

***Implementation of ISBT128 in a
medium size cellular therapy
product processing laboratory
–
thoughts, challenges and personal
experience***

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From Leigh's presentation

Q: Who should be on my implementation team?

A: ISBT 128 will affect many departments in the facility.

The staff involved with administration of the product will need to know where to find specific information located on the new label.

The laboratory personnel will need to be familiar with product codes when performing modifications.

The Accounting Department will need to understand the products that they will be billing.

Medical records personnel will also be affected.

A recognized Team Leader should be chosen to spearhead the project.

ISBT128 Cellular Therapy

- n As previously mentioned it is not required by any of the accrediting organizations*
- n The terminology is, however, required by AABB, FACT-JACIE; Netcord; NMDP; and provided in the Circular of Information.*
- n So, how one can be compelled to go to the next step...*

ISBT128 Cellular Therapy

Our story...

- n ISBT 128 for blood products has been now mandatory for almost a year.*
- n Our Blood Bank Software was initially able to accept ISBT128 labeled blood products but eventually (June 2008) was upgraded to generate ISBT128 labels for blood products.*
- n Subsequently, our Blood Donor Program moved to ISBT128 labels (October 2008) with a new release of its software...*

ISBT128 Cellular Therapy

Our story...cont'd

ISBT 128 (Blood Bank)

ISBT 128 (BDP)

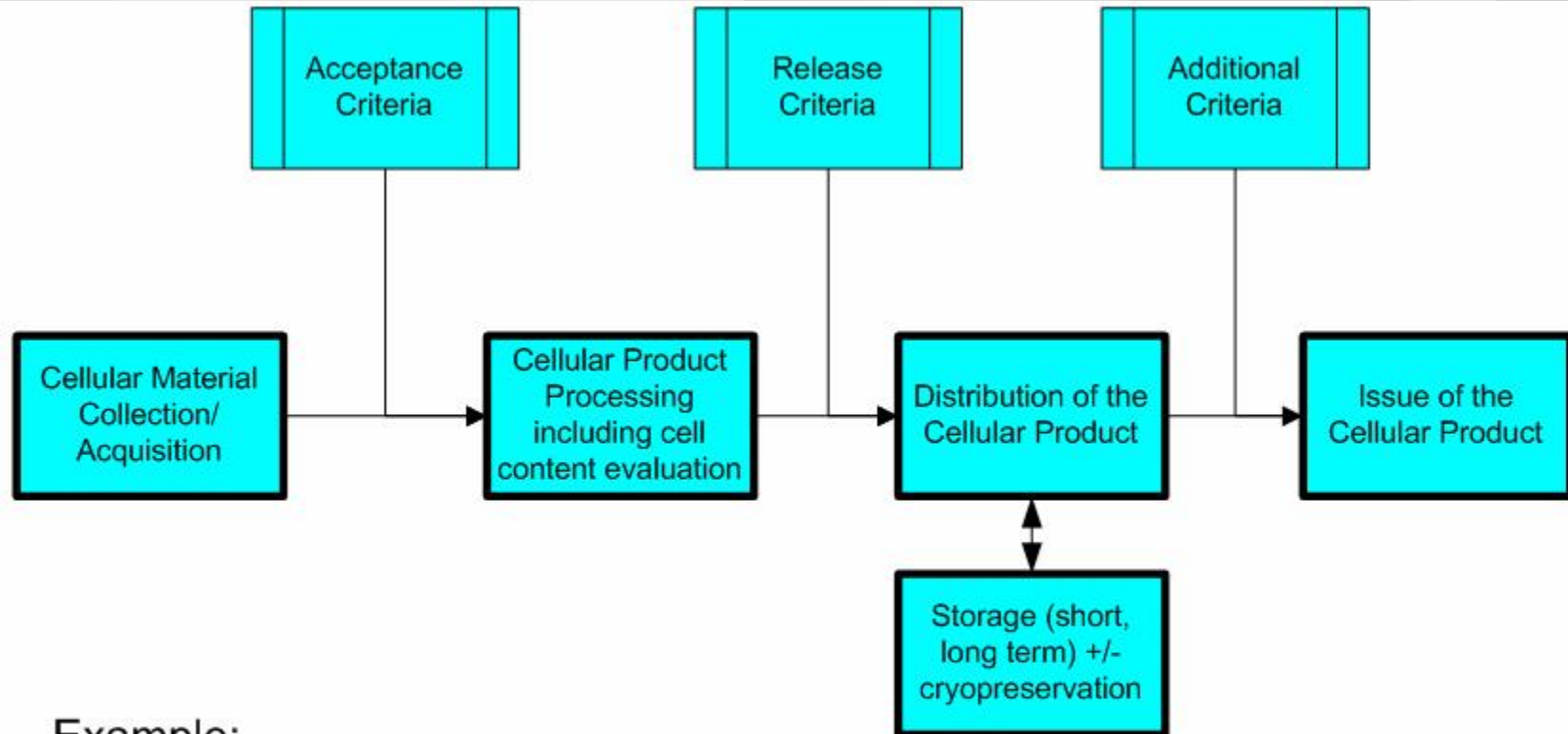
ISBT 128
(CTC)

Blood products
(number / label)

Cellular Therapy
Products
(number)

Terminology
Number
Full label

Analyze your process first...



Example:

HPC, Apheresis

Implementation process

Intro to ISBT128

- Outline project timeline
- Review terminology
- Map-up the process, identify correct S codes

Software

- Select ISBT128 compliant software
- Select stand-alone vs. mainframe

Validation

- Validation of the software/printers
- Validation of the labels stock/content
- Implement the system

Stand alone vs. primary system

Manufacturer A	Manufacturer X
Large Blood Bank Software Company	Stand alone label making company
Significant Delays in Introduction of S codes (not yet available)	Willing to work with the laboratory (beta site)
Future updates (likely in July 2009) will have S codes as part of the release	Responsive to identified issues during the implementation process
Recently dropped blood donor program module	



Manufacture X and challenges...

YOU ONLY LIVE TWICE...

Resolution of initial problems with Manufacturer X...

- n After the first viewing of the software "...I must say that I am extremely disappointed in this software; I was excited about it due to the excellent experience we had with both the Manufacturer X server and stand-alone systems. However, I cannot say that this software is up to the prior Manufacturer X standard..."*
- n This was followed by a lengthy list of limitations...*

Resolution of initial problems with Manufacturer X...a week later...

- n "... Thank you for the responses. It would have been very helpful, and less frustrating, if this information had been known before I started testing..."*
- n And a few days later..." ..I am about ready to start the validation of these labels..."*
- n This was a definitely mutually enriching experience for us and the engineers from the Manufacturer X.*

And finally...

- n "...All sounds good! The S codes we will be using are:*
- n S1129, S1177, S1186, S1183, S1181, S1167, S1166, S1194, S1196, S1297, S1298, S1134, S1219, S1221, S1188, S1179, S1185, S1299, S1301, S1302*
- n We will be using the 3x2 label with the face perf, the 1.5x.75 cryo vial label and the 3x2 base label..."*

Implementation process

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Manufacturer X

SOFTWARE PRESENTATION

Initial screen...

Product Code Edit Product Code	
Scan DIN Barcode	
Enter DIN Barcode Facility ID W138 Number 25 Flag 00 Character 00	
Blood Type	Specialty
(if applicable)	
Intended Use	
Donation Type	
Donor Type	Division 1 0
Donor Name	Division 2 0
Donor Number	
Donor DOB	
Recipient Name	
Recipient ID	
Recipient DOB	
Select Facility Collection Facility Processing Facility Edit Facilities	
View Print Log	

 W138 09 25 8 4 Collection Date/Time: GMT  00 RxOnly See Attached Documentation for Details	 00 Donor #: Date of Birth: Expiration Date/Time: GMT Intended Recipient: MRN#: Date of Birth:
Print Configure Printer Supplies Support	

Product code selection

The screenshot shows a blood collection form with various fields and sections. Two red circles highlight specific areas:

- Product Code Selection:** A dropdown menu showing 'S1190' and an 'Edit Product Code' button.
- Barcode Label:** A label with a barcode and the text 'HPC, APHERESIS Plasma reduced'.

Form Fields:

- Product Code:** S1190 (dropdown), Edit Product Code (button)
- Scan DIN Barcode:** (input field)
- Enter DIN Barcode:** Facility ID (W138), Number (25), Flag Characters (00)
- Blood Type:** (dropdown)
- Intended Use:** (dropdown)
- Donation Type:** (dropdown)
- Donor Type:** (dropdown)
- Donor Name:** (text field)
- Donor Number:** (text field)
- Donor DOB:** (text field)
- Special Message (if applicable):** (dropdown)
- Division 1:** 0 (dropdown)
- Division 2:** 0 (dropdown)
- Recipient Name:** (text field)
- Recipient ID:** (text field)
- Recipient DOB:** (text field)
- Select Facility:** Collection Facility (dropdown), Processing Facility (dropdown), Edit Facilities (button)
- View Print Log:** (button)
- Print:** (button)
- Configure Printer:** (button)
- Supplies Support:** (button)

Barcode Label:

- W138 09 25 S 4
- 00
- Collection Date/Time: _____ GMT
- Do Not Irradiate
- Do Not Use Leukoreduction Filter Rx Only
- S119000
- HPC, APHERESIS**
- Plasma reduced
- See Attached Documentation for Details
- Approximately _____ mL in _____ mL
- Store at Room Temperature
- Donor #: _____
- Date of Birth: _____
- Expiration Date/Time: _____ GMT
- Intended Recipient: _____
- MRN#: _____
- Date of Birth: _____

Scanning of the number, ABO type...

Product Code: S1130

Scan DIN Barcode

Enter DIN Barcode

Facility ID: W138 Flag Characters: 00
Number: 25

Special Message (if applicable):

Blood type: A RhD Positive
Intended Use: For Autologous Use Only
Donation Type: For Autologous Use Only

Donor Type:
Donor Name:
Donor Number:
Donor DOB:

Division 1: 0
Division 2: 0

Select Facility

Collection Facility:
Processing Facility:

Barcode 1: W1383 08 601622 S A

Barcode 2: 6400

ABO Type: A
Rh Type: Rh Positive

Collection Date/Time: GMT

Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only

Barcode 3: S1190100 AUTOLOGOUS

HPC, APHERESIS
Plasma reduced

See Attached Documentation for Details
Approximately _____ mL in _____ mL
Store at Room Temperature

For Autologous Use Only
For Autologous Use Only

Donor Date of Birth:
Expiration Date/Time: GMT

Intended Recipient:
MRN#:
Date of Birth:

Insert patient's name...
(a computer challenging for that...)

Product Code: S1190

Scan DIN Barcode **-Or-** **Enter DIN Barcode**

Facility ID: W138 Flag Characters: 00
Number: 25

Blood Type: A RhD Positive Special Message (if applicable):

Intended Use: For Autologous Use Only

Donation Type: For Autologous Use Only

Donor Type: Division 1: 0 Division 2: 0

Donor Name: Macdonald-Szczepiorkowski, Jane

Donor Number:

Donor DOB:

Recipient Name:

Recipient ID:

Recipient DOB:

Select Facility

Collection Facility:

Processing Facility:

Barcode Labels:

W1383 08 601622 S A
6400

Collection Date/Time: _____ GMT

Do Not Irradiate
Do Not Use Leukoreduction Filter Rx Only

S1190100 AUTOLOGOUS

HPC, APHERESIS
Plasma reduced

See Attached Documentation for Details
Approximately _____ mL in _____ mL
Store at Room Temperature

For Autologous Use Only

Macdonald-Szczepiorkowski
Donor #:
Date of Birth:

Expiration Date/Time: _____ GMT

Intended Recipient:

MRN#:
Date of Birth:

Donor/Recipient Name..

Product Code: S1190 Edit Product Code	
Scan DIN Barcode W13830860162200	
-Or-	
Enter DIN Barcode Facility ID: W138 Flag Characters: 00 Number: 25	
Blood Type: A RhD Positive	Special Message (if applicable):
Intended Use: For Autologous Use Only	
Donation Type: For Autologous Use Only	
Donor Type:	Division 1: 0
Donor Name: Macdonald-Szczepiorkowski, Jane	Division 2: 0
Donor Number: 999999999-987	
Donor DOB: 10/16/1966	
Recipient Name: Macdonald-Szczepiorkowski, Jane	
Recipient ID: 999999999-987	
Recipient DOB: 10/16/1966	
Select Facility Collection Facility: Processing Facility: Edit Facilities	
View Print Log	

 W1383 08 601622 A	 6400 A Rh Positive
Collection Date/Time: GMT	For Autologous Use Only Macdonald-Szczepiorkowski Donor #: 9999999 Date of Birth: 10/16/1966 Expiration Date/Time: GMT
Do Not Irradiate Do Not Use Leukoreduction Filter Rx Only  S1190100 AUTOLOGOUS	Intended Recipient: Macdonald-Szczepiorkowski MRN#: 999999999-9 Date of Birth: 10/16/1966
HPC, APHERESIS Plasma reduced See Attached Documentation for Details Approximately _____ mL in _____ mL Store at Room Temperature	
Print	
Configure Printer	Supplies Support

Facility selection...

Product Code S1190 Edit Product Code	
Scan DIN Barcode W13830860162200	
-Or-	
Enter DIN Barcode Facility ID W138 Flag Characters 00 Number 25	
Blood Type A RhD Positive	Special Message (if applicable)
Intended Use For Autologous Use Only	
Donation Type For Autologous Use Only	
Donor Type	Division 1 0
Donor Name Macdonald-Szczepiorkowski, Jane	Division 2 0
Donor Number 999999999-987	
Donor DOB 10/16/1966	
Recipient Name Macdonald-Szczepiorkowski, Jane	
Recipient ID 999999999-987	
Recipient DOB 10/16/1966	
Select Facility Collection Facility Dartmouth Hitchcock Processing Facility Dartmouth Hitchcock Edit Facilities	
View Print Log	

 W1383 08 601622 S A Dartmouth Hitchcock Med. One Medical Center Drive Lebanon, NH 03756 Collection Date/Time: _____ GMT	 A Rh Positive 6400
Do Not Irradiate Do Not Use Leukoreduction Filter Rx Only  S1190100 AUTOLOGOUS HPC, APHERESIS Plasma reduced See Attached Documentation for Details Approximately _____ mL in _____ Store at Room Temperature	For Autologous Use Only For Autologous Use Only Macdonald-Szczepiorkowski Donor #: 9999999 Date of Birth: 10/16/1966 Expiration Date/Time: _____ GMT Intended Recipient: Macdonald-Szczepiorkowski MRN#: 999999999-9 Date of Birth: 10/16/1966 Dartmouth Hitchcock Med. Ctr. One Medical Center Drive Lebanon, NH 03756
Print	
Configure Printer Supplies Support	

Split product (division)...

Product Code: S1190 Edit Product Code	
Scan DIN Barcode W1383086016220	
-Or-	
Enter DIN Barcode Facility ID: W138 Number: 28 Flag Characters: 00	
Blood Type: A RhD Positive	Special Message (if applicable):
Intended Use: For Autologous Use Only	
Donation Type: For Autologous Use Only	
Donor Type:	Division 1: A
Donor Name: Macdonald-Szczepiorkowski, Jane	Division 2: a
Donor Number: 999999999-987	
Donor DOB: 10/16/1966	
Recipient Name: Macdonald-Szczepiorkowski, Ja	
Recipient ID: 999999999-987	
Recipient DOB: 10/16/1966	
Select Facility Collection Facility: Dartmouth Hitchcock Processing Facility: Dartmouth Hitchcock Edit Facilities	
View Print Log	

 W1383 08 601622 S A Dartmouth Hitchcock Med. One Medical Center Drive Lebanon, NH 03756 Collection Date/Time: _____ GMT Do Not Irradiate Do Not Use Leukoreduction Filter Rx Only	 A Rh Positive 6400 For Autologous Use Only For Autologous Use Only Macdonald-Szczepiorkowski Donor #: 9999999 Date of Birth: 10/16/1966 Expiration Date/Time: _____ GMT Intended Recipient: Macdonald-Szczepiorkowski MRN#: 999999999-9 Date of Birth: 10/16/1966 Dartmouth Hitchcock Med. Ctr. One Medical Center Drive Lebanon, NH 03756
 S11901Aa AUTOLOGOUS REFRESIS Plasma reduced See Attached Documentation for Details Approximately _____ mL in _____ mL Store at Room Temperature Part: Aa	

Areas to improve...

The screenshot shows a software interface for creating blood product labels. It includes fields for product code, facility information, donor and recipient details, and a preview of the final label. Four red circles highlight specific areas for improvement:

- Circle 1:** The 'Collection Date/Time' field on the label preview, which currently shows 'GMT'.
- Circle 2:** The 'Expiration Date/Time' field on the label preview, which also shows 'GMT'.
- Circle 3:** The 'Do Not Irradiate' and 'Do Not Use Leukoreduction Filter' instructions on the label preview.
- Circle 4:** The 'HPC, APHERESIS' section on the label preview, which includes 'Plasma reduced' and volume fields.

The main form contains the following fields:

- Product Code: S1190 (with an 'Edit Product Code' button)
- Scan DIN Barcode: W1383086016220
- Enter DIN Barcode: Facility ID (W138), Number (28), Flag Characters (00)
- Blood Type: A RhD Positive
- Special Message (if applicable)
- Intended Use: For Autologous Use Only
- Donation Type: For Autologous Use Only
- Donor Type
- Donor Name: Macdonald-Szczepiorkowski, Jane
- Donor Number: 99999999-987
- Donor DOB: 10/16/1966
- Recipient Name: Macdonald-Szczepiorkowski, Ja
- Recipient ID: 99999999-987
- Recipient DOB: 10/16/1966
- Select Facility: Collection Facility (Dartmouth Hitchcock), Processing Facility (Dartmouth Hitchcock)
- Buttons: Edit Facilities, View Print Log, Print, Configure Printer, Supplies Support

The good news is that the new version of the software will be available within next 7-10 days...

Examples of labels

W1383 08 601622 S A
NMDP

Collection Date/Time: _____ GMT

Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only

HPC, APHERESIS

See Attached Documentation for Details
Approximately _____ mL in _____ mL
and _____ mL in _____ mL
Store at Room Temperature

For Use of Intended Recipient(s) Only
Unrelated Donor

Donor # _____
Date of Birth: _____
Expiration Date/Time: _____ GMT

Intended Recipient
MRN# _____
Date of Birth: _____

Dartmouth Hitchcock Med. Ctr.
One Medical Center Drive
Lebanon, NH 03756

A
Rh Negative

Can these fields all be lined up so left margin is the same?

W1383 08 601622 S A
Dartmouth Hitchcock Med.
One Medical Center Drive
Lebanon, NH 03756
Collection Date/Time: _____ GMT

Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only

HPC, APHERESIS

See Attached Documentation for Details
Approximately _____ mL in _____ mL
and _____ mL in _____ mL
Store at Room Temperature

For Autologous Use Only

Donor # _____
Date of Birth: _____
Expiration Date/Time: _____ GMT

Intended Recipient
Jackson, Jennifer
MRN#: 555245165-9
Date of Birth: 9/22/1950

Dartmouth Hitchcock Med. Ctr.
One Medical Center Drive
Lebanon, NH 03756

A
Rh Negative

Can the DIN be raised up so when removes the # part is not left on the base label
intended use needed to get type to display
if don't select donation type to avoid double "for autologous use only" for displaying product code not correct - needs donation type to add 1 to the S code (should be S1129100 for an auto unit)

W1383 08 601622 S A
Dartmouth Hitchcock Med.
One Medical Center Drive
Lebanon, NH 03756
Collection Date/Time: _____ GMT

Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only

HPC, APHERESIS
Plasma reduced

See Attached Documentation for Details
Approximately _____ mL in _____ mL
Store at Room Temperature

For Autologous Use Only
For Autologous Use Only

Intended Recipient:
Macdonald-Szczepiorkowski
Donor #: 9999999
Date of Birth: 10/16/1966

Expiration Date/Time: _____ GMT

A
Rh Positive

Macdonald-Szczepiorkowski
Donor #: 9999999
Date of Birth: 10/16/1966

Dartmouth Hitchcock Med. Ctr.
One Medical Center Drive
Lebanon, NH 03756

Implementation process

Intro to ISBT128

- Outline project timeline
- Review terminology
- Map-up the process, identify correct S codes

Software

- Select ISBT128 compliant software
- Select stand-alone vs. mainframe

Validation

- Validation of the software/printers
- Validation of the labels stock/content
- Implement the system

An abstract graphic featuring a series of curved, overlapping lines in shades of gray and white on the left side, creating a sense of depth and movement. A dark, curved shape is positioned in the center, resembling a stylized eye or a swoosh. The background is a solid light gray.

VALIDATION

Validation (labels)

- n First, the stock labels needed to be validated under the following conditions:*
- Storage for 1 week in a liquid nitrogen freezer (Label A)*
 - Storage for 1 week in the 37°C CO₂ incubator (Label B)*
 - After 30 minutes in a 37°C water bath (Label C)*
 - Storage for 48 hours at 1-6°C (Label D)*
 - Storage for 24 hours at 22-24°C (Label E)*

Validation (labels) cont'd

- 1. *Is the label firmly attached to the bag with no evidence of peeling?***
- 2. *Is all handwritten information clearly visible on the bag?***
- 3. *Is all handwritten information present in a non-smudged condition?***
- 4. *Is there any evidence of portions of the written information flaking off the label?***
- 5. *If you run your finger over the handwriting does it remain clear and unaltered without evidence of smudging or flaking?***
- 6. *Is all the printed information on the label present in a non-smudged condition?***
- 7. *Is there any evidence of any of the printed information flaking off the label?***
- 8. *If you run your finger over the printed information does it remain clear and unaltered without evidence of smudging or flaking?***
- 9. *Can the following barcode be read correctly?***
- 10. *DIN ; ABO Rh type; Product Code***

Final results...

Label Stock Validation for Manufacturer X-CT ISBT Labeling System

	Label A	Label B	Label C	Label D	Label E
Is the label firmly attached to the bag with no evidence of peeling?	yes	yes	yes	yes	Yes
Is all of the handwritten information clearly visible on the bag?	yes	yes	yes	yes	Yes
Is all of the handwritten information present in a non-smudged condition?	yes	yes	yes	yes	No
Is there any evidence of portions of the written information flaking off the label?	no	no	no	no	No
If you run your finger over the handwriting does it remain clear and unaltered without evidence of smudging or flaking?	no	no	no	no	No
Is all the printed information on the label present in a non-smudged condition?	yes	yes	yes	yes	yes
Is there any evidence of any of the printed information flaking off the label?	no	no	no	no	no
If you run your finger over the printed information does it remain clear and unaltered without evidence of smudging or flaking?	yes	yes	yes	yes	yes
Can the following barcode be read correctly?	yes	yes	yes	yes	yes
DIN	W13830860162200	W13830860162200	W13830860162200	W13830860162200	W13830860162200
ABORh Type	8600	8600	8600	8600	800
Product code	<S1129100	<S1129100	<S1129100	<S1129100	<S1129100

Label validation

Tag label

W1383 08 601622 8 A
Dartmouth Hitchcock Med
One Medical Center Drive
Lebanon, NH 03756
Collection Date/Time: 4/20/09 1400 GMT
For Autologous Use Only
For Autologous Use Only
Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only
Expiration Date/Time: 4/20/09 1400 GMT
Donor #
Date of Birth:
Intended Recipient:
Smith, Jackson
MRN: 3456789-0
Date of Birth: 12/12/1967
HPC, APHERESIS
A

Main Label/Tag Label

W1383 08 601622 8 A
Dartmouth Hitchcock Med
One Medical Center Drive
Lebanon, NH 03756
Collection Date/Time: 4/20/09 1400 GMT
For Autologous Use Only
For Autologous Use Only
Do Not Irradiate
Do Not Use Leukoreduction Filter
Rx Only
Expiration Date/Time: 4/20/09 1400 GMT
Donor #
Date of Birth:
Intended Recipient:
Smith, Jackson
MRN: 3456789-0
Date of Birth: 12/12/1967
HPC, APHERESIS
D

Validation (labels)

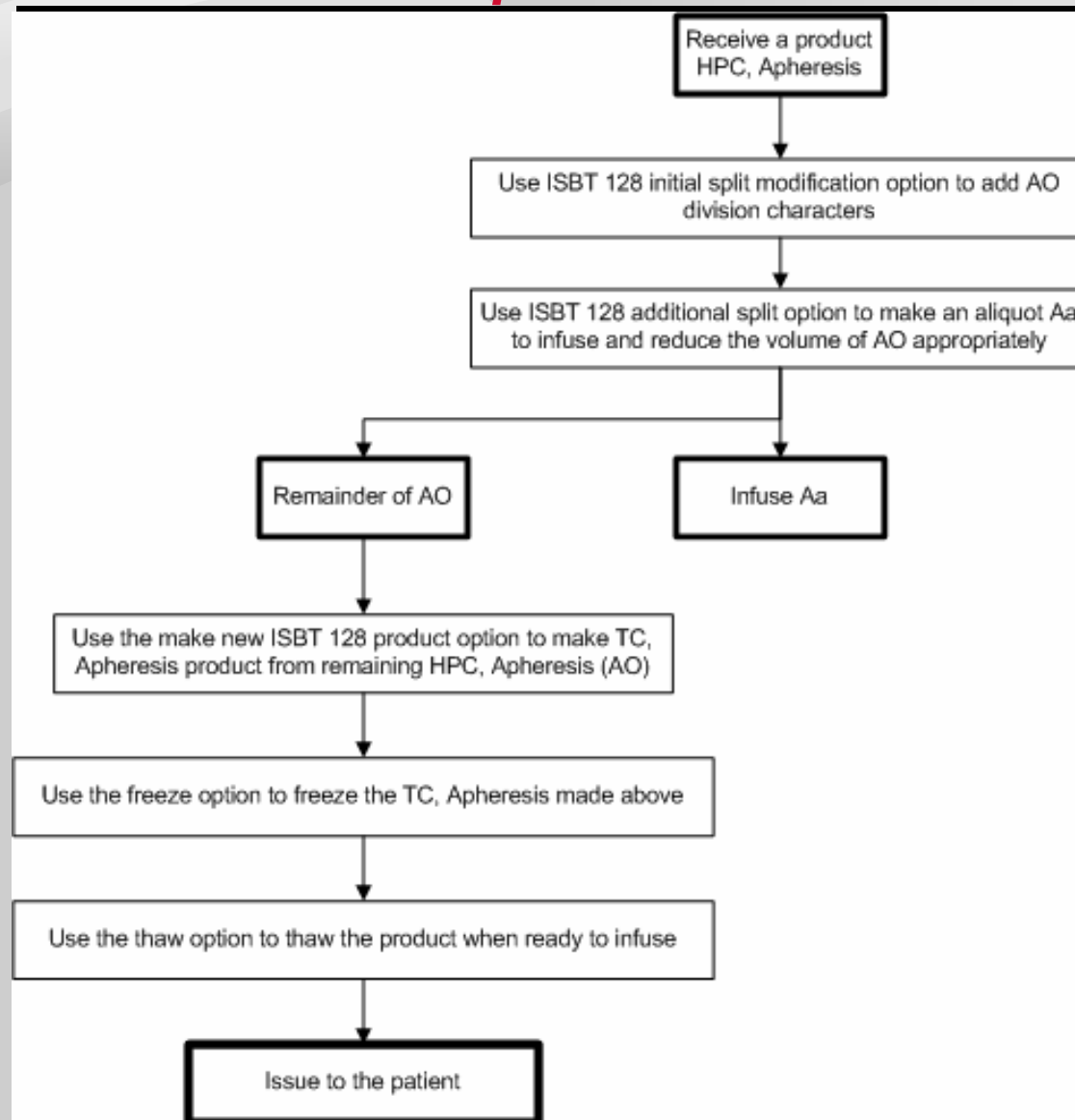
The second part of label validation is associated with computer/software validation. This will be performed once the final version of the software is available and all three printers are available.

Pathology Document Control System		Official Copy
Dartmouth-Hitchcock Medical Center Blood Bank/Transfusion Medicine Service Lebanon, NH 03756		
PROCESS VALIDATION PROTOCOL		
Process Title: Validation of ISBT-128 HPC labels printed using the XXXXX-CT ISBT labeling system		
I. Purpose of Validation: Validation is required in order to document that the labels that print from the XXXXX-CT system contain the information as entered in the screen, all information displays correctly and all barcodes can be read with the expected response.		
II. System Description: The XXXXX-CT labeling system was designed to provide ISBT 128 labeling for bone marrow and peripheral hematopoietic progenitor cell products. Labels will be printed as follows:		
All blood types included in the system will be printed at least once. These blood types include the following:		
A	A RhD Negative	B RhD Positive
B	A RhD Positive	AB RhD Negative
O	O RhD Negative	AB RhD Positive
AB	O RhD Positive	Bombay, RhD Positive
A	B RhD Negative	Bombay, RhD Negative
		Para-Bombay, RhD Positive
		Para-Bombay, RhD Negative
		Special Message
All special messages shown below will be printed at least once.		
None		
Autologous Collection		
Biohazard		
Discard (to be destroyed)		
For fractionation use only		
For research use only		
Not for transfusion based on testing		
Quarantine/hold for further testing		
All the intended use options shown below will be printed at least once.		
Directed (Dedicated/Designated) Collection Use Only		
Directed (Dedicated/Designated) Collection/Biohazardous		
Directed (Dedicated/Designated) Collection/Eligible for Crossover		
For Autologous Use Only		
For Autologous Use only/ Biohazardous		
For Emergency Use Only		
Intended Use Not Specified		
ISBT labels for CTC		
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Validation (software)

- n We have postponed software validation to second version of the software from “manufacturer X”*
- n It seemed critical that the software will have some if not all shortcomings eliminated prior to the full validation.*
- n We expect it to be accomplished within next 2 months.*

Splitting products – example where ISBT implementation experience is necessary



Cost analysis of introduction of CT ISBT128 in the cell processing laboratory

	COST /TIME
Printers (ZEBRA-CT-GX43-E)*	\$ 3000.00
Stock labels	
CT-44 -G	\$115.00
CT-232-FOLD-G 3x2 (4600)	\$147.00
CT-15x75-G cryo vial (3000)	\$50.00
Selection of codes	1-4 weeks
Interface build (if necessary)	1-4 weeks
Software validation	2-3 months
Label validation	1-4 weeks

*depending on the number of label sizes used; we have selected 3 for ease of operation

Summary

- n Plan appropriately for the extent and experience of IT Specialist involvement. Do not underestimate the complexities of the system...*
- n Establish relationship with software manufacturer*
- n Map up your processes and consider changes in your products to adequately select “S” codes.*
- n Validate your labels and software*
- n Consider the overall costs [e.g. technologists time; IT time; validation time (software and labels); stock labels; printers; client computers, if necessary etc]*