

## ICCBBA, Inc

### United States Industry Consensus Standard for Uniform Labeling of Blood and Blood Components Version Control Sheet

	Chapter or Section	Change	Rationale
<b>Version 2.0.0 United States Industry Consensus Standard for Uniform Labeling of Blood and Blood Components, November 2005 vs. Version 1.2.0, November 1999</b>			
1	Introduction	Added Warranty and Liability information	Legal requirements
2	Introduction	Added definitions section	Standardize use of terminology
3	Introduction	Added illustration of terms used in text	Clarify terminology
4	1	Deleted names of documents that are no longer available.	Accurately reflect available resources
5	2	Added historical information about Version 1.2.0 of this document	Bring reader up-to-date with history of this US Industry Consensus document
6	3	Added Table 2 to define "Special Purpose" codes for the ABO/Rh data structure	Allows for more flexibility in the use of the standard
7	3	Renumbered Table 2 to Table 3. Added n-3 (emergency release) donation type	Consistent with information found in 3.5.3.1.2
8	3.3	Deleted information designating national groups responsible for definition of tables that have limited use	Most tables are now internationally defined.
9	3.5.1	Explained how data structures may be used with technologies other than linear bar codes	Clarification
10	3.5.2.1.3	Allowed for the use of flag characters in the Donation Identification Number data structure	Allows for more flexibility in the use of the standard
11	3.5.3.1.2	Allowed for use of n-3 (For Emergency Use Only) donation type in the ABO/Rh data structure.	Allows for more flexibility in the use of the standard
12	3.5.3.1.2	Indicated that special labeling ("For Designated Recipient Only") in the Upper Right Quadrant is used when the unit cannot be crossed over for use by another recipient	Clarification
14	3.5.3.1.3	Deleted former section 3.5.3.1.3 (which included definitions) and replaced it with instructions for labeling of directed units that can be crossed over for use by another recipient.	Include most definitions in a glossary at the beginning of the document. Standardize the labeling of directed units.

15	3.5.5.2	Changed name of “Apheresis: Additional Information” to “Apheresis and Container—Additional Information.	Better reflect information contained within this group.
16	3.5.4.1	Changed wording from discouraging the use of 2359 in the bar code text when a product is not time dependent to disallowing it.	To create standardization in expressing time of expiration when the product is not time dependent.
17	3.5.5.2	Changed the name of “Pools—Additional Information” to “Dosage—Additional Information.”	Better reflect information contained within this group.
18	3.5.5.2	Added three attribute groups (Hematocrit, Platelet Count and Monitoring).	Consistent with International agreement
19	3.5.5.2	Allowed for the use of A0000-D9999 product codes for “local” products.	Provide a mechanism to label products that are not standardized
20	3.5.5.3.3	Allowed for some therapeutic collections not to be labeled as therapeutic if facility has FDA approval to do so	Consistent with FDA guidelines
21	3.5.5.2	Added a note explaining the use of division/split codes versus multiple container codes	Clarification
22	3.5.5.3	Deleted reference to maintenance by ICCBBA, Inc of a column in the Product Description data base defining the US terminology for a given component	There may be alternate means to provide this information in the future.
23	3.5.5.3.3	Omitted the use of L donation type (for directed recipient use only, limited exposure)	Not a common labeling need in the US
24	3.5.5.3.4	Allow facilities to print division information in eye-readable form beneath the storage temperature	More obvious designation of divisions for users
25	3.5.6	Deleted need for an extra data structure for anticoagulant information	Standardized with international requirements. This information is contained within existing data structures.
26	3.5.7	Allowed use of internationally-defined Special Testing codes	International standardization
27	3.5.8	Allowed for use of red cell antigen data structure	International standardization
28	3.5.9	Allowed for use of Serologically-Determined Platelet HLA and Platelet-Specific Antigens	International standardization
29	4.1.2	Moved definitions to glossary, renumbered remaining sections in Chapter 4	
30	4.1.5.1 (renumbered to 4.1.4.1)	Designated upper left quadrant for Collected and Processed by information for collection facility. Reserved lower right quadrant for identification of a facility that modifies the product.	Ensure space for identification of facilities that modify a product.
31	4.5	Updated information to include FDA requirement to use machine readable labels	Consistent with CFR

32	5	Deleted table of contents within this section	Incorporated into general table of contents
33	5	Deleted bar code that specified anticoagulant in illustrations	Consistent with information in 3.5.6
34	5	Included eye-readable text for manufacturer information on platelet base labels	Consistent with other labels
35	5	Added an example of a simplified Intended Recipient Information label	Greater flexibility
36	5	Gave examples of how division and container information can be included in eye-readable form beneath the storage temperature information.	More obvious designation of containers and divisions for user
37	5	Moved examples of recovered and source plasma labels to be with other product labels	Keep product code label examples together.
38	5	Added examples of special testing and red cell antigen labels	Clarification
39	5.2	Added requirement to print class, modifiers and attributes in upper case letters	Clarification. While this was shown in the examples, it had not been stated clearly.
40	6.3	Deleted description of Container Manufacturer Identification code; renumbered remaining sections of this chapter	No longer needed
41	7	Updated references	
42	Appendix 1	Renamed Appendix A	
43	Appendix A	Removed the requirement to include the original collection volume on Washed, Frozen, Rejuvenated and Deglycerolized Red Blood Cells. Required the actual volume.	Consistent with CFR.
44	Appendix 2	Renamed Appendix B	
45	Appendix B	Moved "Apheresis" to the Modifier column.	Consistent with database
46	Appendix B	Added Liquid Apheresis Plasma, Washed Apheresis Red Blood Cells, Frozen Apheresis Red Blood Cells, Deglycerolized Apheresis Red Blood Cells, Rejuvenated Apheresis Red Blood Cells, Frozen Rejuvenated Apheresis Red Blood Cells and Deglycerolized Rejuvenated Apheresis Red Blood Cells	Additions to database
47	Appendix 3	Renamed Appendix C	
48	Appendix C	Noted that it is not necessary or recommended to include the actual platelet count on a leukocyte reduced product	Consistent with US labeling requirements
49	Appendix C	Deleted "supernatant removed"	Supernatant reduced is the preferred terminology in the US
50	Appendix C	Changed name of "Apheresis: Additional Information" group to "Apheresis and Container: Additional Information"	Better description of group
51	Appendix C	Changed name of "Pools: Additional Information" to "Dosage: Additional Information"	Platelet counts are used for both pools and apheresis products

52	Appendix C	Added Platelet Count and Monitoring Groups	Additions to database
53	Appendix 4	Renamed Appendix D.	
54	Appendix D	Moved label examples to Chapter 5	Keep most label examples together.
55	Appendix D	Deleted option for L donation type. Added option for s donation type.	Reflecting usage in the US
56	Appendix E	Renamed Appendix 5	
57	Appendix 6	Deleted	Information found in international documents
58	Appendix 7	Deleted.	No longer used.