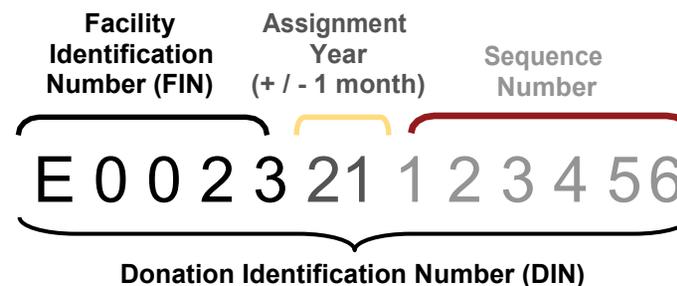


ISBT 128 and Traceability

ISBT 128 supports traceability through the combined use of a globally unique Donation Identification Number and a Product Code.

Globally Unique Donation Identification Number (DIN)

Because the first five characters of an ISBT 128 DIN identify the facility that collected (or pooled) the product, the DIN may be used as the first step in tracing the product back to the facility that collected it.



The Facility Identification Number (FIN) is assigned by ICCBBA, the not-for-profit organization that maintains the ISBT 128 Standard. The database that maps the FIN to a facility is available to all ICCBBA-licensed facilities and is located in the password protected area of the ICCBBA Website (www.isbt128.org). The name of this Excel file is Registered Facilities – xlsx. It is also available on the Website as a text file (called Registered Facilities – Text File).

An excerpt of the Excel file is shown:

FIN	Firm Name	City	State/Province	Country	Postal Code	Website
E0023	Centro de Transfusión Banco De Sangre De La Rioja	Logrono	La Rioja	Spain	26006	www.bancosangrerioja.org
E0024	Red Andaluza de Transfusión (Granada)	Granada		Spain	18012	www.transfucion.granada-almeria.org
E0025	Banc De Sang I Teixits	Barcelona		Spain	08005	www.bancsang.net
E0026	Ivi Cordon, S.A.	Madrid		Spain	28035	www.ivida.es

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The Registered Facilities database provides the name, location, and website of the collection facility.

For instance, if a product is received with the DIN E0023 21 123456, it can be seen that it was collected by Centro de Transfusion Banco De Sangre De La Rioja in La Rioja, Spain.

FIN	Name	City	State/Province	Country	Postal Code	Website
E0023	Centro de Transfusión Banco De Sangre De La Rioja	Logrono	La Rioja	Spain	26006	www.bancosangrerioja.org

A lookup program is also available on the ICCBBA Website at (www.iccbba.org/lookup-tools/find-facility-information).

This program allows the user to find information on a collection facility by entering the FIN in the Search option of the program.

The screenshot shows a web interface titled "FIN Lookup Tool". It features a search input field containing "E0023" and a "Search" button. Below the search area, a "Search Results" section displays a table with the following data:

FIN	Firm Name	City	State/Province	Country	Postal Code	Web site
<u>E0023</u>	Centro de Transfusion Banco De Sangre De La Rioja	Logrono	La Rioja	Spain	26006	www.bancosangrerioja.org

ISBT 128 and Traceability

Product Codes

Traceability requires that each medical product of human origin be identified uniquely. Because all products from a single donation will have the same DIN, uniqueness of each product is achieved through a combination of the DIN and the Product Code (with some exception to tissue products). For example, while both the Red Cells and the Plasma from a single donation will have the same DIN, they will have different Product Codes.

ISBT 128 Product Codes have eight characters. For example, a Blood Product Code is E0401VA0.



The first five characters in the example blood code comprise the Product Description Code and are mapped to their descriptions on a database found in the password protected area of the ICCBBA Website (www.isbt128.org). This database is called ISBT 128 Product Description Codes Database. E0401, the code used in this example, is the code for Red Blood Cells with CPD anticoagulant, AS-5 additive, with a nominal collection volume of 450 mL, stored at a refrigerated temperature and has been leukocyte reduced. It appears in the database in a format as shown below. Some columns from the database have been deleted in the example for simplicity.

PRODESCRIPCODE	Class Identifier	Modifier Identifier	PRODESCRIP0	CODEDATE	Product Formula
E0401	C0002	M0000	RED BLOOD CELLS CPD>AS5/450mL/refg ResLeu:<5E6	19 JUL 1996	C0002-M0000-V0001022-V0014004

The sixth character of the blood Product Code indicates the type of collection. The key to this code is found on Table **RT008** in the *ISBT 128 Standard Technical Specification* (ST-001). Some examples from this table are Volunteer homologous (V), Autologous (1), and Directed (2).

If a product is divided (that is, a Red Blood Cell component is divided into multiple pediatric aliquots), ISBT 128 allows each division to be uniquely identified

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through the use of the seventh and eighth positions in the data structure. When a product is not divided, the characters in the seventh and eighth positions are zeroes (e.g., E0401V00). If this product is divided into two aliquots, the zero in the seventh position changes to an upper-case letter. One division becomes E0401VA0 and the other division becomes E0401VB0, allowing each to be traced separately. If the first division (E0401VA0) is subsequently divided again (perhaps into syringe aliquots), the eighth character changes to a lower-case letter (E0401VAa).

Some of the ISBT 128 product codes utilize the sixth, seventh, and eighth characters of the product code as a three-digit division code. The tissue product code below is an example of this.



This is important to note because the division code is an essential element for traceability. Using an incorrect division code could lead to a duplication of identifiers and may ultimately compromise traceability. For detailed information about DINs and Product Codes see the *ISBT 128 Standard Technical Specification (ST-001)*.

It can be seen that ISBT 128 provides a tool to achieve traceability for medical products of human origin by uniquely identifying each product that is made. The globally unique DIN allows each donation to be linked to a donor, and, in combination with a Product Code, allows each product from that donation to be linked to a recipient.

MPHO Unique Identifier

The ISBT 128 Standard also has an MPHO Unique Identifier that can be captured in Electronic Health Records as a single unique identifier for each MPHO unit administered to the patient. This serialization of each unit is achieved by assigning a twenty-nine character code that is a combination of the processing facility code (5 characters), product description code (5 characters), ISBT 128 DIN (13 characters), and division code (6 characters). This MPHO Unique Identifier can also be conveyed in an electronic message such as an XML message. Reference Table RT042 contains the ISBT 128 Data References for use in Electronic Messages. This information is available via the ICCBBA website <https://www.isbt128.org/uri>.

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ICCBBA, the not-for-profit standards organization that maintains the ISBT 128 Standard, does NOT keep records of donors or recipients. These records must be kept by facilities in accordance with national regulatory requirements for traceability and confidentiality.