

## Guidelines for the Blood Transfusion Services

### 23.2: The labelling system

<http://www.transfusionguidelines.org/red-book/chapter-23-specification-for-the-uniform-labelling-of-blood-blood-components-and-blood-donor-samples/23-2-the-labelling-system>

### 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 (please refer to Chapter 7). Applied at the time of component manufacture by the Blood Establishments.

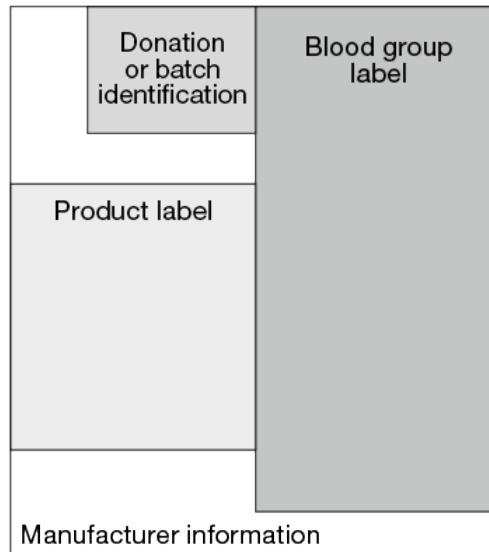
The labels indicated in the second to fifth points above are all affixed onto the base label (see Chapter 26).

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. For some specialised components, there may be a requirement for alternative labelling arrangements, e.g. when blood packs or base labels are smaller or the container has size limitations. In such cases, these labelling arrangements must be reviewed and approved by SACBC, and this will include consideration of amending guidance in the relevant component specification.

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 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)