

Guidelines for the Blood Transfusion Services

Chapter 23: Specification for the uniform labelling of blood, blood components and blood donor samples

<http://www.transfusionsguidelines.org/red-book/chapter-23-specification-for-the-uniform-labelling-of-blood-blood-components-and-blood-donor-samples>

Chapter 23: Specification for the uniform labelling of blood, blood components and blood donor samples

23.1: Introduction

23.1.1: General information

The information contained in this chapter is intended to inform all persons involved in labelling blood and blood components of the specifications for uniform labelling. It is intended for users, software developers and suppliers of pre-printed labels.

The specification covers labels required by the United Kingdom Blood Transfusion Services (UKBTS) for the labelling of blood donation (collection) packs, satellite packs, associated samples and documentation. It utilises barcodes to encode information in addition to eye-readable symbols.

Blood pack labelling is in a period of transition as the established Codabar system is replaced with the International Society of Blood Transfusion (ISBT) international standard ISBT 128. Currently the UKBTS use ISBT 128 data structures for the donation identification number (DIN) and the blood group code.

Where this document refers to ISBT 128 cross-reference should be made to the ICCBBA Inc. (www.iccbba.org) ISBT 128 Standard Technical Specification which gives detailed information on data structures and labelling. This chapter interprets relevant sections of the Technical Specification in the light of UK requirements, and in some cases it limits the available options or deviates from the Technical Specification. In all such cases, this chapter takes precedence.

Further migration to ISBT 128 involves converting and/or adding more data structures and adopting the ISBT 128 definitions. The timetable for further changes is currently under consideration and development.

Note: Barcodes included in all figures are not readable and are for visual purposes only.

23.1.2: The purpose of a standardised, structured coding system

The objective is to reduce the dangers of incompatible blood transfusions caused by human error and a central part of the label design is machine-readable coding of essential information.

Each blood donation pack, plus connected satellite packs and associated samples and documentation, must be identified by a **unique** identification number applied at the time of donation. Additionally each pack

requires identification by labelling showing the ABO group, RhD type and the component type. Such a system will ensure unique identification of every blood component, and help secure association between donations and samples.

Further adoption of an international coding system such as ISBT 128 will facilitate the movement of blood components across national and international boundaries.

23.1.3: Applicability

All blood pack/sample labels for use by the UK Blood Establishments must comply with the specifications in this document.

23.1.4: Referenced document

ISBT 128 Standard Technical Specification. See current version on the ICCBBA website (www.iccbba.org).

23.2: The labelling system

The labelling system for blood and blood components comprises the following elements:

- **The base label:** The label applied to the blood pack by the manufacturer of the blood pack or harness (see Chapter 26) and other critical consumables (see Chapter 27).
- **The donation identification number label:** A label bearing the ISBT 128 (donation identification number – ICCBBA Data Structure 001) with a barcode and eye-readable equivalent. Produced in sets these labels ensure the accurate and unique identification of a donation event (can include donation, sample(s) and documentation). Allocated at the point of donation, this number is fundamental to the secure audit trail for blood components.
- **The batch identification number label:** Also a label bearing the unique ISBT 128 (ICCBBA Data Structure 001) with a barcode and eye-readable equivalent. Applied to identify pooled blood components (prepared from a number of donations), for instance pooled platelets.
- **The blood group label:** A label bearing the ISBT 128 (nationally assigned data structure – see ICCBBA specification table RT003) defined short form unit identifier barcode, the ISBT 128 (Blood Groups [ABO and RhD] – ICCBBA Data Structure 002) blood group barcode and the Codabar expiry date barcode. This label also contains eye-readable information and label text on blood group, expiry and other blood characteristics. This label is applied by the Blood Establishments prior to a component's release into stock.
- **The component label:** A label currently utilising the Codabar component barcode, together with component-specific information. Applied at the time of component manufacture by the Blood Establishments.

The labels indicated in the second to fifth points above are all affixed onto the base label (see Chapter 26).

The final or complete arrangement of labels is shown in Figure 23.1. This diagram is for orientation purposes only. See under the appropriate sections for details of each label content and layout.

All labels must conform to the recommendations set out in the appropriate section of the ISBT 128 Standard Technical Specification unless specifically stated otherwise in this document.

Linear barcodes specified as ISBT 128 must comply with the Code 128 Bar Code Symbology and Application Specification. Barcodes specified as Codabar must be built to Codabar ABC standard with a recommended density of 10 (ten) characters per 25 mm. Any use of ISBT Data Matrix 2D barcodes will need to comply with the ICCBBA specifications and be authorised by the Joint UKBTS/HPA Professional Advisory Committee (JPAC) on advice from its Standing Advisory Committee on Information Technology (SACIT).

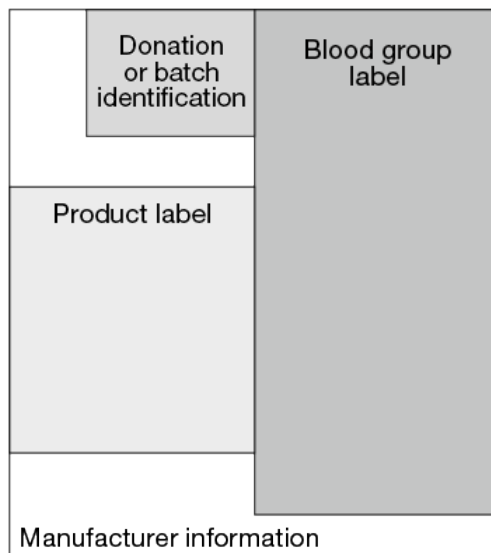


Figure 23.1 Layout of labels on the manufacturer's base label

All labels must be:

- self-adhesive using a non-invasive biocompatible adhesive (see ISO 10993 series – expanded in Chapter 26)
- tamper-evident (i.e. removal must deface the label)
- smear-resistant
- resistant to water, alcohol and humidity
- capable of being affixed readily to paper documents, base label material and sample containers (e.g. plastic or glass). Once applied, winging ('winging' is defined as the lifting of a label from the surface to which it is applied) must not exceed 2.5 mm as the maximum linear distance of the label not adhering to the surface at any label edge, measured after 24 hours of refrigeration at 4°C
- capable of withstanding a temperature range of –80°C to +56°C after application to the blood pack. This range may be extended by the ordering authority at the time of order
- capable of being applied without slippage during use where subject to temperature variation, e.g. tubes/packs stored in a vehicle and then used at normal ambient temperature, such equipment being by definition 'damp'
- non-flaking ('flaking' is defined as disintegration of the label or print material potentially affecting readability) regardless of instrumentation used for reading

- where sets of pre-printed labels are purchased from a vendor or created 'in-house' by appropriate systems, they must be printed at a quality standard that overall has a decodability of 'C' or above to be acceptable for use (ISO/IEC 15416 Barcode Quality Specification, 2000).

23.3: Barcode reading and interpretation

Barcoding is carried out to ensure the accuracy of transmitted information. To gain the maximum benefit from such coding, systems reading and interpreting the codes need to ensure that valid codes have been scanned. The following minimum checks should be carried out by the receiving application software:

- Ensure that the barcode identifiers (ICCBBA data identifiers) are correct for the code being read. For example, ISBT 128 Component code (ICCBBA Data Structure 003) would be expected to have a data identifier of '=<'.
- Ensure that the format (length and character types) of the received data string matches the defined format for the expected code. For example ISBT 128 Component code (ICCBBA Data Structure 003) should be ten characters long (two data identifiers plus eight data characters).
- Ensure that where checksums are used to validate correct data transmission, they are checked and valid.
- Any barcode scanning devices used to read linear ISBT 128 barcodes must conform to the industry standard ISO/IEC 15417: 2007 (E): Information technology – Automatic identification and data capture techniques – Code 128 barcode symbology specification.

23.3.1: ISBT 128 barcoding

Code 128 and Data Matrix (2D code) are high-density alphanumeric barcode symbologies which have been adopted by ICCBBA for the provision of a worldwide unique numbering and coding system for blood and blood components. ICCBBA defines the data structures of this system, the supporting reference databases and application-specific information. The specification for concatenation support provided by standard Code 128 has been modified at the request of ICCBBA to incorporate the need for spatial and/or temporal limitation on concatenated reading (refer to ICCBBA Technical Specification). Barcode readers used for reading these codes must comply with this specification.

23.3.1.1: The importance of data identifiers in ISBT 128 data structures

ISBT 128 barcodes comprise two main elements:

- The data identifier characters that identify which ISBT 128 data structure is being transmitted
- The data characters which provide the data values to be interpreted in accordance with the definition of the appropriate structure.

In order to accurately interpret information from an ISBT 128 barcode, it is essential that application software carries out the following steps before interpreting the data values:

- Analyse the data identifiers to ensure that the barcode entered is of the correct type
- Verify that the data length and format match that defined for the barcode type and included ISBT structure(s).

Failure to carry out these checks could lead to incorrect assignment of critical information.

23.3.1.2: Concatenation

Concatenation for the purpose of this requirement is defined as:

The reading of two horizontally adjacent barcodes together as a single input using a barcode-scanning device.

Concatenation requirements for ISBT 128 are laid out in the ICCBBA ISBT 128 Standard Technical Specification. Where concatenated codes are to be read, it is essential that the barcode readers used support concatenation.



Figure 23.2 Two concatenation processes. On the left the donation identification number (DIN) with nationally defined structure, and on the right the DIN with the ABO/Rh blood group barcode

In the UK correct blood group labelling can be confirmed by up to two concatenation processes (see Figure 23.2).

- Concatenation of the donation identification number (ICCBBA Data Structure 001) with the short form unit identifier printed on the blood group label (this nationally defined code is a non-ICCBBA defined structure but is ICCBBA registered – see section 23.3.1.3 on National ISBT 128 definitions). This concatenation is mandatory for all UK Blood Establishments.
- Concatenation of the donation identification number (ICCBBA Data Structure 001) with the blood group (ICCBBA Data Structure 002) printed on the blood group label. (This concatenation is at the discretion of the Blood Establishment providing it can demonstrate other safety measures are in place.)

23.3.1.3: National ISBT 128 definitions

National bodies are permitted by ICCBBA to allocate nationally defined codes identified by data identifiers of '&' followed by a lower-case alpha character. Within the UK this responsibility lies with SACIT (Standing Advisory Committee on Information Technology).

The following national codes have been assigned by SACIT.

Short form donation identification number (Version 1)

&a

Defined for the shortened form of a donation number used on demand-printed group labels for concatenated read with the donation number as part of label verification. This code must not be used as the primary identifier of a component. The code structure is:

&annnnnn

Where:

&a	are the ISBT 128 data identifiers
nnnnnn	is the six-digit unit serial number from the donation number definition (ICCBBA Data Identifier 001).

Short form donation identification number (Version 2)

&b

Defined for the shortened form of a donation number used on demand-printed group labels for concatenated read with the donation number as part of label verification. This code must not be used as the primary identifier of a component. The code structure is:

&bnnnnnnk

Where:

&b	are the data identifiers
nnnnnn	is the six-digit unit serial number from the donation number definition (ICCBBA Data Identifier 001)
k	is a single-digit iteration number, used to assist in controlling labelling where more than one labelling process takes place (e.g. an additional group label has to be placed over the initial label to display additional testing information such as CMV (cytomegalovirus) status).

Note: Where the counter is not utilised, its default value is 0.

Patient sample identification number for patient samples

&d

Defines a sample identification number for patient samples. The data structure is:

&daaaaaynnnnnff

Where:

&d	are the data identifiers
aaaaa	is the facility identifier. The first character will always be zero. Values in the range 09900 to 09999 are assigned for use by NHSBT.
yy	is the nominal year of collection (slippage of 1 month either side of the end of year is permitted)
nnnnnn	is a six-digit sequence number
ff	are barcode check characters. These are derived from a two-digit checksum calculated from the data sequence aaaaaynnnnnn as described in the ICCBBA 128 Technical Specification for ISBT 128.

In the eye-readable form of this number, the checksum is represented as a single boxed character.

23.3.1.4: Codabar ABC barcoding

The Codabar ABC barcoding encodes the following characters:

- ten numerics {0, 1, 2, 3, 4, 5, 6, 7, 8, 9}
- six control characters {-, \$, ., +, :, /}
- four start/stop (or pause) characters {a, b, c, d}.

Control codes

Within Codabar there are alpha characters assigned as start/stop characters. In some instances these are accompanied by a numeric (0–9), thus forming left-hand/right-hand control codes. These are used to identify the type of data encoded between the controls.

The assigned alpha characters are a, b, c, d.

Where an alpha character is accompanied by a numeric character, the combination will normally constitute the complete left/right-hand control and needs to be treated as such in decoding. Within the UK, however, there are instances where the numeric constituent of the left-hand control has been utilised as part of the data message (see section 23.6).

Codabar is only used in blood component labelling for component coding and expiry date representation.

23.3.1.5: Barcode specifications

Barcode dimensions

The minimum acceptable height for barcodes on labels in the UK is 6 mm. The standard density of the encoded characters is 0.4 character per mm. Inter-character gaps must be a minimum of 0.2 mm to provide adequate resolution between characters. Gap dimensions are not critical as each character is read independently and gaps do not carry information. The barcode is a series of straight parallel lines perpendicular to a base reference line.

Individual characters must not be misaligned by more than five degrees from adjacent characters.

A minimum border ('quiet zone') of 2.5 mm must be allowed at each end of the encoded message (but see section 23.4.1). The border above and below the code is not critical, but will normally include eye-readable information, the printing of which must not touch the code. Maximum depression or embossment of the printed barcode must not exceed 0.05 mm.

Optical parameters

The symbol is insensitive to the light-scattering properties of the substrate, except to the extent to which background reflectance is affected. Background diffuse reflectance is not specified as a separate parameter as it is integral in the definition of contrast (see below). However, a background diffuse reflectance of at least 70% (optical density 0.1) in the 500–950 nm range is necessary.

Contrast

Defined as the nominal difference in the diffuse reflectance between the background and the ink film, this should be at least 50% as measured over the 500–950 nm range. Measurements should be averaged over an area equivalent to a 0.2 mm diameter circle. A print contrast ratio of at least 90% is recommended.

Voids and ink specks

The missing ink coverage or 'white' spots within the bars or the extraneous dark specks between bars must not exceed 0.05 mm diameter, or subtend more than 25% of the area within a 0.10 mm diameter circle.

Edge roughness

The maximum area of edge irregularities subtending a 0.1 mm diameter circle must not exceed 25% of the area of that circle. The area of irregularity is to be measured with respect to the nominal bar edge.

Ink fill uniformity

Variation in ink film reflectance across the character should not exceed 5% within the same character.

Ink fill-in

Must not expand individual bars within characters to dimensions exceeding the tolerance specified for dimensional parameters ('see Barcode dimensions' above).

23.4: Donation identification numbers (DIN)

23.4.1: General structure

The donation identification number ('donation number') – ICCBBA Data Structure 001, plays a critical role in the safety of the blood supply. It provides a unique identification number which cross-references blood components and samples taken at the time of donation.

An example set of identification numbers is shown in Figure 23.3. Barcode density information is provided in the ICCBBA ISBT 128 Standard Technical Specification. The structure of the donation identification number is described further below. The example shows labels of various sizes and densities due to their use. If required, a tag can be incorporated in the labels designed for the blood tubes to facilitate the placing on the tube straight by users. This alignment is critical for blood samples being tested in analysers where the barcodes are read 'in situ' by internal barcode readers.

The donation identification number contains the facility code from where the donation has originated. These codes can be viewed on the ICCBBA website.

Blood Establishments can optionally add text below each number in the set to show from which Blood Establishment the donation originated.



Figure 23.3 ISBT 128 donation number sets (with and without Blood Establishment text)

23.4.1.1: General

All labels should have tamper evidence designed into the numbers sets to reduce the chance of a label being removed and re-stuck, i.e. any tampering with a label should deface the label making it unusable.

Labels should be self-adhesive using a non-invasive biocompatible adhesive (see ISO 10993 series – expanded in Chapter 26).

23.4.1.2: Requirements for pre-printed labels

Donation identification number (DIN) labels must be generated in primary sets under strictly controlled conditions which ensure that all the labels in a set bear the same number, and that each set is unique. It is the responsibility of the manufacturer of the label sets to undertake appropriate quality control measures to ensure these conditions are met.

The required number of individual labels comprising a set, the configuration of the labels and the commencing number for the print run, must be defined by the ordering authority at the time of order.

Quality control of sequential print must be organised to obviate the possibility of duplication within a print run, and also to avoid the misplacement of the various cutting devices which would cause any set to contain two different numbers.

Any unusable numbers or missing numbers must not be replaced.

Any roll/pad containing an incomplete sequence for any reason must have the discrepancy marked at the beginning of the roll/pad, or the manufacturer must supply a separate list of missing numbers. The total permissible missing numbers must not exceed 1% of the quantity ordered. Each roll/pad should not contain more than six missing numbers per 200 sets.

Pre-printed barcodes on number sets should be of decodability level no less than B to reduce label mis-reads.

The layout of the eye-readable numbers should follow the 4,3,3,3,1 format (see Figure 23.4).

Labels printed should have the correct facility identification code.

No barcodes within the number sets should have a height of less than 6 mm.

A quiet zone of at least 2 mm either side of each barcode is included in the label design.

Any incorporated check digits must be correct. This includes both barcode-incorporated and eye-readable check digits included in the design.

All adhesives used in production of these labels must be non-invasive biocompatible (see ISO 10993 series – expanded in Chapter 26).

Label colour: The labels must be printed black on a white background. Where required by the ordering establishment, part of an order may incorporate a coloured stripe (usually to assist in the identification of new (first-time) donors or sample-only donations). A colour must be selected which will not interfere with the efficiency of any barcode reader in decoding essential information.

23.4.1.3: Requirements for demand-printed labels

Additional donation identification labels may be demand-printed at the point of use.

Where demand-printing is used to generate additional labels for an existing set, the label must only be generated in direct response to the electronic input of a number from the original set.

Where demand-printing is used to generate new label sets, there must be controls to prevent number duplication.

Where ICCBBA flag characters are adopted within ICCBBA Data Structure 001, they must be used in accordance with the standard, and if they are incorporated within final component donation numbers, they must have been authorised by JPAC on advice from SACIT.

Locally printed barcodes should be of decodability grade level not less than C to reduce label mis-reads (see ISO 15416:2001).

The layout of the DIN eye-readable numbers printed should follow the 4,3,3,3,1 format (see Figure 23.4 and section 23.4.2).

Where applicable, labels printed should have the correct facility identification code.

No barcodes should be created with a height of less than 6 mm.

A quiet zone of at least 2 mm either side of each barcode is included in the label design.

Any incorporated check digits must be correct. This includes both barcode-incorporated and eye-readable check digits included in the design.

23.4.2: ISBT 128 donation identification number (DIN) barcode and text

Labels will follow the ISBT 128 Specification for Data Structure 001 with the exception of the eye-readable presentation.

The eye-readable presentation of the donation identification number must be presented in 4,3,3,3,1 format with the check character boxed (see Figure 23.4).

It is strongly recommended that all characters are of equal size and weight. The font used should be selected to clearly distinguish between similar alpha/numerics (e.g. 0 and O, 1 and I), and should be as large as possible within the constraints of label size.

Where keyboard entry of donation number is used, the full number and check character should be entered, and application software should verify the string format and check character value. Use of pre-programmed 'hot keys' is not an acceptable alternative.

Calculation of checksums and the corresponding check characters for the ISBT 128 numbers is described in the ICCBBA Technical Specification.

Note: Currently the UK standard only incorporates the modulus 37,2 check digits. If future developments include the flag characters in the donation number, they must be placed on the label at 90 degrees to the eye-readable text between the six-digit unit serial number and the eye-readable check digit. When the checksum is replaced with flag characters the eye-readable check digit must always be included in the label format. Any use of flag characters must be authorised through JPAC on advice from SACIT (see Figure 23.4, right).





Figure 23.4 Labels showing the use of flag characters. On the left, the label shows the eye-readable format 4,3,3,3,1 layout with the check digit in a box, and on the right, the same label shows the use of the flag character

23.5: Blood group labels

These labels are required for the purpose of blood group identification on the blood collection and satellite packs. The blood group can fall into one of eight classifications as shown in Table 23.1. Alternative labels, for use in special circumstances, are also described.

The blood group label is part of a complete overstick label and must be attached to the blood collection pack and/or satellite pack in the appropriate place immediately adjacent to the donation number. This is to allow a continuous straight-line read of the combined labels.

Label dimensions are defined below:

44 mm \pm 1 mm wide \times 99 mm \pm 1 mm deep

(range 43–45 mm wide \times 98–100 mm deep)

23.5.1: Label colour

All labels must be produced in black and white. All characters must be solid black on white except for RhD negatives where the ABO character must be in outline, and the 'RhD NEGATIVE' must be in solid white on a black background.

23.5.2: Printing

Group labels must be demand-printed at the point of labelling. The label must be generated in response to the electronic entry of a donation number and, once affixed to the blood pack, must be verified by the

concatenated electronic entry of the codes from the donation number label and the group label. Valid blood group labels must only be generated for units which have been fully tested and are suitable for transfusion.

23.5.3: Information content

The label design is illustrated in Figure 23.5. The content is described in the subsections below from the top down.

23.5.3.1: Group label verification number

This must be printed at the top left-hand side of the label in barcode format only. It must be an ISBT 128 number, complying with one of the national definitions (&a or &b; see section 23.3.1.3) . The distance of the barcode from the left-hand edge of the label must not be less than 2.5 mm or more than 4 mm.

The barcode must be between 7 mm and 10 mm high.

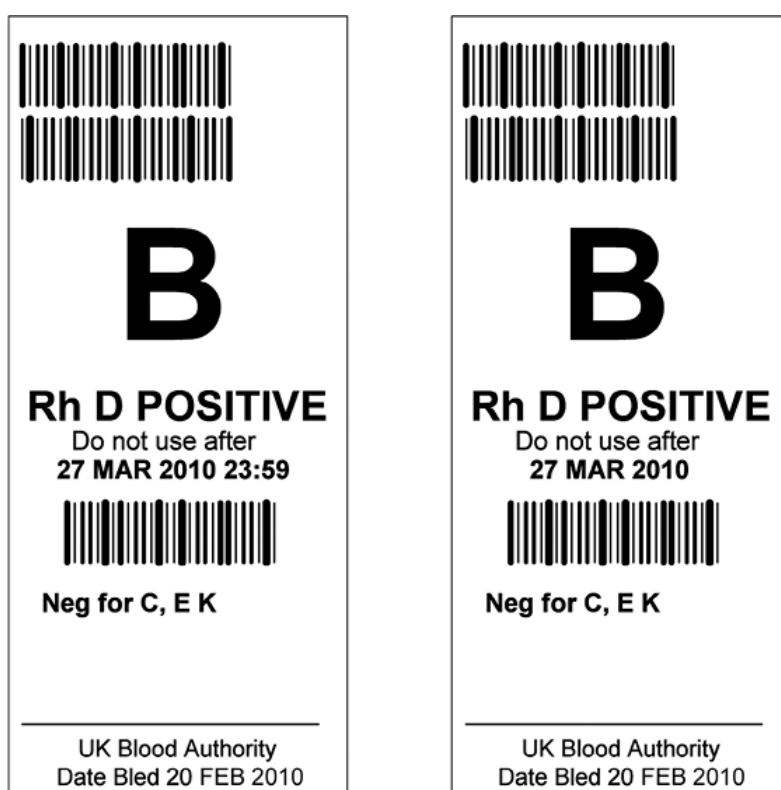


Figure 23.5 ABO/Rh blood group label layouts showing ‘Do not use after’ with and without time

23.5.3.2: Expiry day/month

The day and month of expiry may be included in the top right-hand corner (optional) of the label in eye-readable form and, if present, this must be in a DD/MM format. The text must be at least 2.5 mm away from the printed barcodes.

23.5.3.3: Blood group

The blood group barcode must be positioned below the group label verification number barcode separated by a gap of between 1 mm and 5 mm. The left-hand edges of the codes must be aligned. The blood group barcode must be between 7 mm and 10 mm high.

The format of the ISBT 128 group code will follow IDSBT 128 Data Structure 002 (see ICCBBA Standard Technical Specification).

In Data Structure 002, the value that holds the ABO/RhD and usage information is held in 2 characters labelled as 'gg'. The UK values of 'gg' for standard donations (without donation use limitations) are indicated in Table 23.1.

For donations using these group codes, the eye-readable blood group must be presented in two parts. The ABO group must be printed immediately below the group barcode. The characters must be solid black for RhD positives, and outline for RhD negatives.

The RhD status must be indicated immediately below the group barcode and eye-readable ABO. The text must be 'RhD POSITIVE' in solid black characters, or 'RhD NEGATIVE' in solid white characters enclosed in a black rectangular background.

The UK values of 'gg' used where donation use limitations apply are indicated in Table 23.2.

The eye-readable text associated with these codes is illustrated in Table 23.3 using O RhD POSITIVE as an example.

Table 23.1 Standard blood group classifications

Text	gg value	Text	gg value
O RhD POSITIVE	51	O RhD NEGATIVE	95
A RhD POSITIVE	62	A RhD NEGATIVE	06
B RhD POSITIVE	73	B RhD NEGATIVE	17
AB RhD POSITIVE	84	AB RhD NEGATIVE	28

Table 23.2 Usage limitation

ABO RhD blood groups	Usage – Directed donation only (gg value)	Usage – Emergency use only (gg value)	Usage – Directed donation, crossover permitted (gg value)	Usage – Autologous donation, crossover permitted (gg value)	Usage – Autologous use only (gg value)
O Rhesus D POSITIVE	47	48	50	52	53
O Rhesus D NEGATIVE	91	92	94	96	97
A Rhesus D POSITIVE	58	59	61	63	64

A Rhesus D NEGATIVE	02	03	05	07	08
B Rhesus D POSITIVE	69	70	72	74	75
B Rhesus D NEGATIVE	13	14	16	18	19
AB Rhesus D POSITIVE	80	81	83	85	86
AB Rhesus D NEGATIVE	24	25	27	29	30

Table 23.3 Blood group and donation use label text

gg	Label text
47	DIRECTED USE ONLY O RhD POSITIVE
48	EMERGENCY USE ONLY O RhD POSITIVE
50	DIRECTED (Eligible for Crossover) O RhD POSITIVE
52	AUTOLOGOUS (Eligible for Crossover) O RhD POSITIVE
53	AUTOLOGOUS USE ONLY O RhD POSITIVE

23.5.3.4: Expiry date or 'Do not use after'

The expiry date must be presented in eye-readable and barcode formats. The eye-readable text must be printed with characters of no less than 3 mm height. The content as a minimum must comprise the day number, the month represented by its first three characters, and the four-digit year (e.g. 1 FEB 2010). Where a system can include time to be printed as part of the eye-readable text it must be recorded after the year in the 24-hour format (e.g. 1 FEB 2010 23:59).

Currently the expiry date is coded using a Codabar barcode. The barcode must have a start code of 'a2' and a stop code of '4a'. The data content must be the last three digits of the year, and a three-digit Julian day number; thus 1 Feb 2010 would be represented by '010032', i.e. the 32nd day of the year.

While the current practice may allow the use of either 'Expiry date' or 'Do not use after' to identify when the component expires, consideration should be given to adopt 'Do not use after'.

23.5.3.5: Additional information (standard donations)

Additional information may appear immediately below the expiry date in an area no less than 10 mm and no more than 25 mm high. The data content of this section is at the discretion of the labelling authority, but is available for providing additional information on phenotypes, CMV status etc. Some UK Blood Establishments use a Codabar barcode of a8738a to indicate anti-CMV negative in addition to the eye-readable description.

23.5.3.6: Collection facility identification

The identification of the collecting facility may be indicated in eye-readable format below the additional information section of the group label. Alternatively, this information may be printed as part of the donation identification number (see section 23.4). The text content will be identified by the relevant national service and may comprise one or two lines of text.

23.5.3.7: Date bled

This must be printed in eye-readable form only at the bottom of the label. The characters must be no less than 3 mm high. The format must be day number as two digits, first three characters of the month name, and the four-digit year, e.g. 01 JAN 2010. Where a system can include time to be printed as part of the eye-readable format, it must be recorded after the year in the 24-hour format (e.g. 1 JAN 2010 23:59).

23.5.3.8: Label design for units with use limitations

An example of a blood group label design for units labelled with use limitations is shown in Figure 23.6. The lower section, used for additional information on standard labels, is used to indicate recipient information. It is important to recognise that this information is for identification of the recipient for which the donation is intended, but does not replace the need for crossmatch labelling or documentation.

Note: The NHS No. is in use in England; other countries will have an equivalent patient identification system that will be used in its place. Where this is the case, the numbering system used must be clearly identified so as not to introduce any ambiguity.



Figure 23.6 Label for unit with use limitations

23.5.3.9: Alternative labels

There are five status labels defined for use in the 'blood group label' location. The specification for these labels is divided into two sections, one for essential information which must be present on the label as specified, and one for optional information which may be added if desired.

All labels are to be demand-printed black on white.

The labels covered by this section of the specification are:

- HOLD label for use on donations where testing information is outstanding.
- NOT FOR TRANSFUSION label for use on units which are microbiology negative but not suitable for transfusion.
- RED CELLS NOT FOR CLINICAL USE label for use on donations which are microbiology negative but where the red cell component is unsuitable for transfusion.
- BIOHAZARD label for use on donations found to be microbiology positive.
- EMERGENCY USE ONLY label for use on donations which are to be issued for transfusion prior to completion of all mandatory testing.

23.5.3.10: 'HOLD' label specification

Essential information

ISBT 128 barcode: ISBT 128 group code (ICCBBA Data Structure 002) where gg = 'Mq'. Positioned to allow concatenated read with an adjacent donation number.

Text: The word 'HOLD' in upper-case letters of minimum height 6 mm

Text: The words 'FURTHER INVESTIGATION REQUIRED' in upper-case letters of minimum height 3 mm.

Optional information

Text: The word 'Reason:' followed by a free-format message giving the reason for hold

Text: Identification text of the testing centre

Text: The words 'Date Bled:' followed by the date bled.

23.5.3.11: 'NOT FOR TRANSFUSION' label specification

Essential information

ISBT 128 barcode: ISBT 128 group code (ICCBBA Data Structure 002) where gg = 'Md'. Positioned to allow concatenated read with an adjacent donation number.

Text: The words 'NOT FOR TRANSFUSION' in upper-case letters of minimum height 4 mm.

Optional information

Text: The word 'Reason:' followed by a free-format message

Text: The words 'Blood Group' followed by the ABO/RhD type if known

Text: Identification text of the testing centre

Text: The words 'Date Bled:' followed by the date bled.

23.5.3.12: 'RED CELLS NOT FOR CLINICAL USE' label specification

Essential information

ISBT 128 barcode: ISBT 128 group code (ICCBBA Data Structure 002) where gg = 'Mf'. Positioned to allow concatenated read with an adjacent donation number.

Text: The words 'PLASMA USE ONLY' in upper-case letters of minimum height 2 mm

Text: The words 'RED CELLS NOT FOR CLINICAL USE' in upper-case letters of minimum height 4 mm.

Optional information

Text: The word 'Reason:' followed by a free-format message

Text: The words 'Blood Group' followed by the ABO/RhD type

Text: Identification text of the testing centre

Text: The words 'Date Bled:' followed by the date bled.

23.5.3.13: 'BIOHAZARD' label specification

Essential information

ISBT 128 barcode: ISBT 128 group code (ICCBBA Data Structure 002) where gg = 'Mb'. Positioned to allow concatenated read with an adjacent donation number.

Text: The word 'BIOHAZARD' in upper-case letters of minimum height 4 mm

Text: The words 'HIGH RISK' in upper-case letters of minimum height 6 mm

Symbol: Biohazard warning symbol of minimum height 20 mm

Text: The words 'INACTIVATE BEFORE DISPOSAL' in upper-case letters of minimum height 2 mm.

Optional information

Text: Identification text of the testing centre

Text: The words 'Date Bled:' followed by the date bled.

23.5.3.14: 'USE IN EMERGENCY ONLY' label specification

Essential information

ISBT 128 barcode: Under ISBT 128 it is necessary to include the historical ABO/RhD type within the barcode. This is achieved by using the modified ISBT 128 group code, where gg is as defined in Table 23.2. Positioned to allow concatenated read with an adjacent donation number.

Text: The words 'BLOOD GROUP NOT CONFIRMED, USE IN EMERGENCY ONLY' in upper-case letters of minimum height 4 mm

Text: The words 'UNCONFIRMED BLOOD GROUP:' followed by the unconfirmed ABO/RhD type if known

Text: The words 'DATE BLED:' followed by the date of collection

Text: The words 'EXPIRY DATE:' followed by the expiry date. Minimum text height 2 mm

Optional information

Text: Identification text of the testing centre

Text: Free-format additional status information such as 'Mandatory Microbiology Tests Negative'.

23.6: Component labels

23.6.1: General description

These labels are for use on blood collection packs and/or satellite packs. Each label will display a component description printed in bold text, a Codabar barcode and additional information. All information is printed in black on a white background. These labels may be pre-printed or produced using a demand-printed system where the information is transferred electronically from a host system.

23.6.2: Label dimensions

Label dimensions are defined below:

55 mm \pm 1 mm wide \times 55 mm \pm 1/–3 mm deep

(range 54–56 mm wide \times 52–56 mm deep)

23.6.3: Label specification

The label must meet the following specifications:

- The barcode height must be no less than 10 mm with a 2 mm quiet zone each side of it.
- The barcode must have the eye-readable code textually displayed to accompany the barcode.
- The textual component description must be in bold characters and be exactly as is registered in the UK portfolio.
- Use of abbreviations must be authorised by the Standing Advisory Committee on Blood Components (SACBC) or JPAC groups.
- A UK JPAC agreed instruction statement must be included.
- The volume of the component must be textually displayed on the label as either the exact or as a nominal volume in millilitres (mL).
- Any storage or special instructions for storage must be included.
- The recipe for any included anticoagulant or additive must be indicated on the label in textual form.
- Where the component is part of a split component, the split should be identified as Pack 1, Pack 2 etc. textually on the label.
- If the component has a reference number (i.e. CT number), it should be included on the label in textual form with or without version number as a suffix.

Figure 23.7 shows an example of a component label layout.

23.6.4: Component barcodes

All components have an individual barcode. The barcode comprises three main elements:

- a start code 'a0'
- a five-character code to uniquely denote the component
- a stop code '3b'.

23.6.5: Component code reference table

The current component code reference table is held and managed by SACIT. The table includes:

- the text defining the component. Where possible this text is the same as that defined in Chapter 7 of these guidelines
- the start code for the component
- the code for the component, e.g. 04260
- the stop code for the component.


INSTRUCTIONS Always check patient/component compatibility/identity Inspect pack for signs of deterioration or damage Risk of adverse reaction/infection, including vCJD
 04333
Red Cells Leucocyte Depleted, in additive solution STORE AT 4°C ± 2°C Volume XXX ml
Component collected into CPD anticoagulant. Red cells suspended in 100 millilitres of additive solution with the composition in mmol/l: Sodium chloride 150, Adenine 1.25, Glucose 45 and Mannitol 29

Figure 23.7 Example of a component label layout

23.6.6: Allocation of new component codes

In the event of a UK Blood Establishment requiring a code for a component that will be issued on a regular basis, the following steps must be carried out:

- A request form for a new component code, including a component being trialled, must be completed and sent to SACBC. This committee will determine if the component is a 'new' component or if it is covered by an existing component registration. If it is a new component it will be reviewed by SACBC members and if agreed, the product will be accepted.
- SACBC will authorise the component to be part of the UK component portfolio and it will then be numbered with a new unused Codabar component code.