

2010 A Year End Review

ISBT 128 Cellular Therapy Coding and Labeling Advisory Group

For Cellular Therapy, this advisory group is the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). The group comprises representatives from the following professional organizations: AABB, Asia Pacific Blood and Marrow Transplant (APBMT), American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). In addition to these representatives, technical experts and regulatory liaisons also serve on the committee.



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Participating Organizations



Cellular Therapy Coding and Labeling Advisory Group

The Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) was established in 2004. Its purpose is to advise ICCBBA of the needs of cellular therapy organizations for coding and labeling. Membership comprises representatives from major cellular therapy professional organizations: AABB, APBMT, ASBMT, ASFA, EBMT, FACT, ICCBBA, ISBT, ISCT, JACIE, NMDP, and WMDA. Additionally, the group has invited technical experts to serve as voting members on the group.

The CTCLAG reviews requests for new terminology ensuring consistency and consensus in terminology, prepares educational materials, and organizes workshops for ISBT 128 users around the world. The Standard that resulted from their work was published in July 2007 (Ashford, P, Distler, P, Gee, A, et al. Standards for the Terminology and Labeling of Cellular Therapy Products. Transfusion 2007;47:1319-27).

A significant accomplishment for the group is the recent publication of the Second Consensus Statement on Terminology, Coding, and Labeling of Cellular Therapy Products. The statement is available on the ICCBBA website and included in full on the final page of this publication.

Members of the CTCLAG

Name	Affiliation
Slaper-Cortenbach, Ineke (Chairperson)	JACIE representative
Allman, Sallie	NMDP representative
Ashford, Paul	ICCBBA representative
Distler, Pat (Secretary)	ICCBBA representative
Janssen, William	ASBMT representative
Koh, Mickey	APBMT representative
Lankester, Alan	Technical expert
Larsson, Stella	Technical expert
Loper, Kathy	AABB representative
Miller, John	WMDA representative
Querol, Sergio	EBMT representative
Sims-Poston, Leigh	ISCT representative
Szczepiorkowski, Zbigniew	ASFA representative
Warkentin, Phyllis	FACT representative

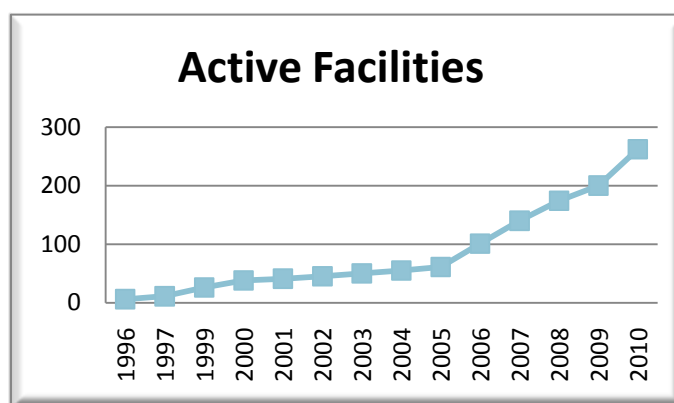


Countries with Cellular Therapy ICCBBA Registered Facilities

During the five years since the inception of CTCLAG, a great deal of progress has been made. As of 31 December 2010, there were 262 active Facility Identification Numbers assigned to Cellular Therapy (CT) facilities in 38 countries. Of these, 57 (22%) registered in 2010.

Number of Cellular Therapy Facilities in Each Country

Country	CT Facilities as of 31 December 2010	Country	CT Facilities as of 31 December 2010
Algeria	1	Japan	1
Argentina	1	Kazakhstan	1
Australia	3	Mexico	2
Austria	13	The Netherlands	2
Belgium	6	People's Republic of China	11
Brazil	20	Poland	21
Canada	11	Portugal	1
Croatia	1	Republic of China	4
Czech Republic	1	Russian Federation	3
Denmark	1	Saudi Arabia	2
Egypt	1	Singapore	2
France	5	South Korea	1
Germany	1	Spain	8
Greece	4	Sweden	1
India	1	Switzerland	2
Iran	1	Thailand	2
Ireland	1	Turkey	4
Israel	3	United Kingdom	8
Italy	2	United States of America	109

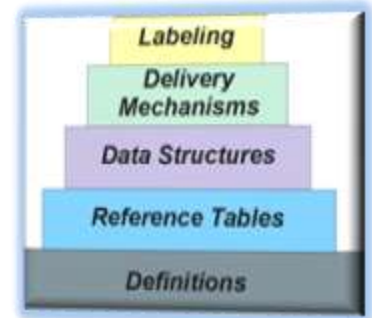


Additions to Terminology in 2010

An important task of the CTCLAG is to review requests for new product descriptions to ensure the appropriate level of detail is used to describe products.

Products are described in terms of classes, modifiers, and attributes.

STRUCTURE OF TERMINOLOGY	
Classes	Classes are broad definitions of products. Examples are HPC, Cord Blood; HPC, Marrow; and TC, Apheresis.
Modifiers	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	Attributes provide the means to uniquely define products.



During 2010, two new classes for products were defined by CTCLAG:

NC, Menstrual Blood	Nucleated cells collected from menstrual blood, with undefined therapeutic use at the time of collection.
NC, Adipose Cells	Nucleated cells collected from adipose tissue, with undefined therapeutic use at the time of collection.

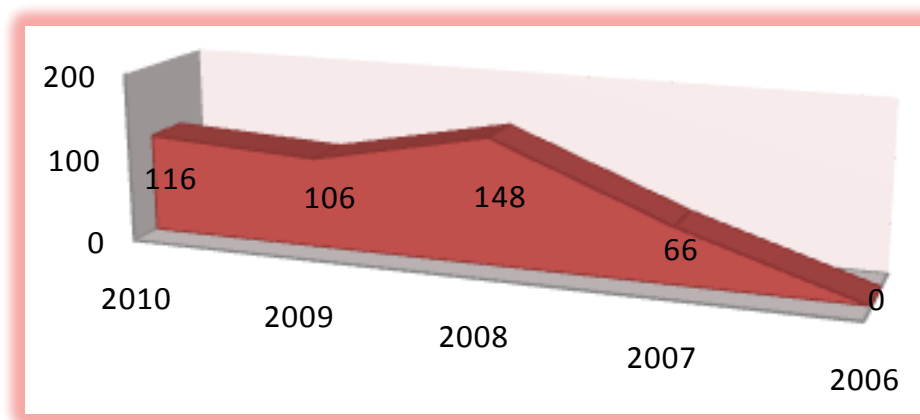
In addition to adding the above terminology, 116 new Cellular Therapy product codes were added in 2010. Product code requests reflect active use of ISBT 128 for Cellular Therapy. These product code requests were received from facilities in:

- Canada
- Singapore
- USA
- France
- Scotland
- The Netherlands
- Sweden

All terms and definitions for ISBT 128 are included in a document called "ISBT 128: Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions" that is available to all at no charge on the ICCBBA Website.

ISBT 128 terminology is required by FACT, JACIE, and AABB for labeling of Cellular Therapy.

Annual Cellular Therapy Product Code Requests



Cellular Therapy facilities that are registered with ICCBBA can request a product code by filling out the form available on the ICCBBA Website.

<http://www.iccbba.org/subject-area/cellular-therapy>

Highlight: Cellular Therapy Facilities that Have Successfully Implemented ISBT 128

In this section we feature comments from two laboratories that have successfully implemented ISBT 128.

Comments provided by:

Boris Calmels, PharmD, PhD
Centre de Therapie Cellulaire

*Departement de Biologie
Institut Paoli-Calmettes*

Marseille, France



Guillaume Bouchet, from the cellular therapy facility, checking a HPC graft before distribution.

When did you implement ISBT 128?

We collaborated with Modul-Bio (a French company specializing in traceability solutions) over the last two years to develop ISBT 128 compliant software. Our go live was March 2011.

Why did you want to implement ISBT 128?

We feel that international transfer of cell therapy products will continue to increase over the years and that a common and accurate identification system is thus mandatory. So far, ISBT 128 is the only global standardized system for coding and labeling cell therapy products.

What are the benefits you perceive to using ISBT 128?

The unique coding system of ISBT 128 allows for all cell therapy products to be unequivocally identified. Moreover, a generation of new product codes for specific or local usage is simple and efficient.

What “words of wisdom” can you share with others about your implementation experience?

Be sure to choose a flexible and user-friendly software for label creation, both in English and in local languages, as it is crucial for staff comprehension and adoption of this new labeling system as their own.



HPC, Cord Blood Unit with ISBT 128 Storage Label prior to Cryopreservation

Comments provided by:

Sharon N. Miller, MT(ASCP), CHS(ABHI)
 Director of Regulatory Affairs
 Supervisor of UCCBB, Stem Cell Laboratory

Clinimmune Labs – Aurora, Colorado

The United States of America

When did you implement ISBT 128?

The University of Colorado Cord Blood Bank implemented ISBT 128 June 8, 2010.

Why did you want to implement ISBT 128?

To be ready when it is required and because using a standardized label will make it easier for us to prepare for cord blood FDA licensure.

What are the benefits you perceive to using ISBT 128?

We are both an HPC, Apheresis stem cell lab and cord blood bank. We understand the difficulty in getting many different label formats from many different cord blood banks for products for infusion to our patients. We look forward to having all HPC facilities using the same standardized format.

What “words of wisdom” can you share with others about your implementation experience?

We have an IT department that designed and formatted our label printing and validation. We decided to print the whole 4 quadrant label to adhere at collection, and then adhere at cryopreservation. We duplicated this storage label to attach to our metal canister, since we needed a partial package label to include all information on the storage label. A third four quadrant update with recipient information is attached (not adhered) at distribution.

We did need to edit our current Cord Blood Identification Number, since it was formatted as 8000000 (7 digits) and ISBT 128 serial number allows only 6 digits, so we truncated the first “8”. We found this created confusion to the transplant centers and needed to prepare a document to match the ISBT 128 label identification with our release report identification number. This document is helpful since the ISBT 128 number includes the Facility Identification Number, the year of collection, and the 6-digit Cord Blood Identification Number (serial number).



HPC, Cord Blood Storage Canister ISBT 128 Package Label



HPC, Cord Blood Processing Technician with ISBT 128 Collection Label

Presentations in 2010

Presentations:

ISCT Webinar, ISBT 128 Labeling for Cellular Therapy February 2010 (Chao-Yong Lee, Giovanna Cameron, and Pat Distler)

ISCT Annual Meeting Workshop, Philadelphia, Pennsylvania, USA, May 2010 (Kathryn M. Bushnell, Lisa Phillips-Johnson, and Leigh Sims-Poston)

ISBT Workshop, Berlin, Germany, June 2010 (Ineke Slaper-Cortenbach and Deirdre Fehily)

ISCT Europe 2nd Regional Meeting, Belgirate, Italy, September 2010, Belgirate, Italy (Stella Larsson and Lex van de Gouw)

AABB Annual Meeting, Baltimore, Maryland, October 2010 (Leigh Sims-Poston and Giovanna Cameron)

Exhibit Hall Participation:

In 2010, ICCBBA staff attended a number of Cellular Therapy meetings and participated in the exhibit halls.

Month	Organization	Location
March	European Group for Blood and Marrow Transplantation (EBMT)	Vienna, Austria
May	International Society for Cellular Therapy (ISCT)	Philadelphia, Pennsylvania USA
June	International Society of Blood Transfusion (ISBT)	Berlin, Germany
September	ISCT – Europe 2 nd Regional Meeting	Belgirate, Italy
October	AABB	Baltimore, Maryland USA
October	Haematology Society of Australia and New Zealand (HSANZ), the Australian and New Zealand Society of Blood Transfusion (ANZSBT) and the Australasian Society of Thrombosis and Haemostasis (ASTH)	Auckland, New Zealand
October	World Marrow Donor Association (WMDA) and National Marrow Donor Program (NMDP)	Minneapolis, Minnesota, USA

Publications in 2010

Ashford, Paul. "Traceability." *Cell and Tissue Banking*, 2010, Volume 11, Number 4, Pages 329-333
<http://www.springerlink.com/content/l8q785495x7t42w4/fulltext.pdf>

Distler, Pat. "ISBT 128: A Global Information Standard." *Cell and Tissue Banking*, 2010, Volume 11, Number 4, Pages 365-373
<http://www.springerlink.com/content/08ru28526212762g/fulltext.pdf>

Sims Poston, Leigh. "ISBT 128 Labeling for Cellular Therapy Products" *Blood and Transplant Matters*, Spring 2010, Issue 30, Page 14
<http://hospital.blood.co.uk/library/pdf/bm30.pdf>

Slaper-Cortenbach, Ineke. "ISBT 128 Coding and Labeling for Cellular Therapy Products." *Cell and Tissue Banking*, 2010, Volume 11, Number 4, Pages 375-378
<http://www.springerlink.com/content/65n1372431n0r711/fulltext.pdf>

Slaper-Cortenbach, Ineke. "ICCBBA and ISBT 128 – Value for Money?" *Blood and Transplant Matters*, Spring 2010, Issue 30, Page 13
<http://hospital.blood.co.uk/library/pdf/bm30.pdf>



 C0020 08 071801 8 	 4900	 Rh Positive
Leukemia/BMT Program of BC Vancouver, BC, Canada V5Z 1M9 Health Canada CTO#: 100014	 BIOHAZARD	
Collection Date/Time 22 JAN 2008 13:59 (22 JAN 2008 20:59 GMT)	For Use by Intended Recipient Only	
Warning: Advise Patient of Communicable Disease Risk	Related Donor: SMITH, JOHN Donor#: S123456789 DOB: 25 MAR 1981	
 S1184300 DIRECTED	Expiration Date/Time: 23 JAN 2008 13:59 (23 JAN 2008 20:59 GMT)	
HPC, MARROW PLASMA REDUCED With <u>115</u> mL PlasmalyteA and <u>7</u> mL Heparin	RBC (In)Compatible Approx Volume: _____ mL	
Store in 2 to 8°C Properly Identify Intended Recipient & Product Do Not Irradiate Do Not Use Leukoreduction Filter	Intended Recipient: SMITH, MARTHA PHN: 0123 456 789 DOB: 07 JUL 1953	
Clinical Cell Therapy Laboratory Leukemia/BMT Program of BC Vancouver, BC, Canada V5Z 1M9 Health Canada CTO#: 100014	Vancouver General Hospital Leukemia/BMT Program of BC Vancouver, BC, Canada V5Z 1M9 Health Canada CTO#: 100014	

Label example provided by
 Giovanna Cameron, RT
 Section Head, Clinical Cell
 Therapy Laboratory
 Leukemia/Bone Marrow
 Transplant Program of
 British Columbia
 Vancouver, British
 Columbia, Canada

(fictitious donor and patient
 names have been used in
 this example)

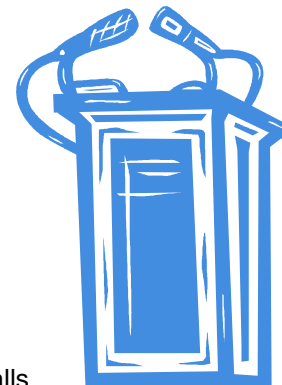
Activities Planned for 2011

Presentations:

ISCT Annual Meeting Workshop, Rotterdam, Netherlands, May 2011

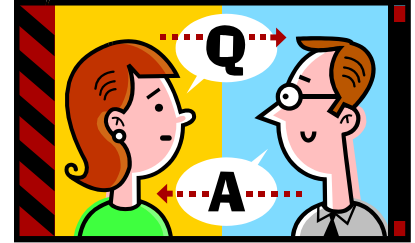
Exhibit Hall Participation:

In 2011, ICCBBA staff plan to attend Cellular Therapy meetings and participate in the exhibit halls.



Month	Organization	Location
April	European Group for Blood and Marrow Transplantation (EBMT)	Paris, France
May	International Society for Cellular Therapy (ISCT)	Rotterdam, Netherlands
June	International Society of Blood Transfusion (ISBT)	Lisbon, Portugal
October	AABB	San Diego, California, USA
October	World Marrow Donor Association (WMDA) and National Marrow Donor Program (NMDP)	Minneapolis, Minnesota, USA
November	Haematology Society of Australia and New Zealand, the Australian & New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis (HAA). Held jointly with ISHAPD (International Society of Hematology, Asia-Pacific Division), APBMT (Asian-Pacific Blood and Bone Marrow Transplantation Group) and the ISCTA (International Society for Cellular Therapy: Australia).	Sydney, Australia
November	International Society of Blood Transfusion (ISBT)	Taipei, Taiwan

FREQUENTLY ASKED QUESTIONS



- Q: I currently use ISBT 128 compliant labels only on my final product, after completion of processing and freeze-down. Is this sufficient for compliance, or do my intermediate product labels (i.e. post collection; mid-processing steps such as plasma reduction) need to be ISBT 128 compliant, as well?
- A: Yes, it is sufficient to have ISBT 128 compliant labels only on the products that will leave your laboratory (either released to the floor or to another facility).
- Q: Since no appropriate “thawed” product codes were available at the time of implementation, I currently do not replace the “cryopreserved” product label once my product is thawed. I issue the thawed product with the cryopreserved product label still attached. Since those product codes are now available, are we expected to replace the “cryopreserved” label with a “thawed” label prior to release for infusion?
- A: Yes, it would be better to label this product with the thawed codes if the thawing occurs in the lab (as opposed to at bedside). This doesn’t have to be done immediately, but is something you should work towards.
- Q: My products are given “indefinite” expiration dates (10%DMSO, continuous LN2 storage), so my labels do not contain a bar coded expiration date. Must I pick a date in order to have it bar coded even though it is not accurate?
- A: You should NOT put an inaccurate date on the product. Not all cellular therapy products have an expiration date so this isn’t a requirement for all products.
- Q: When is it appropriate to use the “Mobilized” modifier?
- A: Currently, the “Mobilized” modifier is to be used only with TC, Apheresis or Bone Marrow. There are other classes in which “Mobilized” does apply (i.e., HPC, Apheresis and HPC, Whole Blood), but these classes have already been defined as being “mobilized unless otherwise stated in the modifier”. Since it is already part of the definition, it would be redundant to have a “Mobilized HPC, Apheresis”.
- Q: To freeze our HPC, Marrow, we RBC reduce and plasma reduce the unit. However, I am only allowed to choose one attribute from the Manipulation attribute group. What attribute would I use to describe this product?
- A: The Standard Terminology document lists and defines each of the ISBT 128 product description terms. In section 3.3.2.2.2 (Manipulation Group), you will find an attribute of “Buffy coat enriched” defined as “cells remaining after the reduction of mature erythrocytes and plasma”.

FREQUENTLY ASKED QUESTIONS - continued

Q: Does the ISBT 128 Standard recommend that laboratories re-label a banked cryopreserved product at distribution with the current ISBT 128 terminology? Having to go back and re-label these products at distribution is a logistical challenge because older paperwork may not identify all needed info like additive volumes/concentrations. There is also risk of endangering the product when handling or re-labeling.

A: No, we do not recommend re-labeling products in inventory. There would be an unnecessary risk of error in re-labeling. It's best to just let the change occur over time.

Q: When is UTC (Universal Coordinated Time) required on ISBT 128 labels?

A: The ISBT 128 Standard requires that the label include the Universal Coordinated Time (UTC) when the product is to be shipped across an international time zone.

The UTC shall be printed beneath the local time in parenthesis with the designation "UTC". Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time:

15 JAN 2011 15:15 EST
(15 JAN 2011 20:15 UTC)

OR

2011-01-15 15:15 EST
(2011-01-15 15:15 UTC)

Note: It is recognized that local time zone designations may have little meaning internationally since two time zones may have the same abbreviation (e.g., EST can mean Eastern Standard Time in Australia, which is UTC+10 hours or Eastern Standard Time in North America, which is UTC -5 hours). However, the Cellular Therapy Coding and Advisory Group (CTCLAG) believe that local time zones are more readily interpreted within a continent. For products shipped to different continents, UTC should be used to interpret time.

Cellular Therapy Coding and Labeling Advisory Group

Participating Organizations



Second Consensus Statement on Terminology, Coding and Labeling of Cellular Therapy Products

In 2005 the Boards of AABB, ASBMT, ASFA, EBMT, FACT, ICCBBA, ISBT, ISCT, JACIE, NMDP and WMDA issued a consensus statement in support of the use of *ISBT 128* in the coding of hematopoietic progenitor cell and other therapeutic cell products and announced the establishment of a co-sponsored International Cellular Therapy Coding and Labeling Advisory Group.

Since that time the Advisory Group has been meeting regularly and has established a well structured terminology for hematopoietic progenitor cells which has been adopted as the formal terminology in the accreditation standards of AABB, FACT, and JACIE. In addition a number of cellular therapy laboratories have implemented the *ISBT 128* Standard for coding and labeling of their products. The Asia Pacific Blood and Marrow Transplantation Group has recently joined the Advisory Group.

Recognizing:

- the need for a common and consistent means of coding and labeling for all cellular therapy products;
- the importance of globally unique identification for cellular therapy products as an essential element of effective traceability;
- the importance of an agreed common structured terminology to describe cellular therapy products;

The Boards of the above organizations:

- acknowledge the substantial progress that has been made by the Cellular Therapy Coding and Labeling Advisory Group;
- encourage cell therapy facilities to move forward with the implementation of *ISBT 128* coding and labeling;
- request the Cellular Therapy Coding and Labeling Advisory Group to extend the terminology to cover non-hematopoietic cellular therapy products, working with other technical advisory groups as appropriate;
- encourage other relevant professional bodies, accreditation bodies, regulators and health authorities to support this drive for global standardization.

For further information on this initiative contact cellulartherapy@isbt128.org