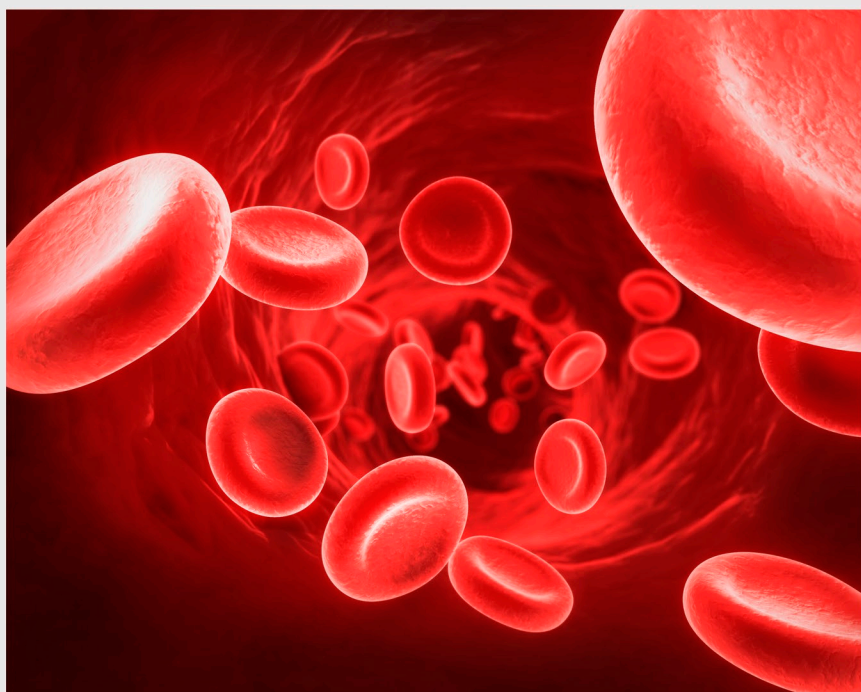




Cellular Therapy ISBT 128 Labeling Implementation



Is your facility compliant with the latest (8th) edition of the **FACT-JACIE International Standards for Hematopoietic Cellular Therapy?**

Required Implementation date: **May 2018**



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Introduction

The 7th edition of the FACT-JACIE International Standards for Hematopoietic Cellular Therapy— Product Collection, Processing and Administration was published in March 2018 by The Foundation for the Accreditation of Cellular Therapy and the Joint Accreditation Committee – ISCT and EBMT. These standards are designed to provide minimum guidelines for programs, facilities, and individuals performing cellular therapy or providing support services for such procedures.

The major objective of these standards is to promote quality medical and laboratory practices in hematopoietic progenitor cell transplantation and related therapies using hematopoietic derived cellular products. Following standardized labeling conventions is one way to help achieve this goal.



ISBT 128 Identification & Labeling Benefits

One of the major revisions in this 7th edition is the following: Implementation of ISBT128 terminology, identification, coding and labeling is required, unless Eurocode has been previously established and maintained. FACT and JACIE recognize the significant benefits of international standardization of coding and labeling in cellular therapy, and support the international efforts to implement ISBT 128 and Eurocode. ISBT 128 is the global standard for terminology, identification, coding, and labeling of Medical Products of Human Origin (MPHO), and has been designed to ensure accuracy and safety for the benefit of patients and donors worldwide.

Section CM7 of the FACT-JACIE International Standards for Hematopoietic Cellular Therapy discusses the coding and labeling of cellular therapy products. Specifically, ISBT 128 and European Coding and labeling requirements, labeling operations using ISBT 128 bar codes, product identification and label content. Find the link for these standards at the end of this document.

The HemaTrax®-CT system– The best solution to ISBT 128 bar code labeling

In order to comply with the FACT-JACIE standards, consider the implementation of the leading on demand IBST bar code printer and software – the HemaTrax®-CT system.

HemaTrax®-CT was specifically designed to meet the needs of cellular therapy operations worldwide. This concise, easy to use system was developed under the ISBT standards to eliminate the mislabeling or misidentification of cellular therapy products and product samples.

Need a way to print the different products you need in a controlled manner and eliminate errors? **HemaTrax®-CT is the perfect solution.**

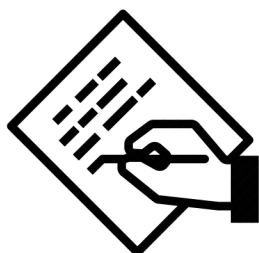
- ▶ Our print on-demand label systems produce cellular therapy labels that are accurate in terms of content, bar code scanning quality and conformity
- ▶ Cellular therapy products that are subsequently re-packaged into new containers can easily be re-labeled before they are detached from the original container with just the push of a button.



- ▶ Digi-Trax keeps facilities compliant and does all the work for you. The labeling elements that are required by applicable regulations are available in our system using our simple software. All data fields on labels will be completed, and the labeling is clear, legible, and complete using ink and label material that withstands harsh conditions including alcohol, bleach and other solvents that could cause unreadable labels in cellular therapy operations.



- ▶ There is no longer a need for any handwritten labels, cardstock overtags or need to write on the bag itself– the standards are very clear and you only need to include the information required.



- ▶ By printing an ISBT 128 bar code with the HemaTrax-CT system, you can rest assured that each cellular therapy product collection is assigned a unique numeric or alphanumeric identifier.
- ▶ All cellular therapy product, product samples, and concurrently collected samples can then be relabeled with the same identifier.



HemaTrax®-CT software

- ▶ Digi-Trax works closely with the relevant cellular therapy committees to ensure that our software is kept up to date. No need to worry that your labels are not ISBT 128 compliant.
- ▶ Within our HemaTrax-CT software, you can store the labels you need and then recall them at a later date. No need to re-enter information or handwrite what you need on a label again and again. The software will save your label formats for you – you can then reprint the labels at a later date.
- ▶ Once this information is saved in the software, you can print multiple types of labels using this the same information.
- ▶ The system is extremely user-friendly and inexpensive (a complete HemaTrax-CT kit starts at less than \$5000) and requires only a simple installation.
- ▶ We provide ongoing dedicated customer service and technical support and are ready to answer your questions.



Resources

For more information, contact Digi-Trax® at **847-613-2100**, info@digitrax.com or at www.digitrax.com

Find the **8th edition of the FACT-JACIE standards** here:

https://www.digitrax.com/wp-content/uploads/2022/07/FACT-JACIE_Standards_Eighth_Edition_8_1_R2_12142021.pdf



Eliminate Errors
with HemaTrax®-CT

About Digi-Trax®

Digi-Trax® serves the healthcare and life sciences communities as a Value-Added-Reseller (VAR) and Systems Integrator (SI). Digi-Trax provides systems, hardware, software, supplies and manufacturer-authorized technical support services. Our target markets are all hospital pharmacies, laboratory operations, blood collection centers, blood transfusion services and clinical patient identification.