

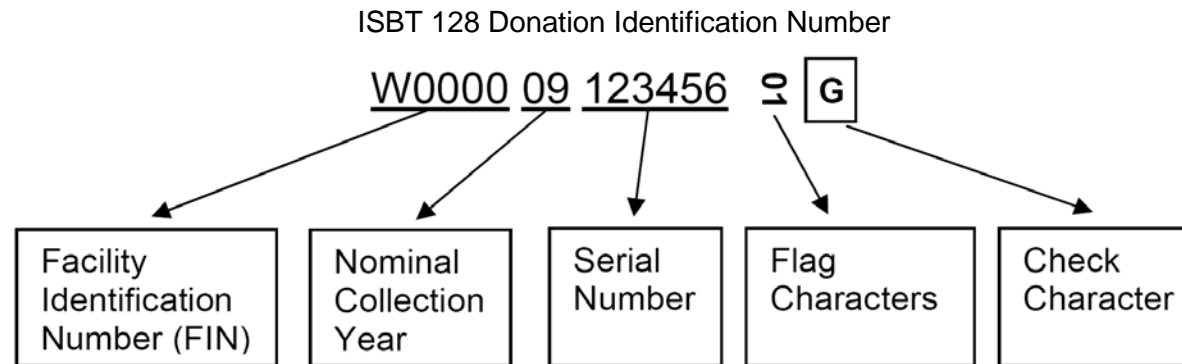


ISBT 128 and Traceability

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 non-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 in the password protected area of the ICCBBA Website (www.iccbba.org). The name of this Excel file is Registered Facilities – xls Database. It is also available on the Website as a text file (called Registered Facilities – Text Database).

An excerpt of the Excel file is shown:

FIN	Name	City	State/Province	Country	Postal Code	Website
E0023	Fundacion Rioja Salud (Centro de Transfusion de la Rioja)	Logrono	La Rioja	Spain	26004	
E0024	Centro Regional de Transfusion Sanguinea Granada-Almeria	Granada		Spain	18012	www.transfusion.granada-almeria.org
E0025	Banc De Sange Teixits	Barcelona		Spain	08035	www.bancsang.net
E0026	Ivi Cordon, S.A.	Madrid		Spain	28035	www.ivi.es

If a product is received with the DIN E0023 09 000122, it can be seen that it was collected by the Fundacion Rioja Salud (Centro de Transfusion de la Rioja) in La Rioja, Spain.

E0023	Fundacion Rioja Salud (Centro de Transfusion de la Rioja)	Logrono	La Rioja	Spain	26004	
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Additionally, a lookup program is available on the ICCBBA Website at <http://www.iccbba.org/lookup-tools/find-facility-information>. Using this program, the collection facility may be identified by entering the FIN.

FIN Lookup • Search Screen Title

Facility Identification Lookup 3 ▾

FIN

E0023

Search

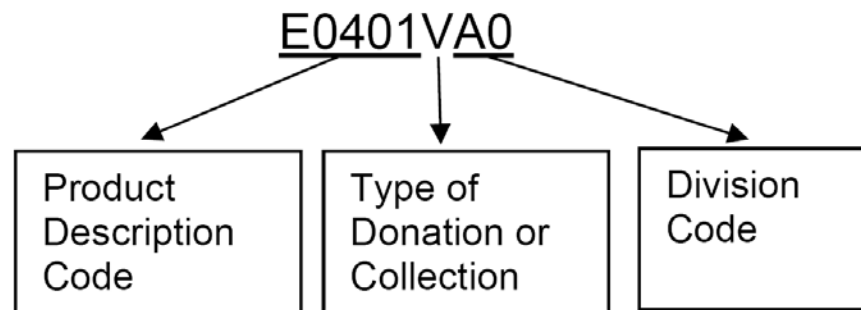
Search Results

FIN	Firm Name	City	State/Province	Country	Postal Code	URL
E0023	Fundacion Rioja Salud (Centro de Transfusion de la Rioja)	Logrono	La Rioja	Spain	26006	www.bancsangreriola.org,

Product Codes

Traceability requires that each biological product 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. That is, 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 product code is E0401VA0.



The first five characters 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.iccbba.org). This database is called Product Codes Database – Access 2000. 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.

PRODDESCRICODE	PRODDESCRIP0	CODEDATE	PRODDESCRICODEFORM
E0401	RED BLOOD CELLS CPD>AS5/450mL/refg ResLeu:<5log6	19 JUL 1996	E002E@22ED4

The sixth character of the product code indicates the type of donation or collection. The key to this code is found on **Table RT 008** in the *ISBT 128 Standard Technical Specification*. Some examples from this table are Volunteer (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 through the use of the seventh and eighth positions in the data structure. When a product is not divided, the characters in the sixth and seventh positions are zeroes (e.g., E0401V00). If this product is divided into two aliquots, the zero in the sixth 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).

For detailed information about DINs and product codes, see the *ISBT 128 Standard Technical Specification*.

It can be seen that ISBT 128 provides a tool to achieve traceability for biological products 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.

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.