

An Introduction to Common ISBT 128 Data Structures

ISBT 128 Donation Identification Number (DIN) Data Structure 001

What is the ISBT 128 DIN?

The DIN is a key element of traceability for medical products of human origin. It provides globally unique identification of products from:

- a donation event [collection or recovery]
- a product pool
- a plasma derivative
- a fertilized oocyte/embryo formed through ART

For full traceability of most MPHO, it must be used in conjunction with a data structure that uniquely identifies individual products from a donation (e.g., Product Description Code and Product Division)

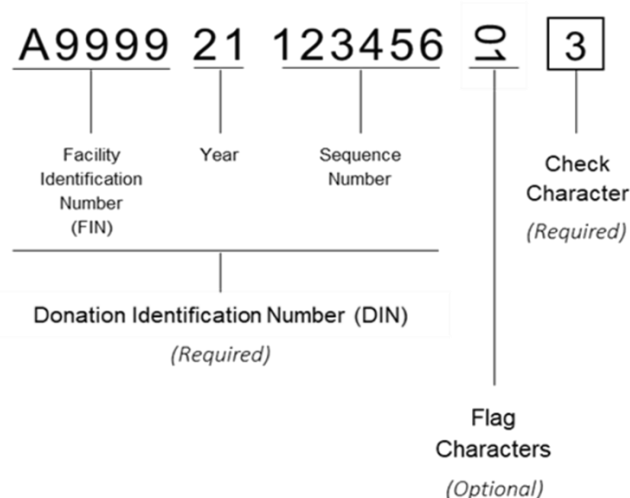
The DIN Data Structure (=αpppppyynnnnnnff) consists of 4 parts:

- Facility Identification Number (FIN) [αppppp]
- Year of assignment [yy]
- Sequence Number [nnnnnn]
- Flag character [ff]

(=α) are the data identifiers for the DIN Data Structure. α is also the first character of the DIN.

Only the first 3 parts of the DIN Data Structure comprise the 13-character DIN.

The use of flag characters is optional. Flag characters allow for additional process control within a facility. They do not contribute to uniqueness or traceability. For more information, reference IG-010.



The boxed character at the end of the DIN is the check character intended to confirm the accurate entry of the DIN when a manual keyboard entry is performed. This is not encoded. For more information, reference Appendix A in ST-001.

An Introduction to Common ISBT 128 Data Structures

Elements of the DIN: Facility Identification Number (FIN)

A9999 21 123456

The DIN is assigned by the facility indicated in the FIN
Facilities are responsible for maintaining records of the numbers they assign.

ICCBBA maintains the ISBT 128 Registered Facilities Database and provides a facility lookup tool to look up information for a FIN.

Facility Lookup Tool

FIN
W0000
Search

Field to enter a FIN in the FIN Lookup Program

Search Results						
<u>FIN</u>	<u>Firm Name</u>	<u>City</u>	<u>State/Province</u>	<u>Country</u>	<u>Postal Code</u>	<u>Web site</u>
W0000	ICCBBA	San Bernardino	CA	USA	92423-1309	www.iccbba.org

Search Result for FIN W0000 in the FIN Lookup Program

<https://www.iccbba.org/lookup-tools/find-facility-information>

Elements of the DIN: Year of Assignment

A9999 21 123456

The assignment year is the last two digits of the year the DIN is assigned.
This number is to ensure uniqueness of the DIN over a 100-year period; it is not intended to be used as a collection date.
This can also cover a 14-month period if necessary:
For example, 21 may be used from December 2020 through January 2022.

An Introduction to Common ISBT 128 Data Structures

Elements of the DIN: Sequence Number

A9999 21 123456

The sequence number is a 6-digit number that is used to identify the collected or pooled product in the specified year for a given FIN.

The facility indicated in the FIN is responsible for assigning the sequence number and maintaining records of what is assigned.

Once a sequence number assigned, it may only be used once in an assignment year in order to maintain uniqueness.

An Introduction to Common ISBT 128 Data Structures

Blood Groups [ABO and RhD] Data Structure 002

What is the Blood Groups [ABO/RhD] Data Structure?

The Blood Groups [ABO/RhD] Data Structure is used to encode information about the Blood Group, RhD Status, Collection Type (e.g., Autologous), and Kell or Miltenberger phenotypes.

It can also be used to encode various special messages instead of blood group information. For example: Biohazardous, For research use only, Not for transfusion based on test results, etc.).

Blood Groups Data Structure 002

The Blood Groups Data Structure is =%ggre

- =% are the data identifiers for the Blood Groups [ABO and RhD] Data Structure

The encoded message contains 3 parts:

ggre

Part 1: (gg) Is used to encode either of the following:

- ABO and RhD blood groups and type of collection information
- This portion shall be encoded and interpreted by reference to Table RT005
- A range of special messages as shown in Table RT006

For example, 64 is interpreted from reference table RT005 as:

- Blood type A RhD positive
- Collection type For Autologous Use Only

Part 2: (r)

Encodes Rh and Kell or Miltenberger phenotypes.

The value shall be encoded and interpreted by reference to Table RT007.

A value of 0 (zero) shall be used if the product does not contain information about these phenotypes.

For example, 1 encodes the following:

No information for anti-Kell results

C- c+ E- e+ for Rh status

Part 3: (e)

This value is reserved for future use.

The value of e shall be set to 0 (zero).

An Introduction to Common ISBT 128 Data Structures

Example of Use

If 4700 is encoded in the ABO/Rh barcode, the interpretation of the information is the following:
The blood type, RhD status, and collection type information (gg) is:

- Blood type: O
- RhD status: Positive
- Collection type: Directed (Dedicated/ Designated) Collection Use Only

The Rh and Kell or Miltenberger phenotypes portion (r) is 0 (zero), indicating that there is no information encoded. The value for future use (e) is set to 0 (zero).

Note: Excerpts of the reference tables are included below.

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
O RhD negative	95	91	92	93	94	96	97	98
O RhD positive	51	47	48	49	50	52	53	54
A RhD negative	06	02	03	04	05	07	08	09
A RhD positive	62	58	59	60	61	63	64	65

Excerpt of Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Collection Information [RT005]

Results with Anti-Kell:			Phenotype:			
No Information	Negative	Positive	C	c	E	e
0	S	T	No Information	No Information	No Information	No Information
1	A	J	negative	positive	negative	positive
2	B	K	positive	positive	negative	positive

Excerpt of Data Structure 002: Rh, Kell, and Mia/Mur Phenotypes [RT007]

Blood Groups [ABO/RhD] Label Text

ABO status may be printed black on white if RhD positive, and outline black on white if RhD negative, but this is not required.

RhD status for the Blood Groups [ABO and RhD] bar code text may be printed black on white if RhD positive; white on black if RhD negative, but this is not required.

If special messages are encoded, you may need to refer to local and accrediting requirements regarding accompanying text.

An Introduction to Common ISBT 128 Data Structures

ISBT 128 Product Code Data Structure 003

What is the ISBT 128 Product Code?

The Product Code is a key element of traceability for Medical Products of Human Origin (MPHO). It provides differentiation of products that have the same DIN.

For traceability of MPHO, it must be used in conjunction with the Donation Identification Number (DIN).

In some cases, the Product Divisions and/or the Processing Facility Identification Code are also needed for traceability.

The Product Code consists of 3 parts for Blood, Cellular Therapy, MPHOs with INN/ USAN names, Regenerated Tissue, Plasma Derivatives, and Clinical Trials Products:

αoooo t ds

Part 1: Product Description Code (PDC)

- The first 5 characters of the Product Code comprise the PDC.
- Represented by the portion **αoooo**
- The product description coding values for **αoooo** are maintained in the ISBT 128 Product Description Code Database. (e.g., E0178, S1143)
- The particular code used should accurately identify the product in the container.

Part 2: Collection Type Code (e.g., for blood and cellular therapy products)

- The 6th character of the Product Code indicates the type of collection.
- Represented by the portion **t**
- The collection type coding values for **t** are located in reference table RT008 found in the ISBT 128 Standard Technical Specification (ST-001).
- Some examples from this table are V (Volunteer homologous), 1 (Autologous), and 2 (Directed).
- For product types other than blood, cellular therapy, MPHOs with INN/ USAN names, Regenerated Tissue, Plasma Derivatives, and Clinical Trials, “t” is part of the division code.

Part 3: Division Code (For Blood, Cellular Therapy, MPHOs with INN/ USAN names, Regenerated Tissue, Plasma Derivatives, and Clinical Trials Products)

- Divided units or aliquots with the same Donation Identification Number and Product Description Code are differentiated via the Division Code.
- The 7th and 8th characters in the Product Code indicate each division/aliquot.
- Represented by the portion **ds**
- Examples of division coding values are seen below.

An Introduction to Common ISBT 128 Data Structures

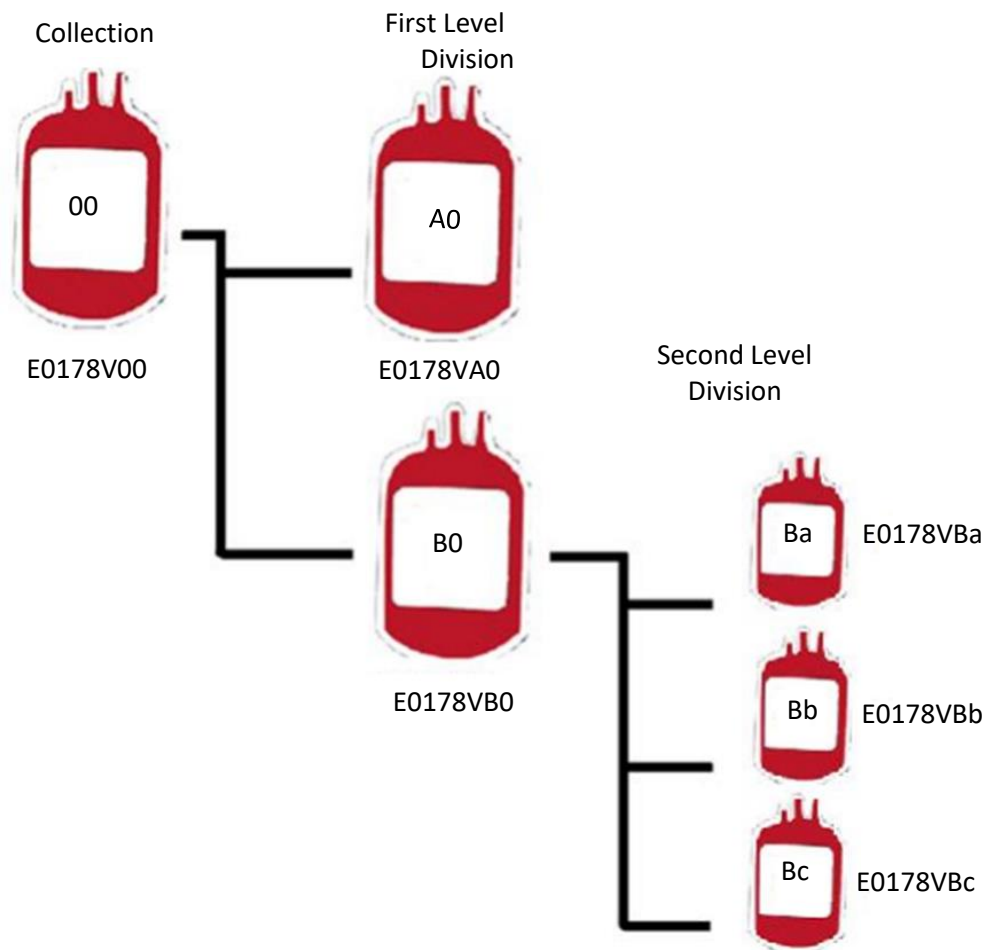
Examples of using the Division Code:

E0178V00

Undivided products use the division code **00**.

If a single first level division is performed:

- The resulting aliquots will be **E0178VA0** and **E0178VB0**.
- If **E0178VB0** is further divided into three aliquots:
- The resulting subdivided products will be **E0178VBa**, **E0178VBb**, and **E0178VBc**.



An Introduction to Common ISBT 128 Data Structures

α0000tds

Part 3: Division Code (For other products such as Tissues, Human Milk, Topical products of human origin, and Fecal Microbiota)

- The 6th, 7th, and 8th characters in the Product Code indicate each division/aliquot.
- “tds” is different for products other than Blood and Cellular Therapy
- “t” is part of the division code for products other than Blood and Cellular Therapy (e.g., Tissues).
- 3-digit division coding values are used for tds.
- For more information, visit section 2.4.3 of ST-001.

Tissue Product Example:

Product Description Code **Division Code**

T1234 001

ISBT 128 Product Code

Alternative Division Code Data Structure

- Alternatively, the product’s division code for Cellular Therapy and Regenerated Tissue products can be encoded with the Product Divisions Data Structure 032.
 - Please visit section 2.4.32 of ST-001 for more information.
 - The Implementation Guide: Use of Product Divisions [Data Structure 032] (IG-023) also provides detailed guidance and information.

An Introduction to Common ISBT 128 Data Structures

Tools for finding a Product Description Code (PDC)

An ISBT 128 Product Lookup Program is available on the ICCBBA website.

<https://www.isbt128.org/find-product-info>



The ISBT 128 Product Lookup Web Application v1.0 is now available. This new web application allows users to search products across all Categories of Medical Products of Human Origin (MPHO) and to submit requests for new Product Description Codes. The following short documents provide instructions on using the ISBT 128 Product Lookup Web App:

- [Lookup Program Instructions - Search Functions](#) – PDF
- [Lookup Program Instructions - Exporting Search Requests](#) – PDF
- [Lookup Program Instructions - Submitting Product Requests](#) – PDF

- **Note:** Click the "Submit" button once when submitting a request to ICCBBA. There may be a slight delay after clicking the button.

Note:

You must log into your account to access the ISBT 128 Product Lookup Program.

Search by Product Description Code

← Field to enter a PDC in the ISBT 128 Product Lookup Program

Result Found

E0178 = RED BLOOD CELLS[CPD/500mL/refg]Irradiated

↑
Product Description result for PDC E0178 in the ISBT 128 Product Lookup Program

An Introduction to Common ISBT 128 Data Structures

Search by Product Description

Category

Blood Components

Subcategory

Blood Components

Class

RED BLOOD CELLS

Modifier

No Modifier

Attribute Group

Irradiation

Attribute Value

Irradiated

Selected Attributes

CPD/500mL/refg
V0001004



Irradiated
V0013002



Clear Attributes

Searching for product description codes via product description with the ISBT 128 Product Lookup Program.

The “Exact Match” search function was used in this example.

Export All Inclusive Results

Clear ALL values

Exact Match Found

E0178 = RED BLOOD CELLS|CPD/500mL/refg|Irradiated



An Introduction to Common ISBT 128 Data Structures

Expiration Date and Time Data Structure 005

What is the Expiration Date and Time?

The expiration date and time may be required to appear on the affixed label by accrediting and regulatory organizations.

ICCBBA does not specify a product's expiration.

The expiration is assigned by the facility.

The expiration may be defined by accrediting or regulatory agencies.

The Expiration Date and Time data structure [005] is commonly used to encode the expiration date and time for the product.

There is also an alternative data structure available mentioned later.

There are three parts to the ISBT 128 Expiration Date and Time:

cyyjjjhhmm

Part 1: Century (c)

- c specifies the century of the year in which the product expires
 - For example, if the year is 2021, the c value is 0 (zero)

Part 2: Year (yy)

- yy specifies the year within the century in which the product expires.
 - For example, if the year is 2021, the yy value is 21.

Part 3: Julian date/ordinal number (jjj)

- jjj specifies the ordinal number within the calendar year (Julian date) on which the product expires.
 - Leap years are also taken into account, so the Julian day for March 1 through December 31 will be different.
 - For example, if the date is December 31 on a regular year, the jjj value is 365.
 - If the date is December 31 on a leap year, the jjj value is 366.

Part 4: Hour (hh)

- hh specifies the hour at which the product expires (00 to 23).
 - For example, if the time is 10:00PM (22:00), the hh value is 22.

An Introduction to Common ISBT 128

Data Structures

Part 5: Minute (mm)

- mm specifies the minute at which the product expires (00 to 59).
 - For example, if a time is 12:30PM, the mm value is 30.
 - A day shall be defined as beginning at midnight (00:00) and ending at 23:59.
 - When a time is not specified, the default of 2359 shall be encoded in the data structure.

Example Expiration Date and Time:

0213651330

- The expiration date is 31 December 2021
 - Century (c) is 0
 - Year (yy) is 21
 - Day (jjj) is 365 or December 31
- The expiration time is 13:30 (1:30PM)
 - Hour (hh) is 13
 - Minute (mm) is 30
- The full expiration date and time is 31 DEC 2021 at 13:30

Alternative Data Structure

- Alternatively, the product's expiration date and time can be encoded with the Flexible Date and Time Data Structure 031 instead of the Expiration Date and Time Data Structure 005
 - The data structure can be used to convey various types of information for the date and time.
 - This includes the type of time (collection, expiration, recovery, etc.) and the time zone (local or UTC).
 - Please visit section 2.4.31 of ST-001 for more information.
 - The Implementation Guide: Use of Flexible Date and Time [Data Structure 031] (IG-024) also provides detailed guidance and information.

An Introduction to Common ISBT 128 Data Structures

References

For more details and additional guidance, reference the following documents and sections:

Standards Documents

- [ISBT 128 Standard Technical Specification \(ST-001\)](#)
 - Section 2.4.1 (Donation Identification Number)
 - Section 2.4.2 (Blood Groups ABO/RhD)
 - Section 2.4.3 (Product Code)
 - Section 2.4.5 (Expiration Date and Time)
 - Section 2.4.31 (Flexible Date and Time)
 - Section 2.4.32 (Product Divisions)
 - Appendix A
- [ISBT 128 Standard Labeling of Human Tissues \(ST-003\)](#)
- [ISBT 128 Standard Labeling of Cellular Therapy Products \(ST-004\)](#)
- [ISBT 128 Standard Labeling of Blood Components \(ST-005\)](#)

Guidance Documents

- [Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution \(IG-010\)](#)
- [Implementation Guide: Encoding Product Information \[Data Structures 003, 032, 033, and 034\] - Tissues \(IG-020\)](#)
- [Implementation Guide: Use of Product Code \[Data Structure 003\] Blood \(IG-021\)](#)
- [Implementation Guide: Product Coding \[Data Structures 003 and 032\] Cellular Therapy \(IG-022\)](#)
- [Implementation Guide: Use of Product Divisions \[Data Structure 032\] \(IG-023\)](#)
- [Implementation Guide: Use of Flexible Date and Time \[Data Structure 031\] \(IG-024\)](#)
- [Implementation Guide: Use of Product Code \[Data Structure 003\] Ocular Tissue \(IG-032\)](#)
- [Implementation Guide: Use of the Donation Identification Number \[Data Structure 001\] \(IG-033\)](#)
- [Implementation Guide: ISBT 128 Facility Identification Number \(IG-034\)](#)

Reference Tables

- [ISBT 128 Product Description Code Database](#)
- Reference tables found in ST-001
 - RT004 - Data Structure 001: Donation Identification Number Flag Characters, ff
 - RT005 - Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Collection Information
 - RT006 - Data Structure 002: Special Messages
 - RT007 - Data Structure 002: Rh, Kell, and Mia/Mur Phenotypes
 - RT008 - Data Structure 003: Type of Collection in 6th Position of Product Code