



ISBT 128 STANDARD

Chain of Identity (Col) Identifier

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1 Introduction

1.1 Purpose

The purpose of this document is to provide:

- specifications for the structure of the Chain of Identity (Col) Identifier
- information on how to obtain and update a Facility Identification Number (FIN)
- rules on the use of the ISBT 128 Col Identifier

Throughout this document where the word “shall” is used, it represents a requirement; where the word “should” is used, it represents a recommendation; and where the word “may” is used, it represents an option.

1.2 Scope

This standard specifies the rules for the structure and use of the ISBT 128 Col Identifier. It also provides information on the associated Facility Identification Number (FIN).

While designed for cell and gene therapy, the use of the Col Identifier in other areas of Medical Products of Human Origin (MPHO) is not prohibited. Future versions of this Standard may be extended to cover other areas of use.

1.3 Intended Audience

The intended audience of this document is cellular therapy collection and processing facilities, clinical trials sponsors, manufacturers of cellular therapy products, software developers, laboratory staff, and staff responsible for the clinical application of products carrying a Col identifier.

1.4 Normative Reference

Implementation Guide: ISBT 128 Facility Identification Number ([IG-034](#))

ISBT 128 Standard Technical Specification ([ST-001](#))

ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing ([ST-018](#))

ISBT 128 Standard for XML Electronic messaging – Standardized XML Elements for Medical Products of Human Origin ([ST-020](#))

ISBT 128 Standard ISBT 128 Dictionary of Standard Data Elements ([ST-027](#))

ISO/IEC 7064:2003(E): Information technology—Security techniques—Check character systems

ISO/IEC 15417: 2007(E): Information technology—Automatic Identification and data capture techniques—Code 128 bar code symbology specification

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix (and correction ISO/IEC 16022:2006/Cor 1:2008)

1.5 Other References

Standards Coordinating Body (SCB) website:
(<https://www.standardscoordinatingbody.org/>)

ICCBBA Website: (www.isbt128.org)

1.6 Background

The ISBT 128 Donation Identification Number (DIN) provides a globally unique identifier that can be used to identify all products derived from a single donation. The DIN is also suitable for identifying pools of donations where the pooling process is performed at an ICCBBA licensed facility.

However, there are circumstances in the collection and processing of cellular therapy products for further manufacture where more than one donation may need to be collected to deliver a given therapy. To ensure that the individual DINs of the collected donations can be linked, and to provide a single identifier for downstream products, a new identifier, the CoI Identifier is required. The CoI Identifier should be allocated either before, or at the time of, collection of the first donation.

The CoI Identifier will not replace the DIN on the collection products but will be an additional identifier that is the same on all donations associated with a patient's given therapy. This is distinct from the assignment of a new DIN in a pooling process.

The CoI Identifier can be utilized on both ISBT 128 Standard labels and non-ISBT 128 labels.

The responsibility for allocating the CoI Identifier may lie with the collecting facility, the clinical trials sponsor, or manufacturers of cellular therapy products. This specification supports these approaches. The entities involved in the collection for a given therapy should have an agreement regarding the scope of a given therapy to be associated with a CoI Identifier and must define who is responsible for allocating the CoI Identifier that will be used throughout the lifecycle of the biological material, and when the CoI Identifier will be allocated.

The following definitions for *Chain of Custody*, *Chain of Identity*, and *Chain of Identity Identifier* were sourced from definitions collaboratively developed with the Standards Coordinating Body. The definition for *Given Therapy* was developed by the CTCLAG.

- **Chain of Custody (COC):** Concurrent, permanent, auditable documentation illustrating the guardianship of a cell or gene therapy product from its origin through its final disposition.

- **Chain of Identity (Col):** The permanent and transparent association of a cell or gene therapy's unique identifiers from procurement of tissue or cells throughout the full product(s) lifecycle including post treatment monitoring.
- **Col Identifier:** A unique end-to-end code used to identify the cell or gene therapy that enables a bidirectional link between the donor(s) and the intended recipient(s). The systematic exchange of the Col identifier along with labeling and verification steps (manual and electronic) maintains the COC.
- **Given Therapy:** A course of cell and/or gene therapy treatment(s) that may result from the administration of a single or multiple product(s) from starting material derived from a single or multiple patient/donor collection(s).

2 Format and Purpose of the FIN in the Col Identifier

ICCBBA assigns Facility Identification Numbers (FINs) to facilities that are licensed to use ISBT 128. The FIN is a five-character alphanumeric code that can be used in a variety of ways to ensure the uniqueness of an identification number and thus is essential to traceability. In the context of the Col Identifier, the FIN identifies the organization that issued the Col Identifier.

The FIN shall be encoded and interpreted by reference to the ICCBBA Facility Identification Number Database published and maintained by ICCBBA on the ICCBBA Website.

Any organization licensed with ICCBBA may use any FIN assigned to it within a Col Identifier. Any organization not currently licensed with ICCBBA can apply for registration and will be allocated a FIN.

The FIN in the Col Identifier is present as a means of ensuring global uniqueness across multiple organizations. However, it is not intended to be parsed as a data item in its own right to identify the organization with which the product is associated. Where it is necessary to transmit the identity of this organization the FIN should be used in a data field specifically designed for the purpose.

A range of FINs has been reserved for validation testing. This range is A9990 through A9999. Facilities should use FINs within this range in a Col Identifier when performing validation testing. This range may also be used for example labels when the use of an actual FIN is not recommended (e.g., a facility wanting to show an example label for educational purposes).

Further information on FIN and the maintenance of the FIN Database is available in *Implementation Guide: ISBT 128 Facility Identification Number (IG-034)*.

3 ISBT 128 Col Identifier Issuing Organizations

All references to Col Identifier issuing organizations refer to organizations that issue ISBT 128 Col Identifiers.

Col Identifier issuing organizations shall be registered and licensed with ICCBBA.

Col Identifier issuing organizations shall ensure that they maintain licensed status and inform ICCBBA of any necessary updates to their organization's registration information.

Col Identifier issuing organizations shall only issue Col Identifiers that contain a FIN assigned to their organization.

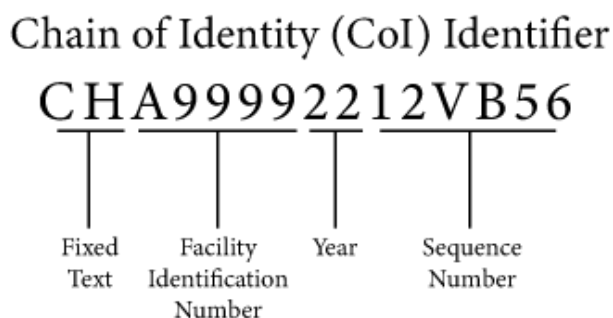
Col Identifier issuing organizations shall have systems in place to control the issue of Col Identifiers in a manner that ensures uniqueness.

4 Col Identifier Allocation and Presentation Rules

4.1 Allocating a Col Identifier

The Col Identifier is a 15-character identifier composed of four elements: the fixed two-character string “CH”; a five-character FIN; a two-digit year of issue; and a six-character sequence number assigned by the Issuing Organization.

Figure 1 Col Identifier Example



The fixed character string “CH” is included in the Col Identifier to clearly distinguish it from the similarly structured Donation Identification Number (DIN) [Data Structure 001].

An organization issuing a Col Identifier shall use a FIN assigned to the organization.

The year indicator ensures uniqueness over a 100-year period. This is a nominal year indicator and may overlap +/- one month of the year assigned.

Sequence numbers shall be controlled in such a manner that when combined with the fixed text, FIN, and year code they uniquely identify a given therapy.

Once assigned, a Col Identifier shall not be reassigned.

4.2 Eye-readable Presentation of the Col Identifier

While keyboard entry is not recommended, it is sometimes essential. Therefore, eye-readable versions of the Col Identifier shall be accompanied by a boxed manual entry checksum (see section 4.3).

When printed in an eye-readable format, the Col Identifier may be divided into blocks using spaces to assist manual transcription.

Spacing between the blocks shall be sufficient to ensure the blocks are clearly separated.

The Col Identifier shall be printed in a font that allows differentiation between similar letters and digits (i.e., 0 and O, 1 and I)

CH A9999 21 123456 V

Checksums shall be calculated as indicated in section 4.3 below.

4.3 Calculating the Checksum

The checksum is used for process control to verify accurate keyboard entry of the Col Identifier. It is not part of the data content of the ISBT 128 Col Identifier and so is not included in the data structure or bar code. This is because it is not intended for use when the Col Identifier is scanned electronically.

The checksum is based on the ISO/IEC 7064 Mod 37-2 algorithm and is calculated on the 15-character ISBT 128 Col Identifier; the two character data identifier (&/) is not included in the calculations.

Computer programs for calculating the checksum using ISO 7064 are described in Appendix A.3 of *ISBT 128 Standard Technical Specification (ST-001)*.

A checksum calculator ([Quick K Calculator](#)) is located in the Lookup Tools section on the ICCBBA Website.

This section shows how the checksum shall be calculated for any given Col Identifier. The calculation is based on the fifteen data characters of the Col Identifier.

The steps in the process are as follows:

1. For each character in the 15-character string, determine its check value as required by ISO 7064 from Table 1 (e.g., character F has value 15);
2. For each character in the 15-character string, determine its weighted check value by multiplying the check value from Table 1 by the n^{th} power of 2 where n is the position of the character from the right-hand end of the string;
3. Sum the weighted check values from step 2;
4. Find the modulus 37 value of the sum from step 3;
5. Subtract the value obtained in step 4 from 38;
6. Find the modulus 37 value of the result of step 5;
7. Using the value in step 6, determine the check character by referring to Table 1 (this time read the character from the value). This is the modulo 37-2 checksum character.

Table 1 Character to ISO/IEC 7064 Check Values [RT035]

Character	0	1	2	3	4	5	6	7	8	9	A	B	C
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	E	F	G	H	I	J	K	L	M	N	O	P
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	S	T	U	V	W	X	Y	Z	*		
Value	26	27	28	29	30	31	32	33	34	35	36		

Example of Checksum CalculationCol Identifier is **CHA999921123456**

Character in the string	STEP 1 ISO 7064 check value (a)	n Position of the character from the right	2^n (b)	STEP 2 Weighted check value (a x b)
C	12	15	32768	393216
H	17	14	16384	278528
A	10	13	8192	81920
9	9	12	4096	36864
9	9	11	2048	18432
9	9	10	1024	9216
9	9	9	512	4608
2	2	8	256	512
1	1	7	128	128
1	1	6	64	64
2	2	5	32	64
3	3	4	16	48
4	4	3	8	32
5	5	2	4	20
6	6	1	2	12

Step 3: sum of last column = 823664

Step 4: modulo 37 of 823664 = 7

Step 5: $38 - 7 = 31$

Step 6: modulus 37 of 31 = 31

Thus, the mod 37-2 checksum is V.

CH A9999 21 123456 V

4.4 Verifying the Col Identifier Checksum

The integrity of a manually transcribed Col Identifier should be verified each time a Col Identifier is received by a computer system through manual entry by performing a checksum calculation as indicated in section 4.3 above.

The calculated value should be checked against the eye-readable check character. If the verification fails an error is indicated and the manual entry should be repeated.

4.5 Electronic Encoding of the Col Identifier

When the Col Identifier is represented in automatic identification and data capture (AIDC) solutions, it shall be encoded as Data Structure 040 in the ISBT 128 Standard.

Purpose: Data Structure 040 shall specify an ISBT 128 Col Identifier.

Structure: &/CHppppyynnnnn

Element	Length	Type
&/	2	data identifiers
CH	2	literal "CH"
α	1	Alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A–N; P–Z; 0–9}; second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if $\alpha = A$ and pppp = BC12, the α pppp will be ABC12).
yy	2	numeric {0-9}
nnnnn	6	Alphanumeric {A-Z; 0-9}

The data content string shall be 15 characters and shall be encoded and interpreted as follows:

CH	The literal string “CH”
apppp	The five-character Facility Identification Number of the Issuing Organization
yy	Two-digit year indicator. (Nominal year of issue)
nnnnnn	Six-character Alphanumeric sequence number assigned by the Issuing Organization

If the Col Identifier is to be represented in a linear bar code, Code 128 shall be used and comply with ISO/IEC 15417: 2007: Information technology—Automatic identification and data capture techniques—Code 128 bar code symbology specification.

Figure 2 Col Identifier linear bar code example



If the Col Identifier is to be represented in a 2-D symbol, Data Matrix shall be used and comply with ISO/IEC 16022:2006: Information technology— Automatic identification and data capture techniques—Data Matrix bar code symbology specification (including the corrections ISO/IEC 16022:2006/Cor 1:2008 and ISO/IEC 16022:2006/Cor 2:2011).

The Col Identifier may be combined with additional information in the 2-D symbol as part of an ISBT 128 Compound Message. Additional information about the Compound Message data structure and requirements for the use of Code 128 and Data Matrix is found in the *ISBT 128 Standard Technical Specification (ST-001)*.

4.6 Col Identifier in Electronic Messages

The Col Identifier can be represented in electronic messages using the data element ChainOfIdentityIdentifier with a unique resource identifier (URI) of <https://www.isbt128.org/uri/ChainOfIdentityIdentifier>

The data value for this data element shall be the 15 data characters of the Col Identifier.

XML Example:

```
<ChainOfIdentityIdentifier Identifier=https://www.isbt128.org/uri/ChainOfIdentityIdentifier value="CHA999921123456"/>
```

Further information on electronic messaging of ISBT 128 information is available in *ISBT 128 Standard for XML Electronic Messaging – Standardized XML Elements for Medical*

Products of Human Origin (ST-020) and ISBT 128 Standard ISBT 128 Dictionary of Standard Data Elements (ST-027).

4.7 Label examples with ISBT 128 CoI Identifiers

The label examples below are apheresis collection products for cellular therapy manufacturing as described in *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing (ST-018)*. Data structures and other information on the example labels are described in detail in ST-018. These labels are provided as examples only. National regulations and appropriate standards must be consulted to ensure full compliance with requirements.

The label examples in Figure 3 and Figure 4 illustrate how the CoI Identifier can be used to link two separate apheresis collections intended for a given therapy. In these examples, the CoI Identifier encodes the FIN of the cell therapy manufacturer, while the DIN encodes the FIN of the collection facility. Figure 5 illustrates a label with the CoI Identifier provided by the Collection Facility. Note that the FIN in the CoI Identifier and Donation Identification Number are the same. The sequence number is also the same, but that is *not* required. The label examples in Figure 6 and Figure 7 illustrate labels with the CoI Identifier provided by the cell therapy manufacturer. These CoI Identifiers contain an alphanumeric sequence number.

In all label examples, both the CoI Identifier and the DIN are encoded in the 2-D symbol along with the Product Code and Expiration Date.

Note: The 2-D symbols in each of the label examples below contain the same 5 data structures:

- Data Structure 023 - Compound Message
- Data Structure 001 - Donation Identification Number
- Data Structure 003 - Product Code
- Data Structure 031 - Flexible Date and Time (Expiration Date and Time used)
- Data Structure 040 - Chain of Identity Identifier

Figure 3 Label Example – CoI Identifier Provided by Cell Therapy Manufacturer




 A9996 22 123458 8 1	For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY
Collection Center City, State, Country, Postal Code	Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01
Collection Date and Time 2022-05-14 13:40	Expiration Date/Time: 2022-05-17 13:40 EST (2022-05-17 18:40 UTC)
Do Not Irradiate  S1303100	COI: CH A9999 22 123456 E Protocol: NCT99999999
MNC, APHERESIS For Further Processing	Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product
Total Volume ___ mL containing approx ___ mL Citrate	
Store at 1 to 10 C	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> Sponsor Info/Logo Area </div>

Figure 4 Label Example – CoI Identifier Provided by Cell Therapy Manufacturer, Subsequent Collection for the Same Therapy Event as Figure 3




 A9996 22 123471 8 7	For Clinical Trial Use Only FOR AUTOLOGOUS USE ONLY
Collection Center City, State, Country, Postal Code	Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01
Collection Date and Time 2022-05-20 13:40	Expiration Date/Time: 2022-05-23 13:40 EST (2022-05-23 18:40 UTC)
Do Not Irradiate  S1303100	COI: CH A9999 22 123456 E Protocol: NCT99999999
MNC, APHERESIS For Further Processing	Collection Center Site No: 47 Autologous Apheresis for Further Use in Manufacturing of XXXXXX Drug Product
Total Volume ___ mL containing approx ___ mL Citrate	
Store at 1 to 10 C	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;"> Sponsor Info/Logo Area </div>

Figure 5 Label Example - Related Donor - CoI Identifier Provided by the Collection Facility






 A9996 22 123458  1 Collection Center City, State, Country, Postal Code Collection Date and Time 2022-01-14 13:40 Do Not Irradiate  S1303400 MNC, APHERESIS For Further Processing Total Volume ___ mL containing approx ___ mL Citrate Store at 1 to 10 C	For Clinical Trial Use Only Related Donor Donor Name: DOE, Alex Charlie Donor DOB: 2000-07-31 Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01 Expiration Date/Time: 2022-01-17 13:40 EST (2022-01-17 18:40 UTC) COI:CH A9996 22 123458  T Protocol: NCT99999999 Collection Center Site No: 47  Sponsor Info/Logo Area
--	--

Figure 6 Label Example - Unrelated Donor - CoI Identifier Provided by the Cell Therapy Manufacturer






 A9996 22 123458  1 Collection Center City, State, Country, Postal Code Collection Date and Time 2022-01-14 13:40 Do Not Irradiate  S1303400 MNC, APHERESIS For Further Processing Total Volume ___ mL containing approx ___ mL Citrate Store at 1 to 10 C	Unrelated Donor GRID: 9991 0120 7043 3201 632 Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01 Expiration Date/Time: 2022-01-17 13:40 EST (2022-01-17 18:40 UTC) COI:CH A9999 22 XYZ456  J Protocol: NCT99999999 Collection Center Site No: 47  Sponsor Info/Logo Area
--	---

Figure 7 Label Example - Related Donor - CoI Identifier Provided by the Cell Therapy Manufacturer - Label Includes the SEC Code

	For Clinical Trial Use Only Related Donor 
A9996 22 123458 8 1 Collection Center City, State, Country, Postal Code	Donor Name: DOE, Alex Charlie Donor DOB: 2000-07-31
Collection Date and Time 2022-01-14 13:40	Intended Recipient: Recipient ID: XXN127654 DOE, Charlie Alex Patient DOB: 1999-06-01
<p style="text-align: center;">Do Not Irradiate</p>	Expiration Date/Time: 2022-01-17 13:40 EST (2022-01-17 18:40 UTC)
 S1303600	COI:CH A9999 22 123ABC 4 Protocol: NCT99999999
MNC, APHERESIS For Further Processing Total Volume ___ mL containing approx ___ mL Citrate	Collection Center Site No: 47 EudraCT: 2019-999999-01
Store at 1 to 10 C SEC: GB000123A999622123458 A00S130300020220117	 <div style="border: 1px solid black; padding: 5px; text-align: center;"> Sponsor Info/Logo Area </div>