Implementation of the ISBT 128 coding system in stem cell transplantation programmes

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zna
wij zorgen voor u

JACIE requirements

JACIE 5th edition:

Cellular therapy products shall be identified according to the proper name of the product, including appropriate modifiers and attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions.

→ implementation plan

JACIE 6th edition:

Cellular therapy products shall be identified according to the proper name of the product, including appropriate ~~modifiers and~~ attributes, as defined in ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (Standard D7.1.1)

→ If coding and labeling technologies have not been implemented, the Processing Facility shall be actively implementing ISBT 128 (Standard D7.1.2)

JACIE requirements

Standard D7.1.2: Evidence

Organizations must, minimally, demonstrate a clearly documented infrastructure including:

1. Registration with ICCBBA.
2. Identification or creation of appropriate product codes.
3. Label designs according to the requirements of ICCBBA for Cellular Therapy Products.
4. Label validation.
5. Use of scanned information at the time products are released from collection, received into the laboratory, and at distribution from the processing facility.

Minimum Requirements for ISBT 128 Labels

1. Electronically readable Donation Identification Number (DIN). If a 2-D label is used, both the DIN and the Product Code shall be electronically-readable

2. eye readable Donation Identification Number, flag characters when required (rotated 90˚ clockwise), and the boxed manual check character.

3. eye readable Product Code (Product Description Code, Donation Type Code and Division Code)

4. The product Class name

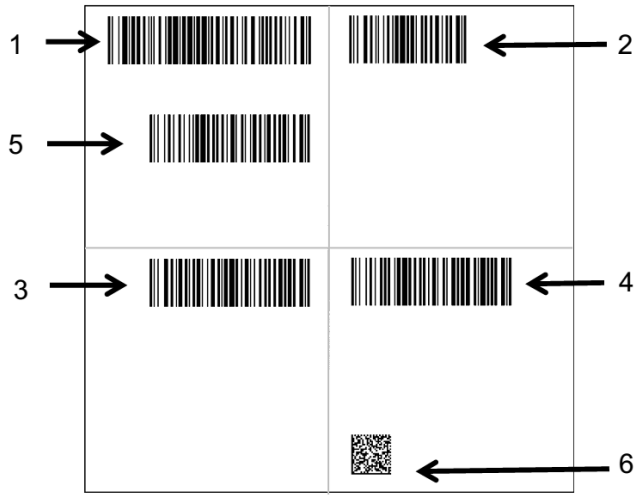
+ requirements JACIE standard and local regulations

a 100 mm by 100 mm label

→ four equal 50 (+/-1) mm by 50 (+/-1) mm quadrants

→ Bar codes for Data Structures

- 001 (Donation Identification Number)
- 002 (ABO and RhD Blood Groups, when known)
- 003 (Product Code)
- 005 (Expiration Date and Time), when applicable (strongly recommended)



Required Bar Codes

1 – Donation Identification Number

2 – Blood Groups [ABO and RhD]

3 – Product Code

Recommended Bar Code

4 – Expiration Date and Time (when applicable)

Optional Bar Codes and Symbols

5– Collection (or Production) Date and Time

6– 2-D bar code with all 5 data structures

Quadrant	Data Structure [Reference number]
Upper Left	Donation Identification Number (required) [001]
	Collection Date and Time (optional) [006, 007] or Production Date and Time (optional) [008, 009] or Flexible Date and Time (optional) [031] encoding Collection or Production Date and Time
Lower Left	Product Code (required) [003]
Upper Right	ABO and RhD Blood Group (required) [002]
Lower Right	Expiration Date and Time [005] or Flexible Date and Time [031] encoding Expiration Date and Time (inclusion of an expiration date bar code is strongly recommended when expiration date is applicable)

Label for autologous HPC, Apheresis - cryopreserved

donor identification number + bar code

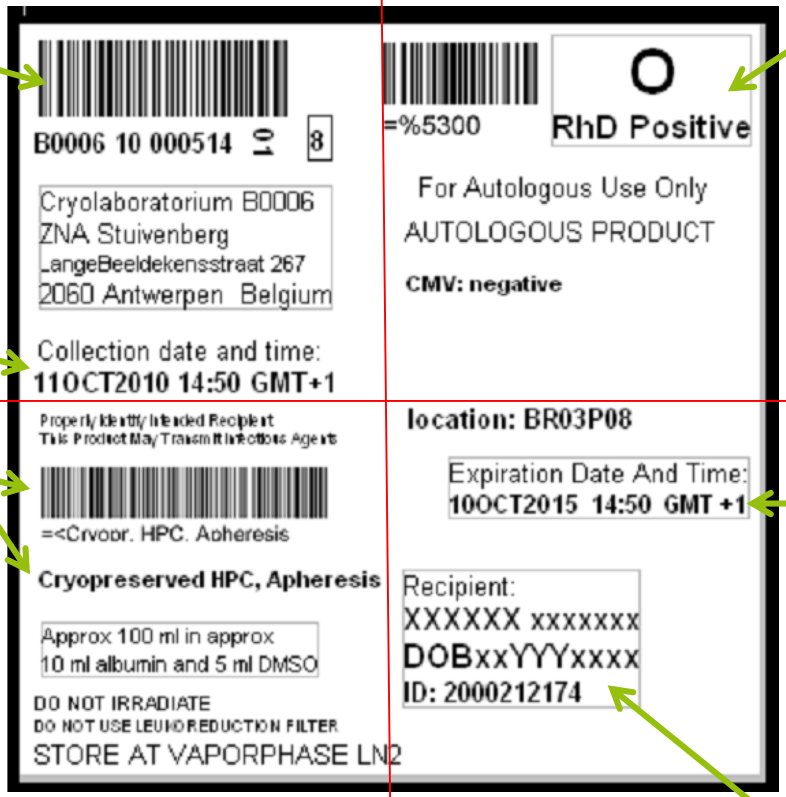
collection date + time

product class + attribute

ABO and RhD blood group + barcode

expiration date + time

intended recipient information



Missing:

- Product code + proper name/attributes
- barcodes for dates
- correct position

Product Name and Code

- Class: cells, comma, source of cells
  - HPC, APHERESIS
  - HPC, CORD BLOOD
  - HPC, MARROW
  - CONCURRENT PLASMA, APHERESIS
  - T CELLS, APHERESIS

- Attributes
  - Core conditions
    - anticoagulant
    - nominal volume
    - storage temperature

    ex: Citrate/XX/<=-150C

- Attributes
  - Groups and Variables
    - Intended Use
    - Manipulation
    - Preparation - Cryoprotectant
    - Preparation – Blood Component from Third Party Donor
    - Preparation – Other Additives
    - Genetically Modified
    - Irradiation
    - Modification
    - Mobilization
    - Pooled Single Donor
    - Cultured
    - Enrichment
    - Reduction

→ default variable for each group

- Attributes
  - Groups and Variables
    - Intended Use → default variable: For administration
    - Manipulation → default variable: Not specified
    - Preparation - Cryoprotectant → default variable: No cryoprotectant
    - Preparation – Blood Component from Third Party Donor → default variable: 3rd Party Comp:No
    - Preparation – Other Additives → default variable: Other Additives:No
    - Genetically Modified → default variable: Genetically Modified:No
    - Irradiation → default variable: Irradiation:No
    - Modification → default variable: Not specified
    - Mobilization → default variable: Not specified
    - Pooled Single Donor → default variable: Not specified
    - Cultured → default variable: Cultured:No
    - Enrichment → default variable: Not specified
    - Reduction → default variable: Not specified

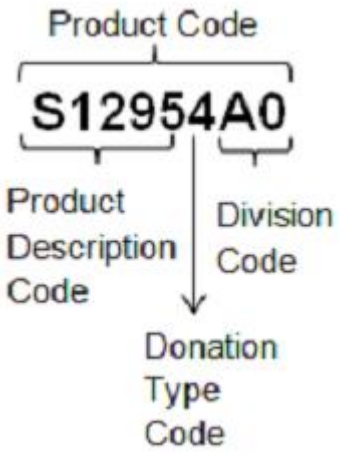
ISBT 128 data structure for the **Product Code** is:

=<αooootds

where

- =<: data identifier for Product Code (barcode)
- αoooo: Product description code
- t: specifies type of donation
- ds: information about unit divided

Character	Type of Donation
0 (zero)	Not specified (null value)
V	Volunteer homologous (allogeneic) donor (default)
R	Volunteer research donor
S	Volunteer source donor
T	Volunteer therapeutic collection
P	Paid homologous (allogeneic) collection
r	Paid research collection
s	Paid source collection
A	Autologous collection, eligible for crossover
1 (one)	For autologous use only
X	For autologous use only, biohazard
D	Volunteer directed collection, eligible for crossover
d	Paid directed collection, eligible for crossover
2	For directed recipient use only
L	For directed recipient use only, limited exposure
E	Medical exception, for specified recipient only (allogeneic)
Q	See (*i.e.*, read [scan]) Special Testing bar code
3	For directed recipient use only, biohazard
4	Designated collection
5	Dedicated collection
6	Designated collection, biohazard
F	Family reserved
C	Replacement collection



Product description code

αoooo

- α = S for cellular therapy product
- describes the product:
  - class
  - attributes:
    - core conditions
    - groups and variables

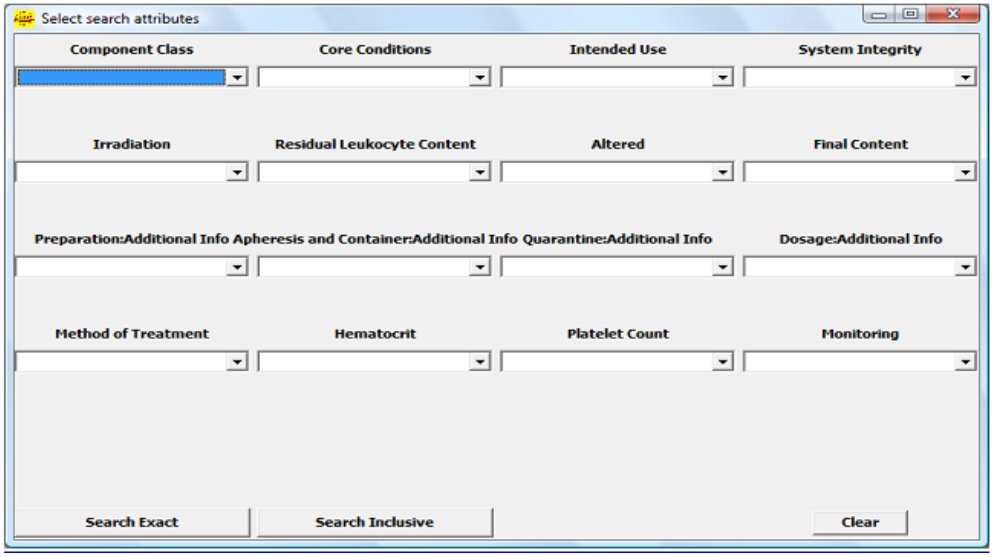
Examples:

- S1128: HPC, APHERESIS|Citrate/XX/refg|Mobilized

- S2081: T CELLS, APHERESIS|Citrate/XX/<=-150C|6% HES + 5% DMSO|3rd Party Comp:Yes|Cryopreserved

How to find the correct Product Description Code?

- Product Look Up program → download via ICCBBA website



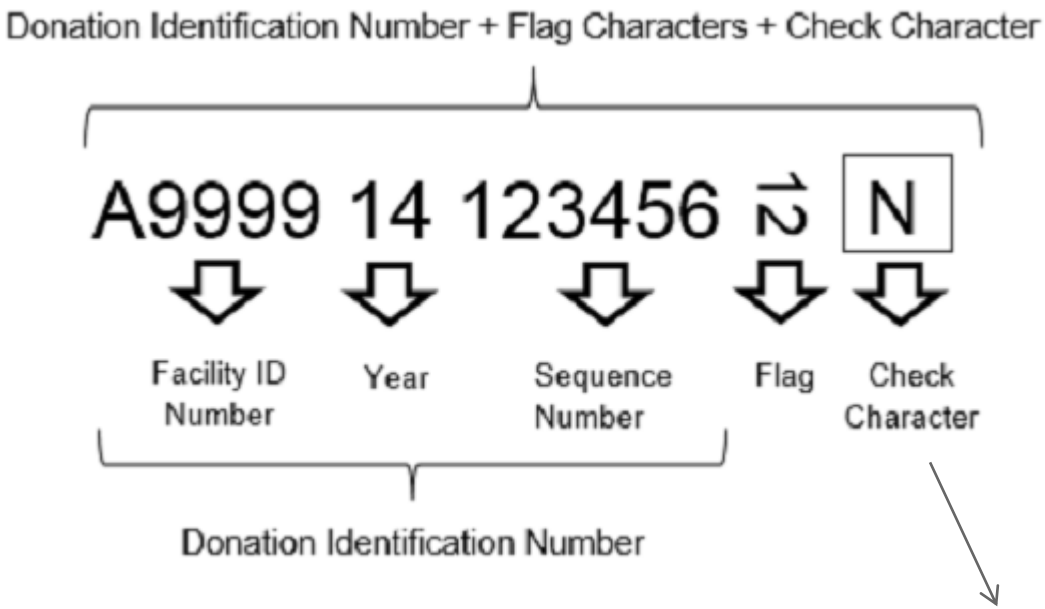
- full list of product description codes : in the ISBT 128 database on the ICCBBA website

- New code: Product Description Code Request Form - Cellular Therapy

Donation Identification number

=αppppyynnnnnnff

αpppp: FIN (facility identification number)
yy: last 2 digits of year
nnnnnn: sequence number
ff: flag characters (not used = 00)



via Quick K Calculator program (ICCBBA website)

Table 1 *ISBT 128* Specified Values for Donation Identification Number Flag Characters, "ff"

Value of "ff"	Meaning
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) "demand-printed" label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Sample for bacterial testing
11-14	Reserved for future assignment
15-19	Container 5 through 9 of a set
20-59	Reserved for assignment and use at national or facility level; therefore the interpretation of "ff" values 20-59 may differ. They should always be interpreted with this in mind.
60-96	ISO 7064 modulo 37,2 check character on the preceding thirteen (13) data characters, "αppppyynnnnnn," including the Collection Facility Identification Code, year and the unit serial number. Value is assigned as 60 + (modulo 37,2 checksum)
97-99	Reserved for future assignment

ABO and RhD Blood group

=%ggre

gg → cfr. table

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
O RhD negative	95	91	92	93	94	96	97	98
O RhD positive	51	47	48	49	50	52	53	54
A RhD negative	06	02	03	04	05	07	08	09
A RhD positive	62	58	59	60	61	63	64	65
B RhD negative	17	13	14	15	16	18	19	20
B RhD positive	73	69	70	71	72	74	75	76
AB RhD negative	28	24	25	26	27	29	30	31
AB RhD positive	84	80	81	82	83	85	86	87
O	55	P2	P3	P4	P5	P7	P8	P9
A	66	A2	A3	A4	A5	A7	A8	A9
B	77	B2	B3	B4	B5	B7	B8	B9

re → 00 if no information about phenotypes

Barcode text for dates

- data identifier: differs per barcode type
  Example: Expiration Date and Time : &>

- cyyjjj (date) or cyyjjjhhmm (date and time)

  Example: Expiration Date and Time:

  c: the century of the year in which the product expires
  yy the year within the century in which the product expires
  jjj: the ordinal (Julian) date on which the product expires
  hh: the hour at which the product expires (00 to 23)
  mm: the minute at which the product expires (00 to 59)

  05NOV2014 12:00 → 0143091200
  Barcode text : &>0143091200

Position of bar codes and text

Bar Code	Vertical Alignment	Horizontal Alignment
Donation Identification Number [001]	3 mm from top of Upper Left Quadrant	Bar code right edge should be 4 mm from right edge of Upper Left Quadrant
Product Code [003]	3 mm from top of Lower Left Quadrant	Bar code right edge should be 4 mm from right edge of Lower Left Quadrant
ABO and RhD Blood Groups [002]	3 mm from top of Upper Right Quadrant	Bar code left edge should be 4 mm from left edge of Upper Right Quadrant
Expiration Date and Time [005 or 031]	3 mm from top of Lower Right Quadrant	Bar code left edge should be 4 mm from left edge of Lower Right Quadrant

Bar Code	Vertical Alignment	Horizontal Alignment
Collection Date (and Time) [006, 007, or 031] or Production date (and Time) [008, 009, or 031]	20 mm from top of Upper Left Quadrant	Bar code right edge should be at 4 mm from right edge of Upper Left Quadrant
Data Matrix symbol	As close to the bottom of the label as practical in the Lower Right Quadrant	Not specified.

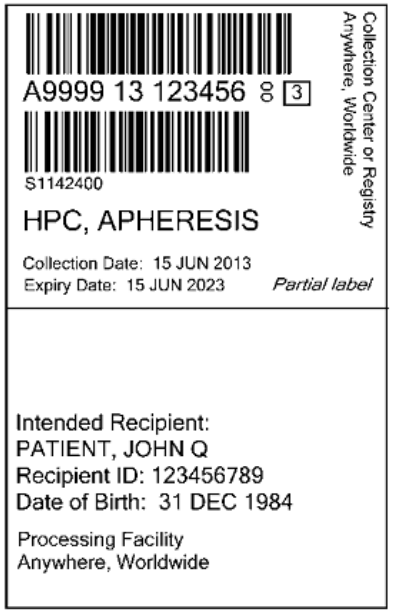
Label for autologous HPC, Apheresis - cryopreserved

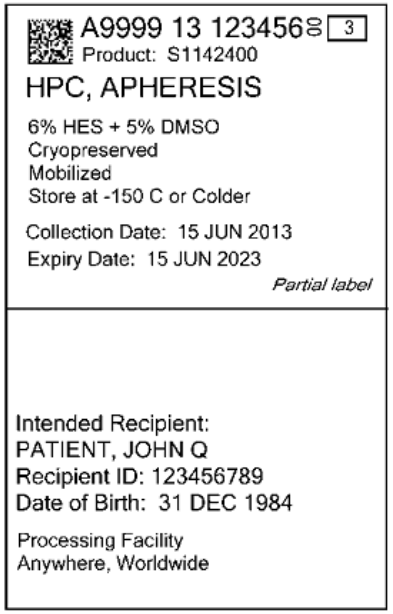
software: IdentiLab
printer: Brady BP-1344

Other examples:

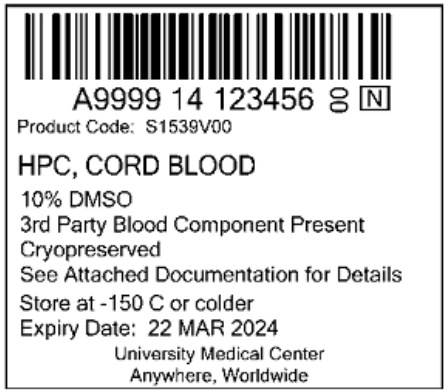
S1152 = HPC, MARROW|Heparin/XX/rt

Labelling containers smaller than 100 mm by 100 mm

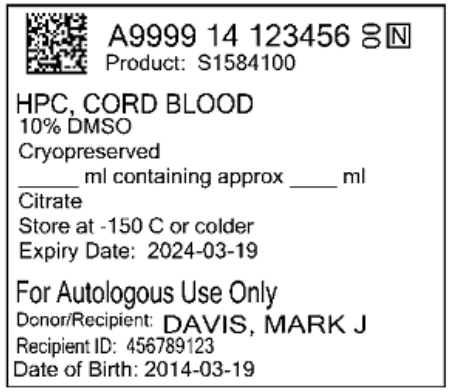




S1142 = HPC, APHERESIS|Citrate+Heparin/XX/<=-150C|6% HES + 5% DMSO|Cryopreserved|Mobilized

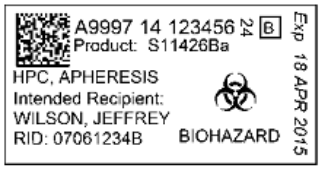


"S1539" = HPC, CORD BLOOD|Citrate/XX/<=-150C|10% DMSO|3rd Party Comp:Yes|Cryopreserved



"S1584" = HPC, CORD BLOOD|Citrate/XX/<=-150C|10% DMSO|Cryopreserved

Cryo Vial Label



S1142 = HPC, APHERESIS|Citrate+Heparin/XX/<=-150C|6% HES + 5% DMSO|Cryopreserved|Mobilized

Usefull ICCBBA documents

www.iccbba.org

→ access to documents after registration

- ISBT 128 Standard - Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions
- ISBT 128 Standard - Technical Specification
- ISBT 128 Standard - Labeling of Cellular Therapy Products
- Implementation guide - Use of the Product Code [Data Structure 003] Cellular Therapy
- Technical bulletin - Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution