Guidelines for the Blood Transfusion Services

Chapter 24: Specification for the uniform labelling of human tissue products using ISBT 128

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Chapter 24: Specification for the uniform labelling of human tissue products using ISBT 128

24.1: Introduction

The ISBT 128 Standard is an internationally defined coding system for the barcoding of information on blood components, progenitor cells and tissues. Designed by the International Society of Blood Transfusion (ISBT) Working Party on Automation and Data Processing, the responsibility for the worldwide management and distribution of the ISBT 128 Technical Specification and associated databases now resides with the International Council for Commonality in Blood Banking Automation Inc. (ICCBBA).

A specification for the use of the coding system for the description of tissue products has been agreed by ICCBBA (ICCBBA Product Code Database, available from the website www.iccbba.org).

Some UK tissue bank facilities use Codabar product codes at present. The use of Codabar product codes for UK tissues will be phased out over time and the ISBT 128 product coding will be fully adopted in its place.

This chapter details the manner in which internationally agreed ISBT 128 tissue donation identification numbers, blood group codes and product description codes will be incorporated into tissue labelling systems in the UK where ISBT 128 is in use. The document cross-references the UK database of tissue product description label text which is maintained by the Joint UKBTS/HPA Professional Advisory Committee (JPAC) Standing Advisory Committee on Tissues and Cellular Therapy Products. The labelling of stem cell donations and products is outside the scope of this document.

The ICCBBA ISBT 128 Technical Specification is provided to companies and Blood Transfusion Services that have registered with ICCBBA, or may be downloaded directly from the ICCBBA website (www.iccbba.org).

24.1.1: The ISBT 128 Technical Specification: summary

The ISBT 128 Technical Specification:

- describes the standard layout for a blood group label
- defines the data identifiers for barcodes used in the tissue bank environment

- defines the data structures that carry information, i.e. how a particular barcode will be recognised by a reader, how many characters there are, and whether the characters are letters, numbers or both

- includes tables that define how complex barcodes should be translated, such as ABO/Rh blood groups.

24.2: The labelling system

The labelling system for retrieved tissues and tissue products comprises the following elements:

- **Base label:** The label applied to the retrieved tissue container following tissue retrieval and/or to the final container following tissue processing. It includes guide marks (preferably corner marks to prevent interference with barcode reading) to assist in the positioning of overstick labels. Retrieved tissue may be from living donors (retrieved during surgery) or from cadaveric donors (retrieved after death). It is noted that in the majority of cases, tissue is transferred during processing to a secondary /final container. In these circumstances a new base label is applied to the final container.

- **Donation identification number label:** A label bearing the ISBT 128 donation number barcode (ICCBBA Data Structure 001). Produced in sets, these labels ensure the accurate and unique labelling of all tissue donations and samples. Allocated at the point of donation, this number is fundamental to the secure audit trail for tissues. Where a retrieved tissue is processed without pooling or is issued unprocessed, the original donation number barcode is used to identify it to the point of implantation. This label will bear the title of the Service supplying the tissue, unless this is included on another label.

- **Batch/pool identification number label:** A label bearing an ICCBBA Data Structure 001 donation identification barcode. These labels are demand-printed when different tissues from one donor are pooled for processing. They ensure the accurate and unique identification of tissues once they have been pooled through to the individual resulting tissue grafts/units each of which bears the same identification number. Ideally, the number sequence used for batch/pool identification numbers should be different from donation number sequences and should be easily identifiable as batches /pools. This label will bear the title of the Service supplying the tissue, unless this is included on another label.

- **Product label:** A label bearing the ISBT 128 tissue product barcode (ICCBBA Data Structure 003) together with tissue product information, applied at the time of tissue retrieval and final tissue product manufacture. Where individual tissue units have been produced from a pool of tissues (from one or more donors) the product barcode can be used to individually identify up to 999 splits from the pool. This label can include unit-specific information.

- **Tissue status label:** A label indicating the status of a particular product in barcoded and eye-readable form. This is equivalent to the blood group label in blood banking. The following status labels can be applied and all use ISBT 128 coding (ICCBBA Data Structure 002):
    - FIT FOR CLINICAL USE (RhD NOT SPECIFIED)
    - QUARANTINE – NOT YET RELEASED FOR CLINICAL USE
    - RhD POS – FIT FOR CLINICAL USE
    - RhD NEG – FIT FOR CLINICAL USE
    - MUST BE STERILISED
    - FOR IN VITRO R & D ONLY
    - BIOHAZARDOUS
    - DISCARD
    - SEE OUTER CONTAINER FOR PRODUCT STATUS (for cryopreserved products)

- AUTOLOGOUS USE – FIT FOR CLINICAL USE
- AUTOLOGOUS USE – QUARANTINE.

The tissue status label will also bear the nationally defined unit identifier in barcode form (this is a non-ICCBBA defined data structure allocated by JPAC's Standing Advisory Committee on Information Technology (SACIT) to meet ICCBBA guidelines) and other donation-specific information (e.g. date of donation or retrieval site). This label will be applied by the tissue provider prior to release into stock, allocation for R&D or discard. (The only exception is the 'See outer container' label, which will be applied to the base label before the product is cryopreserved.) These labels are positioned to allow concatenation between the unit identifier barcode on the base label and the short form identifier and the rhesus/status barcodes on the status label.

- **Expiry date label:** A label indicating the date by which the tissue must be processed (if in quarantine), issued (if in issue stock) or used (if dispatched for clinical use). Different expiry date labels may be overstuck on products at different times. For example, some banks shorten the shelf life of products once they are issued from a bank due to concerns relating to appropriate long-term storage and control in hospitals.

The labels indicated above are all affixed onto a base label, except in the case of cryopreserved products where two status labels may be used: one on the product container itself (applied before cryopreservation), 'See outer container for product status', and one on the outer container giving the product status. In this case, a new base label, product label and expiry label should all be attached to the outer container. The arrangement of labels depends on the product and container type. Two options are shown in Figures 24.1 and 24.2; each would require a different base label. These diagrams are for orientation purposes only: see under the appropriate sections for details of each label content and layout.

The four basic quadrant labels may be printed as combination labels; for example, the donation number label and the product description label may be printed as a single vertical strip label and affixed to cover the left-hand half of a square base label. Similarly, expiry date information may be printed on a status label so that the two right-hand quadrants are printed as a single strip.

24.3: General requirements

24.3.1: Label quality

Labels used for tissue and sample labelling must be:

- self-adhesive using a non-invasive adhesive
- tamper-evident (i.e. removal must deface the label)
- smear-resistant and non-fading
- resistant to water and humidity
- capable of being affixed readily to paper or other base label material, plastic surfaces, glass (particularly glass tubes of 12 mm diameter) without winging ('winging' is defined as the lifting of a label from the surface to which it is applied). Winging should not exceed 2.5 mm as the maximum linear distance of the label not adhering to the tube 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 tissue container. This range may be extended by the ordering authority at the time of order. This condition must extend to the printed text which must not deteriorate due to thermal conditions. Where products are stored at lower temperatures, labels will be sealed into plastic pockets on the container

- capable of being applied without slippage to tubes etc. subject to temperature variation prior to use, for example tubes/packs stored in a vehicle and then used at normal ambient temperature, such equipment being by definition ‘damp’

- non-flaking when read using a hand-held light-pen touching the label.

Figure 24.1 Label positioning: option 1 (example; see cautionary note in text)

Figure 24.2 Label positioning: option 2 (example; not to scale)

24.3.2: Printing requirements: eye-readable information

The ICCBBA ISBT 128 Technical Specification (latest version can be downloaded from the ICCBBA website www.iccbba.org) stipulates that ‘Every bar code, with the exception of the donation identification

number (ICCBBA Data Structure 001), should be accompanied by an exact eye-readable representation of the data characters in the bar code'. In the UK this requirement is not being implemented for the short form unit identifier, and is currently optional for the blood group/status code and expiry date code.

Requirements for each type of label are defined in the appropriate sections.

24.3.3: Printing requirements for barcodes

All barcodes will be printed as specified in the ICCBBA ISBT 128 Technical Specification.

24.3.4: 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 Technical Specification and further expanded in ICCBBA Technical Bulletin No. 5. Where concatenated codes are to be read it is essential that the barcode readers used support concatenation of Code 128 barcodes with the defined temporal/spatial limitations of ISBT 128.

In the UK release status labelling will be confirmed by concatenation of the donation identification number (ICCBBA Data Structure 001) with the non-ICCBBA defined unit identifier (nationally defined – see section 24.3.5) and donation ID. The relevant data identifiers are specified within the appropriate sections of this document. For further details refer to the ICCBBA ISBT 128 Technical Specification (www.iccbba.org).

24.3.5: 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 which will be applied in tissue labelling.

Short form donation identification number (Version 1)

&a

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

&annnnnn

Where:

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

Short form donation identification number (Version 2)

&b

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

&bnnnnnnk

Where:

&b	are the data identifiers
nnnnnn	is the six-digit unit serial number from the ISBT 128 donation number definition
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).

24.4: Tissue product labels

24.4.1: The base label

The base label dimensions are to be at least 110 mm wide by 104 mm high on all tissue containers/labels where the square format is used. Where the horizontal format is used they will be at least 220 mm wide by 52 mm high.

It is noted that where tissues are stored in very small containers, the base label may be attached to a secondary container. In these circumstances, the inner container will be labelled with the donation number barcode to provide a link to the label on the outer packaging.

The guide marks on Figures 24.3 and 24.4 are required to assist positioning of later labels.

24.4.1.1: Square format

The top left-hand quadrant will be used for the application of a donation identification number label. The space below this on the left-hand side of the label between 25 mm and 40 mm from the top edge must be left blank. This space may be pre-printed, for certain donations, by the company supplying the container with the lot/batch number of the container. This text must be visible at all times.

The bottom left-hand quadrant will be overstuck with a product description label.

The top right-hand quadrant will have pre-printed text indicating that the donation is in quarantine, as follows:

QUARANTINE

NOT YET RELEASED FOR CLINICAL USE

The top right-hand quadrant will be overstuck with a status label once its status has been determined (for cryopreserved products, this quadrant can be overstuck with a ‘See outer container for product status’ label). The status label can then be applied to a secondary container.

The bottom right-hand quadrant will be overstuck with an expiry date label which relates to expiry date prior to issue or to expiry date following issue.

24.4.1.2: Horizontal format

The same four quadrants will be used but the order in this case will be as shown in Figure 24.4.

Figure 24.3 Base label design: square format

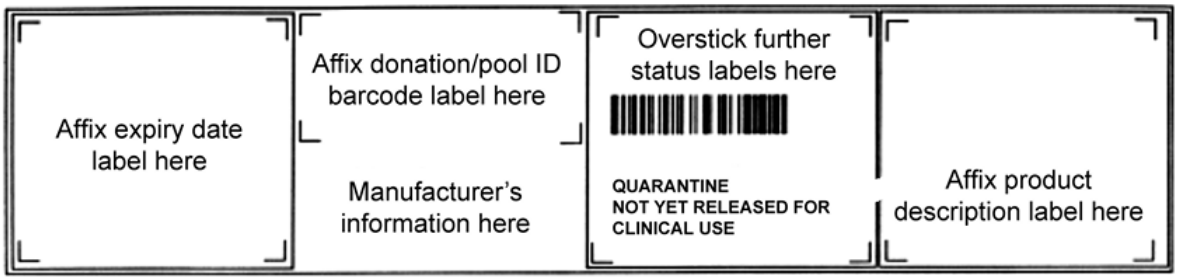

Figure 24.4 Base label design: horizontal format (not to scale)

24.4.2: Donation and pool identification number labels

The donation identification number plays a critical role in the safety of the tissue supply. It provides a unique identification number which cross-references tissue donations and products and samples taken at the time of donation. Where tissue products are not further processed, they are issued with the same donation identification number label.

Donation identification number labels must be generated in 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.

Figure 24.5 Donation identification number label set

Pool identification number labels are generated on demand when donations are processed together, whether from one or more donors.

As tissues are usually transferred from their original containers to secondary and tertiary containers during processing, it is a requirement that donation and pool identification numbers can be printed on demand.

An example set of identification numbers is shown in Figure 24.5. Barcode density information is provided in the ISBT 128 Technical Specification. The structure of the donation identification number is described further below.

For identification number labels to be applied to tissue products, the dimensions of the label are as indicated in Figure 24.6. As with all barcodes, there should be a minimum ‘quiet zone’ of 2.5 mm between the edge of the label and the start of the barcode. This label is affixed to the top left-hand section of the base label.

The donation identification number complies with ICCBBA Data Structure 001. The country/collection facility identification codes included within this data structure are allocated by ICCBBA and a list of these can be downloaded from ICCBBA’s website. Any tissue service site within the UK requiring a new facility code must make a request first to SACIT before applying to ICCBBA for registration.

The collection year characters (6 and 7) should correspond to the last two digits of the year in which collection took place. In practice, this cannot be readily achieved using pre-printed labels without considerable wastage. Within the UK it is therefore permissible to allow a maximum variation of 1 month either way, i.e. it is permissible to use the previous year’s collection year characters up to 31 January in the current year, and to use donation numbers with the following year’s collection year characters from 1 December in the current year.

The use of ICCBBA Data Structure 001 allows either an inclusion of the modulus 37,2 check digits or the ability to use the last two characters as process control flags. At present all UK donation identification numbers incorporate the modulus 37,2 check digits. If the check digits are not used and process control flags are used in their place, they must be registered and authorised by SACIT prior to their use.

The algorithm for calculating 37,2 check characters can be found in the ICCBBA ISBT 128 Technical Specification. Users will need to take into account that units imported from countries outside the UK may well use these flag characters for process control as permitted in the specification.

Figure 24.6 Donation number label dimensions

Figure 24.7 Donation number showing process control/flags characters

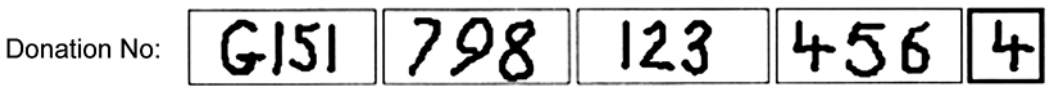

Figure 24.8 Form boxes designed to enable accurate recording

The eye-readable format of the donation identification number in the UK comprises the data characters excluding the flag characters, followed by the manual entry check character. The layout differs from that in the ICCBBA ISBT 128 Technical Specification in that all characters of the number must be of equal size and weight. Printing of the six-digit unit serial number in larger or bold characters is not permitted. Software manufacturers should ensure that only the eye-readable format is presented in screen displays.

If process control flags are used within the donation identification number, they must be displayed as per the standard between the last digit and the boxed eye-readable check digit (i.e. 90 degrees to the rest of the number) as shown in Figure 24.7.

The number should be displayed with the characters grouped in a 4,3,3,3,1 arrangement. It is recommended that the check character be enclosed in a box where this is possible. The check character set uses the characters I and 1, 0 and O, and the font selected should be one which allows easy differentiation between these characters.

Where the donation identification number has to be recorded manually, form designs that assist accurate recording, such as the use of boxes to encourage correct character grouping, are recommended. An example is given in Figure 24.8.

The full eye-readable donation identification number, including check character, must be recorded and entered in all cases. The use of pre-programmed shortcut keys (‘hot’ keys) or pre-printing of part of a number is not acceptable.

24.4.3: The product label

The product label (50–55 mm wide by 50–52 mm high) is affixed to the left lower quadrant of the square base label or the right-hand side of the horizontal base label, if printed as a single quadrant (it may be printed as a combined label with another quadrant). A start product label is attached to all base labels at the time of tissue retrieval. If the tissue remains in the same container until the time of issue for implantation, it is issued with this product label. If it is subjected to further processing while remaining in its original container (e.g. gamma irradiation) the start product label is overstuck with the appropriate final product label before application of a status label. If it is transferred to another container following processing, a new base label is attached and the appropriate final product label is attached to the lower half of the base label following processing. The template for the product label is shown in Figure 24.9.

Codes for tissues and tissue products should only be used if they are registered with ICCBBA, approved by the Standing Advisory Committee on Tissues and Cellular Therapy Products (SACTCTP) and the Standing Advisory Committee on Information Technology (SACIT).

New tissue donations and tissue products will have codes assigned as required by SACIT in liaison with SACTCTP and ICCBBA. Requests for new codes should be made in writing or by e-mail to the Chair of SACIT with notification to the Chair of SACTCTP.

Updates of the Human Tissue Code Database can be obtained from the ICCBBA website (www.iccbba.org).

The first two lines of text contain the tissue component class and modifier, for example:

> CORTICO-CANCELLOUS BONE RING
>
> Freeze-dried

Lines 3 to 7 describe various attributes, where relevant, though one of these can be used to provide further product description information (see section 24.4.5). It is not necessary to include the unit of issue attribute details. Space will be available next to the method of sterilisation attribute where exposure ‘dots’ can be applied. The significance of the dot colour need not be detailed on the label but can be explained in the package insert. The volume/dimension field will contain either the actual or nominal tissue volume or other relevant dimensions (e.g. length, depth etc.). Immediately under the product barcode will be the unique reference number of the label which will correspond to the eye-readable barcode without the data identifier characters.

An example of a product label is given in Figure 24.10.

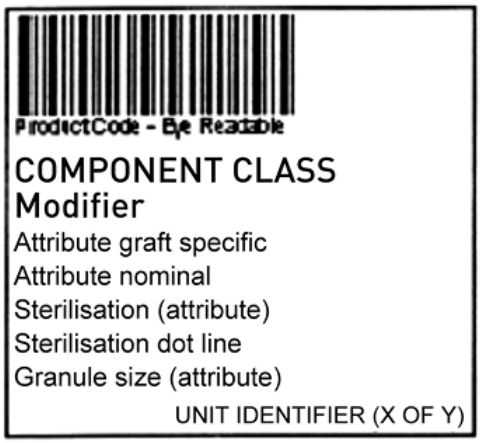

Figure 24.9 Tissue product label template

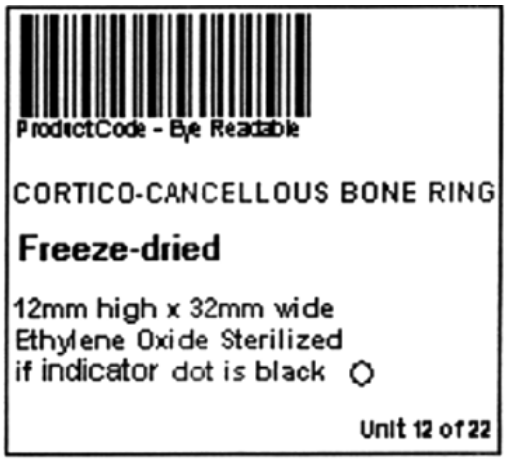

Figure 24.10 Product label (example)

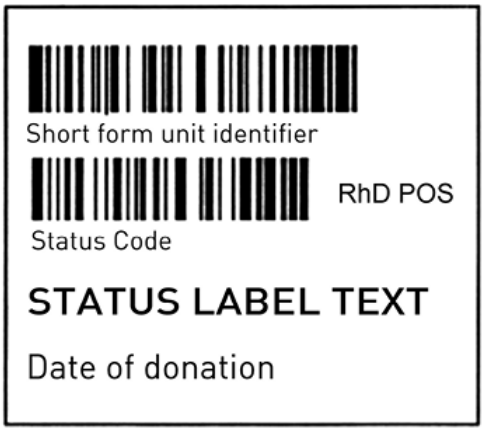

Figure 24.11 Tissue release status label

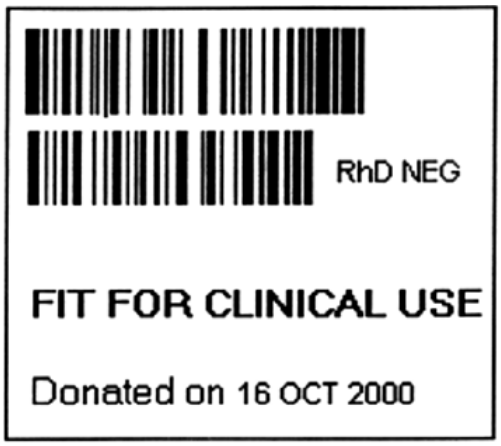

Figure 24.12 Status label (example)

24.4.4: The tissue status label

The tissue status label is a demand-printed label (50–55 mm wide by 50–52 mm high). The overall layout of the label is shown in Figure 24.11. This label can include graft-specific information such as date and site of donation.

An example of a status label is given in Figure 24.12.

The elements of the label content from top to bottom are described in the following sections.

24.4.4.1: Non-ICCBBA defined data structure – unit identifier (short form ID)

The tissue status label is unique to a specific donation. To ensure that it is affixed to the correct container a barcode, the nationally defined identification code, is printed on the label. This is used by the Service in a concatenated read with the donation identification number at the time of labelling. (Note: Although this is a non-ICCBBA defined data structure, it is ICCBBA authorised and controlled in the UK through the SACIT committee.)

The structure of the short form unit identifier is defined in section 24.3.5. Either the '&a' or '&b' versions of the code can be used.

Barcode indicating product status and the statement of product status

The statement of product status (which appears below the barcode) will be one of those listed in Table 24.1.

The barcode giving the product status is taken from the ICCBBA ISBT 128 Technical Specification.

24.4.4.2: Donation-specific information

Specific information which applies to the donation may be included on this label. This includes the RhD blood group and the date of donation.

The RhD blood group is only relevant where red cells remain in the final tissue product and where the product is supplied for female recipients of childbearing age.

Below the short form unit identifier is printed the RhD blood group barcode for certain products. The text relating to RhD type will be printed to the right of the status barcode. Where the RhD type is indicated, products will always be fit for clinical use.

Within the UK the blood group data structure will reflect that given in the ICCBAA Data Structure 002:

=%ggre

Where:

‘gg’ is the ABO/Rh/status code. The default ABO/Rh codes or the special message codes described in the ICCBBA ISBT 128 Technical Specification will be used as indicated. The characters r and e from this data structure are not used in the UK at this time and are both set to 0 (i.e. 00).

For example, an RhD positive unit will code as:

=%T100

The barcode and text content of these labels is described in section 24.4.5.

Date of donation can also be included on this label following the conventions described for expiry dates. This information does not need to be barcoded; it is represented in text only and must comprise the day number, the month represented by its first three characters, and the four-digit year (e.g. 1 FEB 2002).

24.4.5: Status label definitions

For each of the special message codes indicated in the status label section an associated status label is defined. 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.

Table 24.1 Statements of product status

Statement	Status code
FIT FOR CLINICAL USE (RhD NOT DEFINED)	T3
QUARANTINE NOT YET RELEASED FOR CLINICAL USE	Mq
RhD POS FIT FOR CLINICAL USE	T1
RhD NEG FIT FOR CLINICAL USE	T2
MUST BE STERILIZED	T6
BIOHAZARDOUS	Mb
DISCARD	Md

FOR IN VITRO R & D ONLY	Mr
SEE OUTER CONTAINER FOR PRODUCT STATUS	T5
AUTOLOGOUS USE FIT FOR CLINICAL USE	Ma
AUTOLOGOUS USE QUARANTINE	T4

24.4.5.1: T3 'FIT FOR CLINICAL USE' (RhD not specified)

Essential information

Barcode: ISBT 128 group code, where gg = 'T3'. Positioned to allow concatenated read with an adjacent donation number

Text: The words 'FIT FOR CLINICAL USE' in upper-case letters of minimum height 4 mm.

24.4.5.2: Mq 'QUARANTINE – NOT YET AVAILABLE FOR CLINICAL USE'

Essential information

Barcode: ISBT 128 group code where gg = 'Mq'. Positioned to allow concatenated read with an adjacent donation number

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

Text: The words 'NOT YET RELEASED FOR CLINICAL USE' 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.

24.4.5.3: T1 'RH D POS – FIT FOR CLINICAL USE'

Essential information

Barcode: ISBT 128 group code where gg = 'T1'. Positioned to allow concatenated read with an adjacent donation number

Text: The words 'RhD POS' in upper-case letters (except the 'h') of minimum height 6 mm to appear to the right of the status barcode

Text: The words 'FIT FOR CLINICAL USE' in upper-case letters of minimum height 3 mm.

24.4.5.4: T2 'RhD NEG – FIT FOR CLINICAL USE'

Essential information

Barcode: ISBT 128 group code where gg = ‘T2’. Positioned to allow concatenated read with an adjacent donation number

Text: The words ‘RhD NEG’ in upper-case letters (except the ‘h’) of minimum height 6 mm to appear to the right of the status barcode

Text: The words ‘FIT FOR CLINICAL USE’ in upper-case letters of minimum height 3 mm.

24.4.5.5: T6 ‘MUST BE STERILIZED’

Essential information

Barcode: ISBT 128 group code where gg = ‘T6’. Positioned to allow concatenated read with an adjacent donation number

Text: The words ‘MUST BE STERILIZED’ in upper-case letters of minimum height 3 mm.

Optional information

Text: The word ‘Reason:’ followed by a free-format message.

24.4.5.6: Mb ‘BIOHAZARDOUS’

Essential information

Barcode: ISBT 128 group code where gg = ‘Mb’. Positioned to allow concatenated read with an adjacent donation number

Text: The word ‘BIOHAZARDOUS’ 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.

24.4.5.7: Md ‘DISCARD’

Essential information

Barcode: ISBT 128 group code where gg = ‘Md’. Positioned to allow concatenated read with an adjacent donation number

Text: The words ‘DISCARD’ in upper-case letters of minimum height 4 mm.

Optional information

Text: The word ‘Reason:’ followed by a free-format message.

24.4.5.8: Mr ‘FOR IN VITRO R & D ONLY’

Essential information

Barcode: ISBT 128 group code where gg = ‘Mr’. Positioned to allow concatenated read with adjacent donation number

Text: The words ‘FOR IN VITRO R & D ONLY’ in upper-case letters of minimum height 3 mm.

24.4.5.9: T5 ‘SEE OUTER CONTAINER FOR PRODUCT STATUS’

Essential information

Barcode: ISBT 128 group code where gg = ‘T5’. Positioned to allow concatenated read with adjacent donation number

Text: The words ‘SEE OUTER CONTAINER FOR PRODUCT STATUS’ in upper-case letters of minimum height 3 mm.

24.4.5.10: Ma ‘AUTOLOGOUS USE (FIT FOR CLINICAL USE)’

Essential information

Barcode: ISBT 128 group code where gg = ‘Ma’. Positioned to allow concatenated read with adjacent donation number

Text: The words ‘AUTOLOGOUS USE’ to appear in upper-case letters of minimum height 4 mm

Text: The words ‘FIT FOR CLINICAL USE’ to appear in upper-case letters of minimum height of 4 mm.

24.4.5.11: T4 ‘AUTOLOGOUS USE (QUARANTINE)’

Essential information

Barcode: ISBT 128 group code where gg = ‘T4’. Positioned to allow concatenated read with adjacent donation number

Text: The words ‘AUTOLOGOUS USE’ to appear in upper-case letters of minimum height 4 mm

Text: The words ‘QUARANTINE’ to appear in upper-case letters of minimum height 4 mm.

24.4.6: The expiry date label

An expiry date label will be applied to base labels at the time of tissue retrieval and whenever another base label is used. A final expiry date label may be applied at the time of issue if the bank follows a policy of shortening the shelf life at the time of issue.

The use of a barcoded version of expiry date is optional. If used, it should follow either ICCBBA Data Structure 004 or 005 (it should be noted that Data Structure 004 will be stood down in the near future and only Data Structure 005 will be valid).

24.4.6.1: For ICCBBA Data Structure 004

=>cyyjjj

Where => are the data identifiers, ‘c’ designates the century (e.g. 9 for 1999; 0 for 2000); ‘yy’ designates the year and ‘jjj’ is the Julian date (i.e. the number of the day in the year, e.g. 022 is 22 JAN).

24.4.6.2: For ICCBBA Data Structure 005

&>cyyjjjhhmm

Where &> are the identifiers, cyyjjj are as Data Structure 004 and hhmm signifies the hour and minutes the product expires. It should be noted the default expiry for a product with a lifespan counted in full days will be 23:59, i.e. the product will expire on the last day at 23:59.

24.4.6.3: Other information

The expiry date must be presented in eye-readable format. Additional text will follow each expiry date and will be specific for each product. For instance:

22 JAN 2003 if stored at –40°C or lower

The eye-readable text must be printed with characters of no less than 3 mm height. The content must comprise the day number, the month represented by its first three characters, and the four-digit year (e.g. 1 FEB 2002).

The use of the date format DD MMM YYYY avoids problems which may arise due to national differences in the order of the elements of numerically expressed dates. The accepted month abbreviations are JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC.

The expiry date label should also include the following text:

See package insert for further information

Unit-specific product information such as product weight may also be included on the expiry date label. For example:

84 g

Where the expiry date label is printed as a quadrant label on its own it should also have the short form donation number barcode identifier (see section 24.3.5). This is not necessary where the label is printed as part of a status label (already including this identifier). An example of an expiry date label is shown in Figure 24.13.

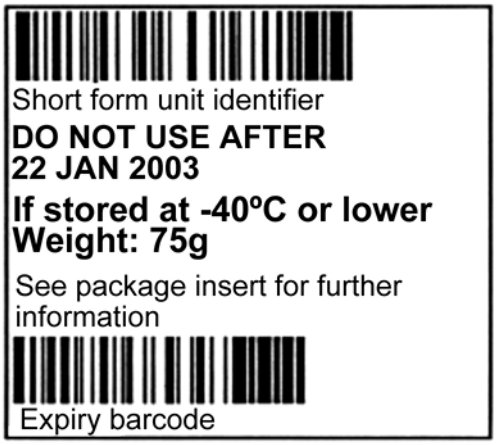

Figure 24.13 Expiry date label (example)