

Terminology Group



Cellular Therapy Coding &
Labeling Advisory Group



Task Group Members



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Assignment

- Review existing definitions in ISBT 128 data base for cellular therapy products
- Recommend:
 - Standard definitions for cellular products
 - Rules for future assignment of cellular product codes
 - Retirement of existing terminology that does not fit



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Information Hierarchy

Labeling

Delivery Mechanisms

Data Structures

Reference Tables






Definition

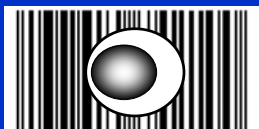


Product Code

Product Definitions

Product

 W1234 06 123456 8 1 Collection Center or Registry Anywhere, Worldwide	 5100 Rh Positive
Collection Date  006030 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	 006031 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



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Methodology

- Work within existing product code structure
- Review existing terminology (FACT, AABB, NMDP, COI)
- Start at the top with existing terms and definitions plus suggested list from Alan Lankester

Class → Modifiers → Attributes:

Core Conditions → Groups and variables

- For each existing term, determine to retain, modify or retire; then define.
 - Concentrate on most common products
- Suggest new terms needed within each area
- Open consultation and publication



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Product Code Hierarchy

- **CLASS** – broad description of product
 - » Each product has only one class
- **MODIFIER** – describes physical state of product
 - » Each product may have up to one modifier
- **ATTRIBUTE** » Each product may have many
 - **CORE CONDITIONS:**
 - Anticoagulant / Collection Media » Only one
 - Collection volume » XX
 - Storage temperature » Only one
 - **GROUPS and VARIABLES:**



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Product Code Hierarchy

- **GROUPS and VARIABLES**

» Each product can have many groups but only one variable from each group; variables are mutually exclusive.

- Intended Use
- Manipulation
- Cryoprotectant
- Preparation: blood component from third party donor
- Preparation: other additives (non human source)
- Genetically modification



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Example

- CLASS HPC, APHERESIS
- MODIFIER Cryopreserved
- ATTRIBUTES: Core Conditions
 - Anticoagulant Citrate
 - Collection Volume NS
 - Storage Temperature $\leq -150\text{C}$
- ATTRIBUTES: Variables
 - Intended Use For Patient Use
 - Manipulation Plasma reduction
 - Cryoprotectant 10% DMSO
 - Additional additives none



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1. Class: the product as collected

Retained the classes:

HPC, APHERESIS

HPC, CORD BLOOD

HPC, MARROW

HPC, WHOLE BLOOD

CONCURRENT PLASMA, APHERESIS

Retire:

POOLED HPC, APHERESIS

[“pooled, single donor” became modifier]



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1.CLASS: Therapeutic cells

Current classes at collection, indicating the purpose of collection:

TC, APHERESIS

TC, WHOLE BLOOD

TC, MARROW

TC, CORD BLOOD

After manufacture the intended active component is described:

TC-T CELLS

TC-CYTOTOXIC LYMPHOCYTES

TC-T REGULATORY CELLS

TC-DENDRITIC CELLS

TC-NATURAL KILLER CELLS

TC-TUMOR DERIVED CELLS

TC-MSC

TC-APC

TC-INV



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2. MODIFIER – describes physical state of product

Mobilized

Non-mobilized

Cryopreserved

Pooled

Thawed and Washed

Washed

Thawed



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3. ATTRIBUTE:

3.1 CORE CONDITIONS

Anticoagulants:

None
Citrate
Heparin
Citrate and Heparin
NS (not specified)

Volume: (no change)

XX

Storage Temperature:

Refr
RT
 $\leq -18\text{ }^{\circ}\text{C}$
 $\leq -80\text{ }^{\circ}\text{C}$
 $\leq -120\text{ }^{\circ}\text{C}$
 $\leq -150\text{ }^{\circ}\text{C}$
LN2



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3. ATTRIBUTE:

3.2. Groups and Variables

- Intended Use group
 - For administration (Patient use)
 - Not for patient use or processing
 - For further processing



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3. ATTRIBUTE:

3.2. Groups and Variables

➤ Manipulation group

➤ None

➤ Diluted

➤ Plasma reduced

➤ RBC reduced

➤ Buffy coat enriched

➤ MNC enriched

➤ T Cell reduced

➤ B Cell reduced

➤ T/B Cell reduced

➤ CD 8 reduced

➤ CD 34 enriched

➤ CD 133 enriched

➤ Tumor cells reduced

➤ PUV treated

➤ Cultured



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3. ATTRIBUTE:

3.2. Groups and Variables

- Preparation - cryoprotectant group
 - No cryoprotectant
 - 6% HES + 5% DMSO ($\pm 1\%$)
 - 10% DMSO ($\pm 2\%$)
 - 5% DMSO ($\pm 1\%$)
 - DMSO reduced



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3. ATTRIBUTE:

3.2. Groups and Variables

- Preparation – third party blood component group
 - No: not added
 - Yes: added, see *accompanying paperwork*
- Preparation – genetic modification
 - No: not genetically modified
 - Yes: genetically modified (see *accompanying paperwork*)
- Preparation – Other additives
 - No: no other additives than as part of the anticoagulation at time of collection
 - Yes: added, see *accompanying paperwork*



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Next Steps

- Translation into codes (ICCBBA)
- Promote use
- Translation of eye readable information into different languages (WHO)
- Feedback on new suggested new terminology



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