



ISBT 128 STANDARD

ISBT 128 Dictionary of Standard Data Elements

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1 Introduction

1.1 Purpose

The purpose of this document is to provide a dictionary of standard data elements.

1.2 Scope

The document describes the data elements defined within ISBT 128 and identifies the corresponding unique resource identifier for each element. These data elements are for use in electronic messages.

1.3 Intended Audience

The intended audience of this document is electronic message developers, software developers, and staff working in facilities collecting, processing, and using medical products of human origin (MPHO) (management, information technology, quality, validation, laboratory, and clinical application).

1.4 Normative Reference

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

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

ISBT 128 Standard Chain of Identity (Col) Identifier ([ST-028](#))

1.5 Other Reference

ICCBBA Website (www.isbt128.org)

[Reference Table RT042](#) – ISBT 128 Data References for use in Electronic Messages

Implementation Guide: Use of Product Divisions [Data Structure 032] ([IG-023](#))

Implementation Guide: Use of the Donation Identification Number [Data Structure 001] ([IG-033](#))

Date and Time – Representations for Data Interchange (ISO 8601-1:2019)

1.6 Background

The ISBT 128 Standard is well established and in widespread use for the coding of information related to medical products of human origin (MPHO), and the labeling of these products using bar coding.

Information encoded using ISBT 128 has previously been described using data structures – information packets specifically designed to be suitable for use in linear bar codes. Data structure design had to take into consideration the capacity of the linear bar code, and the available space on the label and this led to the necessity for data compression.

As a consequence of these limitations ISBT 128 data structures often combine several distinct data elements into a single data structure. In addition, to reduce the number of data structures required on one label, some data elements may be encoded in more than one data structure. This approach, while essential to meet bar coding requirements, leads to complexity in coding and decoding of the data elements.

With the transition to the use of electronic messages to transmit ISBT 128 information the need for data compression is relaxed, and there needs to be a far greater focus on the separation of data elements and the simplicity of coding/decoding.

For this reason, ICCBBA have re-visited the way in which ISBT 128 information is defined and have developed a dictionary of data elements for use in electronic messaging. The information carried in these elements maps to the same information carried in data structures to ensure that information from either source is consistent.

This dictionary defines the data elements and provides the mapping to allow transition between data element and data structure. This information is supplementary to the data structure definitions in the ISBT 128 Technical Specification and existing rules regarding the use of ISBT 128 in bar codes are unaffected.

Future versions will expand the list to cover all data elements used within ISBT 128.

1.7 Changes in this Version

The following table indicates the major changes between Version 1.2.0 and Version 1.3.0. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print. When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Dictionary of Standard Data Elements Version Control: Version 1.2.0 vs. Version 1.3.0.

	Version 1.2.0 Chapter, Section, Table, or Figure	Version 1.3.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	1.5	1.5	Added link to RT042.	For consistency and accessibility
2.	3	3	New subsections added for the following data elements: <ul style="list-style-type: none"> Chain of Identity Identifier HPA Type Processor Product Identification Code Product Consignment Transfusion Transmitted Infection Screening Result Status 	To provide information on additional data elements.
3.	3	3	Adjusted the order of the data elements listed throughout the document.	For consistency.
4.	3.8	3.8	Adjusted the location of the Reference Tables within the section	For consistency with the presentation of information throughout the document.
5.	3.12	3.13	Updated the Data Element Name to be consistent with what is found within RT042	For consistency and accuracy.

2 Data Element Dictionary Structure

The data dictionary is laid out in the following format:

URI:

Each data element is identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL). This URL references a page on the ICCBBA website that carries the data element definition.

Data Element Name: This is the name commonly used to describe the data element.

XML Element Tag:

This is an XML element tag based on the data element name. It contains no spaces and uses UpperCamelCase format.

Purpose: This text describes the purpose of the data element.

Type:

This describes the data type of the information carried in the data element. Types include:

String	A sequence of ASCII characters that provides a direct representation of information.
Coding	A string that is interpreted by direct lookup in a specified ISBT 128 reference table or alternative reference specified within the ISBT 128 Standard.
Compound	A combination of elements that together form a valid concept. The constituent elements will be of the String or Coding data type.
DateTime	A date time conforming to ISO 8601-1:2019.
DSformat	The data content from a specified ISBT 128 data structure. This may include a combination of data elements representing multiple concepts and will need to be interpreted following the same rules for the corresponding data structure.

Format: Defines the format of the data in terms of character sets and lengths.

Description: Provides additional information about the data element.

Requirements: Specifies rules that apply to the data element.

Examples: One or more examples of valid data.

Associated Reference Tables for Coding Values:

For coded elements, provides links to reference tables used to code/decode the information.

ISBT 128 Data Structures Linked with this Data Element:

Cross reference to the ISBT 128 data structures that carry the data element.

3 Data Element Dictionary

3.1 ABO RhD

URI: <https://www.isbt128.org/uri/ABORhD>

Data Element Name: ABO RhD

XML Element Tag: ABORhD

Purpose: Provides the fundamental blood grouping information of ABO type and RhD status.

Type: Coding

Format: Two-character alphanumeric code.

Description:

This element contains the basic ABO/RhD status. More detailed information on ABO and Rh antigens may be provided in the Red Cell Antigens data element, but this remains the core information used in selection of blood units.

Requirements: The value shall be one of the values represented in reference table RT500.

Examples: 62

Associated Reference Tables for Coding Values: [RT500](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-002: The ABO RhD information may be combined with other information on intended use and a compound code value used.

3.2 Chain of Identity Identifier

URI: <https://www.isbt128.org/uri/ChainOfIdentityIdentifier>

Data Element Name: Chain of Identity Identifier

XML Element Tag: ChainOfIdentityIdentifier

Purpose: Carries an ISBT 128 Chain of Identity Identifier.

Type: String

Format: Fifteen-character alphanumeric string.

Description:

This element carries an ISBT 128 Chain of Identity (CoI) Identifier used in Clinical Trials and manufactured cell and gene therapies. The CoI Identifier is defined as "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 CoI identifier along with labeling and verification steps (manual and electronic) maintains the chain of custody."

Requirements:

The string shall be constructed in accordance with ISBT 128 Standard ST-028 Chain of Identity (CoI) Identifier (ST-028).

Examples: CHA99992212VB56

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-040: The CoI Identifier is carried in this data structure.

3.3 Collection Date and Time

URI: <https://www.isbt128.org/uri/CollectionDateTime>

Data Element Name: Collection Date and Time ISO

XML Element Tag: CollectionDateTime

Purpose:

Provides the date and, optionally time, of collection of an MPHO in a format specified in ISO 8601-1:2019.

Type: DateTime

Format: Date shall be expressed as YYYY-MM-DD.

Time is optionally expressed with the letter 'T' followed by time in the format of HH:MM:SS OR as an offset from UTC expressed as + or - followed by the offset as HH:MM.

Description:

This element contains the collection date or the collection date and time of an MPHO.

Requirements:

When mapping from expiration dates held in DS-006 and DS-007 the date shall be transformed from the YYYYJJJ format used in these data structures to the ISO format used in this data element.

Examples:

2021-09-21 (YYY-MM-DD);

2021-09-21T07:45:00 (time format of HH:MM:SS);

2021-03-02T14:49:32-06:00 (time format using UTC)

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-006: Provides information on the collection or recovery date of a MPHO.

DS-007: Provides information on the collection or recovery date and time of a MPHO.

3.4 Collection Type

URI: <https://www.isbt128.org/uri/CollectionType>

Data Element Name: Collection Type

XML Element Tag: CollectionType

Purpose:

Provides information associated with the collection of an MPHO. This information may be required to determine the suitability of the product for the recipient.

Type: Coding

Format: One-character case-sensitive alphanumeric code.

Description:

This element contains information about the collection. It may contain information about the relationship between the donor and intended recipient (e.g., autologous, directed), the donation arrangements (e.g., volunteer, replacement, paid), and it may also carry a risk warning (biohazardous). Note that information on the donor/intended recipient relationship may be carried in the Product Description Code data element for some MPHO types.

Requirements:

The value shall be one of the values represented in reference table RT008. If the collection information is encoded in DS-003, then the code value shall be taken directly from RT008. If the collection information is encoded in DS-002 the following mapping to values in RT008 shall be used:

Interpretation from DS-002	RT008 code to be used
Autologous collection/Eligible for crossover	A
For autologous use only	1
For autologous use only/Biohazardous	X
Directed/Dedicated/Designated Collection Use Only	B
Directed/Dedicated/Designated Collection/Biohazardous	H
Directed/Dedicated/Designated Collection/Eligible for Crossover	J
For Emergency Use Only	G

Examples: V

Associated Reference Tables for Coding Values: [RT008](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-003: For some categories of MPHO product collection type information is held in the sixth data character.

DS-002: Collection type information may be held in the first and second characters of this data structure as a compound code along with the ABO/RhD information.

3.5 Container Catalog Number

URI: <https://www.isbt128.org/uri/ContainerCatalogNo>

Data Element Name: Container Catalog Number

XML Element Tag: ContainerCatalogNo

Purpose: Contains the catalog number of the container into which an MPHO was collected.

Type: String

Format:

Seven-character alphanumeric string. Leading and trailing zeros, if present, are significant. Alpha characters may be upper or lower case.

Description:

Used in conjunction with the Container Manufacturer and Container Lot Number data elements to identify the collection set. Used primarily for blood and cell therapy collections.

Requirements:

The ContainerCatalogNo shall be a fixed length (7-character) string. If the catalog number is less than seven characters long leading zeros shall be used.

Examples: 0027QZE

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-017: The Catalog Number is carried in this data structure.

3.6 Container Lot Number

URI: <https://www.isbt128.org/uri/ContainerLotNo>

Data Element Name: Container Lot Number

XML Element Tag: ContainerLotNo

Purpose: Contains the lot number of the container into which an MPHO was collected.

Type: String

Format:

Ten-character alphanumeric string. Leading and trailing zeros, if present, are significant. Alpha characters may be upper or lower case.

Description:

Used in conjunction with the Container Manufacturer and Container Catalog Number data elements to identify the collection set. Used primarily for blood and cell therapy collections.

Requirements:

The ContainerLotNo shall be a fixed length (10-character) string. If the lot number is less than seven characters long leading zeros shall be used.

Examples: 0000123456

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-018: The Manufacturer's Lot Number is carried in this data structure.

3.7 Container Manufacturer

URI: <https://www.isbt128.org/uri/ContainerManufacturerID>

Data Element Name: Container Manufacturer

XML Element Tag: ContainerManufacturerID

Purpose: Identifies the manufacturer of the container into which an MPHO was collected.

Type: Coding

Format: Two-character alpha code.

Description:

Used in conjunction with the Container Catalog Number and Container Lot Number data elements to identify the collection set. Used primarily for blood and cell therapy collections.

Requirements: The manufacturer code shall correspond to a value in Reference Table 016.

Examples: IC

Associated Reference Tables for Coding Values: [RT016](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-017: The container manufacturer ID is carried in this data structure.

3.8 Dimensions, Single

URI: <https://www.isbt128.org/uri/Dimension>

Data Element Name: Dimensions, Single

XML Element Tag: Dimension

Purpose: Information on a single dimension of a product.

Type: Compound

Format: A twelve-character numeric string.

Description:

This element is a compound element carrying information on a single dimension. The sub-elements include information on the type of value (indicates if the value is an exact measurement (within tolerance), a nominal measurement, or an inequality.), the type of dimension (also includes the unit of measurement), the value (digits only), and the decimal point location.

The sub-elements of this compound element are:

1	Value type	Coding	two-digit	Decoded using RT037
2	Dimension type	Coding	four-digit	Decoded using RT038
3	Value	Numeric	five-digit	
4	Decimal place	coding	one-digit	Decoded using RT039

Requirements:

The value type shall be a value taken from RT037. The Dimension type shall be a value taken from RT038. The Value shall be five digits long, and if less than five digits, shall be required to be padded with leading zeros. The Decimal place shall be a value taken from RT039.

Examples:

010001002570 decodes as the volume of the product is equal to 257 ml

060001002500 decodes as the nominal volume of the product is 250 ml

010003002512 decodes as the width of the product is 2.51mm

040007003000 decodes as the platelet count is less than 300×10^9

Associated Reference Tables for Coding Values:

[RT037](#)

[RT038](#)

[RT039](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-029: Provides the dimensions (length, area, volume, etc.) of a MPHO.

3.9 Division Identifier

URI: <https://www.isbt128.org/uri/DivisionIdentifier>

Data Element Name: Division Identifier

XML Element Tag: DivisionIdentifier

Purpose:

Identifies individual items of the same product type allocated with the same Donation Identification Number.

Type: String

Format:

Six-character alphanumeric string. Leading and trailing zeros, if present, are significant.

Description:

Identifies individual items of a particular product type allocated with the same Donation Identification Number. When combined with the Donation Identification Number and Product Description Code, and in some very specific cases the Processing Facility Identifier, provides a globally unique identifier for the item.

The Division Identifier forms one component of the MPHO Unique Identifier data element.

Requirements:

When mapping from a two-character Division Code in Data Structure 003, trailing zeros shall be added, thus a Division Code of Ab shall be represented in the Division Identifier as Ab0000, and a Division Code of B0 shall be represented as B00000.

When mapping from a three-digit Division Code in Data Structure 003, leading zeros shall be added, thus a Division Code of 123 shall be represented in the Division Identifier as 000123, and a Division Code of 004 shall be represented as 000004.

When mapping from Data Structure 032 on the label, the Division Identifier shall be identical to the six-character data string of this data structure. See IG-023 for further information on Data Structure 032.

Examples:

002933
000001
ABAA00
Ab0000

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-003: Uses a shortened form of the Division Identifier, which may be either a three-digit number or a two-character alpha value. See Requirements above for mapping into the Division Identifier.

DS-032: Uses a six-character form of the Division Identifier that can be mapped directly into the Division Identifier data element.

3.10 Donation Identification Number

URI: <https://www.isbt128.org/uri/DonationIdentificationNumber>

Data Element Name: Donation Identification Number

XML Element Tag: DonationIdentificationNumber

Purpose:

The Donation Identification Number (DIN) identifies one of the following: a donation event [collection or recovery]; a product pool; for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; a fertilized oocyte/embryo formed through ART.

Type: String

Format:

Thirteen-character string. The following limitations on character values apply:

Character Position	Type
1	alphanumeric {A–N; P–Z; 1–9}
2-3	alphanumeric {A–N; P–Z; 0–9}
4-13	numeric {0–9}

Description:

The DIN is a globally unique identifier managed by ICCBBA as an issuing agency. ICCBBA assigns Facility Identification Numbers (FINs) to Issuing Organizations and maintains a register of all such organizations. Issuing Organizations assign DINs in accordance with ISBT 128 Standard requirements.

The DIN forms one component of the MPH0 Unique Identifier data element.

Requirements:

The DIN shall be formed from a sequential combination of the five-character Facility Identification Number of the facility issuing the identifier as assigned by ICCBBA, the last two digits of the year associated with the allocation of the DIN, and a six-digit sequence number.

The facility issuing the identifier shall ensure that each DIN it allocates is unique within its range of assigned FINs through a 100-year period.

Further information on DIN allocation, presentation, and the use of check characters is provided in IG-033.

Examples: A999921123456

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-001: Contains the thirteen-character DIN.

3.11 Expiration Date and Time ISO

URI: <https://www.isbt128.org/uri/ExpirationDateTime>

Data Element Name: Expiration Date and Time ISO

XML Element Tag: ExpirationDateTime

Purpose: Provides the expiration date and time in a format specified in ISO 8601-1:2019.

Type: DateTime

Format:

Date and time in format:

Date expressed as YYYY-MM-DD

The letter 'T'

Time expressed as HH:MM:SS

Optionally, an offset from UTC expressed as + or - followed by the offset as HH:MM

Description: This element contains the expiration date and time of the product.

Requirements:

If expiration is at the end of the day, then the time shall be represented as 23:59:00.

Offset is required for all products that are being shipped across time zones and where expiration is set to a specified time.

When mapping from expiration dates held in DS-004 and DS-005 the date shall be transformed from the YYYYJJJ format used in these data structures to the ISO format used in this data element.

When mapping from DS-004 a time of 23:59:00 shall be used.

Examples:

2021-09-21T23:59:00

2021-03-02T14:49:32-06:00

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-004: Provides information on the Expiration Date of a MPHO.

DS-005: Provides information on the Expiration Date and Time of a MPHO.

DS-031: Provides information about the date and time of collection, recovery, production, cross clamp, etc. of a MPHO.

3.12 Facility Product Code

URI: <https://www.isbt128.org/uri/FacilityProductCode>

Data Element Name: Facility Product Code

XML Element Tag: FacilityProductCode

Purpose:

A processing facility defined code used by the processor to provide sub-categorization of products carrying the same Product Description Code.

Type: String

Format: A six-character alphanumeric string.

Description: This element contains a processing facility assigned value.

Requirements:

The value is assigned by the processing facility. It has no interpretation at an international level and the same value may be used by different processing facilities for different purposes.

Examples: AB7878

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-033: Contains the Facility Product Code (FPC).

DS-034: Contains the Facility Product Code (FPC).

3.13 Global Registration Identifier for Donors (GRID)

URI: <https://www.isbt128.org/uri/GRID>

Data Element Name: Global Registration Identifier for Donors

XML Element Tag: GRID

Purpose: A globally unique identifier for a donor listed in a bone marrow donor registry.

Type: String

Format: A nineteen-character alphanumeric string.

Description:

The GRID is a globally unique identifier for a donor on a bone marrow registry. The GRID comprises a four-digit Issuing Organization Number allocated to the issuing registry by ICCBBA, and a thirteen-character alphanumeric identifier assigned by the Issuing Organization. The final two characters are a Mod 37-2 checksum calculated from the preceding 17 characters.

Requirements:

The GRID shall be allocated in compliance with ST-015 Standard Global Registration Identifier for Donors: ION Database and GRID Rules.

Examples: 9999000000AX1072501

Associated Reference Tables for Coding Values: GRID Issuing Organizations Database

ISBT 128 Data Structures Linked with this Data Element:

DS-039: Carries the GRID.

3.14 HPA Type

URI: <https://www.isbt128.org/uri/HPAType>

Data Element Name: HPA Type

XML Element Tag: HPAType

Purpose: Carries information on Human Platelet Antigen (HPA) typing.

Type: Compound

Format: Variable length alphanumeric string.

Description:

This element carries information on the test results and history for a single HPA.

The sub-elements of this compound element are:

1	Result interpretation	Coding	Two-digit	Decoded using RT040
2	Number of Tests	Coding	Two-digit	Decoded using RT041
3	Specificity	String	variable	

Requirements:

The string shall be constructed using the HPA antigen names listed in the [ISBT Human Platelet Antigen \(HPA\) Database](#).

Examples: 0106HPA-1a

Associated Reference Tables for Coding Values:

[RT040](#)

[RT041](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-014: The Platelet HPA type is carried in this data structure.

3.15 MPHO Unique Identifier

URI: <https://www.isbt128.org/uri/MPHOUniqueIdentifier>

Data Element Name: MPHO Unique Identifier

XML Element Tag: MPHOUniqueIdentifier

Purpose: Provides a globally unique instance identifier for a medical product of human origin.

Type: String

Format: Twenty-nine-character alphanumeric string.

Description:

This element is constructed from four other elements which together create a globally unique identifier for an MPHO Product instance. The elements included are the Processing Facility Identification Number (5 characters), Product Description Code (5 characters), Donation Identification Number (13 characters), and the Division Identifier (6 characters).

Requirements:

The MPHO Unique Identifier shall be created by combining information from the Processing Facility Identification Number, Product Description Code, Donation Identification Number, and the Division Identifier as they appear on the product label.

If the Processing Facility Identification Number is not encoded on the product label, then the Processing Facility Identification Number element shall be set to five zeros.

Examples:

W9999T0123W000018123456000123
00000E0001A999921123456000000

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

See the entries for the corresponding constituent data elements.

3.16 Processing Facility Identification Number (FIN(P))

URI: <https://www.isbt128.org/uri/ProcessorFIN>

Data Element Name: Processing Facility Identification Number

XML Element Tag: ProcessorFIN

Purpose:

Identifies the facility that processed the product and applied the Product Description Code and Division Code.

Type: String

Format: Five-character alphanumeric string.

Description:

The Processor FIN identifies the processing facility responsible for the application of the PDC and DIV codes. It is not required in all cases, but if present in electronic format on the product label, then it should be present in the electronic message.

Requirements:

The facility using a FIN(P) shall be registered and licensed with ICCBBA and shall use the FIN allocated to it by ICCBBA.

Examples: A9999

Associated Reference Tables for Coding Values: [RT065](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-033: FIN(P) is carried in this data structure.

DS-034: FIN(P) is carried in this data structure.

3.17 Processor Product Identification Code

URI: <https://www.isbt128.org/uri/ProcessorProductIdentificationCode>

Data Element Name: Processor Product Identification Code

XML Element Tag: ProcessorProductIdentificationCode

Purpose:

Provides the full processor product identification code that fulfils the role of the UDI Device Identifier (DI) for medical devices containing MPH0.

Type: String

Format: Sixteen-character alphanumeric string.

Description:

This element contains information on the processing facility and the product type in the format required for a medical device UDI-DI.

Requirements:

When constructing the ProcessorProductIdentificationCode the following rules apply:

- Characters 1-5 shall specify the Facility Identification Number (FIN) of the assigning facility. The FIN shall be encoded and interpreted by reference to the ICCBBA Registered Facilities table published and maintained by ICCBBA.
- Characters 6-11 shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility, which indicates a catalog or other number that identifies the product within the processing organization's system.
- Characters 12-16 shall be encoded and interpreted by reference to the ISBT 128 Product Description Codes database table, with the exception of Clinical Trials PDCs which are in a separate database.

Examples: A9997AB3456T0123

Associated Reference Tables for Coding Values:

See above for decoding individual sub-elements.

ISBT 128 Data Structures Linked with this Data Element:

DS-034: The Processor Product Identification Code is carried in this data structure.

3.18 Product Consignment

URI: <https://www.isbt128.org/uri/ProductConsignment>

Data Element Name: Product Consignment

XML Element Tag: ProductConsignment

Purpose: Provides the consignment number for a consignment of MPHOs.

Type: String

Format: Sixteen-character alphanumeric string.

Description:

This element contains a globally unique consignment number for a consignment of MPHOs.

Requirements:

When constructing the consignment number the following rules apply:

- Characters 1-5 shall specify the Facility Identification Number (FIN) of the assigning facility. The FIN shall be encoded and interpreted by reference to the ICCBBA Registered Facilities table published and maintained by ICCBBA.
- Characters 6-7 shall be the last two digits of the year the identifier is allocated.
- Characters 8-12 shall specify a serial number for the product consignment identifier that is unique within the year.
- Characters 13-14 shall specify the number of the container within the consignment. For dispatch documentation (paper or electronic), this field shall be set to "00".
- Characters 15-16 shall specify the total number of containers in the consignment.

Examples: A999922123450002

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-028: The Product Consignment identifier is carried in this data structure.

3.19 Product Description Code

URI: <https://www.isbt128.org/uri/ProductDescriptionCode>

Data Element Name: Product Description Code

XML Element Tag: ProductDescriptionCode

Purpose:

Provides an internationally agreed upon description of the product or, a unique description of a clinical trial product provided by the sponsor/manufacturer, or for products with limited usage, a national or local Product Description Code.

Type: Coding

Format: Five-character alphanumeric string.

Description:

The Product Description Code provides a means to identify a product type in an internationally consistent manner. This is particularly important for product crossing national boundaries and is valuable in biovigilance across all MPHO.

The Product Description Code forms one component of the MPHO Unique Identifier data element.

Requirements:

The value shall be either:

- 1) An international code that appears in the Product Description Code database table (RT064) published and maintained by ICCBBA.
- 2) A code assigned to a clinical trial sponsor/manufacturer to uniquely encode their product. These codes do not have internationally specified definitions and can only be interpreted by reference to the clinical trial sponsor/manufacturer.
- 3) A national or local code with value taken from a range specified for such use in the ISBT 128 Standard. These codes do not have internationally specified definitions and can only be interpreted by reference to the labeler.

Examples: E0001

Associated Reference Tables for Coding Values: [RT064](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-003: PDC is included in this data structure.

DS-034: PDC is included in this data structure.

DS-038: PDC is included in this data structure.

3.20 Red Cell Antigen

URI: <https://www.isbt128.org/uri/RedCellAntigen>

Data Element Name: Red Cell Antigen with Test History, Individual

XML Element Tag: RedCellAntigen

Purpose: Carries information on the test results and history for a single red cell antigen.

Type: Compound

Format: Ten-character numeric string.

Description:

The Red Cell Antigen data element is a compound element carrying the antigen specificity, the testing result, and test history information.

The sub-elements of this compound element are:

1	Antigen specificity	Coding	Six-digit	Based on ISBT Blood Group Terminology
2	Result interpretation	Coding	Two-digit	Decoded using RT040
3	Number of Tests	Coding	Two-digit	Decoded using RT041

Requirements:

The antigen specificity shall be a six-digit code that corresponds to the ISBT allocated three-digit code for the blood group system followed by the allocated three-digit code for the antigen.

The result interpretation shall be a value taken from RT040.

The number of tests shall be a value taken from RT041. When antigen results are mapped from data structures that do not carry test history the value of "06" shall be used.

Examples:

0040020104

Blood Group System 004 – Rh

Blood Group Antigen 002 – C

Result Interpretation 01 - Negative – Test methodology not specified

Number of Tests 04 - Tested ≥ twice on different collections (historic only) with concordant results

0060020206

Blood Group System 006 – Kell

Blood Group Antigen 002 – k

Result Interpretation 02 - Positive – Test methodology not specified

Number of Tests 06 - Test history not specified

Associated Reference Tables for Coding Values:

ISBT Blood Group System and Antigen reference table – see <https://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology/>

[RT040](#)

[RT041](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-030: Carries multiple instances of this information.

Other data structures carry more limited red cell antigen information that can be mapped into this data structure:

DS-002: Blood grouping information may be carried in the third data character of this data structure. The information may need to be mapped to multiple occurrences of the red cell antigen element. As an example, a value of “F” in this character position provided information on five red cell antigen results: C Neg, c Pos, E Pos, e Neg, K Neg and would thus require five red cell antigen elements.

DS-011 (Retired), DS-012, DS-013: These three data structures all carry information on multiple red cell antigen results in the first sixteen characters. For example, the data string 8800000087000000 in these positions of DS-012 carries the information for ten antigen results: C Neg, c Pos, E Neg, e Pos, K Pos, k Pos, Fy(a) Pos, Fy(b) Pos, Jk(a) Pos, Jk(b) Neg and would thus require ten red cell antigen elements.

3.21 Single European Code (SEC)

URI: <https://www.isbt128.org/uri/SingleEuropeanCode>

Data Element Name: Single European Code

XML Element Tag: SingleEuropeanCode

Purpose: Contains the Single European Code as specified by the European Commission.

Type: String

Format: Forty-character alphanumeric string.

Description:

The Single European Code (SEC) is a required code in the European Union that has to appear on all products regulated under the tissues and cells legislation (with certain exceptions).

Requirements:

The SEC shall be constructed as specified in ST-012 ISBT 128 and the Single European Code.

Examples: GB0GY120G999914123456A00S14160Ab20161231

Associated Reference Tables for Coding Values: None

ISBT 128 Data Structures Linked with this Data Element:

DS-038: The SEC is carried in this data structure.

3.22 Special Testing General

URI: <https://www.isbt128.org/uri/SpecialTestCode>

Data Element Name: Special Testing General

XML Element Tag: SpecialTestCode

Purpose: Contains a code that indicates special characteristics of a product.

Type: Coding

Format: Five-character alphanumeric string.

Description: The five-character code is interpreted using reference table RT068.

Requirements:

Values shall correspond to entries in RT068.

Values in data structure DS-010 that encode multiple pieces of data should be resolved to individual data elements encoding a single data concept. For example, in DS-010 the value N0131 encodes the two pieces of information: "High titer antibody to either the A or B antigen present; Test for Zika virus negative". When mapping to the data element this should be treated as two occurrences of the data element with values N0109 (High titer antibody to either A or B antigens present) and N0127 (Test for Zika virus negative).

Information in some other data structures may also be represented using this data element and these are identified below.

Examples: N0003

Associated Reference Tables for Coding Values: [RT068](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-010: Carries Information on general Special Testing.

DS-012: Carries information on HbS Negative and IgA deficient.

DS-013: Carries information on IgA deficient.

DS-014: Carries information on high titer anti-A and anti-B status.

3.23 Transfusion Transmitted Infection Screening Result Status

URI: <https://www.isbt128.org/uri/TTIStatus>

Data Element Name: Transfusion Transmitted Infection Screening Result Status

XML Element Tag: TTIStatus

Purpose: Carries information on the test results for a single TTI infection and marker/technique.

Type: Compound

Format: Five digits, may include leading zeros.

Description:

The TTIStatus data element is a compound element carrying the infection type, marker/technique, and the testing result.

The sub-elements of this compound element are:

1	Infection Type	Coding	Two-character (Decoded using RT069)
2	Marker/Technique	Coding	Two-character (Decoded using RT070)
3	Result	Coding	One-character (Decoded using RT071)

Requirements:

When constructing the TTIStatus the following rules apply:

Characters 1-2 shall specify the infection type using a value taken from RT069.

Characters 3-4 shall specify the marker/technique using a value taken from RT070 that is compatible to the infection type.

Character 5 shall be the result using a value taken from RT071.

Examples:

01002 – CMV Positive

01021 – CMV Negative by genome testing

08142 – WNV Positive by genome testing

Associated Reference Tables for Coding Values:

[RT069](#)

[RT070](#)

[RT071](#)

ISBT 128 Data Structures Linked with this Data Element:

DS-027: All three elements of the TTI Status for multiple markers are carried in this data structure.

Other data structures may carry information on screening for a specific infective agent as follows:

DS-010: Screening results for CMV, Parvovirus B19, and Zika.

DS-012: Screening results for CMV, and Parvovirus B19.

DS-013: Screening results for CMV.

DS-014: Screening results for CMV.

4 Data Structures as Data Elements

Mapping ISBT 128 information into the data elements defined in the above chapter simplifies the presentation of the information in the electronic message making it easier for systems to interpret. However, it is recognized that there may be some use cases where it is beneficial to provide the information in the electronic message in the same format as it is held in the data structures.

To support this, data structures may be represented as data elements by using the data structure identifier as the URI, as the XML Element Tag, or by using the data content of the data structure as the data.

The data structure identifier shall be represented as the characters DS followed by the three-digit data structure number as specified in ST-001. For example, for the Product Code [Data Structure 003] the URI would be <https://www.isbt128.org/urids/DS003> and the XML element tag would be DS003.

Only data characters are carried in the data element. Data identifier characters shall not be included in the data element.

In general:

URI: <https://www.isbt128.org/urids/DSxxx>

Data Element Name: Data Structure xxx

XML Element Tag: DSxxx

Purpose: Provide an exact copy of the data characters held in an ISBT 128 data structure.

Type: String

Format:

As specified in ST-001 for the corresponding data structure. Data Identifier characters shall not be included.

Description:

Carries the data characters of the corresponding data structure as it appears on the product label.

Requirements:

The content shall be the data content of the corresponding data structure on the product label.

Examples: See ST-001.

Associated Reference Tables for Coding Values:

Decoded as for the corresponding data structure in ST-001.

END OF PUBLICATION

FOR ICCBBA USE ONLY

These links are for internal document control and cannot be used externally:

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

[ST-020 ISBT 128 Standard for XML](#)

[ST-028 ISBT 128 Standard Chain of Identity Identifier](#)

[IG-023 Use of Product Divisions \[Data Structure 032\]](#)

[IG-033 Use of the Donation Identification Number \[Data Structure 001\]](#)