



Label Design Task Group



ISCT
Berlin 2006

*Cellular Therapy Coding &
Labeling Advisory Group*



Members



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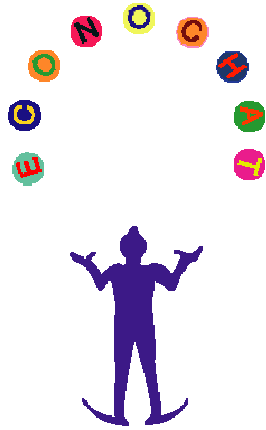




Task

- To come up with draft labels for common cell therapy products
- Present these for review and discussion





Challenges

- Variety of Product types
- Variety of container types
- Variety of container sizes
- Variety of storage conditions
- Amount of information per label





Approach

- Choose 3 common label sizes
 - Standard Transfer pack label
 - Small vial label (1.5 x 0.75 inches)
 - Bioarchive label (cord blood banking)
- Generate samples for common products










© SURU

Transfer Pack Label MUD Apheresis

Standard
Quadrant
Design

Collection Facility Year Collection Number



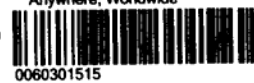


 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide Collection Date  0060301515 30 JAN 2006 15:15 GMT Properly Identify Intended Recipient. May transmit infectious agents.	 O Rh Positive 5100 FOR USE BY INTENDED RECIPIENT ONLY Matched Unrelated Donor Donor # 123654987 Validation Counts and other Laboratory Testing Information
 S0057V00 HPC, APHERESIS Approx ____ mL in approx ____ mL ACD DO NOT IRRADIATE DO NOT USE LEUKOREDUCTION FILTER Store at 1 to 6 C Processing Laboratory Elsewhere, Worldwide	 Expiration Date and Time 0060311515 31 JAN 2006 15:15 GMT Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country



Transfer Pack Label

MUD Apheresis

Donor Information

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5100 O Rh Positive
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Blood Group

Required Warnings

Donor Information

Test results etc.



Transfer Pack Label

MUD Apheresis






Collection Information

Donor Information

Collection Center ID

Collection Date & Time

Required Warnings

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5100 O Rh Positive
Collection Date  0060301515 30 JAN 2006 15:15 GMT	FOR USE BY INTENDED RECIPIENT ONLY Matched Unrelated Donor Donor # 123654987
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Blood Group
If applicable

Required Warnings

Donor Information

Test results etc.



Transfer Pack Label

MUD Apheresis

Collection Information

Donor Information

Collection Center ID

Collection Date & Time

Required Warnings






Product Proper Name

Volume & additives

Required Warnings

Storage conditions

Processing Lab ID

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5100 Rh Positive
Collection Date  0060301515 30 JAN 2006 15:15 GMT	FOR USE BY INTENDED RECIPIENT ONLY Matched Unrelated Donor Donor # 123654987
Properly Identify Intended Recipient. May transmit infectious agents.	Validation Counts and other Laboratory Testing Information
 S0057V00 HPC, APHERESIS	 0060311515 31 JAN 2006 15:15 GMT
Approx ____ mL in approx ____ mL ACD DO NOT IRRADIATE DO NOT USE LEUKOREDUCTION FILTER Store at 1 to 6 C Processing Laboratory Elsewhere, Worldwide	Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country

Product Information

Blood Group
If applicable

Required Warnings

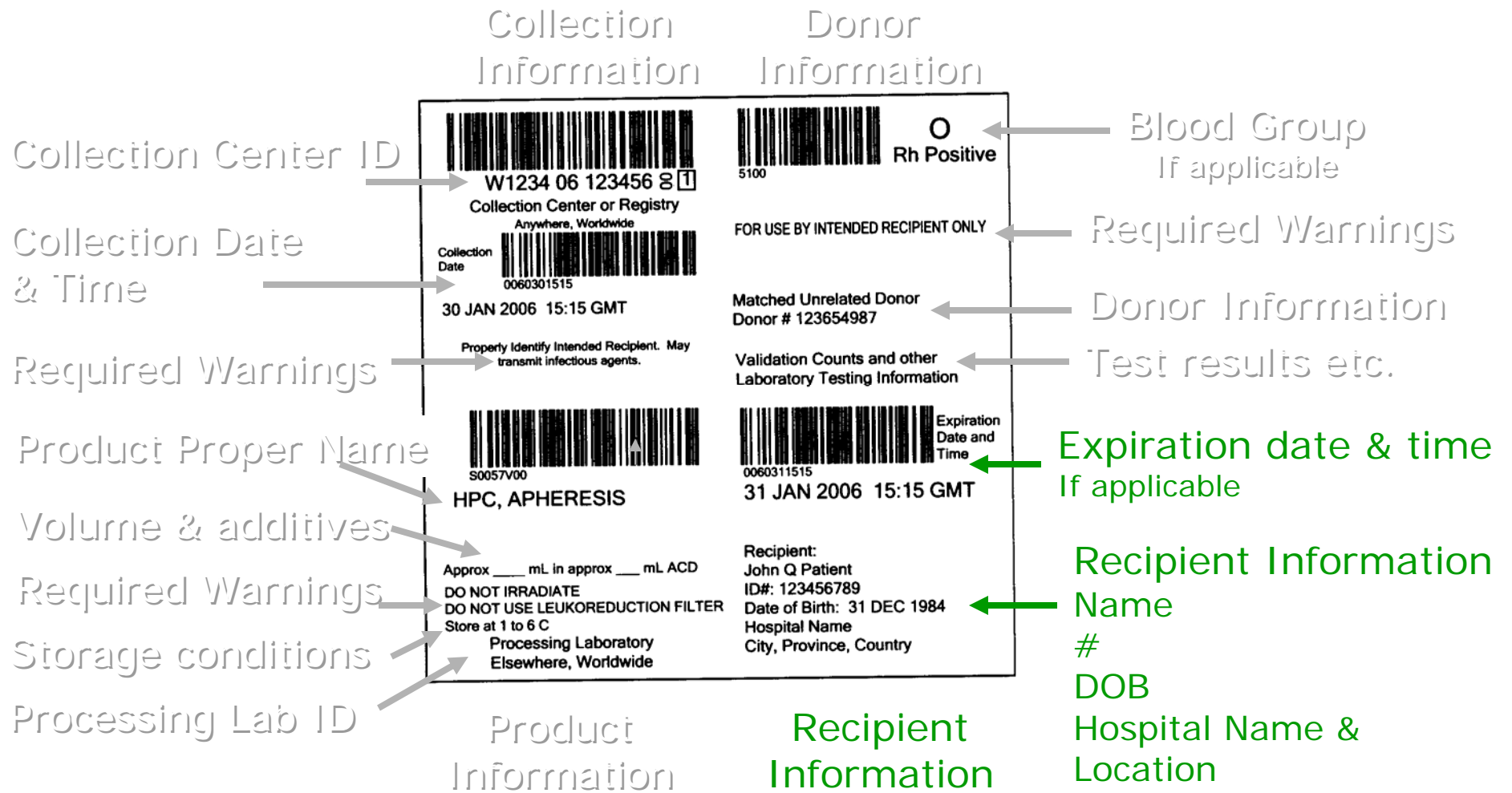
Donor Information

Test results etc.



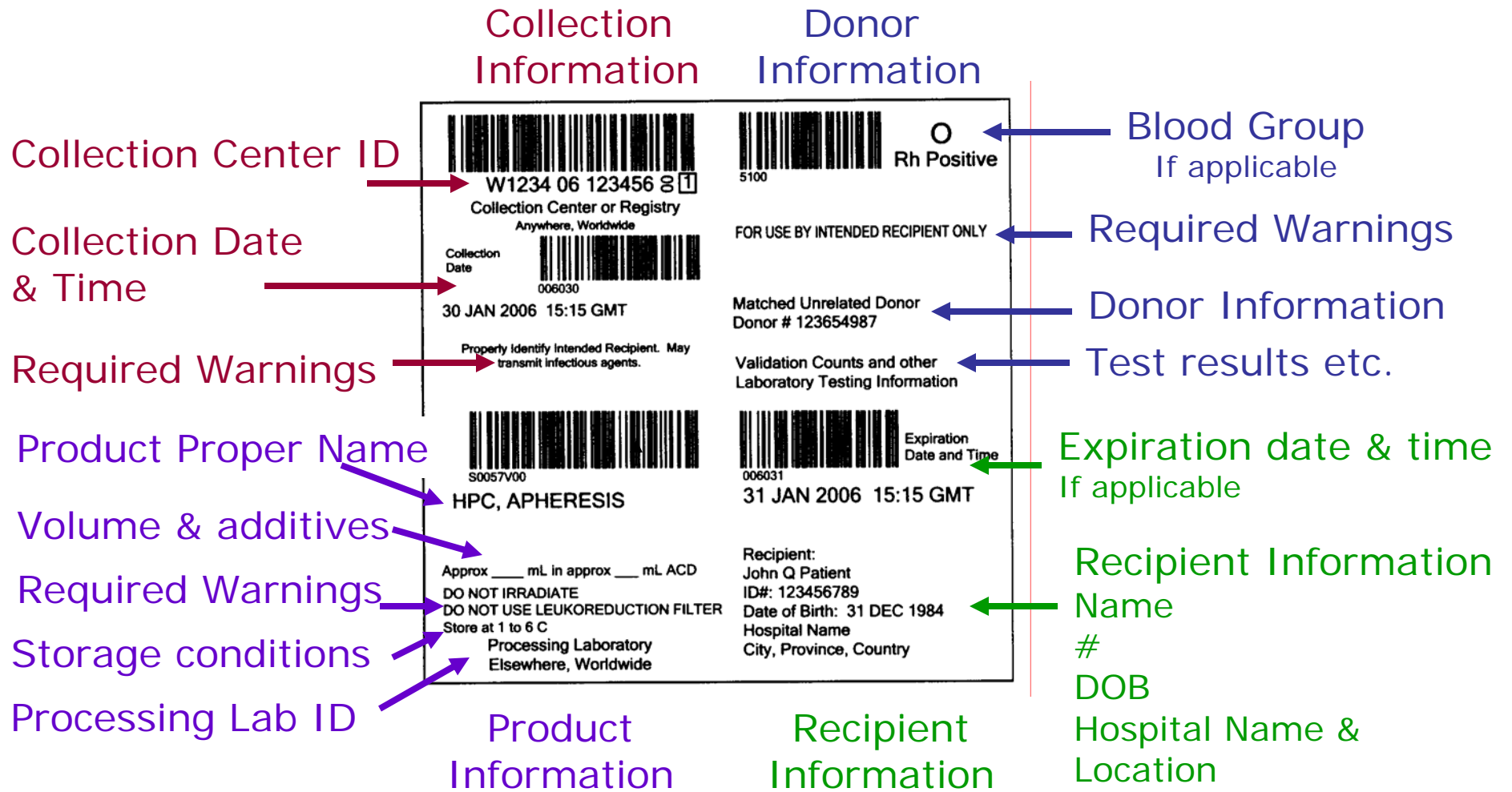
Transfer Pack Label

MUD Apheresis









Transfer Pack Label

Apheresis



Autologous Donor

Donor Information

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5400 Rh Positive
Collection Date  0060301515 30 JAN 2006 15:15 GMT	 BIOHAZARDOUS FOR AUTOLOGOUS USE ONLY
Properly Identify Intended Recipient. May transmit infectious agents.	Validation Counts and other Laboratory Testing Information
 S0057X00 AUTOLOGOUS HPC, APHERESIS	 0060311515 Expiration Date and Time 31 JAN 2006 15:15 GMT
Approx ____ mL in approx ____ mL ACD DO NOT IRRADIATE DO NOT USE LEUKOREDUCTION FILTER Store at 1 to 6 C Processing Laboratory Elsewhere, Worldwide	Recipient: John Q Patient ID#: 123456789 Date of Birth: 31 DEC 1984 Hospital Name City, Province, Country

Blood Group
If applicable

Required
Warnings
& Autologous
Designation

Test results etc.





Vial Label

2 Dimensional
barcode



Component #: C1234567

Therapeutic Cells, T-cells

Recipient: SMITH, John

TCH MRN #: 98705324

Information required on
Partial Label

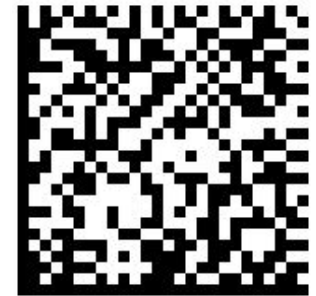
Unique identifier of product

Proper name of product

Recipient name & Identifier



2-Dimensional Barcodes



- Allow encryption of a lot of data
- Not readable by many linear barcode readers
- Not FDA approved
- Multiple formats
- Dual format barcode readers ~\$1,000
- Expert panel in place to make recommendations



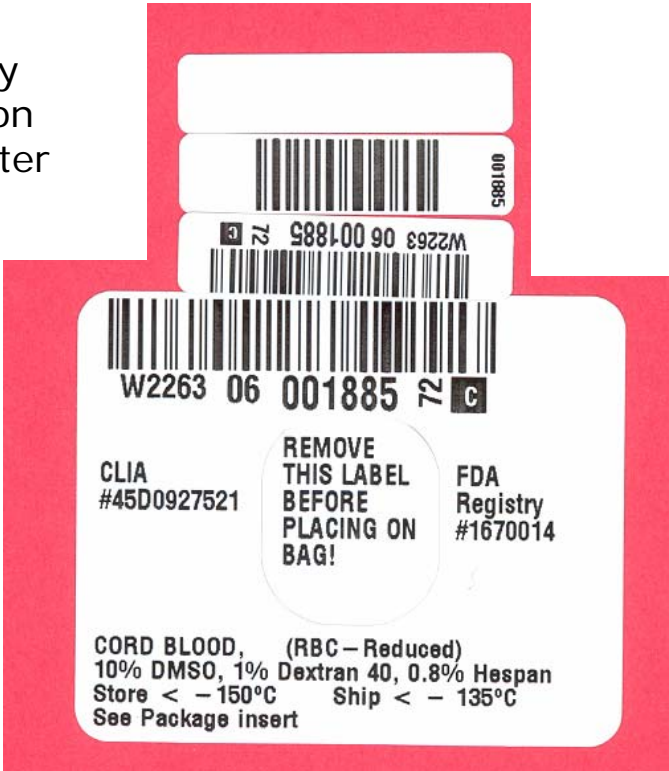
BioArchive™ Cord Blood Labels



Courtesy of Thermogenesis

As used by
MD Anderson
Cancer Center

1.75"



2"





NMDP Operational Issues/Questions

- Current NMDP donor identification code is not specific to the donation.
 - Adoption of new numbering system must link with donor registry number.
- Will all collection facilities (including bone marrow) have the capability to generate labels?
- Centers need to have continued capability of including a local donor/product ID on label
- Will there be mandatory fields of entry on the label that will prevent printing of the label?

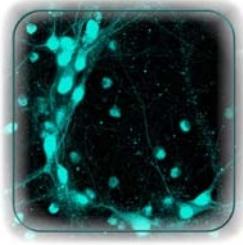


Future Tasks

- Feedback on draft label designs
 - Individuals
 - Cell Processing Centers
 - Registries
 - Regulatory Agencies
 - Professional organizations
 - Any others

Send to apgee@txccc.org





Future Tasks

- Label modifications
- Use of new terminology on labels
- Resolution of 2-D label issues
 - Input from expert panel
 - Feedback from centers
 - Acceptance by regulatory agencies

