Comparison of Labelling & Coding

ahcta alliance for harmonisation of cellular therapy accreditation

The tables are populated with data from the standards from FACT-JACIE, Netcord-FACT, WMDA, and AABB. Consult the current versions. EFI standards do not cover these activities. The crosswalks are intended to point out similarities or general principles of the standards and do not necessarily list specific requirements.

Definitions	Abbreviation
WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries Version 2017	W
FACT-JACIE International Standards for Cellular Therapy Product Collection, Processing and Administration 6th Edition	F-J
Netcord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration 6th Edition	NC-F
AABB Standards for Cellular Therapy Services 6th Edition	AA
Standards are addressed	X
Element not required	-
Not Applicable	NA
Cord Blood	CB
attached	**T**
affixed	**F**
accompanied	**C**

Label contents

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration or to clinical program			
	W	**F-J**	**NC-F**	**AA**	**W**	**F-J**	**NC-F**	**AA**	**W**	**F-J**	**NC-F**	**AA**	**W**	**F-J**	**NC-F**	**AA**
Unique numeric or alphanumeric identifier	-	F	T	F	X	F	F	F	NA	F	F	F	X	F	F	F
Proper name of product	-	F	T	F	X	F	F	F	NA	F	F	F	X	F	F	F
Product modifiers	-	-	NA	F	X	-	NA	F	NA	-	NA	F	X	-	NA	F
Product attributes (manipulations)	-	-	-	-	NA	NA	NA	NA	NA	C	C	C	-	C	NA	-
Recipient name and identifier (if applicable)	-	-	-	F	X	T	T	F	NA	T	T	C	X	T	T	C
Identity and address of collection facility or donor registry	-	-	-	-	-	T	T	C	NA	C	-	C	-	C	-	C
Date collection ends	-	-	-	-	X	T	T	C	NA	C	C	C	X	C	C	C

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration or to clinical program			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Time collection ends, and (if applicable) time zone	-	-	-	-	X	T	C	C	NA	C	-	C	X	C	X	C
Approximate volume (NA for CB unit)	-	-	-	-	-	T	NA	C	NA	T	NA	C	-	T	NA	C
Volume or weight of the CB unit at the end of collection.	-	-	-	-	NA	NA	C	C	NA	NA	NA	NA	NA	NA	C	-
Volume or weight of the CB unit at the end of processing	-	-	-	-	NA	NA	NA	C	NA	NA	C	C	NA	NA	C	-
Name and volume or concentration of anticoagulant and other additives	-	-	-	-	-	T	F	C	NA	T	C	T	-	T	C	T
Donor identifier and (if applicable) name	-	-	-	-	X	T	T	F	NA	T	T	T	X	T	T	C
Recommended storage temperature range	-	-	-	-	-	T	T	C	NA	T	F	C	-	T	F	C
Biohazard and/or Warning Labels (as applicable).	-	-	-	T	-	T	C	T	NA	T	C	T	-	T	C	C
Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES” (if applicable)	-	-	-	T	NA	T	C	T	NA	T	C	T	-	T	C	C
Statement “WARNING: Advise Patient of Communicable Disease Risks” (if applicable)	-	-	-	T	-	T	C	T	NA	T	C	T	-	T	C	C
Statement “WARNING: Reactive Test Results for [name of disease agent or disease]” (if applicable)	-	-	-	C	-	T	C	T	NA	T	C	C	-	T	C	C
Identity and address of processing and distribution facility(ies)	-	-	-	-	-	-	-	-	-	C	-	C	-	C	-	C

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration or to clinical program			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Statement “Do Not Irradiate”	-	-	-	C	-	-	-	-	NA	T	-	T	-	T	T	T
Expiration Date (if applicable)	-	-	-	-	-	-	-	-	NA	T	-	T	-	T	-	T
Expiration Time (if applicable)	-	-	-	-	-	-	-	-	NA	C	-	T	-	T	-	T
ABO and Rh of donor (if applicable)	-	-	-	-	X	-	-	-	NA	C	-	C	X	C	C	C
RBC compatibility testing results (if applicable)	-	-	-	-	-	-	-	-	NA	-	-	-	-	T	-	C
Statement "Properly Identify Intended Recipient and Product"	-	-	-	T	-	-	-	-	NA	-	-	T	-	T	T	T
Statement indicating that leukoreduction filters should not be used.	-	-	-	-	-	-	-	-	NA	-	-	T	-	T	T	T
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)	-	-	-	T	NA	T	-	T	NA	T	-	T	NA	T	-	T
Statement “Directed Donor” (Directed Allogeneic and Autologous CB units)	-	-	NA	-	NA	-	NA	-	NA	-	NA	-	NA	-	NA	-
Statement “For Use By Intended Recipient Only" (if for allogeneic recipient)	-	-	-	T	-	-	-	-	NA	-	-	T	-	T	C	T
Statement «Related Donor» (if applies)	-	-	NA	-	NA	-	NA	-	NA	-	NA	-	NA	-	NA	-
Statement “For Nonclinical Use Only” (if applicable)	-	-	-	T	NA	-	-	-	NA	-	-	T	NA	T	C	T
Statement «Rx Only»	-	-	-	-	NA	-	-	-	NA	-	-	-	NA	-	T	-
Statement “Caution: New Drug – Limited by Federal (or United States) law to investigational use.”	-	-	-	-	NA	-	-	-	NA	-	-	-	NA	-	T	-
Date of distribution	-	-	-	-	X	-	-	-	-	-	-	-	X	C	C	C
HLA phenotype	-	-	-	-	-	-	-	-	-	-	-	C	-	-	C	C

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration or to clinical program			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Number of nucleated cells post processing.	-	-	-	-	X	-	-	-	X	-	C	C	X	-	C	C
Gender of CB unit infant donor	-	-	-	-	NA	-	-	-	T	-	C	C	T	-	C	C
Identity of the CB Bank	NA	-	-	-	NA	-	-	-	T	-	F	C	T	-	F	C

SHIPPING LABELS

Element	Inner Container document				Outer shipping container label			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Date of distribution	T/C	C	-	C	X	C	-	F
Time of distribution	T/C	C	-	-	X	F	-	-
Statement “Do Not X-Ray”	T/C	C	-	C	X	F	F	F
Statement “DO NOT IRRADIATE”	T/C	C	-	C	-	F	-	F
Statement “Medical Specimen”, “TISSUES AND CELLS” or similar	T/C	C	-	C	X	F	F	F
Statement “HANDLE WITH CARE” or similar	T/C	C	-	C	X	F	-	-
Shipper handling instructions	T/C	C	-	C	T/C	F	F	F
Shipping facility name, address, phone number	T/C	C	-	C	T/C	F	F	F
Receiving facility name, address, phone number	T/C	C	-	C	T/C	F	F	F
Identity of person or position responsible for receipt of the shipment	T/C	C	-	C	T/C	F	F	F
Storage instructions	T/C	-	-	C	T/C	-	-	-
Statement indicating Cord Blood for Transplantation	T/C	-	-	-	T/C	-	F	-
Statement “NOT EVALUATED FOR INFECTIOUS SUBSTANCES” if applicable	-	C	-	C	-	-	-	-
Statement “WARNING: Advise Patient of Communicable Disease Risks” if applicable	-	C	-	C	-	-	-	-
Statement “WARNING: Reactive Test Results for [name of disease agent or disease]” if applicable	-	C	-	C	-	-	-	-
Biohazard and/or Warning Labels if applicable	-	C	-	C	-	-	F	-
“FOR AUTOLOGOUS USE ONLY”	NA	-	-	T	NA	-	-	T
Donor’s Infectious Disease marker results in the enclosed documents	T/C	-	-	C	T/C	-	-	-

ACCOMPANYING DOCUMENTS AT DISTRIBUTION

F-J – For "products collected in or designated for use in the U.S."

Documentation	Allogeneic Donors-Eligible				Allogeneic Donor- Ineligible[1]				Allogeneic Donor-Incomplete[1]				Autologous Donors			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Statement that the donor has been determined to be either eligible or ineligible, based upon results of donor screening and testing	X[2]	X	X	X	-	X	X	X	-	-	-	X	NA	-	-	-
Summary of records used to make the donor-eligibility determination[3]	X[2]	X	X	X	-	X	X	X	-	-	-	X	NA	-	-	-
Name and address of the establishment that made the donor-eligibility determination	X[2]	X	X	X	-	X	X	X	-	-	-	-	NA	-	-	-
Listing and interpretation of the results of all communicable disease testing performed	X[2]	X	X	X	-	X	X	X	-	X	X	X	NA	-	-	X
Statement that the communicable disease testing was performed by a laboratory meeting regulatory requirements[4]	-	X	X	X	-	If Ap	If Ap	X	-	If Ap	If Ap	X	NA	-	-	X
Statement noting the reason(s) for the determination of ineligibility	-	-	-	-	-	X	X	X	-	-	-	-	NA	-	-	-
Documentation of notification of the physician using the product of the results of all testing and screening	X[2]	-	-	-	-	X	-	X	-	X	X	X	NA	-	-	-
Statement that the donor-eligibility determination has not been completed	-	-	-	-	-	-	-	X	-	X	X	X	NA	-	-	-
Statement that the product must not be transplanted or infused until completion of the donor-eligibility determination, except under condition of urgent medical need	NA	-	-	-	-	-	-	-	-	X	X	X	NA	-	-	-
Listing of any required screening or testing that has not yet been completed	-	-	-	-	-	-	-	-	-	X	X	X	NA	-	-	-

[1] May only be distributed after release by the Processing Facility Medical Director due to urgent medical need.
[2] These documents are requested by WMDA Standards before distribution
[3] Access (electronic or otherwise) to the source documents by the distributing facility and/or receiving facility is sufficient.
[4] Includes laboratories certified under CLIA of 1988, as amended from time to time, or those that have met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

Documentation	Allogeneic Donors-Eligible				Allogeneic Donor- Ineligible[1]				Allogeneic Donor-Incomplete[1]				Autologous Donors			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
Documentation that the physician using the cellular therapy product was notified of incomplete testing or screening	-	-	-	X	-	-	-	X	-	X	X	X	-	-	-	-
Results of donor screening that has been performed	-	-	-	X	-	-	-	X	-	X	-	X	-	-	-	X
Instructions for product use to prevent the introduction, transmission, or spread of communicable diseases	-	X	X	X	-	X	X	X	-	X	X	X	-	-	-	-
Instructions for reporting serious adverse reactions or events to the distributing facility[5]	-	X	-	X	-	X	-	X	-	X	-	X	-	-	-	X
The physician's approval for use of the product	-	-	-	X	-	-	-	X	-	-	-	X	-	-	-	X
For nonconformances that may affect safety, the physician's agreement to discuss the risks, if any, associated with the use of the nonconforming product with the recipient or the recipient's authorized representative	-	-	-	X	-	Informed consent of recipient required for use of ineligible donor	Requires consent for use from transplant physician	X	-	-	-	X	-	-	-	X

[5] Access to the Transplant Program SOPs and forms could suffice when the distributing and clinical facilities are within the same facility.

OTHER REQUIREMENTS

REQUIREMENTS	W	F-J	NC-F	AA
Processes to ensure that the CT or CB unit identifier is unique to prevent errors in identification	-	X	X	X
Records (with minimal content) maintained for ten (10) years or as required by applicable laws and regulations	X	X	X	X
Labeling operations conducted in a manner adequate to prevent mislabeling or misidentification of CT products and product samples	X	X	X	X
Observe applicable laws and regulations	X	X	X	X
Information verified by at least two (2) staff members	X	X	X	X
There shall be a human and machine-readable system of identification for the CB unit, reference samples, maternal samples, and associated documents	-	-	X	X
The labeling operation shall include, at a minimum, the following controls:				
Check labels upon receipt from the manufacturer against a copy or template to ensure accuracy regarding identity, content, and conformity	-	X	X	X
Validate Print on demand label systems validated to ensure accuracy regarding	-	X	X	X
A system for label version control shall be employed	-	X	X	X
Control Stocks of unused labels	-	X	X	
Stocks of obsolete labels destroyed	-	X	X	X
Representative obsolete labels shall be archived for a minimum of ten years with inclusive dates of use	-	X	X	X
A system of checks in labeling procedures used to prevent errors in transferring information to labels.	-	X	X	X
All labeling clear, legible, and completed using indelible ink	-	X (indelible to all relevant agents)	X	X
CT products that are re-packaged into new containers labeled with new labels before they are detached from the original container	-	X	X	X (covered by labeling controls)
The label validated as reliable for storage under the conditions in use	-	X	X	X
Sufficient area of the container shall remain uncovered to permit inspection of the contents.	-	X	X	-
All data fields on labels completed	-	X	X	-
Labeling SOP required (including associated forms and samples)	-	X	X	X
If a single cellular collection is stored in multiple containers, there a system to identify each container	-	X	X	X (covered by traceability)

	W	F-J	NC-F	AA
If CT products from the same donor are being pooled, the pool identifier shall allow tracing to the original products	-	X	No mention of pooling	X
Facilities may designate an additional or supplementary unique numeric or alphanumeric identifier to the cellular therapy product	-	X	X	X
The facility associated with each identifier noted on the label	-	X	X	X
Supplementary identifiers shall not obscure the original identifier	-	X	X	X
No more than one supplementary identifier shall be visible	-	Not specified in FACT-JACIE. Updated in table	X	-
Products collected for a registry may be shipped without the donor name and facility identifiers as long as there is sufficient documentation to allow tracing to the donor. Minimal information should accompany the product.	X	X	-	-
Use of proper name of the product, as defined by ISBT 128	-	X	X	X
Product names and descriptions according to the Standard Terminology	X	Names, modifiers, and manipulations according to ISBT	Names, modifiers, and manipulations according to ISBT	X
Significant modifications made to the cellular therapy product subsequent to collection and prior to cryopreservation noted on label	-	X	X	-
CT products that are subsequently re-packaged into new containers labeled with new labels before they are detached from the original container	-	X	X	X
The cellular therapy product, concurrent plasma, and samples taken labeled with the same identifier	-	X	Requires adequate identification so all samples can be related to specific CB unit	X
Minimal information shall be present on the cellular therapy product during all stages of processing	-	X	X	X
Any container bearing a partial label shall be accompanied by the required information attached securely to the cellular therapy product on a tie tag or enclosed in a sealed package to accompany the product	X	X	X	X
Bank required to maintain records of all severe or unexpected adverse events or adverse reactions during CB collection and infusion	X	-	X	X
A nonconforming product shall be released by exception only when there is a documented clinical need for the product and when approved by the medical director.	-	Required for ineligible donor and for failure to meet release criteria	Required for ineligible donor	X