is being given to the use of the Production Date and Time [Data Structure 009] for these components. A future version update to the specification will be made if necessary.)

7.3 UK Specifics and example of proposed use of 2-D barcoding

In summary, data structures [001];[002];[003];[005];[010];[012];[014];[027]; (and [007] for non-pooled components), will be combined in an unspecified sequence format of a compound message data structure [023].

The follow is an example of application:

=+08000=G09130310066690=%5100=<E0033000&>0133152359&(N0106=\230000004000000084&{000000000000000000&”0000010003000000000&*020801500

Here =+08000 identifies this as a compound message of unspecified sequence.
‘Note: Because of the complexity created by multiple product categories and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of undefined messages.’
= G09130310066690 is the Donation Identification Number Data Structure;

=%5100 is the Blood Groups Data Structure – this unit is O RhD positive;

=<E0033000 is the Product Code Data Structure – this unit is Whole Blood leucocyte depleted (CPD);

&>0133152359 is the Expiration Date and Time Data Structure – this unit expires just before midnight between 11/11/2013 and 12/11/2013.

&(N0106 is the for general special testing – this unit is HbS negative.

=\230000004000000084 is the red blood cell antigen special testing – this unit is R1R1(C-c+E+e-),K-,Fya-Fyb-,Vel-

&{000000000000000000 is the platelet HLA and Platelet Specific Antigens special testing – this unit has not been tested for these antigens.

&”000001000300000000 is an example of the use of the Infectious Markers data structure where the donation is CMV and HEV negative.

&*0202801500 is the donation collection date and time – this donation was collected at 15:00 on the 07/10/13.

Ideally, systems should be able to read and interpret any code combination associated with data structures defined in the ICCBBA standards for labelling of blood components, to ensure no compromise of use for ICCBBA compliant imported units. Systems utilising the [Data Structure 023] from a UK 2-D barcode must be able to interpret the specified contributing data structures independent of the order within the code. Each contributing data structure carries defined data identifiers.