

SOLVENT DETERGENT PLASMA STANDARDIZED LABEL

Author: Erwin Cabana, ICCBBA

Co-authors: Paul Ashford, ICCBBA; Angela Brazier, NHS Blood and Transplant; Scott Greenwell, American Red Cross; Teemu Laakso, Finnish Red Cross Blood Service; Wanda LeFresne, Canadian Blood Services; Bernie Quirke, Irish Blood Transfusion Service; Marc Rechsteiner, Octapharma AG; Angeline Riezebos, Sanquin; Renny Skagestad, Labcraft AS

BACKGROUND

Unlike most products that are made from plasma from a large number of donors, ABO blood group is relevant to Solvent Detergent-Treated Plasma (SDP). Therefore, the blood group must be on the affixed label, preferably in both eye- and electronically-readable format. The relevancy of blood group, and the fact the product is handled in a similar way to Fresh Frozen Plasma, mean it is typically managed by blood banks rather than pharmacies. Because blood banks use ISBT 128, and because ISBT 128 supports the encoding of blood groups and other key information, both ICCBBA and GSI recommend labeling SDP using the ISBT 128 Standard on the affixed label.

AIM

The aim of the work was to design a globally standardized affixed label with key information presented in both eye- and electronically-readable format. Such a label would improve patient safety, as well as improve the accuracy and efficiency of recording information required for traceability.

METHODS

ICCBBA, the organization that manages the ISBT 128 Standard, established a team of experts to design an internationally standardized affixed label for SDP. The team, which met by conference call, comprised professionals responsible for managing SDP in blood centers and hospitals, ICCBBA staff, and a representative of Octapharma, a major manufacturer of SDP. A proposed label design was released for public comment and the comments received were incorporated into a final label design.

RESULTS

The standardized affixed label includes critical information in the upper half of the label encoded into linear bar codes following the ISBT 128 Standard. Corresponding text information is placed near each bar code. This critical information includes:

- Donation Identification Number (DIN) to uniquely identify each plasma product
- ABO blood group
- Product code
- Expiration date

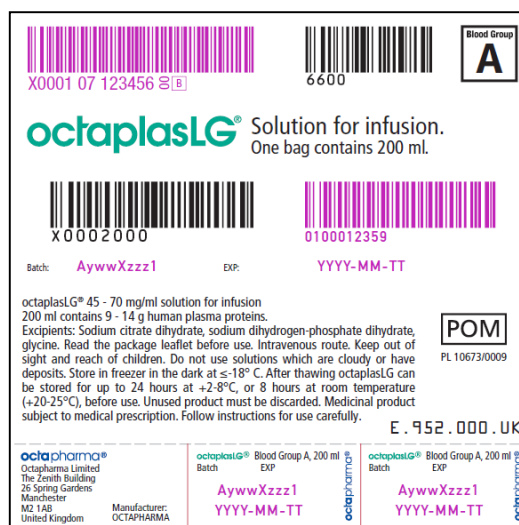
RESULTS (cont.)

The relative position of the bar codes is the same as on an ISBT 128 blood label. DIN and blood group bar codes are at the top of the label placed in a way to support concatenation, while product code and expiration date bar codes are beneath the DIN and blood group, also placed to support concatenation.

Regulatory and other country-specific information is just beneath the horizontal center of the label and may be bar coded. Manufacturer information, lot number, and peel-off labels are on the bottom of the label.

Text may be in any language and two languages on a label are possible.

Other electronic information may appear on outer packaging of an SDP unit. Two-dimensional (2-D) symbols may be used to encode this information.



CONCLUSIONS

An internationally standardized affixed label for SDP utilizing ISBT 128 has been designed and approved. ISBT 128 is commonly used in blood banks around the world and its use on SDP supports automated capture of critical information by computer systems in these facilities. Accurate entry of key information improves patient safety and as well as the accuracy and efficiency of record keeping. Organizations are encouraged to request that their supplier of SDP provide products labeled with ISBT 128.

