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 3.29 August 2009**
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 2009**
1		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
**Version 3.23 February 2009**
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	Retired cellular therapy attribute

		with the "DMSO reduced" attribute	
**Version 3.22 January 2009**
1	3.1.1	Revised the definition for TC-INV	This name should not be used for a product that is part of a blinded comparison study.
2	3.1.1	Added new Class and definition for TC-BLINDED STUDY	Requested by CTCLAG
**Version 3.21 December 2008**
1		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
**Version 3.20 November 2008**
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.
**Version 3.19 October 2008**
1	3.3.2.2.2	Added Monocytes enriched	Requested by Austria
**Version 3.18 September 2008**
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 2008	
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	
1	3.1.2	Added standardized abbreviations	These terms are commonly abbreviated in documents and standardization is desirable.
2	6.2.3.1	Deleted alb, HES, NaCitrate, Plasma and SSPP from Core Conditions retired codes	These terms only appeared in conjunction with other terms. The combinations are already on the list.
3	6.2.3.3.2	Indicated 6% HES + 5% DMSO and 10% DMSO have been moved to the Cryoprotectant group.	Clarity
4	6.2.3.3.4	Added From Buffy Coat, Density Enriched, and CD56 enriched	Inadvertently omitted.
		Version 3.14 May 2008	
Title	Title	Title of document has been changed to Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions	To better describe the purpose of the document.
1	1	Changed title of chapter	To better describe the introductory nature of chapter
2	1	Reworded chapter	To better describe how product descriptions are created within the ISBT 128 Standard
3		Deleted information indicating that some terms found in the database do not appear in this in this document	These terms now appear in the chapter on retired codes
4	2.3.2.2.5	Added Complement inactivated	At the request of Sweden
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 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			
1	2.1.1	Added POOLED FRESH FROZEN PLASMA as a product class	Per the request of Spain
2	3	Indicated information about "retired codes" could be found in Chapter 6 as well as in the Transition document	Retired code definitions are now included in this document
3	5	Added a chapter on retired codes.	A mechanism to retire codes (maintain them in the database for backwards compatibility but recommend against their use for new products) was established.
Version 3.12 February 2008			
1	1	Reworded	To add clarity and to include Derivatives
2	4.1.1	Added TENDON, PATELLA, WHOLE, SHAPED	Per request of the UK
3	5	Added Chapter 5, Derivatives	Per request of Finland
Version 3.11, January 2008			
1	2.3.2.2.11	Added Riboflavin-treated	Per request of US
Version 3.10, December 2007			
1	2.3.1.1	Added PASIIIMgK	Per request of Spain
Version 3.9, November 2007			
1	2.3.2.2.9	Added Quar:>=90d/retested	Per request of Spain
Version 3.8, October 2007			
1		No changes were made to this document. The numbering was updated to correspond with current Product Code Description database.	
Version 3.7, August 2007			
1	1	Indicated requests for new 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 found in the database are not present in the Product Coding Bounded Lists and Definitions document.	Clarified the process
2	2.3.2.2.1	Reworded definition for "For mnf: non-injectable restr use	Clarity and consistency
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 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	More accurate definitions
5	4.1.2	Redefined the Modifier Cleaned Frozen	More accurate definition
6	4.1.2	Changed Class names (from →to) and re-alphabetized: • Acellular Pericardial Patch → Pericardial Patch • Cancellous Bone Knee Slice → Cancellous Femoral Knee Slice • Cardiovascular Non-Valved Conduits → Aortic Non-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 Femoral Bone Strip • Whole Meniscus → Menisci • Meniscus, Whole, Left → Menisci, Left • Meniscus, Whole, Right → Menisci, Right • Tendon, Semitendinosis → Tendon, Semitendinosus	More accurate descriptions *Note: Names which appear as label text may be nationally defined. Therefore, changes in names to the database do not have to affect the name printed on the label. However, consideration should be given to using the more accurate terms for products labeled in the future.*
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
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 • CONCURRENT PLASMA, APHERESIS • TC, APHERESIS	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.
2	3.1	Changed HPC, CORD to HPC, CORD BLOOD	More precise term.
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	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.

		• TC-CTL, APHERESIS	
		• TC, WHOLE BLOOD	
		• TC-T, WHOLE BLOOD	
		• TC-CTL, WHOLE BLOOD	
		• TC-DC, MARROW	
		• TC-DC, CORD	
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: • Cryopreserved • Thawed • Heparinized • Washed	Per the Cellular Therapy 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: • Mobilized • Non-mobilized • Pooled, Single Donor • Thawed Washed	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.
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	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.

		• CPDA-1+10% DMSO+30% SSPP+10% plasma • CPDA-1+10% DMSO+0.8% HES+1% dextran • DMSO • HES • HES-DMSO • NaCitrate • PBS • 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: • Citrate • Citrate and Heparin	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 temperatures: • rt	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.
12	3.3.1.1	Added Storage Temperature: • ≤-150C • N_2	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):	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.

		• Minimal • Extensive • CD8-depleted • CD34-removed • AC133-selected • From buffy coat • T-Cells depleted	
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 • 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	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.
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	Added variable terms to	Per the Cellular Therapy

	3.5: 3.3.2.2.4	Preparation: Blood component from third party donor group • Default: Not Specified • 3rd Party Component: No • 3rd party Component: Yes	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 Genetically modified: Yes	Per the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). See *Cellular Therapy Product Coding Transition Document* for rationale.
**Version 3.4, May 2007**		
1	2.3.3.10	Added 10 donor pool to Dosage: Additional Information Group	Per request of the US
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		
1	2.3.1.1	Added NaCitrate—HES—ACD-A	Per request of the US
	Version 3.1.x, February 2007		
1	2.3.1	Updated reference in note to current edition of Mollison's Blood Transfusion in Clinical Medicine	Update
2	2.3.1.1	Added MAP as an additive; corrected spelling of "hydroxyl"	Per request of China; typographical error
3	2.3.3.14	Added definition of default for monitoring	Inadvertent omission
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	2.3.3.7	corrected spelling of "hydroxyl"	Typographical error
7	3.3.1.1	Added definition for "XX"	Inadvertent omission
8	3.3.3.1	Corrected spelling of citrate	Typographical error
	Version 3.0, January 2007		
		No changes made to this document. Numbering updated to correspond with	

		current Product Code Description database.	
**Version 2.18, December 2006**
		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
**Version 2.17, November 2006**
		No changes made to this document. Numbering updated to correspond with current Product Code Description database.	
**Version 2.16, September 2006**
	4.1	Revised or added definitions for Costal Cartilage, Osteochondral, bone and tendon.	
**Version 2.15, August 2006**
	2.3.3.5	Added Plasma Reduced/Plasma added	Per request of the US
	2.3.3.6	Change Ml 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**
		No changes made to this document. Numbering updated to correspond with current Product Code Description database	
**Version 2.12, April 2006**
		No changes made to this document. Numbering updated to correspond with current Product Code Description database	