



Version 6.23 December 9, 2016			
	Section	Change	Rationale
1.	2.3.2.2.6	Added Attribute Variable: <ul style="list-style-type: none"><li>• &lt;125 mL</li></ul>	Attribute Value was previously added to the Product Description Code Database
2.	2.3.2.2.6	Updated ISBT 128 Database Name <ul style="list-style-type: none"><li>• From “LowVol: anticoag adjusted” to “LowVol:anticoag adj”</li></ul>	Updated to reflect current name in the Product Description Code Database
3.	2.3.2.2.9	Updated ISBT 128 Database Name <ul style="list-style-type: none"><li>• From “Nationally defined” to “Quar: nationally defined”</li></ul>	Updated to reflect current name in the Product Description Code Database
4.	2.3.2.2.10	Added Attribute Variable: <ul style="list-style-type: none"><li>• 2.0-4.0 E12 plts</li></ul>	Attribute Value was previously added to the Product Description Code Database
5.	2.3.2.2.12	Added Attribute Variables: <ul style="list-style-type: none"><li>• Hct 0.60-0.85</li><li>• Hct 0.70-0.85</li></ul>	Attribute Values were previously added to the Product Description Code Database
6.	3.2.2.2.13	Updated ISBT 128 Database Name <ul style="list-style-type: none"><li>• From “Tumor cells reduced” to “Tumor cell reduced”</li></ul>	Updated to reflect current name in the Product Description Code Database
7.	8.2.1.1	Added Attribute Variable: <ul style="list-style-type: none"><li>• &lt;=-25C</li></ul>	Attribute Value was previously added to the Product Description Code Database
8.	9.2.1.1	Added Attribute Variable: <ul style="list-style-type: none"><li>• &lt;=-25C</li></ul>	Attribute Value was previously added to the Product Description Code Database



Version 6.23 December 9, 2016			
	Section	Change	Rationale
9.	9.2.1.5	Added Attribute Variable: <ul style="list-style-type: none"><li>Specified recipient</li></ul>	Attribute Value was previously added to the Product Description Code Database

Version 6.22 November 11, 2016			
	Section	Change	Rationale
1.	2.1.1	Changed the definition for existing Class POOLED PLASMA.  From: <ul style="list-style-type: none"><li>A product prepared by combining two or more single units of Plasma into one container.</li></ul> To: <ul style="list-style-type: none"><li>A product prepared by combining two or more single units of Plasma into one container. Unless otherwise specified the product has been obtained from Whole Blood and frozen.</li></ul>	For consistency with the other PLASMA product definitions.
2.	5.2.1.8	Added New Attribute Variable: <ul style="list-style-type: none"><li>Sixth</li></ul>	Requested by Australia
3.	5.2.1.11	Added New Attribute Variables: <ul style="list-style-type: none"><li>Aqueous humor</li><li>Vitreous humor</li></ul>	Requested by the US
4.	13.1	Added New Class: <ul style="list-style-type: none"><li>REGENERATED CORNEAL EPITHELIUM</li></ul>	Requested by the US



Version 6.21 October 7, 2016			
	Section	Change	Rationale
1.	2.3.2.2.3	Corrected the ISBT 128 Database Name for the following Attribute Values.  From: <ul style="list-style-type: none"><li>• Irradiated&lt;=5days</li><li>• Irradiated&lt;=14days</li></ul> To: <ul style="list-style-type: none"><li>• Irradiated&lt;=5d</li><li>• Irradiated&lt;=14d</li></ul>	Error correction.  For consistency with the Product Description Code Database.
2.	3	Reference to <i>Implementation Guide, Revised Cellular Therapy Terminology (2013)</i> was changed to <i>Technical Bulletin, Revised Cellular Therapy Terminology (2016)</i> .	This document was converted from an Implementation Guide to a Technical Bulletin.

Version 6.20 September 5, 2016			
	Section	Change	Rationale
1.	2.3.2.2.3	Updated definition for Irradiated attribute to address that information on the time interval between collection and irradiation is not encoded.	The updated definition distinguishes the Irradiated attribute from the new attributes added that specify the time interval between collection and irradiation.
2.	2.3.2.2.3	Added New Attribute Values: <ul style="list-style-type: none"><li>• Irradiated&lt;=5d</li><li>• Irradiated&lt;=14d</li></ul>	Requested by Australia



Version 6.20 September 5, 2016			
	Section	Change	Rationale
3.	3.2.2.2.2	<p>Renamed attribute "PUV treated" to "Photodynamic treatment".</p> <p>Changed Attribute definition from "Cells treated with psoralen/ultra violet light" to "The use of a process that involves treating cells with a photosensitizing agent followed by a light source to activate the agent".</p>	<p>Requested by Canada</p> <p>The attribute was renamed as "Photodynamic treatment" to include several types of extracorporeal photopheresis protocols available, the exact protocol used can be listed in accompanying documentation. The previous attribute name "PUV treated" is encompassed within the new attribute name and definition.</p>
4.	16	<p>Added a new section entitled "Other References".</p>	<p>This section contains references to additional ICCBBA publications that reference key information regarding ISBT 128 terminology otherwise not found in the Standard Terminology document.</p>
5.	Throughout Document	<p>Each page within a section lists the section name within the header.</p>	<p>To help users easily identify each section.</p>



Version 6.19 August 5, 2016			
	Section	Change	Rationale
1.	3.1.2	Added Class: <ul style="list-style-type: none"> <li>iPSC, SKIN</li> </ul>	Requested by the US
2.	3.2.2.2.3	Added New Cryoprotectant Attribute: <ul style="list-style-type: none"> <li>NS Dextran + NS DMSO</li> </ul>	Requested by CTCLAG
3.	4.1.3	Changed the definition of the Class BONE, DOWEL.  From: "Cylindrical piece of bone."  To: "Bone cut/shaped into a cylindrical piece."	For consistency with the other class definitions
4.	5.1	Added Class: <ul style="list-style-type: none"> <li>OCULAR TISSUE, NON-CLINICAL</li> </ul>	Requested by EBTAG  A single class will be used to emphasize the non-clinical status of products.
5.	5.2	Added Attribute Group: <ul style="list-style-type: none"> <li>Type of Non-Clinical Tissue</li> </ul>	Requested by EBTAG  Needed to specify the type of tissue products for non-clinical use
6.	5.2.1.11	Added New Attribute Group and Variables: <ul style="list-style-type: none"> <li>Type of Non-Clinical Tissue</li> <li>Default: Not applicable or not specified</li> <li>Cornea</li> <li>Iris</li> <li>Lens</li> <li>Optic nerve</li> <li>Posterior part</li> <li>Retina</li> </ul>	Requested by EBTAG  Needed to specify the type of tissue products for non-clinical use



Version 6.19 August 5, 2016			
	Section	Change	Rationale
7.	Section 14.4	Renumbered subsequent sections upon the addition of section 14.4.1 for Ocular Classes.	New section needed for retired Ocular classes.
8.	14.4.1	Added section for Retired Ocular Classes: <ul style="list-style-type: none"> <li>• IRIS</li> <li>• LENS</li> <li>• OPTIC NERVE</li> <li>• POSTERIOR PART</li> <li>• RETINA</li> </ul>	Requested by EBTAG  Classes now reflected as attributes in the Attribute Group "Type of Non-Clinical tissue".

Version 6.18 July 1, 2016			
	Section	Change	Rationale
1.	2.1.1	Corrected the class name from (PLATELET-RICH BUFFY-COAT) to (PLATELET-RICH BUFFY COAT).	For consistency with the appearance in the database.
2.	2.3.2.2.3	Added New Attribute Variable: <ul style="list-style-type: none"> <li>• RBC Irradiated</li> </ul>	Requested by the US
3.	2.3.2.2.12	Updated the attributes within the Hematocrit group. The Common Name is preceded with "Hematocrit" and the ISBT 128 Database Name is preceded with "Hct".	For clarification to provide context to the attribute values.
4.	5.2.1.5	Updated the attribute within the Endothelial Cell Density group. The common name is listed as "Cell density information provided" and the ISBT 128 Database Name was updated from "Information provided" to "Cell density info provided"	For clarification. It was not clear what type of information was provided.

Version 6.17 June 3, 2016			
	Section	Change	Rationale
1.	2.3.2.2.16	Added New Attribute Variable: <ul style="list-style-type: none"> <li>• Tetanus</li> </ul>	Requested by Australia



Version 6.16 May 2, 2016			
	Section	Change	Rationale
1.	2.3.1.1	Added New Core Condition to the First Position – bounded list: <ul style="list-style-type: none"><li>• NaCitrate-Dextran</li></ul>	Requested by Sweden
2.	3.2.2.2.12	Added New Attribute Variable: <ul style="list-style-type: none"><li>• CD14 enriched</li></ul>	Requested by the US
3.	9.1	Added New Class: <ul style="list-style-type: none"><li>• SERUM, DILUTED</li></ul>	Requested by Croatia
4.	13.1	Added New Classes: <ul style="list-style-type: none"><li>• REGENERATED CARTILAGE</li><li>• REGENERATED DERMIS TISSUE</li><li>• REGENERATED ELASTIC CARTILAGE</li><li>• REGENERATED FIBROCARILAGE</li><li>• REGENERATED HYALINE CARTILAGE</li><li>• REGENERATED LIVER TISSUE</li><li>• REGENERATED ORAL MUCOSA TISSUE</li><li>• REGENERATED SKIN TISSUE</li></ul>	Requested by TEPTAG
5.	13.2.1.1	Added New Attribute Variables: <ul style="list-style-type: none"><li>• Chondrocytes</li><li>• Hepatocytes</li><li>• Epithelial cells</li><li>• Melanocytes</li><li>• Fibroblasts</li><li>• Urothelial cells</li><li>• Multiple cell types</li></ul>	Requested by TEPTAG



Version 6.16 May 2, 2016			
	Section	Change	Rationale
6.	14.2.4.1.7	Retired Attribute Variable: <ul style="list-style-type: none"><li>• Non-mobilized</li></ul>	After careful consideration CTCLAG felt that the non-mobilized attribute should be retired. This would maintain consistency in the intent of the Product Descriptions by describing what has been performed rather than describing what has not been performed.

Version 6.15 April, 1 2016			
	Section	Change	Rationale
7.	1	'Serum Eye Drops' was replaced with 'Topical Products of Human Origin'.	Section was updated to accurately reflect the name of the product category.

NOTE: The Cellular Therapy Coding and Labeling Advisory Group made a decision to discontinue the use of the attribute "Non-mobilized" for ISBT 128 cellular therapy products. The product descriptions were intended to describe what has been done to the product, rather than what has not been done.

ICCBBA plans to remove the "Non-mobilized" attribute from existing product descriptions and product formulas. The product description codes themselves will remain the same; only the product descriptions and formulas will change. A transition period is expected in which some products are labeled with the Non-mobilized attribute and some are not.

ICCBBA Plans to have this change reflected in the May 2016 version of the ISBT 128 Product Description Code database and the ISBT 128 Standard Terminology for Medical Products of Human Origin.

If you have any comments, questions, or concerns regarding this change please contact us at [iccbba@iccbba.org](mailto:iccbba@iccbba.org)





Version 6.14 March 3, 2016			
	Section	Change	Rationale
1.	2.1.1	Added Class: <ul style="list-style-type: none"><li>• IMMUNE PLASMA</li></ul>	Requested by Australia
2.	2.3.2.1	Added Attribute Group: <ul style="list-style-type: none"><li>• Antibody Specificity</li></ul>	Requested by Australia
3.	2.3.2.2.13	Changed the definition of the Bacterial test attribute. From: “A one-time bacterial test performed at greater than or equal to 24 hours of incubation meeting national specifications for extension of expiry date.” To: “Tested with a point-in-time test that meets national specifications for extension of expiry date.”	The new definition now allows the attribute to be applicable to bacterial tests performed more than once to extended platelet dating
4.	2.3.2.2.16	Added Attribute Group and Variables: <ul style="list-style-type: none"><li>• Antibody Specificity</li><li>• Default: Not applicable</li><li>• Not specified</li><li>• CMV</li><li>• Hepatitis A</li><li>• Hepatitis B</li><li>• Varicella zoster</li><li>• RHD</li><li>• Rabies</li><li>• Anthrax</li></ul>	Requested by Australia
5.	5.2.1.4	Changed the attribute “None” to “No storage solution”.	To add clarity to the attribute.



Version 6.13 February 5, 2016			
	Section	Change	Rationale
1.		No changes made to this document. Version numbering updated to correspond with current Product Description Code Database.	

Version 6.12 January 01, 2016			
	Section	Change	Rationale
1.	2.2.1	Added New Modifier: <ul style="list-style-type: none"><li>• Lyophilized Apheresis</li></ul>	Requested by the US
2.	2.3.2.2.14	Added New Attribute Variable: <ul style="list-style-type: none"><li>• From 10 donors</li></ul>	Requested by The Netherlands
3.	3.2.2.1	Updated the definition of Enrichment and Reduction Groups:  Added the following statement: “When applied to a product collected by apheresis, this attribute is used when an additional [enrichment or reduction] step is performed in the laboratory after the apheresis collection has been completed and often prior to additional processing or manufacturing.”	Added for clarification
4.	3.2.2.2.12	Changed definition for attribute variable buffy coat enriched.  Removed the following statement: “When applied to a product collected by apheresis, this attribute is used when an additional enrichment step is performed in the laboratory after the apheresis collection has been completed and often prior to additional processing or manufacturing.”	Enrichment Group definition now contains the statement for clarification, therefore it is not needed in the definitions of individual attributes within the group.



**ISBT 128 Standard Terminology for Medical Products of Human  
Origin - Version Control Sheet 2016**



<b>Version 6.12 January 01, 2016</b>			
	<b>Section</b>	<b>Change</b>	<b>Rationale</b>
5.	4.3.2.2.12	Added New Attribute Variables: <ul style="list-style-type: none"><li>• Mixed <math>\leq</math> 8 mm</li><li>• Mixed <math>\leq</math> 12 mm</li></ul>	Requested by The Netherlands