ISBT 128 Standard

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

For Use with Product Description Code Database
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Editorial Board

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

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1 Introduction

This document provides a standard terminology for describing transfusion and transplantation products. It is designed to allow distinction between products where such is required on safety, clinical practice, or inventory management grounds. Although primarily developed to ensure standard labelling of products, the terminology has a wider application in ensuring a common international understanding of specialized terms. Other professional and accreditation bodies have adapted their terminology to be consistent with this document.

The terminology is under constant review in order to keep pace with clinical developments, and this document is regularly updated.

The underlying structure of the terminology is based on the concepts of Class, Modifiers, and Attributes:

Classes are broad descriptions of products. Examples are RED BLOOD CELLS; HPC, APHERESIS; CANCELLOUS BONE PEG; and SOLVENT DETERGENT POOLED PLASMA.

Modifiers are applied to Classes in order to provide the next step in the categorization of the product. Examples are Cryopreserved, Thawed Washed, and Mobilized.

Attributes provide the means to uniquely define the product. For Blood, Cellular Therapy, and Derivative products, there is a mandatory attribute group called Core Conditions which must be explicitly selected.

Core Conditions convey three types of information:

- anticoagulant and/or additive,
- nominal collection volume, and
- storage temperature.

There are also attribute groups which have a default value if not explicitly assigned. These remaining attribute groups are the general categories used to describe detailed characteristics of products. Within each attribute group there are a number of possible values, referred to as variables, of which only one can be selected. For example, “intended use” is a group; “for transfusion” is a variable within that group. Where a product does not have a variable assigned for a particular group, the default variable for that group will apply.

The following sections describe the terminology for each of the families of products supported by *ISBT 128*: Blood Components, Tissues, Cellular Therapy, and Derivatives.

1.1 Use of the Terminology in *ISBT 128* Product codes

The *ISBT 128* Product Database, which is maintained and published by ICCBBA, uses product descriptions based on this terminology. It is the responsibility of users of *ISBT 128* product codes to check the definitions before using a code to ensure that their product is correctly described within this terminology.

Where a list is specified as bounded then all the permitted values are shown. If a new value is required that is not in the list, then a request needs to be made by submitting an e-mail request to ICCBBA describing the new value required and providing a clear and concise definition.

Unbounded lists, such as those for volume or temperature ranges, are those where example values are given but additional values may exist.

The default value for each attribute group is the value taken if no attribute value is selected for that group.

Where new characterizations of products become necessary, ICCBBA will assign new attribute groups.

In some cases there will be additional information that may be of value to the administering clinician, but does not need to be encoded. Such information can be included in eye-readable text on the label and/or in the accompanying documentation.

The values presented in this document match the values held in the product database with a corresponding version number. Thus version 3.1 of this document corresponds with database versions 3.1.x.

Each Product Code represents a unique combination of Class, Modifier, and Attribute values. The codes can therefore be used to map to the text descriptions required to describe the product in accordance with individual national requirements.

2 Blood Components

2.1 Class

2.1.1 Bounded List and Definitions

CRYOPRECIPITATE	A product containing the major portion of Factor VIII and fibrinogen prepared from a unit of Fresh Frozen Plasma.
FRESH FROZEN PLASMA	Plasma that has been frozen by a process and to a temperature that will maintain the activity of labile protein fractions. Unless otherwise specified the product has been obtained from Whole Blood.
GRANULOCYTES	A product in which the major cellular component is granulocytes; preparation includes a sedimenting agent. Unless otherwise specified the product has been obtained from Whole Blood.
GRANULOCYTES-PLATELETS	A product in which the major cellular components are granulocytes and platelets. Unless otherwise specified the product has been obtained from Whole Blood.
LEUKOCYTES	A product in which the major cellular component is leukocytes. Unless otherwise specified the product has been obtained from Whole Blood.
LYMPHOCYTES	A product in which the major cellular component is lymphocytes. Unless otherwise specified the product has been obtained from Whole Blood.
MONOCYTES	A product in which the major cellular component is monocytes. Unless otherwise specified the product has been obtained from Whole Blood.
PLASMA	Plasma. Unless otherwise specified the product has been obtained from Whole Blood and frozen.
PLATELET-RICH BUFFY-COAT	Buffy-coat prepared by initial hard centrifugation of whole blood for later recovery of the platelets in a second, gentle centrifugation step.
PLATELET-RICH PLASMA	Plasma containing platelets removed from whole blood by a process designed to obtain maximum platelet recovery.

PLATELETS	A product that contains platelets as the major cellular component. Unless otherwise specified the product has been obtained from Whole Blood.
POOLED CRYOPRECIPITATE	A product prepared by combining two or more single units of Cryoprecipitate into one container.
POOLED FRESH FROZEN PLASMA	Pooled plasma that has been frozen by a process and to a temperature that will maintain the activity of labile protein fractions. Unless otherwise specified the product has been obtained from Whole Blood. When this class is associated with psoralen treatment, the plasma may have been frozen and thawed prior to the psoralen treatment
POOLED GRANULOCYTES	A product prepared by combining two or more single units of Granulocytes into one container.
POOLED PLASMA	A product prepared by combining two or more single units of Plasma into one container.
POOLED PLATELET-RICH BUFFY-COAT	A product prepared by combining two or more single units of Platelet-Rich Buffy-Coat into one container.
POOLED PLATELETS	A product prepared by combining two or more single units of Platelets into one container.
POOLED SERUM	A product prepared by combining two or more single units of Serum into one container.
RED BLOOD CELLS	Blood from which most of the plasma has been removed. Unless otherwise specified the product has been obtained from Whole Blood.
SERUM	The liquid portion of blood following the completion of the clotting process.
WHOLE BLOOD	A unit of blood collected into an anticoagulant and not further processed unless otherwise specified.

2.2 Modifier

2.2.1 Bounded List and Definitions

Apheresis	A blood collection process in which some part of the donation is returned to the donor.
Deglycerolized	The removal of glycerol by washing.
Deglycerolized Apheresis	The removal of glycerol by washing from an apheresis product.
Deglycerolized Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen, and subsequently thawed and deglycerolized.
Deglycerolized Rejuvenated Apheresis	An apheresis product in which the cells were rejuvenated (*see* below), glycerol added and then frozen, and subsequently thawed and deglycerolized.
Frozen	A product maintained in the frozen state after preparation.
Frozen Apheresis	An apheresis product maintained in the frozen state after preparation.
Frozen Rejuvenated	A product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Frozen Rejuvenated Apheresis	An apheresis product in which the cells were rejuvenated (*see* below), glycerol added and then frozen.
Liquid	A product that has been stored in the liquid state and has not been previously frozen.
Liquid Apheresis	An apheresis product that has been stored in the liquid state and has not been previously frozen.
Rejuvenated	The treatment of Red Blood Cells by a method known to restore 2,3 DPG and ATP to normal levels or above.
Rejuvenated Apheresis	The treatment of apheresis Red Blood Cells by a method known to restore 2,3 DPG and ATP to normal levels or above.
Thawed	A product that is currently in the liquid state but has been previously frozen.
Thawed Apheresis	An apheresis product that is currently in the liquid state but has been previously frozen.
Washed	The treatment of a cellular product using a compatible solution to remove most of the plasma proteins.
Washed Apheresis	The treatment of an apheresis cellular product using a compatible solution to remove most of the plasma proteins.

2.3 Attribute

2.3.1 Core Conditions

Core Conditions is the term used to describe three pieces of information:

- The anticoagulant/additive/cryoprotectant solution
- The nominal volume of the original collection excluding anticoagulant
- The temperature at which the product should be stored

Abbreviated names are used in accordance with standard naming conventions for anticoagulants/additives.

Note: For the formulations for many of the preservative solutions see: Klein, HG and Anstee, DJ: Mollison's Blood Transfusion in Clinical Medicine, 11th edition, Blackwell, 2005, pp 855 et seq.

Specific temperatures are not always given in the description since differing specific temperature ranges must be adhered to within a given country. For example, refg (refrigerated) is used rather than a specific range, such as 1–4 C. When a specific temperature is given it is expressed in degrees Celsius.

2.3.1.1 Core Conditions lists and definitions

First Position – bounded list

Anti-coagulant	Description
0.5 CPD	CPD Half-strength
ACD-A	Acid Citrate Dextrose, Formula A
ACD-A>AS1	Acid Citrate Dextrose, Formula A – Additive Solution 1
ACD-A>AS3	Acid Citrate Dextrose, Formula A – Additive Solution 3
ACD-A>PASIII	Acid Citrate Dextrose, Formula A – Platelet Additive Solution III
ACD-B	Acid Citrate Dextrose, Formula B
AS1	Additive Solution 1
AS2	Additive Solution 2
AS3	Additive Solution 3
AS5	Additive Solution 5
CPD	Citrate Phosphate Dextrose
CPD>AS1	Citrate Phosphate Dextrose – Additive Solution 1
CPD>AS3	Citrate Phosphate Dextrose – Additive Solution 3
CPD>AS5	Citrate Phosphate Dextrose – Additive Solution 5
CPD>PASIII	Citrate Phosphate Dextrose – Platelet Additive Solution III
CPD>SAGM	Citrate Phosphate Dextrose – Saline-Adenine-Glucose-Mannitol
CPD-50	Citrate Phosphate Dextrose 50
CPD-50>SAGM	Citrate Phosphate Dextrose 50 – Saline-Adenine-Glucose-Mannitol
CPDA-1	Citrate Phosphate Dextrose Adenine, Solution 1
CP2D	Citrate Phosphate Double Dextrose
CP2D>AS3	Citrate Phosphate Double Dextrose – Additive Solution 3
CP2DA	Citrate Phosphate Double Dextrose Adenine
DMSO	Dimethylsulfoxide
Gly17%	Glycerol 17%
Gly35%	Glycerol 35%
Gly40%	Glycerol 40%
Heparin	Heparin
MAP	Mannitol-Adenine-Phosphate
NaCitrate	Sodium Citrate solution
NaCitrate-HES	Sodium Citrate solution – Hydroxy-ethyl starch
NaCitrate-HES-ACD-A	Sodium Citrate solution – Hydroxy-ethyl starch –Acid Citrate Dextrose, Formula A

PAGGS-M	Phosphate Adenine Guanosine Glucose Saline – Mannitol
PASII	Platelet Additive Solution II
PASIII	Platelet Additive Solution III
PASIIIMgK	Platelet Additive Solution III Mg K
SAGM	Saline-Adenine-Glucose-Mannitol
None	no significant amount of anticoagulant or additive is present
NS	not specified

Second Position – examples (this list is not bounded, other volumes may be defined)

Volume	**Description**
250mL	
450mL	
500mL	
XX	"XX" specifies that the original collection volume not encoded as part of the core conditions. Specific information may be given as additional label text.

Third Position – examples (this list is not bounded, other temperature ranges may be defined)

Storage Temperature	**Description**
refg	refrigerated (between 1 to 10 C; narrower range may be nationally-specified)
rt	Ambient room temperature (a specific range may be nationally-specified)
<37C	Below 37 C
20-24C	Between 20 and 24 C; intended for the use in platelet products
<=-18C	Less than or equal to -18 C

2.3.2 Groups and Variables

Any additional manipulation or change to the product from its "core" state is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

2.3.2.1 Groups: Bounded list and definitions

Group Name	Description
Intended Use	Describes the expected use of the product.
System Integrity	Describes the microbiological integrity of the collection/storage system.
Irradiation	Describes any exposure of the product to irradiation to prevent graft versus host disease.
Residual Leukocyte Content	Describes the target residual leukocyte content of the product.
Altered	Describes the adding of and/or removing from a product specified elements.
Final Content	Provides supplementary information on the volume of the final product.
Preparation — Additional Information	Provides supplementary information about the preparation of a product.
Apheresis Container— Additional Information	Provides additional information related to an apheresis procedure.
Quarantine — Additional Information	Provides information related to the time a product is stored prior to retesting a second sample subsequently collected from the donor.
Dosage— Additional Information	Provides information related to the number of donations or number of platelets in a pooled product.
Method of Treatment	Provides information about a treatment method used to reduce the possibility of the transmission of disease.
Hematocrit	Specifies the packed cell volume of a Red Blood Cells product.
Platelet Count	Specifies whether additional platelet count information is provided.
Monitoring	Provides information on the on-going assessment of the product.

2.3.2.2 Variables – bounded lists and definitions

For each group, the variable value shown in bold characters is the default value.

2.3.2.2.1 Intended Use Group

Default: For transfusion	**The product is intended for transfusion.**
For mnf: injectable	For further manufacturing — injectable: a product that is intended for injection into humans after further manufacturing (processing).
For mnf: non-injectable	For further manufacturing — non-injectable: a product that is intended for further manufacturing into a product that is not intended for injection into humans.
Not for tx or mnf	Not for transfusion or further manufacturing: a product that is not intended for transfusion or further manufacturing.
For mnf: non-injectable restr use	For further manufacturing — non-injectable, restricted use: a product that is intended for further manufacturing into a product that is not intended for injection into humans. The use of the product is further restricted by national regulation or guidelines
For mnf: injectable restr use	For further manufacturing — injectable, restricted use: a product that is intended for injection into humans after further manufacturing (processing). The use of the product is further restricted by national regulation or guidelines

2.3.2.2.2 System Integrity Group

Default: Closed	**The product has been prepared in a closed system and the microbiological integrity of the system has not been compromised.**
Open	Open System: the system has been opened and the microbiological integrity may have been compromised.

2.3.2.2.3 Irradiation Group

Default: Not irradiated	**The product has not been exposed to irradiation.**
Irradiated	The product has been exposed to irradiation sufficient to prevent the proliferation of lymphocytes upon transfusion; the dose requirement is specified by each national regulatory organization.

2.3.2.2.4 Residual Leukocyte Content Group

Default:Leuk Cont not reduced	**Leukocyte Content not reduced: the product has not been processed to yield a target residual leukocyte content.**
ResLeu: NS	Residual Leukocyte Content Not Specified: a procedure has been used to reduce the leukocyte count of the product but the target count is not specified.
ResLeu: <2log5	Residual Leukocyte Content $<2x10^5$: the target residual leukocyte content is $<2x10^5$
ResLeu: <5log5	Residual Leukocyte Content $<5x10^5$: the target residual leukocyte content is $<5x10^5$
ResLeu: <8.3log5	Residual Leukocyte Content $<8.3x10^5$: the target residual leukocyte content is $<8.3x10^5$
ResLeu: <1log6	Residual Leukocyte Content $<1x10^6$: the target residual leukocyte content is $<1x10^6$
ResLeu: <2.5log6	Residual Leukocyte Content $<2.5x10^6$: the target residual leukocyte content is $<2.5x10^6$
ResLeu: <5log6	Residual Leukocyte Content $<5x10^6$: the target residual leukocyte content is $<5x10^6$
ResLeu: <5log8	Residual Leukocyte Content $<5x10^8$: the target residual leukocyte content is $<5x10^8$
ResLeu: <1.2log9	Residual Leukocyte Content $<1.2x10^9$: the target residual leukocyte content is $<1.2x10^9$
ResLeu: <1log6,WB filtr	Residual Leukocyte count $<1x10^6$. The target residual leukocyte content of $<1x10^6$ is achieved by filtration of the whole blood before separation of components.
ResLeu: <1log6,RBC filtr	Residual Leukocyte count $<1x10^6$. The target residual leukocyte content of $<1x10^6$ is achieved by filtration of the red cells following separation from whole blood.

2.3.2.2.5 Altered Group

Default: not altered	**The product has not been altered by the addition or removal of liquid or cells.**
Albumin added	Albumin has been added to the blood product.
Cryo reduced	Cryoprecipitate reduced: the amount of cryoprecipitate in the blood product has been reduced from the original amount.
Complement inactivated	The product has been heat treated to inactivate complement.
Plasma added	A blood product to which plasma has been added.
Plasma reduced	A blood product from which a portion of the plasma has been removed.
Plasma reduced/Albumin added	A blood product from which a portion of the plasma has been removed, and albumin has been added.
Plts reduced	Platelets reduced: the platelets have been reduced from the original amount.
Plts/Cryo reduced	Platelets and cryoprecipitate reduced: the platelets and cryoprecipitate have been reduced from the original amount.
Supernat reduced	Supernatant reduced: the supernatant additive/anticoagulant or other solution has been reduced from the original amount.
Supernat rem	Supernatant removed: a blood product from which most of the supernatant additive/anticoagulant or other solution has been removed.
Supernat rem/Plasma added	Supernatant removed and plasma added: a blood product from which most of the supernatant additive/anticoagulant or other solution has been removed and, in a further step, a quantity of plasma has been added to the product.
RBC reduced by sedimentation	Red Blood Cells reduced by sedimentation: a blood product from which most of the red cells have been removed following separation by a sedimentation process.

Buffy coat removed	A blood product from which the buffy coat has been removed
Plasma reduced/Plasma added	Plasma reduced and plasma added; a blood product from which most of the original plasma has been removed and, in a further step, a quantity of plasma has been added to the product
Complement Inactivated	Product has been heat treated to inactivate complement.

2.3.2.2.6 Final Content Group

Default: usual nominal volume	The contents are consistent with the expected, usual volume.
25 mL	Approximately 25 mL; actual range of volume established by processing facility
50 mL	Approximately 50 mL; actual range of volume established by processing facility
<200 mL	The volume of the blood product is less than 200 mL.
>=200 mL<400 mL	The volume of the blood product is greater than or equal to 200 mL and is less than 400 mL.
>=400 mL<600 mL	The volume of the blood product is greater than or equal to 400 mL and is less than 600 mL.
>=600 mL	The volume of the blood product is greater than or equal to 600 mL.
Fin Con:NS	No information is provided regarding the final content
LowVol: anticoag adjusted	Low volume, anticoagulant volume adjusted: the volume of the product is less than the expected volume and the volume of the anticoagulant into which the original collection was made was adjusted to compensate.
LowVol: anticoag not adj	Low volume, anticoagulant volume not adjusted: the volume of the product is less than the expected volume and the volume of the anticoagulant into which the original collection was made was not adjusted to compensate.

2.3.2.2.7 Preparation — Additional Information Group

Default: no additional information	There is no additional information about the preparation of the product.
Granulocytes prep: HES	Granulocytes prepared using Hydroxy-ethyl starch: Hydroxy-ethyl starch was used as the sedimenting agent in the laboratory preparation of the product.
Frozen <=2h	The plasma was frozen within 2 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <=-30 C.
Frozen <=6h	The plasma was frozen within 6 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <=-30 C.
Frozen <=8h	The plasma was frozen within 8 hours or less from the time it was collected in a system that assured complete freezing within one hour to a temperature of <=-30 C.
Frozen <=15h	The plasma was placed in the freezer within 15 hours or less from the time of collection.
Frozen <=18h	The plasma was frozen within 18 hours or less from the time of collection in a system that assured complete freezing within one hour to a temperature of <=-30C.
Frozen <=24h	The plasma was frozen in 24 hours or less from the time of collection.
Frozen <=26h	The plasma was frozen in 26 hours or less from the time of collection.
Frozen >24h	The plasma was frozen more than 24 hours after the time of collection.
Frozen <=48h	The plasma was frozen in 48 hours or less from the time of collection.
Frozen <=72h	The plasma was frozen in 72 hours or less from the time of collection.
Frozen <=120h	The plasma was frozen in 120 hours or less from the time of collection.
Buffy-coat plts prep	Platelets prepared from buffy-coat: the platelets were prepared from the buffy-coat following centrifugation.

2.3.2.2.8 Apheresis container— Additional Information Group

Default: no additional information	**No additional information related to the apheresis procedure used or the number of containers harvested is given.**
1st container	The first of two or more containers prepared during a single apheresis procedure.
1st container: not auto	The first of two containers prepared from a single non-automated apheresis procedure.
2nd container:	The second of two or more containers prepared during a single apheresis procedure.
2nd container: not auto	The second of two containers prepared from a single non-automated apheresis procedure.
3rd container	The third of three or more containers prepared during a single apheresis procedure.
4th container	The fourth of four or more containers prepared during a single apheresis procedure.
5th container	The fifth of five or more containers prepared during a single apheresis procedure.
6th container	The sixth of six or more containers prepared during a single apheresis procedure.
7th container	The seventh of seven or more containers prepared during a single apheresis procedure.
8th container	The eighth of eight or more containers prepared during a single apheresis procedure.
Aphr not automated	The apheresis procedure used was a manual method.

2.3.2.2.9 Quarantine — Additional Information Group

Default: no additional information	No information related to a quarantine period prior to release is given.
Quar: >=112d/retested	The product was stored for not less than 112 days, after which a new sample from the donor was retested
Quar: >=4m/retested	The product was stored for not less than 4 months, after which a new sample from the donor was retested
Quar: >=6m/retested	The product was stored for not less than 6 months, after which a new sample from the donor was retested
Nationally defined	The product was stored for a period (nationally determined), after which a new sample from the donor was retested
Quar: >=62d/retested	The product was stored for not less than 62 days, after which a new sample from the donor was retested
Quar:>=90d/retested	The product was stored for not less than 90 days, after which a new sample from the donor was retested

2.3.2.2.10 Dosage — Additional Information Group

Default: no additional information	No information related to dosage is provided.
Approx 120 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 150 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 180 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 240 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 300 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)

Approx 360 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 420 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure)
Approx 480 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
Approx 540 log9 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
<3 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
3.0-4.7 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
4.8-5.9 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
>6.0 log11 plts	The number of platelets. (Actual count or average expected yield from a standardized procedure.)
From 2 donors	Pool prepared from donations from 2 donors
From 3 donors	Pool prepared from donations from 3 donors
From 4 donors	Pool prepared from donations from 4 donors
From 5 donors	Pool prepared from donations from 5 donors
From 6 donors	Pool prepared from donations from 6 donors
From 7 donors	Pool prepared from donations from 7 donors
From 8 donors	Pool prepared from donations from 8 donors
From 9 donors	Pool prepared from donations from 9 donors
From 10 donors	Pool prepared from donations from 10 donors

2.3.2.2.11 Method of Treatment Group

Default: no treatment	**No treatment method was used.**
Heat-treated	The blood product has been subjected to a validated heat-treatment method known to reduce the risk of disease transmission.
Methylene blue-treated	The blood product has been subjected to a validated methylene blue-treatment method known to reduce the risk of disease transmission.
Psoralen-treated	The blood product has been subjected to a validated psoralen-treatment method known to reduce the risk of disease transmission.
Solvent detergent-treated	The blood product has been subjected to a validated solvent detergent treatment process known to reduce the risk of disease transmission.
Riboflavin-treated	The blood product has been subjected to a validated riboflavin treatment process known to reduce the risk of disease transmission.

2.3.2.2.12 Hematocrit Group

Default: not specified	**The packed cell volume is not specified.**
0.5-0.6	The packed cell volume of the product is between 50 and 60 percent.
0.5-0.7	The packed cell volume of the product is between 50 and 70 percent.
0.55-0.75	The packed cell volume of the product is between 55 and 75) percent.
>0.7	The packed cell volume of the product is greater than 70 percent.

2.3.2.2.13 Platelet Count

(Group withdrawn – this attribute group will not be used for future code assignments)

Default: no information	**Platelet Count may or may not be specified**
Count not encoded	Platelet count is provided in eye-readable form only

2.3.2.2.14 Monitoring

Default: not specified	**No monitoring is specified**
Bacterial monitoring	A product subjected to on-going bacterial monitoring meeting national specifications for extension of the expiry date.
Bacterial Test	a one-time bacterial test performed at =>24 hours of incubation meeting national specifications for extension of expiry date

3 Cellular Therapy

Important Note: The terms and definitions represented in this section were developed in 2007. Products labeled prior to the introduction of this terminology and coding system were defined using a different coding system. See Chapter 6 for definitions of these codes. The document *ISBT 128 Standard Cellular Therapy Product Coding Transition, June 2007* provides a crosswalk from previously used codes and definitions to those currently used.

3.1 Class

Cellular therapy products are divided into two class name categories.

Category 1:
At collection, the product code will describe the intended purpose of the collection (TC or HPC) and the source material (e.g., TC, Apheresis) These products can be collected for direct infusion without further manipulation. If these cells undergo manipulation such as cryopreservation and thawing, the class doesn't change but the modifier is added into the product code (e.g., Cryopreserved HPC, Apheresis). This category is usually identified by a comma in the full name

Category 2:
After manufacture/processing, the intention of the product can be identified by its active component. These class names are based on function followed by a further more specific delineation of the type of cells thought to predominate in the product. After processing, the class name will describe the intended active component (e.g., a donor lymphocyte infusion identified as TC-T Cells). This category is usually identified by a hyphen in the full name.

3.1.1 Bounded Lists and Definitions

HPC, APHERESIS	Peripheral blood collected by apheresis as a source of hematopoietic progenitor cells. Mobilized unless otherwise stated in Modifier
HPC, CORD BLOOD	Umbilical cord blood and/or placental blood collected as a source of hematopoietic progenitor cells.
HPC, MARROW	Bone marrow collected as a source of hematopoietic progenitor cells
HPC, WHOLE BLOOD	Whole blood collected as a source of hematopoietic progenitor cells. Mobilized unless otherwise stated in Modifier.
CONCURRENT PLASMA, APHERESIS	Plasma collected from the donor as part of an apheresis cell collection procedure for use by the laboratory in further processing of that donor's product.
TC, APHERESIS	Source of nucleated cells obtained by an apheresis procedure intended for therapeutic use other than HPCs. Non-mobilized unless otherwise stated in the modifier.
TC, MARROW	Bone marrow collected as a source of nucleated cells intended for therapeutic use other than HPCs.
TC, WHOLE BLOOD	Whole blood collected as a source of nucleated cells intended for therapeutic use other than HPCs
TC, CORD BLOOD	Umbilical cord blood and/or placental blood collected as a source of nucleated cells intended for therapeutic use other than HPCs
TC, TUMOR DERIVED	A product containing malignant cells or elements derived from them.
TC-T CELLS	A therapeutic cell product from any source containing a quantified T cell population.
TC-CTL	A therapeutic cell product containing cytotoxic lymphocytes for therapeutic use.
TC-T REG CELLS	A therapeutic cell product containing T regulatory lymphocytes for therapeutic use
TC-DC	A therapeutic cell product containing dendritic cells for therapeutic use.
TC-NK CELLS	A therapeutic cell product containing natural killer cells for therapeutic use.
TC-MSC	A therapeutic cell product containing mesenchymal stromal cells for therapeutic use.
TC-APC	A therapeutic cell product containing antigen presenting cells other than dendritic cells for therapeutic use

TC-INV	Therapeutic cell product for an investigational study that is accompanied by appropriate identifying study information. This class is used for a specific product, not a product that is part of a blinded comparison study. Throughout the study, products labeled as TC-INV will be the same product, although the dose may vary within a specified range defined by the study.
TC-TIL	Therapeutic cells consisting of autologous tumor infiltrating lymphocytes (TIL) which have been isolated from the excised patient's tumor and cultured with lymphokines.
TC-BLINDED STUDY	This class is reserved for use only in blinded studies of therapeutic cells that is accompanied by appropriate identifying study information. Products labeled as TC-Blinded Study may include different doses or may include an active product and a placebo.

3.1.2 Abbreviations

Abbreviations are sometimes needed in documents (published papers, SOPs, etc.). The following abbreviations may be used for this purpose, but should not be used in the labeling of products.

HPC(A) for HPC, Apheresis
HPC(CB) for HPC, Cord Blood
HPC(M) for HPC, Marrow
HPC(WB) for HPC, Whole Blood

No spaces should be present before the parentheses in these abbreviations. This will prevent separation of "HPC" from the parenthetical information when the abbreviation appears at the end of a printed line.

3.2 Modifier

3.2.1 Bounded Lists and Definitions

Mobilized	Applies to cells that have been obtained from a donor treated with an agent to increase the concentration of the target cell population(s) [to be used only for TC, Apheresis or bone marrow]
Non-Mobilized	Applies to cells that have been obtained from a donor not treated with an agent to increase the concentration of the target cell population(s) [To be used only for HPC, Apheresis or HPC, Whole Blood]
Cryopreserved	Applies to cells in the frozen state after the addition of cryoprotectant(s)
Pooled, Single Donor	Applies to the combination of multiple collections of the same product type from the same donor.
Thawed Washed	Applies to cryopreserved cells that have been thawed and subsequently washed to remove cryoprotectant or other solution(s).
Washed	Applies to cells from a non-cryopreserved product that have been washed to reduce the amount of plasma, anticoagulant, and/or other solution(s).
Thawed	Applies to cryopreserved cells that have been thawed without washing prior to final issue for administration.

3.3 Attribute

3.3.1 Core Conditions

Core Conditions is the term used to describe three pieces of information:

The anticoagulant solution
"None" specifies that no significant amount of anticoagulant or additive is present.

"NS" indicates that the anticoagulant and/or additive are not specified.

The nominal volume of the original collection excluding anticoagulant
"XX" specifies that the volume is variable and not provided as part of the core conditions of the product description (blood components). Specific information may be given as additional label text.

The temperature at which the product should be stored
Specific temperatures are not always given in the description since differing specific temperature ranges must be adhered to within a given country. For example, refg (refrigerated) is used rather than a specific range, such as 1–4 C. When a specific temperature is given it is expressed in degrees Celsius.

3.3.1.1 Core Conditions—Lists and Definitions

First Position—Bounded List

Anticoagulant type	Description
Citrate	Any anticoagulant containing citrate used as the sole method of anticoagulation
Heparin	Heparin used at any concentration as the sole method of anticoagulation
Citrate and Heparin	Combined use of citrate and heparin at any concentration in the anticoagulant medium
NS	Anticoagulant not specified in coding
None	No anticoagulant

Second Position – examples (this list is not bounded, other volumes may be defined)

Volume	Description
XX	Volume not specified in coding

Third Position – examples (this list is not bounded, other temperature ranges may be defined)

Storage Temperature	Description
Refg	Refrigerated (between 1 – 10 C; narrower range may be nationally specified)
RT	Ambient room temperature (range may be nationally specified)
≤ -18C	Less than or equal to -18 C
≤ -80C	Less than or equal to -80 C
≤ -120C	Less than or equal to -120 C
≤ -150C	Less than or equal to -150 C
N2 liquid	Completely immersed in the liquid phase of nitrogen

3.3.2 Groups and Variables

Any additional manipulation or change to the product from its "core" state is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

3.3.2.1 Groups: Bounded Lists and Definitions

Group Name	Description
Intended Use	Describes the expected use of the product
Manipulation	Describes processing applied to the collection
Preparation — Cryoprotectant	Active cryoprotectant in the product
Preparation – Blood component from third party donor	Describes blood products from other donors used during processing, such as albumin, Fresh Frozen Plasma, AB serum, Red Blood Cells
Preparation – Other Additives	Describes additives introduced other than as part of the anticoagulant solution at the time of collection
Genetically Modified	Cells which have been modified by the insertion of exogenous genetic material.

3.3.2.2 Variables: Bounded Lists and Definitions Tables

3.3.2.2.1 Intended Use Group

Default: for administration	For patient use: The product is intended for administration to patients
Not for admin	Not for patient use; a product that is not intended for use in patient treatment
For further processing	For further processing into a product that may be administered; not intended for direct administration

3.3.2.2.2 Manipulation Group

Default: no mani-pulation	**No further processing has occurred following collection.**
Diluted	A product to which an additional diluent (e.g. Concurrent Plasma) has been added after collection to reduce cell concentration for transit, storage, processing, or cryopreservation
Plasma Reduced	Cells remaining after a portion of the plasma has been depleted by sedimentation or centrifugation
RBC Reduced	Cells remaining after reduction of mature erythrocytes
Buffy coat enriched	Cells remaining after reduction of mature erythrocytes and plasma.
Mono-nuclear cells enriched	Cells remaining after reduction or depletion of mature erythrocytes, granulocytes and plasma
T-cell reduced	Cells remaining after T cells have been reduced
B-cell reduced	Cells remaining after B cells have been reduced
T/B-cell reduced	Cells remaining after T&B cells have been reduced
CD8 reduced	Cells remaining after the CD8 cell population has been reduced
CD34 enriched	Product in which the CD34 cell population has been enriched
CD133 enriched	A product in which the CD133 cell population has been enriched
Tumor cells reduced	An identified tumor cell population has been reduced
PUV treated	Cells treated with psoralen/ultra violet light
Cultured	Cells that have been maintained ex vivo to activate, expand, or promote development of a specified cell population in the presence of specified additive(s).
Monocyte enriched	Product in which the monocyte cell population has been enriched

3.3.2.2.3 Cryoprotectant Group

Default: no cryo-protectant	**No cryoprotectant has been added.**
6% HES + 5% DMSO	The cells were frozen using 6% HES and 5% DMSO by volume as cryoprotective agents
10% DMSO	The cells were frozen using 10% DMSO by volume as a cryoprotective agent
7.5% DMSO	The cells were frozen using 7.5% DMSO by volume as the cryoprotective agent
5% DMSO	The cells were frozen using 5% DMSO by volume as the cryoprotective agent

3.3.2.2.4 Blood Component from Third Party Donor Group*

Default: 3rd party comp:NO	**Default. No third party blood component added**
3rd party comp:YES	Third party blood component added. See accompanying paperwork.

3.3.2.2.5 Preparation: Other Additives Group*

Default: other additives:NO	**Default. No additives other than as part of the anticoagulant solution at the time of collection**
Other additives:YES	Other additives. See accompanying paperwork

3.3.2.2.6 Genetically Modified Group*

Default: genetically Modified:NO	**Default. Not genetically modified**
Genetically modified:YES	Genetically modified by the insertion of exogenous genetic material. See accompanying paperwork

** Note: The default values of the groups Blood Component from Third Party Donor, Other Additives, and Genetically Modified have changed from those originally published. When initially published, "Not Specified" was the default value. The default value has been changed to that shown above to reflect the most common condition (that which would be expected unless otherwise noted).*

4 Tissues

4.1 Class

4.1.1 Bounded Lists and Definitions

ABDOMINAL BIFURCATION	The lower section of the abdominal aorta and up to 5cm of each iliac artery.
AMNIOTIC MEMBRANE	Amniotic membrane, not specified as to size.
AMNIOTIC MEMBRANE, LARGE	Amniotic membrane graft, cut in pieces larger than 3cm x 3cm — surface area indicated on packaging.
AMNIOTIC MEMBRANE SHEET	Amniotic membrane graft, cut into pieces larger than 12cm x 20cm
AMNIOTIC MEMBRANE, SMALL	Amniotic membrane graft, cut in squares of 3 x 3cm or less — surface area indicated on packaging.
AORTIC ARCH	A section of the aorta, including branches of the brachiocephalic, left common carotid and left subclavian arteries.
AORTIC NON-VALVED CONDUIT	A section of aortic conduit, not containing a valve.
AORTIC PATCH	A piece of the aorta
BLOOD VESSEL	A tube in the body carrying blood to (vein) or from (artery) the heart
BONE	Bone, not further specified. Porous rigid tissue making up the skeleton.
CADAVERIC CANCELLOUS BONE	Cancellous bone from a cadaveric donor
CADAVERIC CORTICAL BONE	Cortical bone from a cadaveric donor.
CALCAR FEMORALE	Vertically oriented bone that originates in posteromedial portion of femoral shaft under lesser trochanter which radiates laterally toward posterior aspect of greater trochanter
CANCELLOUS BONE CHIPS	Cancellous bone, cut in pieces of nominally 6mm x 6mm x 30mm.
CANCELLOUS BONE CUBES	Cancellous bone, cut in cubes of nominally 1cm.
CANCELLOUS BONE DOWEL	A cancellous bone cylinder of 9–11mm length and 14–16mm diameter.
CANCELLOUS BONE PEG	Cancellous bone, cut as a single piece of nominally 15 x 15 x 30mm.

CANCELLOUS FEMORAL KNEE SLICE	Slice taken across the distal femur in the medial, lateral plane: depth nominally 1cm.
CANCELLOUS TIBIAL KNEE SLICE	Slice taken across the proximal tibia in the medial, lateral plane: depth nominally 1cm.
CORTICAL FEMORAL BONE RING	A hollow cylinder of cortical bone, cut from the central portion of the shaft of a femur — depth in mm indicated on packaging.
CORTICAL SHEET	Cortical bone, cut in sheets of 100–300µm thickness.
CORTICAL FEMORAL BONE STRIP	A length of the central part of the femur, cut in narrow strips of varying width, usually 5–20mm in the proximal distal plane — length in cm indicated on packaging.
CORTICO-CANCELLOUS FEMORAL BONE RING	A cylinder of cortical bone, enclosing a cylinder of cancellous bone, cut from the distal or proximal part of the femur — depth in mm indicated on packaging.
CORTICO-CANCELLOUS FEMORAL BONE STRIP	Distal or proximal part of femoral shaft, including cortical and cancellous bone, cut in the proximal, distal plane in narrow strips of varying width, usually 5–20mm — length in cm indicated on packaging.
COSTAL CARTILAGE	Tough elastic tissue extensions from the ribs towards the front of the chest
COSTAL CARTILAGE PIECES	Costal cartilage transected from sterno-costal joint of sternum — length in cm indicated on packaging.
CRANIAL PLATE	Piece of bone from the cranium component of the skull.
EYE, LEFT	A left eye removed from its socket.
EYE, RIGHT	A right eye removed from its socket.
FEMORAL CONDYLE, LATERAL, LEFT	Lateral lower extremity of the left femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, LATERAL, RIGHT	Lateral lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL, LEFT	Medial lower extremity of the left femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL CONDYLE, MEDIAL, RIGHT	Medial lower extremity of the right femur inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
FEMORAL HEAD	Proximal head of the femur.
FEMORAL HEAD, HALF	Either half of a femoral head bisected in the distal proximal plane.
FEMORAL HEAD, LEFT	Proximal head of the femur removed from the left femur by transecting the femoral neck.

FEMORAL HEAD, RIGHT	Proximal head of the femur removed from the right femur by transecting the femoral neck.
FEMORAL HEAD SLICE	A slice of the femoral head, taken in the distal proximal plane 4–8mm deep.
FEMORAL SHAFT, LEFT	The mid-portion of the left femur removed by transecting the femur just below the tuberosities and just above the distal joint.
FEMORAL SHAFT, RIGHT	The mid-portion of the right femur removed by transecting the femur just below the tuberosities and just above the distal joint.
FEMUR, DISTAL, LEFT	Distal portion of the left femur, including the femoral condyles and part of the femoral shaft, removed by transecting the shaft in the mid-portion.
FEMUR, DISTAL, RIGHT	Distal portion of the right femur, including the femoral condyles and part of the femoral shaft, removed by transecting the shaft in the mid-portion.
FEMUR, PROXIMAL, LEFT	Proximal part of the femur, including the head, tuberosities and part of the shaft removed by transecting the left femoral shaft in the mid-portion.
FEMUR, PROXIMAL, RIGHT	Proximal part of the femur, including the head, tuberosities and part of the shaft removed by transecting the right femoral shaft in the mid-portion.
GROUND BONE	Predominantly cancellous bone morcellized and free of cartilage.
HEART	Whole heart or block from the heart including the aortic and/or pulmonary valves (start product).
ILIAC CREST	Pieces of iliac crest (start product).
KNEE JOINT, LEFT	The distal femur still attached to the proximal tibia of the left leg removed by transecting the femur above the joint and the tibia below the joint.
KNEE JOINT, RIGHT	The distal femur still attached to the proximal tibia of the right leg removed by transecting the femur above the joint and the tibia below the joint.
KNEE TRIMMINGS	Assorted pieces of cortical and cancellous bone and cartilage removed from the distal femur and proximal tibia during knee replacement surgery.
MENISCI,	A single graft consisting of both the lateral and medial meniscus dissected from the knee joint. Anatomically identified as left or right.
MENISCI, LEFT	A single graft consisting of both the lateral and medial meniscus dissected from the left knee joint.

MENISCI, RIGHT	A single graft consisting of both the lateral and medial meniscus dissected from the right knee joint.
MENISCUS	A meniscus.
MENISCUS, LATERAL, LEFT	A lateral meniscus dissected from the left knee joint.
MENISCUS, LATERAL, RIGHT	A lateral meniscus dissected from the right knee joint.
MENISCUS, MEDIAL, LEFT	A medial meniscus dissected from the left knee joint.
MENISCUS, MEDIAL, RIGHT	A medial meniscus dissected from the right knee joint.
OSTEOCHONDRAL	Tissue comprising bone and cartilage from an articulating joint.
PATELLA BONE BLOCK	An entire patella inclusive of cartilaginous posterior surface, tendon removed from points of insertion.
PELVIS, MASSIVE ALLOGRAFT, LEFT	Massive allograft of left pelvis comprising the majority of the Os Innominatum (nameless bone)
PELVIS, MASSIVE ALLOGRAFT, RIGHT	Massive allograft of right pelvis comprising the majority of the Os Innominatum (nameless bone)
PERICARDIAL PATCH	Pericardium, cut into a piece – surface area indicated on the packaging.
PERICARDIUM	Conical membranous sac that normally surrounds the heart
PULMONARY PATCH	A section of the pulmonary trunk
SKIN	Skin, not specified as to size.
SKIN, LARGE	Split thickness skin graft of greater than $10cm^2$ — surface area indicated on packaging.
SKIN, SMALL	Split thickness skin graft of $10cm^2$ or smaller — surface area indicated on packaging.
STRUT, NARROW	A length of the central part of the femur, cut in quarters in the proximal distal plane — length in cm indicated on packaging.
STRUT, WIDE	A length of the central part of the femur, cut in halves in the proximal distal plane — length in cm indicated on packaging
SUPERFICIAL FEMORAL ARTERY	A section of the femoral artery from the bifurcation of the common femoral artery with the profunda femoris artery to the popliteral artery.
TENDON	A cord or band of tough tissue normally found attaching muscle to bone
TENDON, ACHILLES	An Achilles tendon, attached to a bone block from the calcaneus: at least 15cm in length, including bone block.

TENDON, ACHILLES, LEFT	An Achilles tendon, attached to the bone block from the left calcaneus: at least 15 cm in length, including bone block.
TENDON, ACHILLES, RIGHT	An Achilles tendon, attached to the bone block from the right calcaneus: at least 15 cm in length, including bone block.
TENDON, PATELLA, HALF	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia, bisected in the distal proximal plane.
TENDON, PATELLA, HALF, SHAPED	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia, bisected in the distal proximal plane. Bone blocks shaped to form cylinders which pass through spacers of specified diameter indicated on packaging.
TENDON, PATELLA, LEFT	A patella tendon attached to the whole left patella bone and a bone block from the left tibia.
TENDON, PATELLA, RIGHT	A patella tendon attached to the whole right patella bone and a bone block from the right tibia.
TENDON, PATELLA, WHOLE	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia.
TENDON, PATELLA, WHOLE, SHAPED	A patella tendon, attached to a bone block from the patella bone and a bone block from the tibia. Bone blocks shaped to form cuboids which pass through spacers of specified diameter-diameter indicated on the packaging.
TENDON, SEMITENDINOSUS	A semitendinosus tendon at least 20cm length.
TENDON, SEMITENDINOSUS, LEFT	A semitendinosus tendon at least 20cm length, obtained from the left leg
TENDON, SEMITENDINOSUS, RIGHT	A semitendinosus tendon at least 20cm length, obtained from the right leg
TENDON, TOE EXTENSOR	A toe extensor tendon at least 9cm length.
THORACIC AORTA	A section of the aorta from the second sternocostal articulation to the forth thoracic vertebra, including branches of the brachiocephalic, left common carotid and left subclavian arteries.
TIBIA, PROXIMAL, LATERAL, LEFT	Lateral upper extremity of the left tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, LATERAL, RIGHT	Lateral upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.

TIBIA, PROXIMAL, LEFT	Proximal part of the left tibia, including the tibial plateau and part of the tibial shaft, without cartilage, removed by transecting the tibial shaft in the mid-portion.
TIBIA, PROXIMAL, MEDIAL, LEFT	Medial upper extremity of the left tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, MEDIAL, RIGHT	Medial upper extremity of the right tibia inclusive of cartilaginous surface transected with 1-2cm cancellous bone.
TIBIA, PROXIMAL, RIGHT	Proximal part of the right tibia, including the tibial plateau and part of the tibial shaft, without cartilage, removed by transecting the tibial shaft in the mid-portion.
TRI-CORTICAL WEDGE	Section of iliac crest, with three facets covered by cortex, cut 30mm in length perpendicular to and 15mm along superior iliac spine.
VALVE, AORTIC	An aortic cardiac valve, comprising the valve leaflets with a specified annular diameter.
VALVE, MITRAL	A mitral cardiac valve, comprising the valve leaflets with a specified annular diameter.
VALVE, PULMONARY	A pulmonary cardiac valve, comprising the valve leaflets with a specified length of pulmonary artery, including lengths and diameters of bifurcations where appropriate and muscle skirt below and of specified diameter.
WHOLE KNEE JOINT, LEFT	The distal femur still attached to the proximal tibia of the left leg (the femur transected above the joint, the tibia transected below the joint), inclusive of the patella tendon, meniscus with intact synovial fluid compartment.
WHOLE KNEE JOINT, RIGHT	The distal femur still attached to the proximal tibia of the right leg (the femur transected above the joint, the tibia transected below the joint), inclusive of the patella tendon, meniscus with intact synovial fluid compartment.

4.2 Modifier

4.2.1 Bounded List and Definitions

Cleaned Frozen	Processed to remove extraneous tissue and, in the case of bone, to deplete blood and bone marrow. Frozen to, and stored at or below –20°C.
Cleaned Frozen Acellular	Processed to remove extraneous tissue and treated to deplete cell, cell remnant and nucleic acid content
Cryopreserved	Processed to remove extraneous tissue and bacterial and fungal contaminants. Cryopreserved using a cryoprotective agent and stored below –135°C.
Decontaminated Frozen	Chemically decontaminated and free of viable bacteria and fungi by culture. Frozen to, and stored at, below –40°C.
Demineralized	Bone that has been acid-treated.
Demineralized Freeze Dried	Bone that has been acid-treated and then freeze-dried to less than 5% residual moisture.
Demineralized Pooled Single Donor	Tissue from a single donor processed as a single batch that has been acid-treated.
Freeze Dried	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Freeze-dried to less than 5% residual moisture.
Frozen	Frozen to, and stored at, below –40°C.
Glycerolized	Disinfected and preserved using high concentration (>90%) glycerol. Free of viable bacteria and fungi by culture. Stored at 2–8°C.
Pooled Multiple Donor	Tissue from more than one donor to be processed, or in process, as a single batch.
Pooled Single Donor	Tissue from a single donor to be processed, or in process, as a single batch.
Refrigerated	Refrigerated (between 1 to 10°C; narrower range may be nationally-specified)
Cleaned Frozen	Processed to remove extraneous tissue and, in the case of bone, to deplete blood and bone marrow. Frozen to, and stored at or below –20°C.
Cleaned Frozen Acellular	Processed to remove extraneous tissue and treated to deplete cell, cell remnant and nucleic acid content
Cryopreserved	Processed to remove extraneous tissue and bacterial and fungal contaminants. Cryopreserved using a cryoprotective agent and stored below –135°C.

Decontaminated Frozen	Chemically decontaminated and free of viable bacteria and fungi by culture. Frozen to, and stored at, below –40°C.
Demineralized	Bone that has been acid-treated.
Demineralized Freeze Dried	Bone that has been acid-treated and then freeze-dried to less than 5% residual moisture.
Demineralized Pooled Single Donor	Tissue from a single donor processed as a single batch that has been acid-treated.
Freeze Dried	Processed to remove extraneous tissue and, in the case of bone, to deplete trabecular bone marrow. Freeze-dried to less than 5% residual moisture.
Frozen	Frozen to, and stored at, below –40°C.
Glycerolized	Disinfected and preserved using high concentration (>90%) glycerol. Free of viable bacteria and fungi by culture. Stored at 2–8°C.
Pooled Multiple Donor	Tissue from more than one donor to be processed, or in process, as a single batch.
Pooled Single Donor	Tissue from a single donor to be processed, or in process, as a single batch.
Refrigerated	Refrigerated (between 1 to 10°C; narrower range may be nationally-specified)

4.3 Attribute

4.3.1 Core Conditions

Core Conditions are not used in the definition of Tissues

4.3.2 Groups and Variables

Any additional manipulation or change to the product is reflected by the addition of one or more attributes from the groups and variables detailed below. Such additional manipulations or changes are indicated by a different Product Description Code.

4.3.2.1 Groups – bounded list and definitions

Group Name	**Description**
Nominal Granule Size	Describes the size range of the product
Sterilization	Describes the method of sterilization of the product.
Unit of Issue	Describes the packaging of the product
Usage	Describes the intended use of the product

4.3.2.2 Variables – bounded lists and definitions

For each group, the variable value shown in bold characters is the default value.

4.3.2.2.1 Nominal Granule Size

Default: not defined	**No information as to granule size is provided**
Coarse >4<=6 mm	Granule size is greater than 4mm and less than or equal to 6mm
Medium >2<=4 mm	Granule size is greater than 2mm and less than or equal to 4mm
Fine <=2 mm	Granule size is less than or equal to 2mm
Ultrafine <=1 mm	Granule size is less than or equal to 1mm
Mixed <=6 mm	Granule size is mixed up to 6mm
Mixed <=4 mm	Granule size is mixed up to 4mm
Medium Powder >=1.2<=2.0mm	Granule size is between 1.2 and 2mm. More information may be specified on packaging
Fine Powder >0.1<1.2mm	Granule size is between 0.1 and 1.2mm. More information may be specified on packaging

4.3.2.2.2 Sterilization

Default: not sterilized	**The product has not been sterilized**
ETO	Sterilized by exposure to ethylene oxide gas in the final container
Irradiated	Exposed to gamma irradiation at a target absorbed dose of not less than 15kGy in the final container
Peracetic Acid	Exposure to peracetic acid used as a sterilant in the processing procedure.

4.3.2.2.3 Unit of Issue

Default: not defined	**No information is provided as to the packaging of the product**
Single	Issued as a single item
Pack	Issued as a pack of multiple items – number specified on packaging

4.3.2.2.4 Usage

Default: not defined	**No information is provided as to the status of the product**
For further processing	Product produced as an intermediate stage. Not suitable for clinical use without further processing.

5 Derivatives

5.1 Class

5.1.1 Bounded Lists and Definitions

SOLVENT DETERGENT POOLED PLASMA	Plasma that has been prepared by combining multiple units from single donors; pathogen-inactivating using a solvent detergent (SD) process with subsequent removal of the SD reagents; aliquoting into individual dose containers; and freezing by a process and to a temperature that will maintain the activity of labile protein fractions

5.2 Attribute

5.2.1 Core Conditions

Please see Section 2.3.1 for an explanation of Core Conditions.

5.2.1.1 Core Conditions lists and definitions

First Position – bounded list

Anticoagulant	Description
NS	Not specified

Second Position – examples (this list is not bounded, other volumes may be defined)

Volume	Description
NS	Not specified

Third Position – examples (this list is not bounded, other temperature ranges may be defined)

Storage Temperature	Description
<=-18C	Less than, or equal to -18 C

5.2.2 Groups and Variables

Additional information about a product is supplied as attributes. Such attributes are indicated by a different Product Description Code.

5.2.2.1 Groups: Bounded list and definitions

Group Name	Description
Blood Group	Specifies ABO Blood Group and/or RhD type

5.2.2.1.1 Variables – bounded lists and definitions

For each group, the variable value shown in bold characters is the default value.

5.2.2.1.2 Blood Group

Default: NS	The blood group is not specified.
O	The product is prepared from Group O donations
A	The product is prepared from Group A donations
B	The product is prepared from Group B donations
AB	The product is prepared from Group AB donations

6 Retired Codes

Over time, codes may become inappropriate, redundant, or errors may be discovered. As a result, a mechanism must exist to discontinue future use of these codes. However, because products may exist in inventories across the world, the codes must be retained in the database for backward compatibility.

To accomplish this goal, a new column has been added to ICCBBA databases. This "Retired Date" column indicates the date on which ICCBBA recommended the codes no longer be used for new products. Software should be written to recognize these codes, but not assign them to newly created products. It is understood that facilities must be given time to retire codes after ICCBBA has made its recommendation.

Below are codes and their definitions that have been retired.

6.1 Blood Codes

6.1.1 Class

No blood class codes have been retired.

6.1.2 Attribute

6.1.2.1 Core Conditions

Term	Definition
CP2D−AS3/XX/refg	E@B0
None/NS/<=-18C	E@BD
None/NS/rt	E@BF
DMSO/NS/<-80C	E@CK

6.1.2.2 Groups and Variables

No Group or Variable codes for blood have been retired.

6.2 Cellular Therapy Codes

6.2.1 Class

Term	Definition
T CELLS	T cells obtained by appropriate manipulation of a Whole Blood collection
T CELLS, Apheresis	T cells obtained by appropriate manipulation of an apheresis collection
LYMPHOCYTES, Apheresis	Lymphocytes obtained by appropriate manipulation of an apheresis collection
POOLED HPC, Apheresis	Pool of multiple HPC Apheresis collections from the same donor
MNC, Apheresis	Mononuclear cells obtained by apheresis
TC-T, Apheresis	(Not defined)
TC-CTL, Apheresis	(Not defined)
TC-DC, Apheresis	(Not defined)
TC-T, WHOLE BLOOD	(Not defined)
TC-CTL, WHOLE BLOOD	(Not defined)
TC-DC, MARROW	(Not defined)
TC-DC, CORD	(Not defined)

6.2.2 Modifiers

Term	Definition
Heparinized	Describes a product prepared by adding a variable amount of heparin to the anticoagulant before beginning the collection procedure, or in which heparin is the sole anticoagulant. Processing records should provide a record of the amount of heparin used; the label text should specify the amount of heparin in the final product.
Frozen	Describes a product in the cryopreserved state at a designated temperature

6.2.3 Attributes

6.2.3.1 Core Conditions, First Position

Term	Definition
ACD-A	Acid Citrate Dextrose, Formula A
ACD-A+10% DMSO	Acid Citrate Dextrose, Formula A – 10% Dimethylsulfoxide
ACD-A + Heparin	Acid Citrate Dextrose, Formula A – heparin
ACD-A + Heparin+6% HES	Acid Citrate Dextrose, Formula A – heparin – 6% Hydroxyethyl Starch
ACD-A + Heparin+6% HES + 10% DMSO	Acid Citrate Dextrose, Formula A– heparin – 6% Hydroxyethyl Starch – 10% Dimethylsulfoxide
CPD	Citrate Phosphate Dextrose
CPD+Heparin	Citrate Phosphate Dextrose – heparin
CPDA-1	Citrate Phosphate Dextrose Adenine
CPDA-1+DMSO	Citrate Phosphate Dextrose Adenine – Dimethylsulfoxide
CPDA-1+10% DMSO+30% SSPP+10% plasma	Citrate Phosphate Dextrose Adenine – 10% Dimethylsulfoxide + 30% Isotonic Albumin + 10% plasma
CPDA-1+10% DMSO+0.8% HES+1% dextran	Citrate Phosphate Dextrose Adenine – 10% Dimethylsulfoxide – 8% Hydroxyethyl Starch + 1% Dextran
DMSO	Dimethylsulfoxide
HES-DMSO	Hydroxyethyl Starch – Dimethylsulfoxide
PBS	Phosphate Buffered Saline
PBS+alb+4% NaCitrate	Phosphate Buffered Saline – albumin – 4% Sodium Citrate
PBS+alb+4% NaCitrate+10% DMSO	Phosphate Buffered Saline – albumin – 4% Sodium Citrate – 10% Dimethylsulfoxide

6.2.3.2 Attributes: Groups

Term	Definition
System Integrity	Describes the microbiological integrity of the collection/storage system
Preparation — Additional Information	Provides supplementary information about the preparation of a product
Final Product — Additional Information	Provides additional information regarding the number of containers of final product prepared from a collection
Further Processing	Describes additional processing steps

6.2.3.3 Attributes: Variables

6.2.3.3.1 System Integrity Group

Term	Definition
Default: Closed	**The product has been prepared in a closed system and the microbiological integrity of the system has not been compromised.**
Open	Open System: the system has been opened and the microbiological integrity may have been compromised.

6.2.3.3.2 Preparation: Additional Information Group

Term	Definition
Default: no preparation information	**There is no information about the preparation of the product.**
Heparin added	A product to which heparin has been added
Plasma removed	A product from which most of the plasma has been removed
Dextran+Albumin added	A product to which dextran and albumin have been added
6% HES+5% DMSO-Plasma added	A product to which Hydroxyethyl Starch, Dimethylsulfoxide and plasma have been added
Plasma added	A product to which plasma has been added
Donor erythrocytes added	A product to which donor erythrocytes have been added
Plasma reduced	A product from which some of the plasma has been removed
1.25% Albumin in saline added	A product to which 1.25% albumin in saline has been added
6% HES + 5% DMSO	Moved to Cryoprotectant Attribute group
10% DMSO	Moved to Cryoprotectant Attribute group

6.2.3.3.3 Final Product: Additional Information Group

Term	Definition
Default	**A single container of final product was prepared from the collection.**
1st container	The first of two or more containers holding a product prepared from one collection
2nd container	The second of two or more containers holding a product prepared from one collection
3rd container	The third of three or more containers holding a product prepared from collection
4th container	The fourth of four or more containers holding a product prepared from one collection
5th container	The fifth of five or more containers holding a product prepared from one collection
6th container	The sixth of six or more containers holding a product prepared from one collection
7th container	The seventh of seven or more containers holding a product prepared from one collection
8th container	The eighth of eight or more containers holding a product prepared from one collection
9th container	The ninth of nine or more containers holding a product prepared from one collection
10th container	The tenth of ten or more containers holding a product prepared from one collection
11th container	The eleventh of eleven or more containers holding a product prepared from one collection
12th container	The twelfth of twelve or more containers holding a product prepared from one collection
13th container	The thirteenth of thirteen or more containers holding a product prepared from one collection
14th container	The fourteenth of fourteen or more containers holding a product prepared from one collection
15th container	The fifteenth of fifteen or more containers holding a product prepared from one collection
16th container	The sixteenth of sixteen or more containers holding a product prepared from one collection

6.2.3.3.4 Manipulation Group

Term	Definition
Minimal	Minimally Manipulated: processed by centrifugation and/or density gradient fractionation to concentrate the mononuclear cell fraction [includes depletion of red blood cells and plasma]
Extensive	Extensively Manipulated: further positive or negative selection of specific fractions from a minimally manipulated product
CD8-depleted	The CD8 cell population has been reduced by appropriate manipulation.
CD34-removed	The CD34 cell population has been reduced by appropriate manipulation.
AC133-selected	The ACC133 cell population has been selected for by appropriate manipulation
T-cells depleted	T-cells have been removed from the product
From buffy coat	Not defined
Density enriched	Not defined
CD56 enriched	Not defined

6.2.3.3.5 Further Processing Group

Term	Definition
Default: no further processing	(Not defined)
Volume DMSO reduced	(Not defined)

6.2.3.3.6 Cryoprotectant Group

Term	Definition
DMSO reduced	The cells were frozen using DMSO as a cryoprotective agent that has subsequently been partially removed using a wash procedure after thawing.

6.3 Tissue Codes

No tissue codes have been retired.

