



Version 6.0 November 21, 2014			
	Section	Change	Rationale
1	Throughout document	The ISBT 128 Product Description Code database has been restructured and the version number has been changed to 6.0.0 to reflect this change. The ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions supports this database and therefore has been given the same version number, 6.0.0.	Requested by ICCBBA to support growth of the ISBT 128 Standard.
2	2.3.2.2.1	 Added New Attribute Variables: For mnf: noninjectable- converted For mnf: injectable- source For mnf:noninjectable- source 	Requested by the US
3	3.2.1.1	Added New Storage Condition: • ≤37 C	Requested by the US
4	4.1.2	Added New Class: CORTICAL BONE BLOCKS	Requested by the US
5	10.2	Added New Attribute Group: Storage State	Requested by the US
6	10.2.1.1	Added New Attribute Variables: No information providedFrozen	Requested by the US

Version 5.4 October 20, 2014			
	Section	Change	Rationale
1		Updated main section titles to more closely reflect the names of the families of products supported by ISBT 128.	For consistency
2	5.1	Added New Class: POSTERIOR PART	Requested by the US





3	13.2.1	Removed Retired Class: T CELLS, APHERESIS	Initially retired in version 3.13 and unretired in version 4.26 with the implementation of New Cellular Therapy terminology.
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	Version 5.3 September 2, 2014			
	Section	Change	Rationale	
1	3.2.2.2.2	Updated the definition of the following attribute variable: • Filtered	For Clarification	
2	3.2.2.2.3	Updated the definitions of the following attribute variables: NS HES + NS DMSO NS HES + 5% DMSO NS HES + 10% DMSO	For Clarification	
3	4.1.2	Added New Tissues Class: ELBOW FEMUR	Requested by the US	
4	4.3.2.2.5	Added New Attribute Variables: Antibiotic solutionVitrification solution	Requested by the ETTAG-NATTAG Cardiovascular working group	
5	8.2.1	Added New Attribute Groups: Milk Type Pooling Status Preparation Nutritional Additives Dietary characteristics Calorie Count Nutritional Analysis Donor Classification	Requested by MBTAG	
6	8.2.1.1	Added New Attribute Variables: • 0 to 4C • Freeze dried • Thawed	Requested by MBTAG	





7	0.04.0	Added New Attribute Variable:	Requested by
7	8.2.1.3	Not for clinical use	MBTAG
8	8.2.1.5	Added New Attribute Variable: • Specified recipient	Requested by MBTAG
9	8.2.1.6	Added New Attribute Variables: ColostrumPre-termTerm	Requested by MBTAG
10	8.2.1.7	Added New Attribute Variables: • Pooled, <7 donors • Pooled, donors ≥7 • Pooled, single donor • Single donor expression	Requested by MBTAG
11	8.2.1.8	Added New Attribute Variable: • Fat reduced	Requested by MBTAG
12	8.2.1.9	Added New Attribute Variable: Nutrients added	Requested by MBTAG
13	8.2.1.10	Added New Attribute Variable: • Special dietary characteristics	Requested by MBTAG
14	8.2.1.11	Added New Attribute Variable: • Calorie value specified	Requested by MBTAG
15	8.2.1.12	Added New Attribute Variable: Nutritional analysis specified	Requested by MBTAG
16	8.2.1.13	Added New Attribute Variables: Volunteer donor Paid donor	Requested by MBTAG
17	9.2	Added Attribute Groups and Variables applicable to Other Therapies category.	For completeness
18	13	Changed section name from Retired Codes to Retired Terminology.	For clarification
19	13	Changed instances of 'codes' to 'terminology 'throughout the section.	For clarification





Version 5.2 August 1, 2014			
	Section	Change	Rationale
1	1	Added reference to In Vivo Diagnostic MPHO in the last paragraph of the Introduction section.	For Completeness
2	3.2.2.2.5	Added a note to the definition of the attribute Concurrent Plasma.	Requested by CTCLAG The Class CONCURRENT PLASMA, APHERESIS specifies that this product only applies to apheresis collections. Therefore,
			this also applies to the attribute.
3	6.3	Added a note to the Attributes section stating that Plasma Derivatives and In Vivo Diagnostic MPHO (Medical Products of Human Origin) are in the Other Blood Products category. They therefore share attribute groups and variables; not all variables are applicable.	For Clarification
4	6.3.1.1	Added Core Conditions applicable to the Other Blood Products category.	For Completeness
5	6.3.2.1	Added Groups applicable to the Other Blood Products category.	For Completeness
6	6.3.2.2.2	Added variables for Altered group applicable to Other Blood Products category.	For Completeness
7	6.3.2.2.3	Added variables for Donor-Intended Recipient Relationship group applicable to Other Blood Products category.	For Completeness
8	7	Added New Section for In Vivo Diagnostic MPHO.	Requested by The Netherlands





9	7.1	Added New In Vivo Diagnostic MPHO Classes: RADIOLABELED DIAGNOSTICS, LEUKOCYTES RADIOLABELED DIAGNOSTICS, PLATELETS RADIOLABELED DIAGNOSTICS, RED BLOOD CELLS	Requested by The Netherlands
10	7.2.1	Added Modifier applicable to Other Blood Products category.	For Completeness
11	7.3.1.1	Added New Core Conditions Variables: • ACD-A • ACD-A-HES • Heparin-HES	Requested by The Netherlands
12	7.3.2.1	Added Attribute Groups:AlteredDonor-Intended Recipient Relationship	Requested by The Netherlands
13	7.3.2.2.1	Added Blood Group Variables applicable to Other Blood Products category.	For Completeness
14	7.3.2.2.2	Added Attribute Variables: Not specified Heat denatured	Requested by The Netherlands
15	7.3.2.2.3	Added Attribute Variables: Not specified Autologous	Requested by The Netherlands
16	8 to 13	Renumbered sections downstream of section 7.	Due to addition of In Vivo Diagnostic MPHO Terminology in section 7





Version 5.1 July 3, 2014			
	Section	Change	Rationale
1	2.3.2.2.7	New Attribute Added to Preparation- Additional Information Group: • Multiple wash cycles	Requested by Canada
2	3.1.3	Added New Abbreviations; CP(A) - CONCURRENT PLASMA, APHERESIS MNC(UCT) - MNC, UMBILICAL CORD TISSUE	Requested by CTCLAG
3	6.3.1.1	New Storage Condition Added: • rt	Requested by the US

	Version 5.0 June 6, 2014			
	Section	Change	Rationale	
1	3.2.2.2.3	New Attribute Added to Cryoprotectant Group: • (NS HES + NS DMSO)	Requested by Belgium	
2	7.2.1	• Changed ≤-80 C to ≤-70 C	MBTAG decided ≤-70 C was more realistic if target temperature was ≤-80 C. No Product Description Codes using ≤-80 C have been used as of 06 Jun 2014.	

Version 4.34 April 24, 2014			
	Section	Change	Rationale
1	2.3.2.2.12	New Attribute Added to Hematocrit Group: • 0.50 – 0.55	Requested by Ireland





2	4.1.1	Changed the ISBT 128 Database name for the class: VALVE, PULMONARY,W MAIN,L/R ARTERIES	Removed 2 spaces to accommodate the 36 character field size of the Class field in the Class table within the ISBT 128 Product Description Code Database.
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	Version 4.33 March 18, 2014			
	Section	Change	Rationale	
1	2.3.1	Updated PAS table to include 'T- PAS+' as an alternative name for PAS-E	Requested by the US	
2	2.3.2.2.5	New Attribute Added: • Plasma removed and SAGM added	Requested by Ireland	
3	2.3.2.2.5	'Red Blood Cells reduced by sedimentation' was changed to 'RBC content reduced'	Requested by Ireland	
4	3.1.2	New Classes Added: • MSC, PLACENTA • MSC, UMBILICAL CORD	Requested by China	
5	3.2.2.2.12	New Attribute Added: • Viral specific T cell enriched	Requested by Singapore Inadvertently omitted in version 4.28	
6	4.1.1	Renamed the Following Classes and updated the defintions: • ABDOMINAL BIFURCATION to AORTOILIAC, CONDUIT • AORTIC ARCH to AORTA, ARCH • COMMON ILIAC ARTERY to ARTERY, COMMON ILIAC • FEMORAL ARTERY to ARTERY, FEMORAL, COMMON	Requested by the ETTAG-NATTAG Cardiovascular terminology working group	





	PULMONARY PATCH to PULMONARY, MAIN ARTERY PATCH SUPERFICIAL FEMORAL ARTERY to ARTERY, FEMORAL, SUPERFICIAL THORACIC AORTA to AORTA, DESCENDING, THORACIC VENA CAVA INFERIOR to VEIN, INFERIOR VENA CAVA	
7	AORTA, ASCENDING, WITH ARCH AORTA, DESCENDING, ABDOMINAL AORTOILIAC, CONDUIT VALVE, AORTIC, WITH ASCENDING AORTA VALVE, AORTIC, WITH ASCENDING AORTA AND ARCH VALVE, AORTIC, WITH ASCENDING AORTA AND PARTIAL ARCH ARTERY, BRACHIAL ARTERY, INTERNAL THORACIC ARTERY, RADIAL ARTERY, ULNAR HEART, PARTIAL, WITH VALVES HEART, PARTIAL, WITHOUT VALVES HEART, WITH PERICARDIUM	Requested by the ETTAG-NATTAG Cardiovascular terminology working group





		 PULMONARY, MAIN ARTERY PULMONARY, MAIN AND RIGHT ARTERIES VALVE, PULMONARY, MONOCUSP VALVE, PULMONARY, ONE LEAFLET VALVE, PULMONARY, TWO LEAFLETS VALVE, PULMONARY, WITH MAIN ARTERY VALVE, PULMONARY, WITH MAIN, LEFT AND RIGHT ARTERIES VALVE, PULMONARY, WITH MAIN, LEFT ARTERY VALVE, PULMONARY, WITH MAIN, LEFT ARTERY VALVE, PULMONARY, WITH MAIN, LEFT ARTERY VALVE, PULMONARY, WITH MAIN, RIGHT ARTERY VEIN, FEMORAL VEIN, GREAT SAPHENOUS VEIN, SMALL SAPHENOUS 	
8	4.1.4	Moved Classes: Pericardial Patch Pericardium	ETTAG-NATTAG Cardiovascular terminology working group determined that these terms will be handled as membrane terminology
9	6.3.2.2.1	Added New Blood Group Attribute: • ABO independent	Requested by Ireland
10	7.2.1	Added New Storage Condition: • ≤-80 C	Requested by Spain
11	12.3.1	Retired Tissue Terminology: • AORTIC NON-VALVED CONDUIT • AORTIC PATCH • BLOOD VESSEL • SAPHENOUS VEIN	Terminology retired by the ETTAG- NATTAG Cardiovascular terminology working group





	Version 4.32 February 6, 2014			
	Section	Change	Rationale	
1	3.1.2	Updated definition of Concurrent Plasma.	Requested by CTCLAG	
2	3.2.2.2.1	New Attribute Added: • For use in further processing donor's cell product	Requested by CTCLAG	

	Version 4.31 January 13, 2014			
	Section	Change	Rationale	
1	2.3.2.2.5	New Attribute Added: Saline added	Requested by the US	
2	4.1.4	New Class Added: • Peripheral Nerve	Requested by the US	





	Version 4.30 December 30, 2013		
	Section	Change	Rationale
1	3.2.1	In section (1) all reference to additives were removed.	Per request of CTCLAG, additives are not encoded in the core conditions for Cellular Therapy products.
2	3.2.2.1	The definition of the Preparation – Other Additive group was broadened to describe all additives present in the products.	Cellular therapy products encode all additive information in this group.
3	3.2.2.2.4 3.2.2.2.5 3.2.2.2.6	Changed the term paperwork to documentation throughout this section.	For consistency
4	4.1.2	Added new Class: CARTILAGE, JOINT, KNEE	Requested by Denmark
5	4.1.2	Added new Classes: RADIUS RADIUS, DISTAL RADIUS, PROXIMAL ULNA, DISTAL ULNA, PROXIMAL	Requested by the UK
6	4.1.4	Added new Classes: LARYNX WITH TRACHEA LARYNX AND TRACHEA WITH BIFURCATION	Requested by Austria
7	4.3.2.1	Added new Attribute Group: • Additives	Requested by Austria
8	4.3.2.2.1	Added new Attribute Variables: Not specifiedAdditives:Yes	Requested by Austria





9	4.3.2.2.1	Added new Attribute Variables: Albumin Albumin + other 3rd Party donor plasma Additives:yes incl animal src Autologous plasma Autologous plasma + other	Requested by ETTAG
10	7	Moved Classes in the Other Therapies group to new sections. • Human Milk • Serum Eye Drops • Fecal Microbiota	Moved to new sections by ICCBBA to better accommodate users in each area of interest.

	Version 4.29 November 26, 2013			
	Section	Change	Rationale	
1	3.1.2	Added new Class: • MNC, UMBILICAL CORD TISSUE	Requested by the US	
2	3.2.1.1	Added new storage temperature: • 10-20 C	Requested by Singapore	
3	4.1.4	Added new Classes: TRACHEA TRACHEA WITH BIFURCATION TRACHEA, PART TRACHEA, PART WITH BIFURCATION	Requested by Austria	
4	5.2	Added new Attribute Group: Transport Solution	Requested by Croatia	
5	5.2.1.8	Added new Attribute Variables: Not specified Dextran	Requested by Croatia	
6	7.1.3	Added new Class: • Fecal Microbiota	Requested by the US	





Version 4.28 October 24, 2013			
	Section	Change	Rationale
1	2.3.2.2.10	Added new attributes: 11 units 12 units	Requested by the US
2	3.2.1.1	Changed Citrate/Heparin to Citrate+Heparin.	Changed to match the ISBT 128 database name.
3	3.2.2.2.13	 Changed Alpha Beta T/B cell reduced to Alpha Beta T+B cell reduced. Changed T/B cell reduced to T+B cell reduced. 	Changed to match the ISBT 128 database name.
4	4.3.2.1	Added new Attribute Group: • Additional Processing	Requested by the UK
5	4.3.2.2	Sub sections renumbered due to addition of new Attribute Group.	For consistency
6	4.3.2.2.1	Added new Attribute Variables: Not specified Marrow depleted Cleaned	Requested by the United Kingdom Requested by Advisory Group

Version 4.27 September 17, 2013			
	Section	Change	Rationale
1	2.3.1.1	Added new third position value: • <-80C	Added for Completeness
2	2.3.2.2.5	Added new Attribute Variable: • Plasma reduced/Saline added	Requested by the US
3	3.1.2	Added new Class: NC, SYNOVIAL FLUID	Requested by the US





4	3.2.1	Added the sentence, "Other volume information may be given as additional label text.	This will allow users to print total volume (including anticoagulant) on the label instead of nominal collection volume.
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Version 4.26 August 15, 2013			
	Section	Change	Rationale
1	3.1.1	Redefined Subcategory 1 class types for cellular therapy.	The Subcategory 1 class name format was revised to describe the composition of the cellular therapy product and will no longer describe the intended purpose of the collection.
2	3.1.1	Redefined Subcategory 2 class types for cellular therapy.	The revised Subcategory 2 class names no longer utilize a hyphen and the use of "TC" (Therapeutic Cell) is no longer used.
3	3.1.2	Renamed the following classes: NC, ADIPOSE CELLS to NC, ADIPOSE TISSUE NC-MSC ATD to MSC, ADIPOSE TISSUE NC-MSC DPD to MSC, DENTAL PULP NC-MSC WJD to MSC, WHARTON'S JELLY NC, TUMOR CELLS to MALIGNANT CELLS, TUMOR TC, APHERESIS to MNC, APHERESIS TC-BLINDED STUDY to INVESTIGATIONAL PRODUCT	The revised class names follow the format of listing the cell type followed by the source. The use of "TC" (Therapeutic Cell) is no longer used.





		 TC, CORD BLOOD to NC, CORD BLOOD TC, MARROW to NC, MARROW TC, MSC MD to MSC, MARROW TC, WHOLE BLOOD to NC, WHOLE BLOOD 	
4	3.1.2	Renamed the class name from TC, PANCREATIC ISLETS to PANCREATIC ISLETS	The use of TC (Therapeutic Cell) is no longer used. This class is an exception that will not follow the cell therapy format of Cell Type, Source. PANCREATIC ISLETS will become a tissue class name in the future.
5	3.1.2	Added the following classes: DC, APHERESIS DC, CORD BLOOD DC, MARROW DC, WHOLE BLOOD MALIGNANT CELLS, APHERESIS MALIGNANT CELLS, WHOLE BLOOD MSC, CORD BLOOD MSC, CORD BLOOD NK CELLS, APHERESIS NK CELLS, CORD BLOOD NK CELLS, MARROW NK CELLS, WHOLE BLOOD T CELLS, WHOLE BLOOD T CELLS, APHERESIS T CELLS, CORD BLOOD T CELLS, WHOLE BLOOD T CELLS, WHOLE BLOOD T CELLS, MARROW T CELLS, TUMOR T CELLS, WHOLE BLOOD	Requested by CTCLAG under the new cellular therapy terminology.
6	3.1.2	Revised the definitions for most cellular therapy class names.	To follow a consistent format with the revised terminology.
7	3.1.3	Expanded table of abbreviations for cellular therapy class names.	To standardize the use of abbreviations.





8	3.2.2.1	Added the following attribute groups:	Requested by CTCLAG
9	3.2.2.2.2	Added new attributes:	Requested by CTCLAG
10	3.2.2.2.5	Added new attributes:	Requested by CTCLAG
11	3.2.2.2.8	Added new Modification attribute group and variables.	Requested by CTCLAG to replace the use of Modifiers in cellular therapy product descriptions.
12	3.2.2.2.9	Added new Mobilized attribute group and variables.	Requested by CTCLAG. Mobilization is no longer addressed in the definitions of relevant class names and is no longer used as a modifier.
13	3.2.2.2.10	Added new Pooled Single Donor attribute group and variables.	Requested by CTCLAG to replace the use of the Pooled Single Donor modifier.
14	3.2.2.2.11	Removed the Cultured attribute from the Manipulation attribute group and created a new Cultured attribute group and variables.	Requested by CTCLAG





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15	3.2.2.2.12	Relocated the following attributes from the Manipulation attribute group to a new Manipulation Enrichment attribute group: • Buffy coat enriched • CD4 enriched • CD34 enriched • CD56 enriched • CD133 enriched • Mononuclear cell enriched • Monocyte enriched	To separate the various types of manipulations and allow for better categorization of attributes.
16	3.2.2.2.12	Added the following attributes to the new Manipulation Enrichment attribute group: T Reg enriched CTL enriched TIL enriched	Requested by CTCLAG to replace the use of these terms as part of the class name.
17	3.2.2.2.13	Relocated the following attributes from the Manipulation attribute group to a new Manipulation Reduction attribute group: • Alpha Beta T cell reduced • Alpha Beta T/B cell reduced • B cell reduced • CD8 reduced • Plasma reduced • RBC reduced • T/B cell reduced • T cell reduced • T cell reduced	To separate the various types of manipulations and allow for better categorization of attributes.
18	10.2.1	Added the following cellular therapy class names to the list of retired terms: • TC-APC • TC-CTL • TC-DC • TC-INV • TC-MSC • TC-NK CELLS • TC-T CELLS • TC-TIL • TC-T REG CELLS • TC, TUMOR DERIVED	Requested by CTCLAG





19	10.2.2	Added the following cellular therapy modifier names to the list of retired terms:	Requested by CTCLAG. Modifiers will no longer be used in cellular therapy product descriptions.
20	10.2.5.1.4	Added the following cellular therapy attributes to the list of retired Manipulation terms: • Alpha Beta T cell reduced • Alpha Beta T/B cell reduced • B cell reduced • buffy coat enriched • CD4 enriched • CD8 enriched • CD133 enriched • Cultured • Diluted • Monocyte enriched • Monocyte enriched • RBC reduced • T/B cell reduced • T cell reduced • Tumor cells reduced	These terms were retired from the Manipulation attribute group and were put into a different attribute group.





Version 4.25 July 11, 2013			
	Section	Change	Rationale
1	3.1.3	Added new Classes: CHONDROCYTES, CARTILAGE KERATINOCYTES, SKIN FIBROBLASTS, SKIN	Requested by Iran
2	3.2.1	Added new Modifier: • Pooled, Single Donor Cryopreserved	Requested by Brazil
3	7.2.1	Added new Storage Condition:<=-20C	Requested by the UK

Version 4.24 June 12, 2013			
	Section	Change	Rationale
1		No changes made to this document. Version numbering updated to correspond with current Product Description Code Database.	

	Version 4.23 May 8, 2013			
	Section	Change	Rationale	
1	2.3.2.2.10	Added new Attribute Variable: Pediatric dose	Requested by the US	
2	3.3.2.2.2	Added new Attribute Variable: αβ T cell reduced	Requested by the Netherlands	
3	4.1.2	Added new Class: ULNA	Requested by Canada	





Version 4.22 April 4, 2013			
	Section	Change	Rationale
1		No changes made to this document. Version numbering updated to correspond with current Product Description Code Database.	

	Version 4.21 March 15, 2013			
	Section	Change	Rationale	
1	1	Added reference to Organ Terminology in the last paragraph of the Introduction section.	For Completeness	
2	3.1.3	Added the sentence, "Mobilized unless otherwise stated in Modifier" to the definition of HPC, APHERESIS.	Inadvertently omitted in version 4.8	
3	7.2	Added New Attribute Group: Additives	Requested by Austria	
4	7.2.1	Added New Attribute Variables: • 20-24C • <=-18C	Requested by Austria	
5	7.2.4	Added New Attribute Group: Additives Group Added Attribute Variable: Saline	Requested by Austria	
6	7.2.5	Added Attribute Variables: Allogeneic Autologous	Requested by Austria	
7	9	Added New Section for Organs	Requested by Austria	





8	9.1	Added New Organ Classes: HEART HEART LUNG INTESTINE KIDNEY, EN BLOC KIDNEY, SINGLE LIVER, SPLIT LIVER, SPLIT, LEFT LIVER, SPLIT, RIGHT LUNG, DOUBLE LUNG, LEFT LUNG, RIGHT MULTIVISCERAL PANCREAS RECONSTRUCTION TISSUE VESSELS FOR RECONSTRUCTION WHOLE LIVER	Requested by UNOS
9	9.2	Added New Attributes Groups: Anatomical Position Donor Type Intended Use Vessels	Requested by UNOS
10	9.2.1	Added Attribute Variables: Not specified Left Right	Requested by UNOS
11	9.2.2	Added Attribute Variables: Deceased Living	Requested by UNOS
12	9.2.3	Added Attribute Variables: • For transplant • For research only • For cell isolation	Requested by UNOS
13	9.2.4	Added Attribute Variables: Not Applicable or Not specified Artery, Iliac Artery, Pulmonary Vein, Iliac	Requested by UNOS
14	10	Renumbered Retired Codes Section	Due to addition of Organ Terminology





	Version 4.20 February 5, 2013			
	Section	Change	Rationale	
1	3.3.2.1	Added Irradiationgroup	Requested by the Netherlands	
2	3.3.2.2.7	Added Irradiation group and attribute variables	Requested by the Netherlands.	
3	7.1	Separated Classes section into categories: • Human Milk • Topical Products of Human Origin	Categories were separated to distinguish the types of products that are not transplanted or transfused.	
4	7.1.2	Added new Class - SERUM EYE DROPS	Requested by Austria	

Version 4.19 January 21, 2013				
	Section	Change	Rationale	
1	1	Added reference to Other Therapies in the last paragraph of the Introduction section.	For Completeness	
2	4.1.2	Updated Tendon Terminology. Soft Tissues Classes that specified right/left in the Class name were changed so that left/right arenow attributes. These changes resulted in renaming classes as well as updating certain definitions. To view a full list of changes contact the ICCBBA office.	Requested by NATTAG	





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3	4.1.2	Added new Tendon Terminology: TENDON, ACHILLES, WITH SHAPED BONE BLOCK TENDON, EXTENSOR DIGITORUM LONGUS TENDON, EXTENSOR HALLUCIS LONGUS TENDON, PATELLAR WITH PROXIMAL TIBIA TENDON, PATELLAR WITH WHOLE PATELLA AND TIBIA BONE BLOCK TENDON, PATELLAR WITH WHOLE TIBIA AND PATELLAR BONE BLOCK TENDON, PERONEUS BREVIS TENDON, PERONEUS BREVIS TENDON, QUADRICEP TENDON, QUADRICEP TENDON, QUADRICEP WITH SHAPED BONE BLOCK	Requested by NATTAG
4	7	Changed name of chapter. Renamed Milk Banking Terminology to Other Therapies.	Made more generic to support broadening the product category to include other products that are not transplanted or transfused.
5	7.2.4	Renamed Milk Banking attribute group: Nutritional Use Status is now Processing Status	Made more generic to support broadening the product category to include other products that are not transplanted or transfused.
6	7.2.5	Added new attribute group, Donor- Intended Recipient Information	Requested by the Austria





7	9.3.1	 MENISCI, LEFT MENISCI, RIGHT MENISCUS MENISCUS, LATERAL, LEFT MENISCUS, LATERAL, RIGHT MENISCUS, MEDIAL, LEFT MENISCUS, MEDIAL, RIGHT TENDON TENDON, ACHILLES, LEFT TENDON, ACHILLES, RIGHT TENDON, PATELLA, LEFT TENDON, PATELLA, RIGHT TENDON, SEMITENDINOSUS, LEFT TENDON, SEMITENDINOSUS, RIGHT TENDON, TOE EXTENSOR To view a full list of changes contact the ICCBBA office.	Requested by NATTAG
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ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions

Version Control Sheet 2012

	Version 4.18 November 19, 2012			
	Section	Change	Rationale	
1		No changes made to this document. Version numbering updated to correspond with current Product Description Code Database.		

	Version 4.17 November 16, 2012			
	Section	Change	Rationale	
1	1	Added reference to reproductive products in the last paragraph of the Introduction section.	For Completeness	
2	4.1.4	Retired tissues class OVARIAN TISSUE	Reclassified as a reproductive product	
3	8	Added new section for Reproductive terminology.	Requested by Sweden	
4	9	Renumbered Retired Code section	Due to addition of Reproductive Terminology	
5	9.2.4.1.4	Removed CD56 enriched	Determined to be a valid attribute	
6	9.3.1	Added OVARIAN TISSUE	Reclassified as a reproductive product	





	Version 4.16 October 19, 2012			
	Section	Change	Rationale	
1	1.1	At a minimum a product description will have a component class; modifiers and attributes are added as applicable.	Clarification	
1	1.1	The previous wording in this section may have suggested that a class, modifier, and attribute values were required for each product description.	Clamication	
2	2.3.1.1	New Core Conditions Added: CPD>PAS-D ACD-A>PAS-D	Requested by Austria	
3	2.3.2.2.5	New Attributes Added to the Altered Group: Supernatant removed and SD-plasma added Supernatant removed and Q-plasma added	Requested by Austria	
4	4.1.4	New Tissues Classes Added: • UMBILICAL CORD TISSUE • ADIPOSE TISSUE	Requested by Taiwan	

Version 4.15 September 2012			
	Section	Change	Rationale
1	1	Added reference to Milk in the last paragraph of the Introduction section.	For Completeness
2	2.3.2.2.7	Updated definitions for the attribute to the Preparation – Additional Information group: RT<=24h refg RT<=24h frozen<=24h	Definition now applicable to apheresis and whole blood collections.
3	3.3.2.2.2	Added new Attribute to the Manipulation group: CD56 enriched.	Requested by Singapore





4	4.1.2	Added New Tissue class: TENDON, SEMITENDINOSUS/GRACILIS	Requested by Scotland
5	4.1.4	Added New Tissue class: PLACENTA PLACENTA WITH UMBILICAL CORD PLACENTA WITH UMBILICAL CORD AND FETAL MEMBRANES FETAL MEMBRANES OVARIAN TISSUE PARATHYROID GLANDS	Requested by Austria
6	7	Added new section for Milk Banking terminology.	Requested by Scotland
7	8	Renumbered Retired Code section	Due to addition of Milk Banking Terminology

	Version 4.14 August 2012			
	Section	Change	Rationale	
1	2.3.1.1	Added definitions for new core conditions: AS7 (Additive Solution 7) CPD (Citrate Phosphate Dextrose – Additive Solution 7)	Requested by the US	
2	2.3.2.2.7	Added new attribute to the Preparation – Additional Information group: RT<=24h refg RT<=24h frozen<=24h	Requested by the US	
3	4.1.2	Added new Tissue class FASCIA LATA	Requested by Denmark	
4	4.3.2.2.4	Added new attribute to the Type of Preservation group, Solvent dehydrated	Requested by Denmark	





Version 4.13 July 2012			
	Section	Change	Rationale
1	1	Add the following statement to the Introduction section of the Standard Terminology document: "All references to biologic materials in this document are of human origin unless specifically stated otherwise."	For Clarification
2	1	Added reference to ocular tissues in the last paragraph of the Introduction section.	For Completeness
3	2.3.2.1	 Added new Donor Exposure attribute group. Revised definition of dosage attribute group. 	Proposal 12-003
4	2.3.2.2.10	 Changed verbiage in Dosage group. Term 'donors' changed to 'units' Note added at the end of the Dosage attribute group section. 	Proposal 11-007
5	2.3.2.2.14	 Added the following Donor Exposure attributes: Default: No information From multiple donors, number not specified – Pool prepared from multiples donors. The number of donors is not specified. From 2 donors – Pool prepared from products from 2 donors. From 3 donors – Pool prepared from products from 3 donors. From 4 donors – Pool prepared from products from 4 donors. From 5 donors – Pool prepared from products from 5 donors. 	Proposal 12-003
6	3.1.3	Added the following cellular therapy class names: NC-MSC ATD NC-MSC DPD NC-MSC WJD	Requested by Taiwan
7	3.3.2.2.5	Added new variable in the Other Additives attribute group: Other Additives:Yes incl animal src	Requested by Taiwan





8	4.1.1	Added the following Tissue class names COMMON ILIAC ARTERY FEMORAL ARTERY VENA CAVA INFERIOR	Requested by Austria
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	Version 4.12 June 2012			
	Section	Change	Rationale	
1	2.3.2.2.4	Replaced "log" with "E" in exponential expressions.	Proposal 11-001	
2	2.3.2.2.10	Replaced "log" with "E" in exponential expressions.	Proposal 11-001	
3	3.3.2.2.3	Reworded definition of 6% HES + 5% DMSO.	To provide clarification on the reagents present by percent	
4	3.3.2.2.3	Added NS HES + 5% DMSO	Requested by CTCLAG	
5	4.1.3	Added new Skin Terminology: DERMIS; SKIN, FULL; SKIN, SPLIT	Requested by ETTAG and NATTAG	
6	4.2.1	Added note about modifiers for Tissues	As part of an overall process to simplify coding, tissue Product Descriptions are being restructured to discontinue use of Modifiers.	
7	4.3.2.1	 Renamed Usage group to Processing Status Added new attribute groups: Storage Solution, Meshed, Donor- Intended Recipient Relationship 	Requested by ETTAG and NATTAG	
8	4.3.2.1	Updated Anatomical Position description	Consistency with Ocular terminology	
9	4.3.2.2	Attribute Variable groups renumbered.	Section reorganized to match organization of Product Description Code Database.	
10	4.3.2.2.1	Added Donor-Intended Recipient Relationship group	Requested by ETTAG and NATTAG	
11	4.3.2.2.2	Added Meshed group	Requested by ETTAG and NATTAG	





12	4.3.2.2.3	Added Storage Solution group	Requested by ETTAG and NATTAG
13	4.3.2.2.4	Added new terms to Type of Preservation group: Cryopreserved, Freeze dried, Glycerol (high conc), Refrigerated	Requested by ETTAG and NATTAG
14	4.3.2.2.5	Updated definitions in Processed to Reduce Cellular Components group by adding the word "intended"	ETTAG requested to acknowledge that sometimes cellular components may be reduced in processes that are not primarily performed for this purpose.
15	4.3.2.2.6	Added clarification to the definitions in the Anatomical Position group.	Consistency with Ocular terminology
16	4.3.3.2.7	Renamed Usage group to Processing Status group.	Requested by ETTAG and NATTAG
17	4.3.2.2.9	Added new terms to Pathogen Reduction group: Antibiotics, Combined process	Requested by ETTAG and NATTAG
18	4.3.2.2.9	 Updated definition of ETO to indicate the method of sterilization is validated Updated definition of Peracetic acid to indicate the method of sterilization is validated 	Requested by ETTAG.
19	5	Added new section for Ocular terminology	Requested by EBTAG
20	6	Renumbered Plasma Derivative section	Due to addition of Ocular terminology by EBTAG
21	7	Renumbered Retired Codes section	Due to addition of Ocular terminology by EBTAG
22	7.3	Retired Tissue terminology: EYE,LEFT EYE, RIGHT	New terminology developed for Ocular tissue.
23	7.3	Retired Tissue terminology from skin bounded list SKIN SKIN, LARGE SKIN, SMALL	New terminology developed for Skin tissue.





	Version 4.11 May 2012				
	Section	Change	Rationale		
1		No changes made to this document. Version numbering updated to correspond with current Product Description Code Database.			

	Version 4.10 April 2012				
	Section	Change	Rationale		
1	2.3.1.1	Added ACD-A-HES	Requested by The Netherlands		
2	3.3.2.2.2	Added Filtered	Requested by The Netherlands		
3	3.3.2.2.2	Added CD4 enriched	Requested by The Netherlands		

Version 4.9 March 2012			
	Section	Change	Rationale
1	3.3.2.2.2	Added Alpha Beta T/B cell reduced	Requested by The Netherlands
2	4.1.2	Added: CORTICAL BONE, GROUND, PASTE CORTICAL BONE, GROUND, PUTTY	Requested by the UK
3	4.1.4	Added SKIN, FULL WITH HYPODERMIS	Requested by the UK
4	4.3.2.1	Renamed the Sterilization attribute group to Pathogen Reduction and updated its description to include decontamination of the product.	Requested by ETTAG
5	4.3.2.1	Added new attribute groups: Processed to Reduce Cellular Components Type of Preservation	Requested by ETTAG





6	4.3.2.2.2	 Renamed the Sterilization attribute group. Changed the attribute group default to "Not specified" and updated the definition. Renamed the Irradiated attribute to "Radiation sterilization" and updated the definition. Added attributes: No pathogen reduction, Pathogen reduced: Method NS. 	Requested by ETTAG
7	4.3.2.2.6	Added this new section for the new attribute group and variables.	Requested by ETTAG
8	4.3.2.2.7	Added this new section for the new attribute group and variables.	Requested by ETTAG

Version 4.8 February 2012			
	Section	Change	Rationale
1	3.1.2	Added this section on the Meaning of "TC"	To provide clarification on the intended use of TC products and specify the terminology is not meant to convey actual therapeutic benefits.
2	3.1.3	Reworded the definitions of TC products to emphasize that the product is intended for therapeutic use.	To provide clarification on the intended use of TC products.

	Version 4.7 January 2012			
	Section	Change	Rationale	
1	2.3.1.1	Added ACD-B>MAP	Inadvertent omission	
2	2.3.1.1	Removed CP2DA and added it to section 6.1.2.1 for retired blood core conditions	Invalid anticoagulant	
3	2.3.1.1	Added ACD-A>SAGM	Requested by Canada	
4	3.1.1	Added PANCREATIC ISLET RINSE SOLUTION	Requested by Scotland	





5	Appendix A	Removed the explanation on the way PAS terminology is reflected in the ISBT 128 Product Description Code Database	This explanation served to help transition into the new terminology. The Generic PAS nomenclature has been fully adopted.
6	•	Added a "Common Name" column to the various tables.	To help users relate the sometimes abbreviated terms used in the ISBT 128 Product Description Code Database with a more familiar term.





ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions

Version Control Sheet 2011

	Version 4.6 December 2011			
	Section	Change	Rationale	
1	2.3.2.2.12	Added Hematocrit 0.7-0.8	Requested by Canada	
2	3.1.1	Added NC, TUMOR CELLS	Requested by the US	
3	3.1.1	Added TC, PANCREATIC ISLETS	Requested by Scotland	
4	3.1.1	Rearranged the order of class names by Category 1 and Category 2 product types	Improve organization	
5	4.1.2	Added the following class names: TENDON, QUADRICEPS, WITH BONE BLOCK TENDON, GRACILIS LIGAMENT, MEDIAL COLLATERAL, WITH BONE BLOCKS MENISCUS, MEDIAL, WITH TIBIA PLATEAU MENISCUS, LATERAL, WITH TIBIA PLATEAU LIGAMENT, ANTERIOR CRUCIATE, WITH BONE BLOCKS LIGAMENT, POSTERIOR CRUCIATE, WITH BONE BLOCKS TENDON, BICEPS FEMORIS, WITH BONE BLOCK TENDON, TIBIALIS ANTERIOR, WITH BONE BLOCK TENDON, TIBIALIS POSTERIOR, WITH BONE BLOCK TENDON, FLEXOR HALLUCIS LONGUS TENDON, FLEXOR DIGITORUM LONGUS TENDON, PERONEUS LONGUS WITH BONE BLOCK TENDON, PERONEUS LONGUS WITH BONE BLOCK	Requested by Denmark	





	Version 4.5 November 2011				
	Section	Change	Rationale		
1	2.3.2.2.5	Added Supernat rem/Albumin added	Requested by Canada		
2	5	Changed the title of the section to Plasma Derivatives and added an introduction.	Clarification		

	Version 4.4 October 2011				
	Section	Change	Rationale		
1	4.1.2	Added TENDON, PATELLA, WHOLE, WITH EXTENSOR	Requested by the UK		

	Version 4.3 September 2011			
	Section	Change	Rationale	
1	4.1.2	Added FEMORAL HEAD, QUARTER	Requested by Canada	
2	4.3.2.2.3	Updated definition of Pack	Added clarification to differentiate the definition of Pack from the new attributes added to the Unit of Issue group.	
3	4.3.2.2.3	Added attributes Pack2 and Pack4	Requested by Canada	
4	Appendix	Updated Reference	Corrected citation	

	Version 4.2 August 2011				
	Section	Change	Rationale		
1		Added John Armitage and Leigh Sims-	Updated to reflect		
	Committee	Poston.	current status		
		Removed Deirdre Fehily.			





		Updated credentials for Diane Wilson	
2	Warranty /	Added a paragraph further describing	Clarification
	Liability	role and responsibilities.	
3	4.1, 4.1.1,	Reorganized the table of tissue classes	Helpful in locating a
	4.1.2,	and separated the classes into 5 broad	particular class name
	4.1.3,	categories in their own section:	
	4.1.4,	Cardio/Vascular, Musculo/Skeletal,	
	4.1.5	Ocular, Skin, Other	
4	4.1.2	Added MENISCUS LATERAL and	Requested by Canada
		MENISCUS MEDIAL	

Version 4.1 July 2011					
	Section	Change	Rationale		
1		No changes made to this document. Version numbering updated to correspond with current Product			
		Description Code Database.			

Version 4.0 June 2011					
	Section	Change	Rationale		
1		No changes made.	No changes made.		

Version 4.0 May 2011					
	Section	Change	Rationale		
1		No changes made.	No changes made.		

Version 4.0 April 2011					
	Section	Change	Rationale		
1		No changes made.	No changes made.		





	Version 4.0 March 2011			
	Section	Change	Rationale	
1		No changes made.	Version number updated for consistency with the Product Description Code Database version	

Version 3.46 February 2011			
	Section	Change	Rationale
1	2.2.1	Added Lyophilized modifier	Requested by the US
2	2.2.1	Added Reconstituted modifier	Requested by the US
3	3.1.1	Added TC-MSC MD class	Requested by the US





ISBT 128 Standard Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions (previously called Product Coding: Bounded Lists and Definitions)

Version Control Sheet

	Section	Change	Rationale
		Version 3.45 December 20)10
1		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
		Version 3.44 November 20)10
1	2.2.1	Added "Washed Thawed" and	Requested by Poland
		"Washed Thawed Apheresis"	·
		modifiers	
2	4.1.1	Added a "TIBIA SHAFT" tissue	Requested by Canada
		class	
		Version 3.43 October 201	10
1	2.3.1	Added PAS-F	Requested by vendor
	•	Version 3.42 September 3,	2010
1		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
		Version 3.41 September 1, 2	2010
1	4.1.1	Added the following class	Requested by Canada
		names: TENDON, TIBIALIS,	
		ANTERIOR; TENDON,	
		TIBIALIS, POSTERIOR; TIBIA;	
		HUMERUS; HUMERUS	
		DISTAL; HUMERUS	
		PROXIMAL; TENDON	
		PLANTARIS; ANKLE; RIB;	
		FIBULA; HAMSTRING;	
		CORTICOCANCELLOUS	
		BONE, CRUSHED;	
		CORTICOCANCELLOUS	
		BONE, GROUND;	
	1001	SAPHENOUS VEIN	
2	4.3.2.1	Added an attribute group for	Better managed as an





		Anatomical Position	attribute		
3	4.3.2.2.5	Added Anatomical Position	Better managed as an		
		attribute group variables	attribute		
		Version 3.40 August 201	0		
1		No changes made to this			
		document. Numbering			
		updated to correspond with			
		current Product Code			
		Description database.			
1	2244	Version 3.39 July 2010			
1	2.3.1.1	Added descriptions in the table of volumes	Clarity		
		Version 3.38 June 2010			
1	3.1.1	Added NC, ADIPOSE CELLS	Requested by CTCLAG		
2	3.1.1	Added NC, MENSTRUAL BLOOD	Requested by CTCLAG		
	ı	Version 3.37 May 2010			
1	2.1.1	Removed LYMPHOCYTES	Retired these terms for the		
		and MONOCYTES from the	labeling of blood products.		
		Class table	These products will be		
			classified as cellular therapy		
			products.		
2	4.1	Added a "TISSUE" class	Requested by NATTAG		
3	6.1.1	Added LYMPHOCYTES and	Retired these terms for the		
		MONOCYTES to the retired blood Class table	labeling of blood products.		
		blood Class table	These products will be classified as cellular therapy		
			products.		
Version 3.36 April 2010					
1	4.3.2.1	Rearranged the group names	Consistency		
		so they are listed in the same			
		order as they appear in the			
		Attribute table of the Product			
	504	Code Database.			
2	5.2.1	Added a "Thawed" modifier	Requested by Sweden		
3	5.3.1.1	Added a "refg" storage	Requested by Sweden		
		temperature			
	224	Version 3.35 March 201			
1	2.3.1	Added a table of the renamed platelet additive solutions with	PASs have non-standard terminology. Two solutions		
		standard <i>ISBT 128</i> terminology	with basically the same		
		and defined them based on	ingredients may be called by		
		their key ingredients.	different names by different		
			companies. Therefore, ISBT		
			128 defines platelet additive		
			solutions in terms of their key		





			ingredients.
2	2.3.1.1	Added extra examples to the	To provide a better global
		unbounded list of volumes and	representation.
		temperatures.	
3	2.3.2.2.12	Added new attribute of 0.4-0.5	Requested by Hong Kong
		to the Hematocrit attribute	
		group.	
4	Appendix A	Relocated the table of platelet	Incorporated this information
		additive solutions.	into section 2.3.1
	_	Version 3.34 February 20	
1	3.3.2.2.3	Added NS DMSO	Requested by Canada
		cryoprotectant attribute	
2	3.3.2.2.3	Revised definitions to describe	Clarity
		DMSO concentration of the	
		actual product, not just the	
		frozen product	
	0.0.1	Version 3.33 January 20	
1	3.2.1	Added Pooled, Single Donor	Requested by the US
		Thawed Washed	
	0.04	Version 3.32 December 20	
1	2.3.1	Added a note in reference to	To provide explanation to new
0	0.044	Appendix A	PAS naming convention
2	2.3.1.1	Defined PASIIIMgK in terms of	To provide greater clarity
3	2.3.1.1	its ingredients. Added PAS-E.	Paguastad by Palgium
4	2.3.1.1		Requested by Belgium.
4	2.3.1.1	Changed wording of definitions from, "The Plasma was frozen	To give greater flexibility for
		within" to "The Plasma was	different practices worldwide.
		placed in the freezer within"	
5	Appendix A	Added Appendix A to the end	To provide explanation to new
3	Appendix A	of the document.	PAS naming convention
	1	Version 3.31 October 200	
1		No changes made to this	
'		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
		Version 3.30 September 2	009
1	Throughout	Alphabetized lists of classes,	Ease in search
•	document	modifiers, and attributes	
2	2.3.2.1	Removed the Platelet Count	Attribute group retired
		Attribute Group]
3	6.1.2.3	Added Platelet Count Attribute	Attribute group retired
		Group	
4	2.3.2.2.1	Revised definition for "Not for	Clarification
		tx or mnf" attribute	
	•		





		Version 3.29 August 200	9
1	3.2.1	Added new modifier combination and definition for Cryopreserved Non-Mobilized	Requested by Sweden. Inadvertent omission in the February 2009 version control.
2	3.2.1	Added new modifier combination and definition for Thawed Washed Non-Mobilized	Requested by Sweden. Inadvertent omission in the February 2009 version control.
		Version 3.28 July 2009	
1	2.3.1.1	Removed reference to Composol for PASIIIMgK	Inappropriate use of commercial name
		Version 3.27 June 2009	
1		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
		Version 3.26 May 2009	
1	2.3.1.1	Added new anticoagulant of CPD-50>SAGM.	Requested by Canada
		Version 3.25 April 2009	
1	3.3.2.2.3	Added new attribute of 7.5% DMSO.	Requested by the US. This attribute was added to the database as part of version 3.18 in September 2008 but was inadvertently omitted from the Standard Terminology document.
	•	Version 3.24 March 200	
1		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
		Version 3.23 February 20	
1	3.3.2.2.3	Removed "DMSO reduced" from the Cryoprotectant attribute group	The Thawed Washed modifier includes DMSO reduction. The two terms describe the same process.
2	6.2.3.3.6	Added a retired table for the Cryoprotectant attribute group with the "DMSO reduced" attribute	Retired cellular therapy attribute
	1	Version 3.22 January 200	
1	3.1.1	Revised the definition for TC-	This name should not be used





		INV	for a product that is part of a
2	3.1.1	Added new Class and definition for TC-BLINDED	blinded comparison study. Requested by CTCLAG
		STUDY	
	1	Version 3.21 December 2	008
1		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
4		Version 3.20 November 2	
1	3.1.1	Changed the Class name from TC-Tumor Derived to TC, Tumor Derived	TC, Tumor may be a collected product. A hyphen always indicates a final product, but a comma may either be a collection product or a final product.
2	3.1.1	Added new Class and definition for TC-TIL	Requested by CTCLAG
3	3.3.2.2.1	Revised the definitions for the Intended Use Group attribute variables	Clarity; products collected as "not for administration" may be further processed into non- transfusable products.
	1	Version 3.19 October 20	
1	3.3.2.2.2	Added Monocytes enriched	Requested by Austria
	I	Version 3.18 September 2	·
1	Pg. 2	Added copyright message	
2	2.3.1	Omitted the text explanation for NS, None, and XX as part of the core conditions definitions	Duplication with the core conditions table
3	2.3.1.1	Revised definition of "XX" in the core conditions volume table	Clarity
4	2.3.1.1	Revised the definitions for "rt" and "20 – 24 C" in the core conditions temperature table	Clarity
5	2.3.1.1	Revised the definition for "None" in the core conditions anticoagulant table	Clarity
6	6.1.2.1	Retired the use of None/NS/<=-18C, None/NS/rt, and DMSO/NS/<-80C core conditions	Discontinued the use of "NS" to specify blood collection volume. The revised definition of XX will allow it to be used in place of "NS".





		Version 3.17 August 200	08
1		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
		Version 3.16 July 2008	
1	2.3.1.1	Added CPD>AS3	At the request of the US
2	2.3.1.1	Added CPD>SAGM	At the request of Canada.
			Previous codes for SAGM do
			not include the anticoagulant,
			which is required in Canada
		Version 3.15 June 2008	3
1	3.1.2	Added standardized	These terms are commonly
		abbreviations	abbreviated in documents and
			standardization is desirable.
2	6.2.3.1	Deleted alb, HES, NaCitrate,	These terms only appeared in
		Plasma and SSPP from Core	conjunction with other terms.
		Conditions retired codes	The combinations are already
			on the list.
3	6.2.3.3.2	Indicated 6% HES + 5%	Clarity
		DMSO and 10% DMSO have	
		been moved to the	
		Cryoprotectant group.	
4	6.2.3.3.4	Added From Buffy Coat,	Inadvertently omitted.
		Density Enriched, and CD56	
		enriched	
		Version 3.14 May 2008	I = 1
Title	Title	Title of document has been	To better describe the
		changed to Standard	purpose of the document.
		Terminology for Blood, Cellular	
		Therapy, and Tissue Product	
1	1	Descriptions Changed title of chapter	To better describe the
l	'	Changed title of chapter	
2	1	Dowarded chapter	introductory nature of chapter To better describe how
	'	Reworded chapter	
			product descriptions are created within the ISBT 128
			Standard
3		Deleted information indicating	These terms now appear in
		that some terms found in the	the chapter on retired codes
		database do not appear in this	
		in this document	
4	2.3.2.2.5	Added Complement	At the request of Sweden
		inactivated	,
5	2.3.2.2.7	Added Frozen <=26h	At the request of Austria





6	3.1	Explained the categories of Cellular Therapy classes	Improve clarity
7	6.2.1	Deleted TC, Whole Blood	Error correction. This code is
	00000	D 1 (100/11/EQ	not retired.
8	6.2.3.3.2	Deleted 6%HES + 5% DMSO and 10% DMSO	Error correction. These codes are not retired.
		Version 3.13 March 2008	3
1	2.1.1	Added POOLED FRESH	Per the request of Spain
		FROZEN PLASMA as a	The state of the s
		product class	
2	3	Indicated information about	Retired code definitions are
_		"retired codes" could be found	now included in this document
		in Chapter 6 as well as in the	new meladed in this decament
		Transition document	
3	5	Added a chapter on retired	A mechanism to retire codes
		codes.	(maintain them in the
		Codes.	database for backwards
			compatibility but recommend
			against their use for new
			products) was established.
		Version 3.12 February 20	
1	1	Reworded	To add clarity and to include
'	'	Neworded	Derivatives
2	4.1.1	Added TENDON, PATELLA,	Per request of the UK
	4.1.1	WHOLE, SHAPED	Tel request of the ort
3	5	Added Chapter 5, Derivatives	Per request of Finland
		Version 3.11, January 200	· ·
1	2.3.2.2.11	Added Riboflavin-treated	Per request of US
'	2.3.2.2.11		-
4	0044	Version 3.10, December 20	
1	2.3.1.1	Added PASIIIMgK	Per request of Spain
	T	Version 3.9, November 20	
1	2.3.2.2.9	Added Quar:>=90d/retested	Per request of Spain
		Version 3.8, October 200	7
1		No changes were made to this	
		document. The numbering	
		was updated to correspond	
		with current Product Code	
		Description database.	
		Version 3.7, August 200	7
1	1	Indicated requests for new	Clarified the process
		product codes should be	
		submitted via an on-line	
		request form. Indicated where	
		instructions for product codes	
		requests may be found,	
		Explained why some codes	





		Te 11 (1 1 ()	<u></u>
		found in the database are not	
		present in the Product Coding	
		Bounded Lists and Definitions	
		document.	
2	2.3.2.2.1	Reworded definition for "For	Clarity and consistency
		mnf: non-injectable restr use	
3	2.3.2.2.1	Added attribute for "For mnf:	Request of the US
		injectable restr use	
4	4.1.2	Redefined the following Class	More accurate definitions
		terms:	
		Pericardial Patch	
		Aortic Arch	
		Aortic Patch	
		Cardiovascular Non-Valved	
		Conduit	
		Meniscus	
		Meniscus, Left	
		Meniscus, Right	
		Tendon, Patella, Left	
		• Tendon, Patella, Right	
		• Tibia, Proximal, Left	
		• Tibia, Proximal, Right	
5	4.1.2	Redefined the Modifier	More accurate definition
	7.1.2	Cleaned Frozen	Word accurate definition
6	4.1.2	Changed Class names (from	More accurate descriptions
		→to) and re-alphabetized:	Note: Names which appear as
		Acellular Pericardial Patch	label text may be nationally
		→ Pericardial Patch	defined. Therefore, changes in
		Cancellous Bone Knee Slice	names to the database do not
		→ Cancellous Femoral	have to affect the name printed
		Knee Slice	on the label. However,
		Cardiovascular Non-Valved	consideration should be given to using the more accurate terms
		Conduits → Aortic Non-	for products labeled in the future.
		Valved Conduit	
		Cortical Bone Ring →	
		Cortical Femoral Bone	
		Ring	
		Cortical Strip → Cortical	
		Femoral Bone Strip	
		Cortico-Cancellous Bone	
		Ring → Cortico-Cancellous	
		Femoral Bone Ring	
		Cortico-Cancellous Bone	
		Strip → Cortico-Cancellous	
		July / Collido Califolious	
		Femoral Rone Strin	
		Femoral Bone Strip • Whole Meniscus → Menisci	





	T		
		 Meniscus, Whole, Left → Menisci, Left Meniscus, Whole, Right → Menisci, Right Tendon, Semitendinosis → Tendon, Semitendinosus 	
7	4.1.2	Deleted Pericarium Pool	While term will be retained in the database for backward compatibility, it should not be selected for new products
8	4.1.2	Added Tendon, Semitendinosus, Left and Tendon Semitendinosis, Right	Inadvertently omitted from this document.
9	4.1.2	Added class: Cancellous Tibial Knee Slice	Per request of Poland and the UK
10	4.2.1	Added modifier: Cleaned Frozen Acellular	Per request of Poland and the UK
11	4.3.2.2.2	Added definition for Paracetic Acid	Completeness
	<u> </u>	Version 3.6, July 2007	
1	3.2.2.4	Deleted "Not Specified" as the default value. Made "No third party component added" the default value.	The default value should be the most common condition. "Not specified" is not the most common condition.
2	3.2.2.5	Deleted "Not Specified" as the default value. Made "No additives other than as part of the anticoagulant solution at the time of collection" the default value.	The default value should be the most common condition. "Not specified" is not the most common condition.
3	3.2.2.6	Deleted "Not specified" as the default value. Made "Not genetically modified" the default value.	The default value should be the most common condition. "Not specified" is not the most common condition.
		Version 3.5, June 2007	
1	3.1	Redefined class terms: • HPC, APHERESIS • HPC, CORD • HPC, MARROW • HPC, WHOLE BLOOD • TC, APHERESIS	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.





		CONCURRENT PLASMA, APHERESIS TO APHERESIS	
2	3.1	• TC, APHERESIS Changed HPC, CORD to HPC,	More precise term.
_	U	CORD BLOOD	
3	3.1	Retired Class terms (these codes should not be assigned to NEW products but are maintained for backward compatibility): • T CELLS • T CELLS, APHERESIS • LYMPHOCYTES, APHERESIS • POOLED, HPC, APHERESIS • MNC, APHERESIS • TC-T • TC-CTL, APHERESIS • TC-T, WHOLE BLOOD • TC-T, WHOLE BLOOD • TC-CTL, WHOLE BLOOD • TC-DC, MARROW • TC-DC, CORD	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
4	3.1	Added Class terms: • TC, MARROW • TC, WHOLE BLOOD • TC, CORD BLOOD • TC-T CELLS • TC-CTL • TC-T REG CELLS • TC-DC • TC-NK CELLS • TC-TUMOR DERIVED • TC-MSC • TC-APC • TC-INV	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG).
5	3.2.1	Redefined Modifier terms:	Per the Cellular Therapy
		CryopreservedThawedHeparinizedWashed	Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
6	3.2.1	Retired modifiers term: Frozen	Was redundant with Cryopreserved
7	3.2.1	Added Modifier terms:	Per the Cellular Therapy





		- Mahili-ad	Coding and Labeling Advisor:
		 Mobilized Non-mobilized Pooled, Single Donor Thawed Washed 	Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document
		• mawed washed	_
8	3.3.1.1	Retired anticoagulants (these codes should not be assigned to NEW products but are maintained for backward compatibility): • ACD-A • ACD-A+10% DMSO • ACD-A+Heparin • ACD-A + Heparin+6% HES • ACD-A + Heparin+6% HES • 10% DMSO • Alb • CPD • CPD+Heparain • CPDA-1 • CPDA-1 + DMSO • CPDA-1+10% DMSO+30% SSPP+10% plasma • CPDA-1+10% DMSO+0.8% HES+1% dextran • DMSO • HES • HES-DMSO • NaCitrate • PBS	for rationale. Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
		• PBS + alb + 4% NaCitrate	
		Plasma SSPP	
9	3.3.1.1	Redefined anticoagulant terms: • Heparin • None • Not specified	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
10	3.3.1.1	Added anticoagulants:	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
11	3.3.1.1	Redefined storage	Per the Cellular Therapy
	1	1	T-7





		tomporatures:	Coding and Labeling Advisor:
		temperatures: • rt	Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
12	3.3.1.1	Added Storage Temperature:	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
13	3.3.2.1	Retired Attribute groups (these codes should not be assigned to NEW products but are maintained for backward compatibility): • System Integrity • Preparation: Additional Information • Final Product: Additional Information • Further Processing	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
14	3.3.2.1	Redefined Attribute group term: • Manipulation	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
15	3.3.2.1	Added Attribute groups: Preparation: Cryoprotectant Preparation: Blood component from third party donor Preparation: Additional additives Genetically modified	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
16	3.3.3.1 (Version 3.5: 3.3.2.2.1)	Reworded variables in Intended Use group: • Changed "For Transfusion" to "For Administration" • Changed "Not for tx" to "Not for administration or further processing"	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
17	3.3.3.1 (Version 3.5: 3.3.2.2.1)	Added a variable to the Intended Use group: • For further processing	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product





			Coding Transition Document for rationale.
18	3.3.3.2	Retired variables from the System Integrity Attribute group (these codes should not be assigned to NEW products but are maintained for backward compatibility):	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
19	3.3.3.3	Retired variables from the Preparation: Additional Information Attribute group (these codes should not be assigned to NEW products but are maintained for backward compatibility):	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
20	3.3.3.4	Retired variables from the Final Product: Additional Information Attribute group (these codes should not be assigned to NEW products but are maintained for backward compatibility):	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
21	3.3.3.5 (Version 3.5: 3.3.2.2.2)	Retired variable terms from Manipulation Attribute group (these codes should not be assigned to NEW products but are maintained for backward compatibility): • Minimal • Extensive • CD8-depleted • CD34-removed • AC133-selected • From buffy coat • T-Cells depleted	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
22	3.3.3.5 (Version 3.5: 3.3.2.2.2)	Redefined variable terms from Manipulation Attribute group: • CD34-enriched • PUV-treated • Buffy coat enriched • RBC-reduced	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
23	3.3.3.5 (Version 3.5: 3.3.2.2.2)	Added variables to the Manipulation Attribute group: • Diluted • Plasma reduced • Mononuclear cells enriched	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.





			,
		 T-cell reduced B-cell reduced T/B-cell reduced CD8 reduced CD34 enriched CD133 enriched Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale. Tumor cells reduced Cultured 	
24	3.3.3.6	Retired variable terms from Further Processing Attribute group (these codes should not be assigned to NEW products but are maintained for backward compatibility) • Default: No further processing • Volume DMSO reduced	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
25	Version 3.5: 3.3.2.2.3	Added variable terms to Cryoprotectant group: • 6% HES + 5% DMSO • 10% DMSO • 5% DMSO • DMSO reduced	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
26	Version 3.5: 3.3.2.2.4	Added variable terms to Preparation: Blood component from third party donor group • Default: Not Specified • 3 rd Party Component: No • 3 rd party Component: Yes	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
27	Version 3.5: 3.3.2.2.5	Added variable terms to Preparation: Other Additives group Default: Not specified Other additives: No Other additives: yes	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document for rationale.
28	Version 3.5: 3.3.2.2.6	Added variable terms to Genetically Modified Group Default: Genetic modification not specified Genetically modified: No	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See Cellular Therapy Product Coding Transition Document





		Genetically modified: Yes	for rationale.
	1	Version 3.4, May 2007	
1	2.3.3.10	Added 10 donor pool to	Per request of the US
		Dosage: Additional	·
		Information Group	
2	4.1	Added Calcar Femorale	Per request of Denmark
		Version 3.3, April 2007	
		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
		Version 3.2, March 2007	7
1	2.3.1.1	Added NaCitrate—HES—	Per request of the US
		ACD-A	
		Version 3.1.x, February 20	
1	2.3.1	Updated reference in note to	Update
		current edition of Mollison's	
		Blood Transfusion in Clinical	
		Medicine	
2	2.3.1.1	Added MAP as an additive;	Per request of China;
		corrected spelling of "hydroxyl"	typographical error
3	2.3.3.14	Added definition of default for	Inadvertent omission
	0004	monitoring	5 (0):
4	2.3.3.4	Added ResLeu:<2.5log6	Per request of China
5	2.3.3.6	Added 25 mL and 50 mL	Per request of China
6 7	2.3.3.7	corrected spelling of "hydroxyl"	Typographical error
	3.3.1.1	Added definition for "XX"	Inadvertent omission
8	3.3.3.1	Corrected spelling of citrate	Typographical error
	1	Version 3.0, January 200	<i> </i>
		No changes made to this document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database. Version 2.18, December 20	
		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database.	
	I	Version 2.17, November 20	006
		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
	1	·	1





		Description database.	
	•	Version 2.16, September 2	006
	4.1	Revised or added definitions	
		for Costal Cartilage,	
		Osteochondral, bone and	
		tendon.	
		Version 2.15, August 200	06
	2.3.3.5	Added Plasma	Per request of the US
		Reduced/Plasma added	
	2.3.3.6	Change MI to mL	Typographical error
		Version 2.14, July 2006	
1	4.1	Added AORTIC PATCH	Per request of the UK
2	4.1	Added PULMONARY PATCH	Per request of the UK
3	4.1	Alphabetized classes	Ease of use
		Version 2.13, June 2006	6
		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database	
	1	Version 2.12, April 2006	
		No changes made to this	
		document. Numbering	
		updated to correspond with	
		current Product Code	
		Description database	