DukeMedicine

Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

DOCUMENT NUMBER: COMM-PAS-005

DOCUMENT TITLE:

Labeling Overview

DOCUMENT NOTES:

Document Information

Revision: 01	**Vault:** COMM-PAS-rel
Status: Release	**Document Type:** COMM-PAS

Date Information

Creation Date: 03 Dec 2012	**Release Date:** 01 Jan 2013
Effective Date: 01 Jan 2013	**Expiration Date:**

Control Information

Author: SLEDG006	**Owner:** SLEDG006
Previous Number: COMM-QA-013 Rev 01	**Change Number:** PAS-CCR-006

COMM-PAS-005
LABELING OVERVIEW

The Department of Health and Human Service proposed an initiative to bar code drugs and biological products in an effort to reduce errors. To properly identify designated blood, HPC (hematopoietic progenitor cells) or tissue products for intended recipients challenges the adequacy of the current electronic data and labeling structure and systems for such products. Increasingly, these products may be collected in one country and used in another. To enhance safety and efficiency, more sophisticated computer systems are now employed to track collection, transfusion and transplantation processes. Transfer of information amongst different facilities is done via electronic devices for speed and accuracy. However, this transfer can only be effective if it follows an internationally agreed standard for data identifiers, data format information and the data pertaining to the product. This standard is known as *ISBT 128.*

ISBT 128 was first proposed in 1989 by the Working Party on Automation and Data Processing of the International Society of Blood Transfusion (ISBT). The standard, data identifiers, and application specification were developed between 1990 and 1994. In 1994, the ISBT Council approved the *ISBT 128 Application Specification* in June and in September established the office for the International Council for Commonality in Blood Banking Automation (ICCBBA) to ensure that any new standard designed around Code 128 would be maintained. In 1995, the ICCBBA was incorporated as a not-for-profit corporation in Virginia.

ISBT 128 specifies

A unique donation identifier worldwide.

The identifier includes a 5-character country and site code, a 2-digit year code, 6-digit sequence number, a 2-digit process control code printed vertically, and a boxed checksum character for use in verifying keyboard entry (see W1234 96 123456 44 S in sample HPC label). This global identifier is unique for 100 years.

The data structures for important information for blood, HPC or tissue donation. The information includes: ABO and Rh(D) Blood Groups; Product Description, Type of Donation, Collection and Expiration Date and Time.

The assignment of product codes by combining: component class, modifier, core conditions, and a range of attributes.

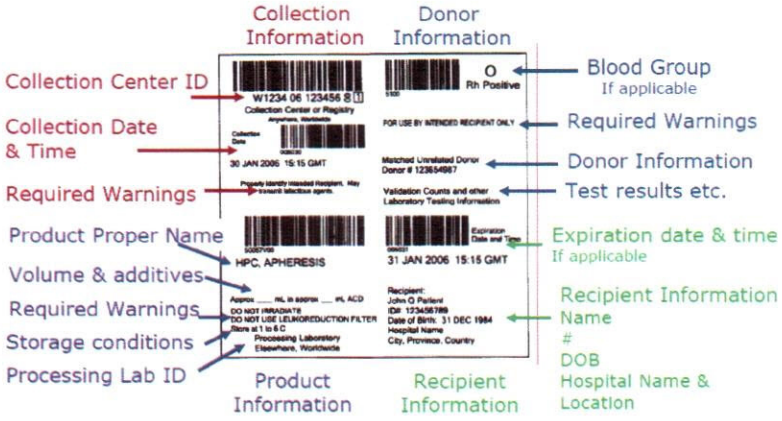
Database tables published on the ICCBBA website provide current *ISBT 128* product codes and description for use by all international registrants.

A data structure to allow software developers to interface necessary input and output messages and to provide a standard reference for transfusion and transplantation information encoded within electronic messages in commonly used software.

The use of the bar coding industry standard Code 128 (which encodes over 100 different characters) instead of the present bar coding system *Codabar* (which only codes numbers and a few symbols). *ISBT 128* specifies the use of bar code to transmit encoded information of blood, HPC or tissue products.

A standard labeling format that ensures a consistent layout of critical information for product labels has been designed by ICCBBA.

This standard is known as ISBT 128. ISBT label is a standard labeling format that ensures a consistent layout of critical information for product labels. The label is divided into four quadrants with bar codes, blood groups and other specific information appearing in fixed positions.



The first quadrant contains the unique donation/ product identifier, date and time of collection, collection facility ID and required warning. The second quadrant contains the ABO and Rh, required warning, test results and other information, e.g. donor information. The third quadrant identifies the product type, volume and type of anticoagulant used, storage temperature, processing facility if different from collection facility, and required warnings. The fourth quadrant identifies the expiration date and time and recipient information. This format is used for labeling the HPC products.

ISBT 128 has gained widespread acceptance. As of 2001, there were facilities in 28 countries across five continents with 81 worldwide vendors for software, bag and label registered with ICCBBA to use *ISBT* 128with the number of registrants increasing each year. International organizations including the American Association of Blood Banks, European Plasma Fractionators Association, European Blood Alliance, and the US Food and Drug Administration (FDA) have endorsed *ISBT 128*. In February 2004, FDA issued a final rule recognizing *ISBT 128* as an acceptable standard for uniform labeling.

Signature Manifest

Document Number: COMM-PAS-005 **Revision:** 01
Title: Labeling Overview

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Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		21 Dec 2012, 09:48:06 AM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		21 Dec 2012, 09:48:07 AM	Email Sent
System Administrator (SYSADMIN)		21 Dec 2012, 09:48:07 AM	Email Sent
Doris Coleman (COLEM002)		21 Dec 2012, 09:48:07 AM	Email Sent
Sharon Hartis (SH259)		21 Dec 2012, 09:48:07 AM	Email Sent