

## Comparison of Labelling & Coding

The tables are populated with data from the FACT-JACIE (4<sup>th</sup> ed.), Nectord-FACT (4<sup>th</sup> ed.), WMDA and AABB (4<sup>th</sup> ed.)

Definitions	Abbreviation
attached	T
affixed	F
accompanied	C
required element but form of label not defined	X
WMDA	W
FACT-JACIE	F-J
Nectord-FACT	NC-F
AABB	AA

## Label contents

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration			
	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	F	F	X	F	F	F	X	F	F	F	X	F	F	F
Proper name of product	F	F	F	F	X	F	F	F	X	F	F	F	X	F	F	F
Product modifiers and manipulations	T/C	F		F	X			F	X	F	C	F	X	F	C	F
Recipient name and identifier (if known)	T/C	F		F	X	T	F	F	X	T		C	X	T	T	C
Identity and address of collection facility or donor registry	T/C				X	T	F	C	X	C		C	X	C		C
Date collection ends	T/C				X	T	F	C	X	C	C	C	X	C	C	C
Time collection ends, and (if applicable) time zone	T/C				X	T	C	C	X	C		C	X	C	X	C
Approximate volume						T		C		T		C		T		C
Volume or weight of the CB unit											C				C	

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
at the end of collection.																
Volume or weight of the CB unit at the end of processing											C	C			C	
Name and volume or concentration of anticoagulant and other additives	T/C				X	T	F	C	X	T	C	T	X	T	C	T
Donor identifier and (if applicable) name	F				X	T	F	F	X	T	F	T	X	T	F	C
Recommended storage temperature						T	T	C		T	F	C		T	F	C
Biohazard and/or Warning Labels (as applicable).				T		T	C	T		T	C	T		T	C	C
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"				T		T	C	T		T	C	T		T	C	C
Statement "WARNING: Advise Patient of Communicable Disease Risks"				T		T	C	T		T	C	T		T	C	C
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"				C		T	C	T		T	C	C		T	C	C
Identity and address of processing and distribution facility(ies)										T		C		T		C
Statement "Do Not Irradiate"				C						T		C		T	T	C
Expiration Date (if applicable)										C		C		T		C
Expiration Time (if applicable)										C		C		T		C
ABO and Rh of donor (if applicable)	T/C				X				X	C	C	C	X	T	C	C
RBC compatibility testing results (if applicable)												C		T		C
Statement "Properly Identify Intended Recipient and Product"				T								T		T	T	T
Statement indicating that												C		T	T	C

Element	Partial label				Label at completion of collection				Label at completion of processing				Label at distribution for administration			
	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA	W	F-J	NC-F	AA
leukoreduction filters should not be used.																
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)			T	T		T	T	T		T	F	C		T	F	C
Statement "Directed Donor" (Directed Allogeneic and Autologous CB units)			T				T				F				F	
Statement "For Use By Intended Recipient Only" (if for allogeneic recipient)				T								C		T	T	C
Statement "For Nonclinical Use Only" (if applicable)				T								C		T	T	C
Date of distribution												C		C	C	C
Date of cryopreservation											C	C			C	C
HLA phenotype											C	C			C	C
Number of nucleated cells post processing.	T/C				X				X		C	C	X		C	C
Gender of CB unit infant donor											C	C			C	C
Identity of the CBB											F				F	?

**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	F		F
Time of distribution	T/C				X			
Statement "Do Not X-Ray"		C		C		F	F	F
"DO NOT IRRADIATE"				C	X			
Statement "Medical Specimen", "Handle With Care"		C		C		F	F	F
"TISSUES AND CELLS" & "HANDLE WITH CARE"								
Shipper handling instructions	T/C	C		C		F	F	F
Shipping facility name, address, phone number	T/C	C		C		F	F	F
Receiving facility name, address, phone number	T/C	C		C		F	F	F
Identity of person or position responsible for receipt of the shipment	T/C	C		C		F	F	F
Storage instructions	T/C							
Statement indicating Cord Blood for Transplantation							F	
Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES" if applicable		C						
Statement "WARNING: Advise Patient of Communicable Disease Risks" if applicable		C						
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]" if applicable		C						
Biohazard and/or Warning Labels if applicable		C					F	
"FOR AUTOLOGOUS USE ONLY"								
Donor's Infectious Disease marker results in the enclosed documents	T/C			C				

**ACCOMPANYING DOCUMENTS AT DISTRIBUTION**

Documentation	Allogeneic Donors-Eligible				Allogeneic Donor- Ineligible <sup>1</sup>				Allogeneic Donor- Incomplete <sup>1</sup>				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 <sup>2</sup>	X	X	X		X	X	X								
Summary of records used to make the donor-eligibility determination <sup>3</sup>	X <sup>2</sup>	X	X	X		X	X									
Name and address of the establishment that made the donor-eligibility determination	X <sup>2</sup>	X	X	X		X	X									
Listing and interpretation of the results of all communicable disease screening and testing performed		X	X	X		X	X			X	X			X	X	X
Statement that the communicable disease testing was performed by a laboratory meeting regulatory requirements <sup>4</sup>		X	X	X		If Ap	If Ap	X		If Ap	If Ap	X		If Ap	If Ap	X
Statement noting the reason(s) for the determination of ineligibility				X		X										
Documentation of notification of the physician using the product of the results of all testing and screening		X	X			X	X			X	X			X	X (Test Only)	
Statement that the donor-eligibility determination has not been completed				X				X		X	X					
Listing of any required screening or testing that has not yet been completed										X	X					
Documentation that the physician using the cellular therapy product was notified of incomplete testing or screening				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	
Instructions for reporting serious adverse reactions or events to the distributing facility <sup>5</sup>		X		X		X		X		X		X		X		X

<sup>1</sup> May only be distributed after release by the Processing Facility Medical Director due to urgent medical need.

<sup>2</sup> These documents are requested by WMDA standards before distribution

<sup>3</sup> Access (electronic or otherwise) to the source documents by the distributing facility and/or receiving facility is sufficient.

<sup>4</sup> 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.

<sup>5</sup> Access to the Transplant Program SOPs and forms could suffice when the distributing and clinical facilities are within the same facility.

Documentation	Allogeneic Donors- Eligible				Allogeneic Donor- Ineligible <sup>1</sup>				Allogeneic Donor- Incomplete <sup>1</sup>				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
The physician's approval for use of the product				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

**OTHER REQUIREMENTS**

REQUIREMENTS	WMDA 2008	FACT-JACIE 4	Netcord-FACT 4	AABB 4
Each cellular therapy product collection shall be assigned a unique numeric or alphanumeric identifier	X	X	X	X
Processes to ensure that the CT or CB unit identifier is unique to prevent errors in identification		X	X	
Records (with min content) maintained for ten (10) years or as required by applicable laws and regulations.	X	X	All records of collection, processing, storage and distribution. Indefinitely	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
<b>The labeling operation shall include, at a minimum, the following controls:</b>				
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 ten years with inclusive dates of use		X	X (indefinitely)	X
A system of checks in labeling procedures used to prevent errors in transferring information to labels.		X	X	
All labeling clear, legible, and completed using indelible ink		X (indelible to all relevant agents)	X	
CT products that are re-packaged into new containers labeled with new labels before they are detached from the original container.		X	X	
The label validated as reliable for storage under the conditions in use.		X	X	X

REQUIREMENTS	WMDA 2008	FACT-JACIE 4	Netcord-FACT 4	AABB 4
Processes to verify that all labels in use are accurate, legible, and maintain physical integrity			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	
If CT products from the same donor are being pooled, the pool identifier shall allow tracing to the original products.		X	X	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			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. Min. 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		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	
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
Collection and Processing facilities must be identified	X	X	X	X
Partial label should include, at a minimum, the unique numeric or alphanumeric identifier of the product, the proper name of the product, the appropriate product modifiers, and, if known, the name and identifier of the intended recipient.	X	X	X	X

REQUIREMENTS	WMDA 2008	FACT-JACIE 4	Netcord-FACT 4	AABB 4
Min information shall be present on the cellular therapy product during all stages of processing.		X	X A partial label shall be present on the CB unit during all stages of processing at a minimum.	
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
Documentation of donor eligibility required as accompanying documentation for allogeneic donors	X (at clearance)	X	X	X
The Circular of Information for CT products shall be available to staff through the Processing Facility		X	X	X
Instructions for handling, thawing, and using product, including short-term storage and preparation for administration, shall accompany the product.		Handling, use, and administration, yes	X	X
The use of the cellular therapy product, indications, contraindications, side effects and hazards, dosage, and administration recommendations		X	X (in definition of COI)	X
Bank required to maintain records of all severe or unexpected adverse events or adverse reactions during CB collection and infusion in B2.10.3.4 .			X	X
Instructions for handling the cellular therapy product to minimize the risk of contamination or cross-contamination.		X	X	X
Appropriate warnings related to the prevention of the transmission or spread of communicable diseases. Also in Appendix III as an accompanying document at distribution		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
For products under Investigational New Drug Application the statement: "Caution: New Drug—Limited by Federal (or United States) law to investigational use."		Elements required by law or regulations	X	X
For licensed products, the statement "Rx Only."		Elements required by law or regulations	X	X