

Guidelines for the Blood Transfusion Services

24.2: The labelling system

<http://aws-lon-jpac.targetservers.uk/red-book/chapter-24-specification-for-the-uniform-labelling-of-human-tissue-products-using-isbt-128/24-2-the-labelling-system>

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 overstocked 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.