

Implementing ISBT128 Labeling for a Multisite BMT Program

Giovanna Cameron, MLT
Section Head, Clinical Cell Therapy Laboratory
Leukemia/Bone Marrow Transplant Program of BC
gcameron@bccancer.bc.ca

ISBT 128 Labeling

Objectives:

- Implementing ISBT 128 labeling for a multi-site BMT program
- Describe and review the labeling system design process, implementation and validation
- Discuss current issues and challenges

ISBT 128 Labeling

Introduction:

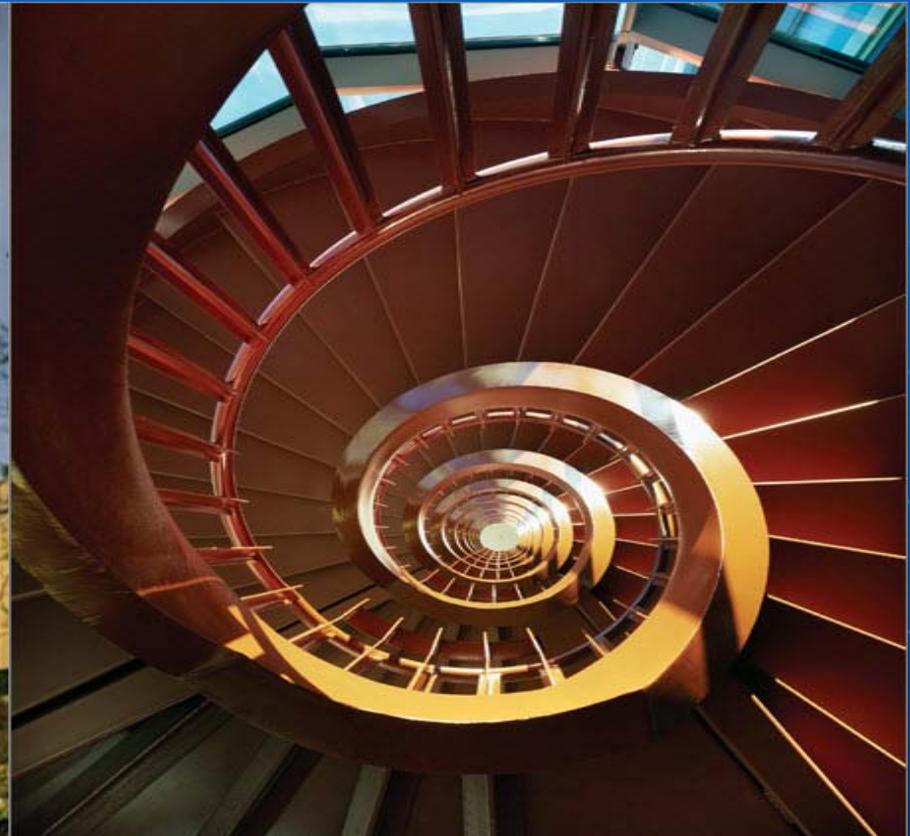
- The Leukemia/Bone Marrow Transplant (BMT) Program of British Columbia (BC) is located in the city of Vancouver.
- Our Program operates 5 main areas:
 - Apheresis Unit
 - Clinical Cell Therapy Laboratory
 - Inpatient Unit
 - Outpatient Daycare Unit
 - Four Outreach Clinics

Find out about us at: <http://leukemiabmtprogram.com>

Background

- **In 2010, Apheresis Program collected/processed 205 products:**
 - **ALLO: 53**
 - 49 HPC, Apheresis
 - 4 TC, Apheresis
 - **AUTO: 152**
- **In 2010, Clinical Cell Therapy Laboratory processed 172 products:**
 - **ALLO: 19**
 - 2 HPC, Cord Blood, thawed/diluted
 - 9 HPC, Apheresis, cryopreserved
 - 8 TC, Apheresis, cryopreserved
 - **AUTO: 153**
 - 1 Bone Marrow, Buffy coat enriched, Plasma Reduced
 - 152 HPC, Apheresis, cryopreserved

BC Cancer Research Centre





BMT Inpatient



Apheresis Unit & BMT OP Daycare



BMT Adm. & Hematology



ISBT 128 Labeling

- Timeline
- Project coordinators
- Where do we start!
- Equipment
- Label Design
- Donation Identification Number
- Product Codes

ISBT 128 Labeling

Timeline

- Exposed to ISBT 128 global labeling system in the mid 2000^{ths} via ISCT and CBMTG conferences.
- Medical Director required automated labels – ISBT 128 provided a global standard for terminology, labeling and identification. Registered with ICCBBA in June 2007
- Registered for AABB audio conference: Implementation of ISBT 128 for Cellular Therapy Collection and Processing Facilities. Aug 2007
- Weekly meetings were initiated Jan 2008
- Implemented ISBT 128 labeling standards in November 2008

ISBT 128 Labeling

Project Coordinators

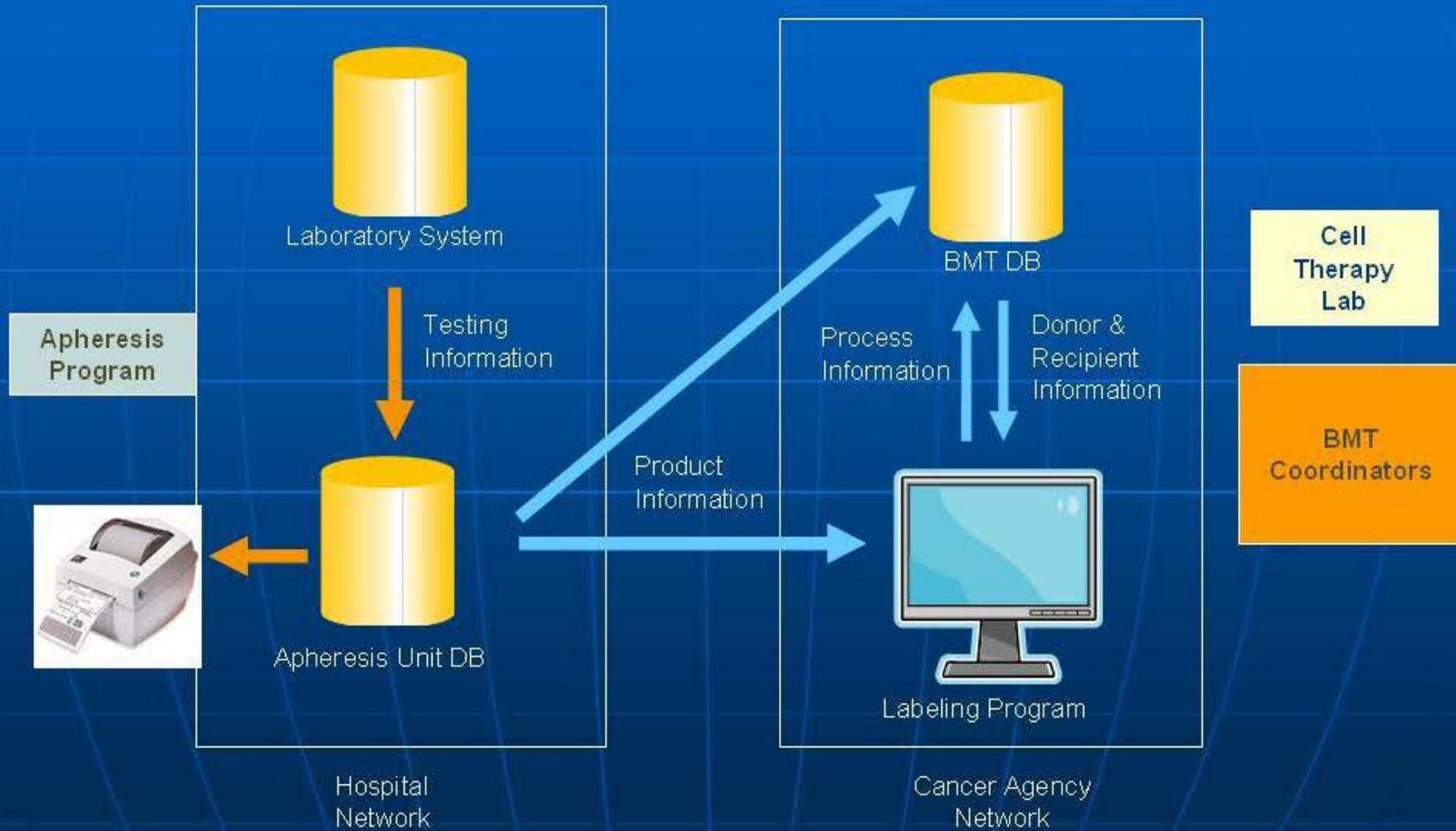
- This project was spearheaded by myself and Chao-Yong Lee who is the software programmer familiar with the different databases from each site
- We divided the tasks into two categories- one would look at the requirements for ISBT 128 standards and the other would look at software issues

ISBT 128 Labeling

Where do we start!

- Reviewed information available on the ICCBBA website
 - ISBT Standard Technical Specification
 - ISBT Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions
 - ISBT 128 Standard: Product Code Structure and Labeling, Cellular Therapy Products
- Transplantation and Cellular Engineering July 2007.
47:1312-1318
ISBT 128 Implementation Plan for Cellular Therapy Products
Paul Ashford, Pat Distler, Adrian Gee, Alan Lankester, Stella Larsson, Irene Feller, Kathy Loper, Derwood Pamphilon, Leigh Poston, Fran Rabe, Ineke Slaper-Cortenbach, Zbigniew Szczepiorkowski, and Phyllis Warkentin

ANALYSIS of DATA FLOW and STORAGE



Equipment Requirements

- Printers: After looking at a number of different options we decided on the Zebra S4M model

It is affordable, simple to use heavy duty label printer with a 8" media roll capacity

The Cell Therapy Laboratory has two printers, one for single labels and one for our cryopreserved product labels. The Apheresis unit has one printer as well as the BMT coordinators

- Scanners: Once we established that we were going to use 2-D bar codes that intern dictated what kind of scanner was required.

Printer & Scanner

Zebra S4M Label Printer



Model DS3478SF



Design labels using ZebraDesigner Pro

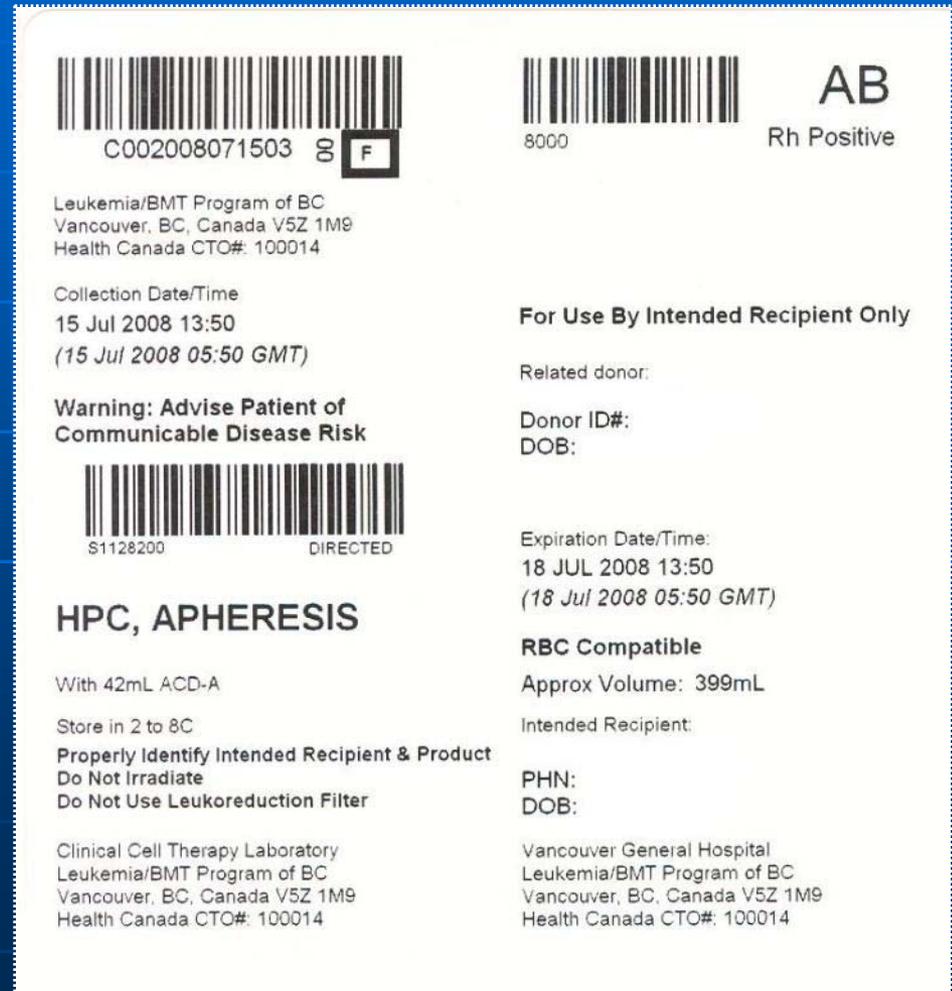
Product label for collection facility:

Label size: 4"x4"

Label content: specified by ICCBBA

Data source: From Apheresis database

We have been buying our labels from Shamrock which is one of the suppliers listed on the ICCBBA website



Labels for Cryopreserved Products

- Labels for cryopreserved products were a little more challenging.
- We determined that we required bag labels and vial labels and we would rather have one 4X4 label sheet provide both configurations.
- We use Baxter cryocyte bags and the label size is the same for all bag sizes. (new bags are validated)
- We came up with the following 7 part label design

Design labels using ZebraDesigner Pro

- Product label for Processing Facility:

- Label size: 4"x4"
- Label is divided into 3 sections:
 - 5 vial labels
 - 1 tie-tag label
 - 1 insert label

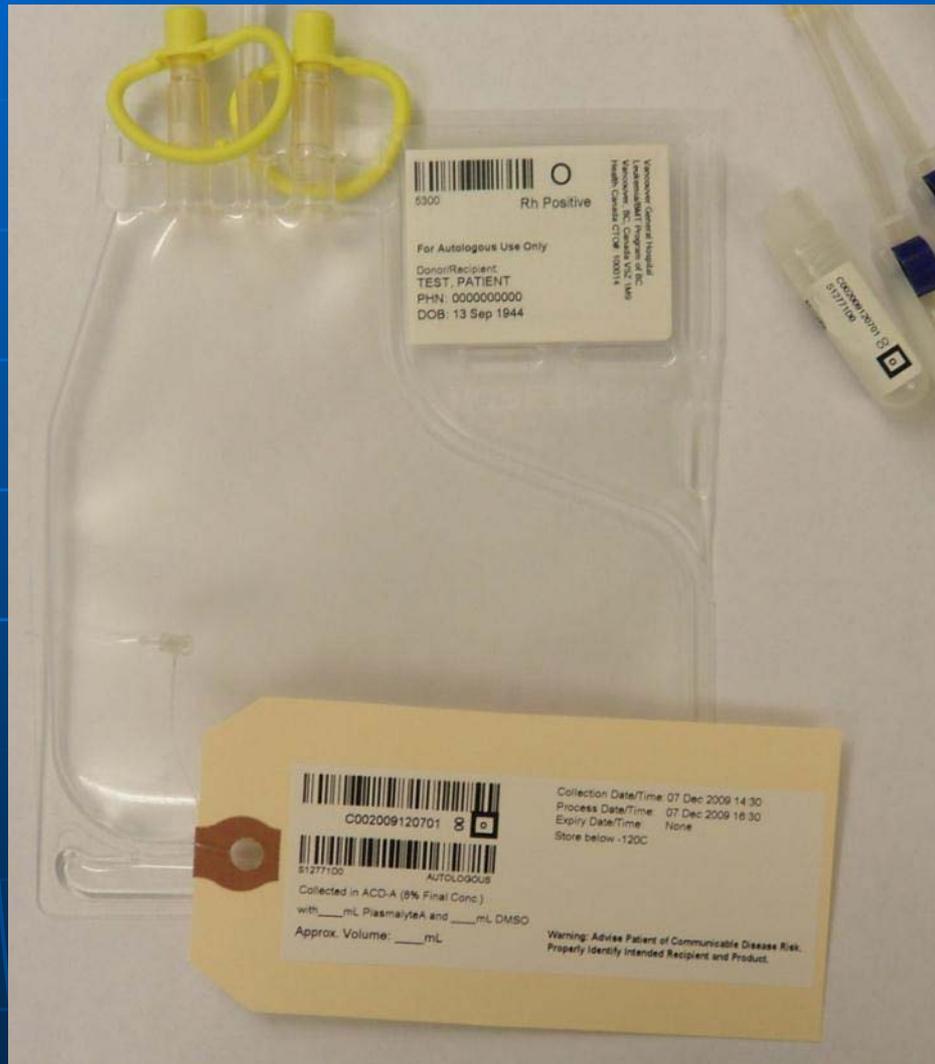


The image displays three types of labels designed for a processing facility:

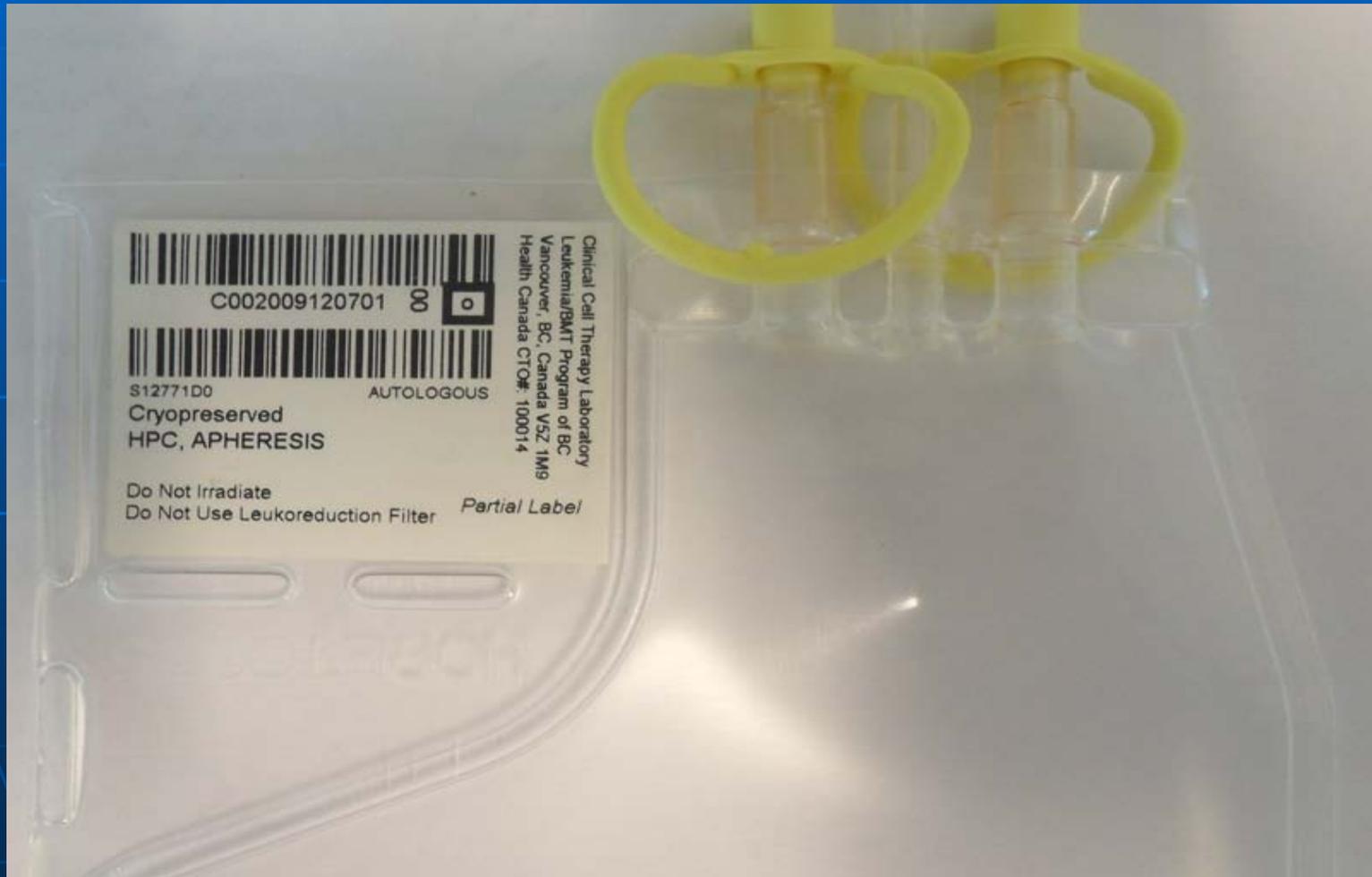
- Five vial labels:** Each label is 4"x4" and contains the following information:
 - Barcode: C0020 08 07180 1 00
 - Barcode: S1277 X00
 - Text: SMITH, MARTHA
 - QR code
 - Warning icon: Biohazard
- Tie-tag label:** Contains the following information:
 - Barcode: C0020 08 07180 1 00
 - Barcode: S1277 X00
 - Text: C0020 08 07180 1 00
 - Barcode: S1277 X00
 - Text: AUTOLOGOUS
 - Text: Collected in ACD-A(8% Final Cone)
 - Text: In ___ mL PlasmalyteA and ___ mL DMSO for freezing
 - Text: Approx Volume: ___ mL
 - Text: Store below -120°C
 - Text: Warning: Advise Patient of Communicable Disease Risk. Properly Identify Intended Recipient and Product.
- Insert label:** Contains the following information:
 - Barcode: C0020 08 07180 1 00
 - Barcode: S1277 X00
 - Text: AUTOLOGOUS
 - Text: Cryopreserved HPC, APHERESIS
 - Text: Do Not Irradiate
 - Text: Do Not Use Leukoreduction Filter
 - Text: Partial Label
 - Text: Clinical Cell Therapy Laboratory, Leukemia/BMT Program of BC, Vancouver, BC, Canada V6Z 1M9, Health Canada CTO#: 1000 14
 - Text: 5400
 - Text: Rh Positive
 - Text: BIOHAZARD
 - Text: For Autologous Use Only
 - Text: Donor/Recipient: SMITH, MARTHA
 - Text: PHN: 0123 456 789
 - Text: DOB: 07 JUL 1953
 - Text: Vancouver General Hospital, Leukemia/BMT Program of BC, Vancouver, BC, Canada V6Z 1M9, Health Canada CTO#: 1000 14

Cryocyte Bag

- Bag Label
- Tie tag
- Vial label



Reverse of the Cryocyte Bag



Donation Identification Number

- Facility Identification number (FIN) e.g. C0020
- Donation identification number: We use the product collection date and sequential number: YYMMDDNN
- Flag (00=default)

Example of DIN: C002011052102⁰

Product Codes

Product codes include Class, Modifier and Attributes:

1. Class

2. Modifier

3. Attributes:

- Anticoagulant
- Storage temperature
- Intended use group
- Manipulation
- Cryoprotectant
- 3rd Party component
- Other additives
- Genetically modified

CODE	DESCRIPTION
S1122	Cryopreserved HPC, MARROW NS XX <=-150C 10% DMSO
S1123	Cryopreserved HPC, APHERESIS NS XX <=-150C 10% DMSO
S1124	Cryopreserved HPC, CORD BLOOD NS XX <=-150C 10% DMSO
S1125	HPC, MARROW Heparin XX refg 3rd Party Donor:Yes
S1126	Cryopreserved HPC, CORD BLOOD NS XX <=-150C 6% HES + 5% DMSO
S1127	Cryopreserved HPC, APHERESIS NS XX <=-150C 6% HES + 5% DMSO
S1128	HPC, APHERESIS Citrate XX refg
S1129	HPC, APHERESIS Citrate XX rt
S1130	HPC, CORD BLOOD Citrate XX refg
S1131	HPC, CORD BLOOD Citrate XX rt
S1132	HPC, CORD BLOOD Citrate XX rt Other Additives:Yes
S1133	HPC, CORD BLOOD Citrate XX refg Other Additives:Yes
S1134	HPC, APHERESIS Citrate XX refg Other Additives:Yes
S1135	HPC, APHERESIS Citrate XX rt Other Additives:Yes

Converting Product Codes

- Generating an excel file for product codes to allow sorting product codes by product specification.

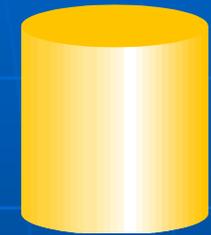
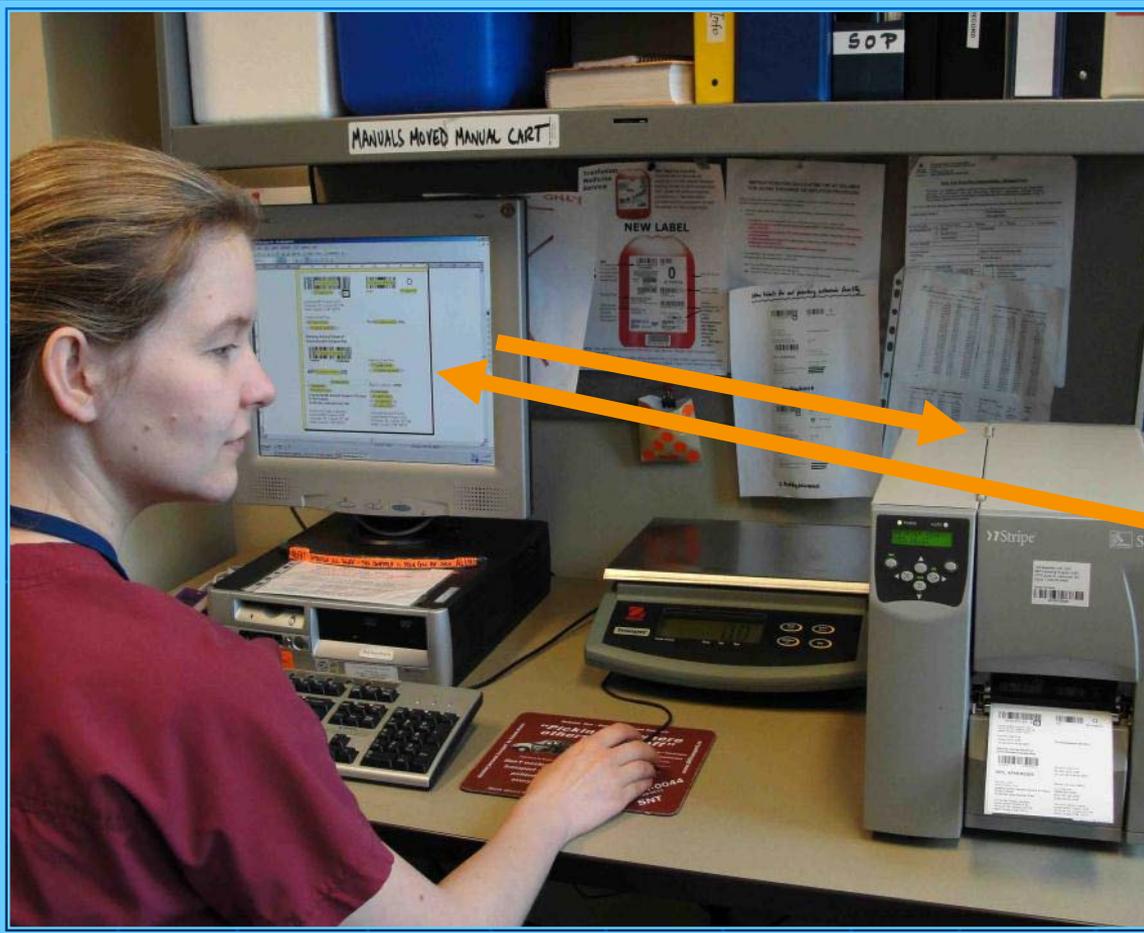
BARCODE DEFINITIONS FOR PRODUCTS (ICCBBA, Apr. 8, 2011)										
CODE	MODIFIER	CLASS	ANTI-COAG	STORET EMP	MANIPULATION	CRYO	3rd Party	Additive	For Use	Gen Mod
S1185		CONCURRENT PLASMA	Citrate	refg						
S1186		CONCURRENT PLASMA	Citrate	rt						
S1157		CONCURRENT PLASMA	Citrate+ Heparin	rt						
S1179		CONCURRENT PLASMA	Citrate+ Heparin	refg						
S1128		HPC, APHERESIS	Citrate	refg						
S1129		HPC, APHERESIS	Citrate	rt						
S1134		HPC, APHERESIS	Citrate	refg				Yes		
S1135		HPC, APHERESIS	Citrate	rt				Yes		
S1144		HPC, APHERESIS	Citrate	refg	CD34 enriched			Yes		
S1146		HPC, APHERESIS	Citrate	rt	CD8 reduced			Yes		
S1147		HPC, APHERESIS	Citrate	refg	CD8 reduced			Yes		
S1148		HPC, APHERESIS	Citrate	refg	CD133 enriched			Yes		
S1149		HPC, APHERESIS	Citrate	rt	CD133 enriched			Yes		
S1156		HPC, APHERESIS	Citrate	rt			Yes			

Type of Donation

(intended use)

- 1 autologous eg. S1475100
- X autologous, biohazard eg. S1475X00
- 2 directed recipient only eg. S1475200
- 3 directed recipient, biohazard eg. S1475300
- E directed recipient, medical exception eg. S1475E00
- 4 designated collection eg. S1475400
- 6 designated collection, biohazard eg. S1475600

How does this work?



BMT DB

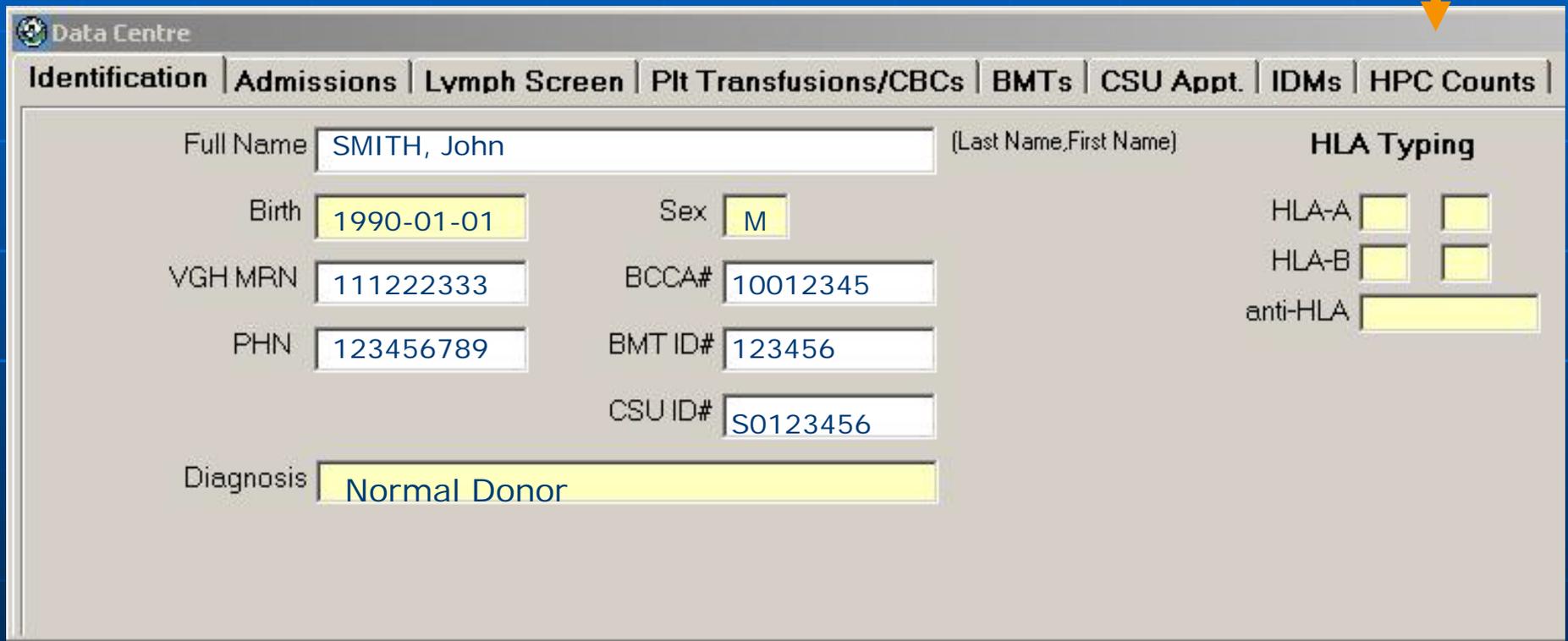
Product
Information



Transfer
label
information

Transferring data from one database to another

Donor/recipient information retrieval:



Data Centre

Identification | Admissions | Lymph Screen | Plt Transfusions/CBCs | BMTs | CSU Appt. | IDMs | HPC Counts

Full Name (Last Name,First Name)

Birth Sex

VGH MRN BCCA#

PHN BMT ID#

CSU ID#

Diagnosis

HLA Typing

HLA-A

HLA-B

anti-HLA

Product information retrieval:

Identification	Admissions	Lymph Screen	Plt Transfusions/CBCs	BMTs	CSU Appt.	IDMs	HPC Counts
BM Type	ALLO HPC	*Prod. ID#/Date	2010021701				
Donor	123456 CSU S012345678	WBC x10(9)/L	125.8	Total	Per Kg		
	SMITH, JOHN	Total WBC x10(8)	440.3				
Birth	1990-01-01	Platelet x10(11)					
Patient	112233 CSU P019920101	RBC Vol (ml)					
	SMITH, JANE	ACD-A (ml)					
Birth	1992-01-01	Total Vol (ml)	350				
Weight	50.0 Kg Primed GCSF	CD34+%					
		Total CD34+ x10(6)					
		Cryopreserved	Yes				
<p>*Click Product ID# field to select the product before click Label button.</p>							

The labeling system automatically fills in data from databases on the screen:

Product Information

Donation ID#
 Facility
 Product ID#
 Flag
 ABO/RhD
 Biohazard
 RBC Compatible
 Collect Date/Time
 Process Date/Time
 Expiry Date/Time

Code	Modifier	Class	Anticoag	StorageTemp	Manipulation	Cryoprotectant	Additive	3rd Part
S1185		CONCURRENT PLASMA,	Citrate	at room temper			No	No
S1185		CONCURRENT PLASMA,	Citrate	in 2 to 8C			No	No
S1157		CONCURRENT PLASMA,	Citrate+Heparin	at room temper			No	No
S1179		CONCURRENT PLASMA,	Citrate+Heparin	in 2 to 8C			No	No
S1156		HPC, APHERESIS	Citrate	at room temper			No	Yes
S1129		HPC, APHERESIS	Citrate	at room temper			No	No
S1135		HPC, APHERESIS	Citrate	at room temper			Yes	No
S1149		HPC, APHERESIS	Citrate	at room temper	CD133 enriched		Yes	No
S1146		HPC, APHERESIS	Citrate	at room temper	CD8 reduced		Yes	No
S1292		HPC, APHERESIS	Citrate	at room temper	RBC reduced		No	No
S1379		HPC, APHERESIS	Citrate	at room temper	RBC reduced		No	Yes
S1134		HPC, APHERESIS	Citrate	in 2 to 8C			Yes	No
S1128		HPC, APHERESIS	Citrate	in 2 to 8C			No	No
S1177		HPC, APHERESIS	YES	in 2 to 8C			No	Yes
S1148		HPC, APHERESIS	Citrate	in 2 to 8C	CD133 enriched		Yes	No
S1144		HPC, APHERESIS	Citrate	in 2 to 8C	CD34 enriched		Yes	No
S1442		HPC, APHERESIS	Citrate	in 2 to 8C	Diluted		No	No
S1443		HPC, APHERESIS	Citrate	in 2 to 8C	Plasma reduced		No	No
S1501		HPC, APHERESIS	Citrate	in 2 to 8C	Plasma reduced		No	Yes
S1441		HPC, APHERESIS	Citrate	in 2 to 8C	T/B-cell reduced		Yes	Yes
S1155		HPC, APHERESIS	Citrate+Heparin	at room temper			No	No

Donor Information **Recipient Information**

ID# PHN

Name Name

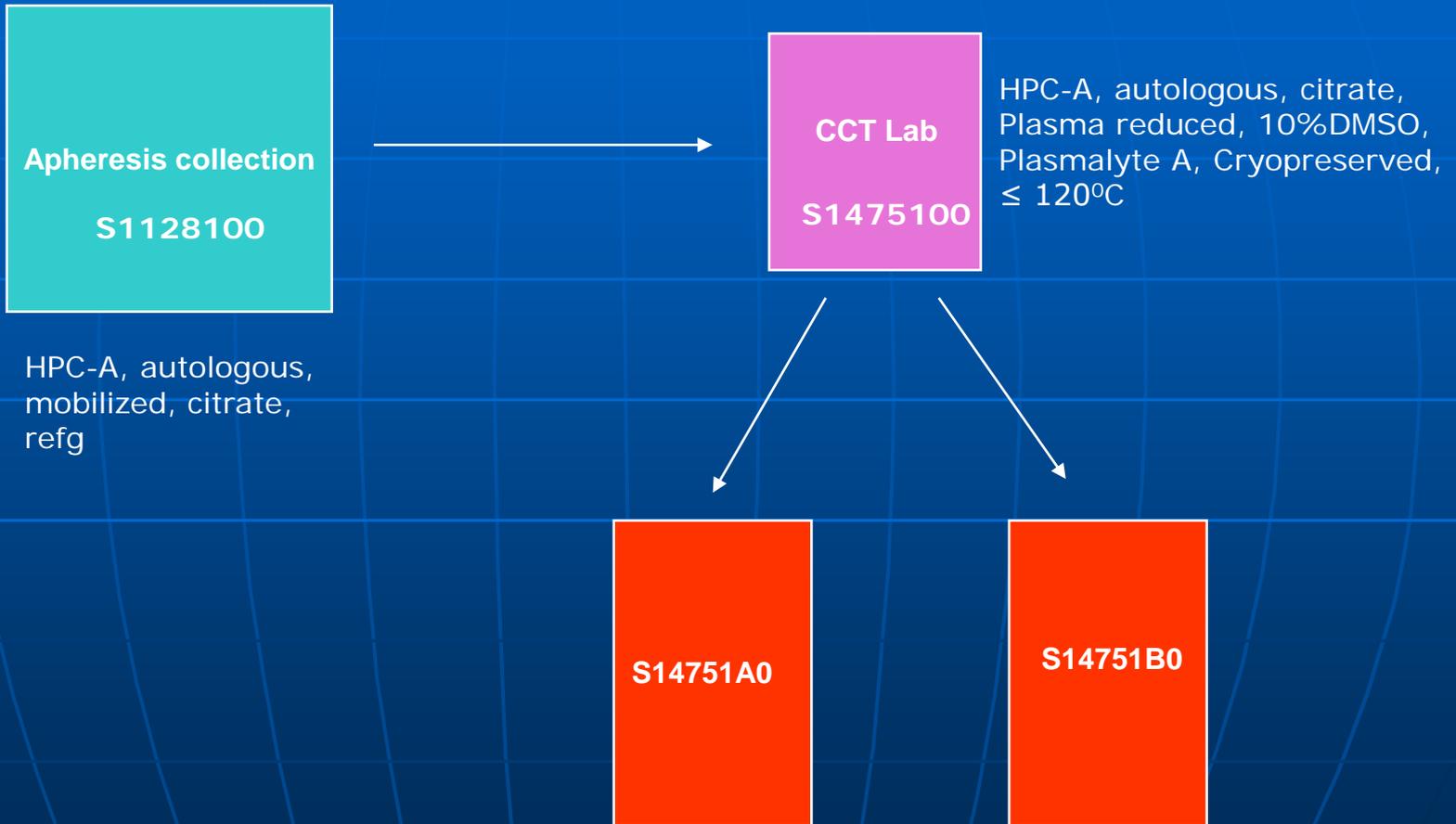
Birth Birth

The labeling system automatically fills in data from databases to the labeling program ZebraDesigner Pro:

The screenshot displays the ZebraDesigner Pro interface for a label design. The title bar reads "ZebraDesigner Pro - [TagHPC.lbl]". The menu bar includes File, Edit, View, Object, Database, Tools, Window, and Help. The toolbar contains icons for file operations, printing, zooming, and database access. The left sidebar lists design tools: Select, Text, Bar Code, Picture, Rectangle, Line, Ellipse, Inverse, RF Tag, EAN.UPC, Linear, 2D, RSS Linear, and RSS Composite. The main workspace shows a label layout with a yellow background. The label contains several data fields and barcodes, including:

- Five "M" icons at the top.
- Five sets of data: "00", "C002000020201", "\$1128240", "TEST.DONOR for TEST.PATIENT", and a barcode.
- Barcode labels: "PmTagData.DINBar", "PmTagData.DIN|1", "PmTagData.ProdCodeBar", "PmTagData.DINBar", "PmTagData.DIN|1", and "PmTagData.ProdCodeBar".
- Text fields: "vr PmTagData.AntType A", "< PmTagData.AddVol", "Approx. Volume: 89mL", "PmTagData.AddVol", "PmTagData.dID 3209", "D(PmTagData.dDOB)0", "PmTagData.ABORHE", "PmTagData.Rh", "PmTagData.ProdUse", "PmTagData.RecpType", and "PmTagData.ProdClass".
- Warnings: "Warning: Advise Patient of Communicable Disease Risk. Properly Identify Intended Recipient and Product." and "For Use By: PmTagData.ProdUse Patient Only".
- Manufacturer information: "Leukemia/BMT Program of BC Vancouver, BC, Canada V6Z 1M6 Health Canada CT.O.#: 100014".
- Logo: "AD" logo.
- Address: "Vancouver General Hospital Vancouver, BC, Canada V6Z 1M6 Health Canada CT.O.#: 1000".

Bag Divisions



Labeling System Features

- User friendly with dropdown selection lists
- Provide reference for product code listings
- Minimal data entry required: Pre-fill data with donor, recipient and product information from existing databases
- Expiry times are automatically calculated
- Flexible labeling design to allow modification
- Automatic data transfer from the labeling system to the database

Implementation

Staff training:

- Prior to system implementation, we provided training sessions for
 - Cell Therapy Lab staff
 - Apheresis Program staff
 - BMT coordinators
 - BMT data coordinators
- Created an online User's Guide for quick reference
- Developed SOP for the labeling system

Validation

- Data Transfer log file:
 - Record the process of data transferring for auditing
- Audit tables in database:
 - Record changes to the database tables
- Weekly data transfer review:
 - Check for any errors or missing data
- Labeling system log file:
 - Record any problems/changes made to the labeling system

Validation

- Print all combinations of Labels
 - Verify label and enables tracking of label version
 - Blank labels available for all combinations for down times
 - One label example completed for all blank labels

Current issues and challenges

- **New product codes**
 - The time required to receive new product codes for new attributes can be longer than expected
- **Understand and select an appropriate product code**

It is not a trivial task to determine a product code for a given product

 - Example: Plasma added as additives vs. as manipulation "diluted"
 - Example: Heparin as anticoagulant vs. as additives

Current Issues and Challenges

- **Products from other facilities before ISBT128 implementation:**
 - Current system requires the donation identification number is defined by the collection date (YYMMDD) and a sequential number (01-89 for internal products and 90-99 for external products)
 - Should we create a donation identification number for the product or use the originating product number?
- **Unrelated donors**
 - Keeping the FIN confidential, currently we are using the registry (OneMatch) which does not have a FIN number. Therefore we use our FIN number in the database, but it does not print on the label
ie*****11052190.

Stand Alone

- Equipment, labels, software are supplied

Acknowledgement

Our project would not be possible without tremendous help and continuing support from:

Erwin Cabana, Information Standards Specialist, ICCBBA
Helped with proper formatting for label design

Pat Distler, MS, MT(ASCP)SBB, Technical Director, ICCBBA
Helped us understand and clarify product codes

Acknowledgement

Chao-Yong Lee



Clinical Cell Therapy Laboratory

