Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

DOCUMENT NUMBER: COMM-PAS-003 JA2

DOCUMENT TITLE:
Cellular Therapy Product Labeling (Appendix II)

DOCUMENT NOTES:

Document Information

Revision: 01	**Vault:** COMM-PAS-rel
Status: Release	**Document Type:** COMM-PAS

Date Information

Creation Date: 17 Jan 2024	**Release Date:** 25 Jan 2024
Effective Date: 25 Jan 2024	**Expiration Date:**

Control Information

Author: WATER002	**Owner:** WATER002
Previous Number: None	**Change Number:** STCL-CCR-553

COMM-PAS-003 JA2
CELLULAR THERAPY PRODUCT LABELING APPENDIX II

APPENDIX II

CELLULAR THERAPY PRODUCT LABELING
Each label shall include at least the elements detailed in the following table[1]:

Element[2]	Label at completion of collection	Label at completion of processing	Partial label at distribution for administration[4]	Label at distribution for administration
Unique numeric or alphanumeric identifier[3]	AF	AF	AF	AF
Proper name of product[5,6]	AF	AF	AF	AF
Product code[5]	AF	AF	AF	AF
Product attributes[5]	AC	AC	AC	AF
Recipient name and/or identifier	AT	AT	AC	AT
Identity and address of collection facility or donor registry	AT	AC	AC	AC
Date, time collection ends, and (if applicable) time zone	AT	AC	AC	AC
Approximate volume	AF	AF	AF	AF
Name and quantity of anticoagulant and other additives	AF	AF	AF	AF
Recommended storage temperature range	AF	AF	AF	AF
Donor identifier and (if applicable) name	AT	AT	AC	AF
Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4)	AT	AT	AC	AT
As applicable: Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"	AT	AT	AC	AT
Statement "WARNING: Advise Patient of Communicable Disease Risks"	AT	AT	AC	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"	AT	AT	AC	AT
Identity and address of processing and distribution facility(ies)	-	AC	AC	AC
Statement "Do Not Irradiate"	-	AT	AC	AF
Expiration Date (if applicable)	-	AC	AC	AF
Expiration Time (if applicable)	-	AC	AC	AC
ABO and Rh of donor (if applicable)	-	AC	AC	AC
RBC compatibility determination (if applicable)	-	-	AC	AC
Statement indicating that leukoreduction filters shall not be used	-	-	AC	AF
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)	AT	AT	AC	AF
Date of distribution	-	-	AC	AC

AF=Affix, AT=Attach or Affix, AC=Accompany, Attach or Affix

[1]Container and full package labeling requirements for licensed products or products under Investigational New Drug (IND) application shall follow Applicable Law. In the U.S., see 21 CFR 312.6(a).
[2]Full implementation of ISBT 128 labeling requires compliance with the ISBT 128 Standard for the location of information on the label and/or the accompanying documentation.
[3]Overlay labels for supplementary identifiers shall not obscure the original identifier.
[4]A partial label at distribution is a label that because of the size of the product container or other constraints, does not contain all of the required information.
[5]Product proper names and attributes must also be identified in words, and are listed in Chapter Three of the ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions. Available at: www.iccbba.org > Subject Area > Cellular Therapy > Standard Terminology. This includes all potential attributes, in addition to the core attribute referenced in this table (Anticoagulant, Volume, Storage Temperature): Intended Use, Manipulation, Cryoprotectant, Blood Component from Third Party Donor, Preparation, Genetically Modified, Irradiation, Modification, Mobilization, Pooled Single, Cultured, Enrichment, and Reduction.
[6] Proper name of product is also referred to as class name in the ISBT 128 Standard Terminology.

Signature Manifest

Document Number: COMM-PAS-003 JA2 **Revision:** 01
Title: Cellular Therapy Product Labeling (Appendix II)
Effective Date: 25 Jan 2024

All dates and times are in Eastern Time.

COMM-PAS-003 JA2 COMM-PAS-003 JA2 Cellular Therapy Product Labeling (Appendix II)

Author

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		22 Jan 2024, 02:25:14 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATER002)		22 Jan 2024, 02:25:28 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		22 Jan 2024, 03:49:33 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Melissa Ritt (MSR68)	GMP, Quality Assurance Associate I	22 Jan 2024, 05:24:09 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Codi Curtis (CWC35)	eQMS System Administrator	23 Jan 2024, 05:04:05 PM	Approved