ICCBBA, Inc

ISBT 128

Bar Code Symbology and Application Specification for Labeling of Whole Blood and Blood Components

Version Number 1.4.0

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Working Party on Automation and Data Processing

Editor's Note

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This *Specification* builds upon previous efforts that established the American Blood Commission (ABC) Codabar system for the labeling of whole blood and blood components (*see Guideline for the Uniform Labeling of Blood and Blood Components*, US Food and Drug Administration, August 1985). When it became apparent that *ABC Codabar* could no longer support the increased complexity and data management needs of blood banking today, the International Society of Blood Transfusion (ISBT), through its Working Party on Automation and Data Processing (WPADP), and with the help of national groups throughout the world, undertook the task of revising the labeling system. This *Specification* is the result of five years of work and sets forth the recommendations of the ISBT WPADP.

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Definitions for This Document

Additional label text:	(abbreviated as label text): information on the label that is not associated with a bar code.
Bar code	The symbolic representation of a data structure that also includes the symbology-specific start and stop codes and the modulo 103 check digit.
Bar code label text:	(abbreviated as bar code text) the interpretation of the eye-readable text.
Collection facility:	A place in which whole blood or plasma is withdrawn from a blood donor or patient, either by manual or instrument-assisted methods. This definition is intended to encompass not only blood and plasma centers but hospitals and clinics.
Concatenation:	A method by which two bar codes can be read as if they were a single bar code. Provides a means for checking one bar code against the other to see that both are in place. Useful in labeling process control.
Control character:	A character inserted into the bar code such as that used to indicate a change in symbology subset.
Data character:	Those characters defined in this specification that together with the data identifier delineate the data content of the bar code.
Data content:	The data characters in a bar code that convey the information for which the bar code is named.
Data identifier:	The first two characters in a bar code and data structure that define the data content of the bar code.
Data structure:	The contents of a bar code, including the data identifier, the data characters, any flag characters and the “shift C” control character if used, but **not** including the symbology-specific and always present start and stop codes and the modulo 103 check digit.
Eye-readable text:	the eye-readable representation of the **data characters** in a bar code (printed left justified immediately below the bar code) — with the

exception of the Donation Identification Number.

Flag character: Non-data characters used in process control or data transmission checking. They are also printed in eye-readable text accompanying the bar code but are distinguished in some manner from the representation of the data characters.

Julian Date: A numbering system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). A very convenient means for computer programs to interpret and adjust dates.

Label: A self-adhesive independent entity that carries a bar code but that also provides other information.

Acronyms

AABB	American Association of Blood Banks
ABC	American Blood Commission
AIM	Automatic Identification Manufacturers
ANSI	American National Standards Institute
BSI	British Standards Institution
CCFIN	Country/Collection Facility Identification Number
CEN	Comité Européen de Normalisation
DIN	Donation Identification Number
EAN	European Article Number
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
EHIBCC	European Health Industry Bar Code Communications Council
ETAG	European Technical Advisory Group (ICCBBA, Inc)
FACT	Federation of Automatic Coding Technologies
HIBBC	Health Industry Bar Code Communications Council
HIMA	Health Industry Manufacturers Association
IEC	International Electrotechnical Commission
ISBT	International Society of Blood Transfusion
ISO	International Organization for Standardization
NATAG	North American Technical Advisory Group (ICCBBA, Inc)
PTAG	Plasma Technical Advisory Group (ICCBBA, Inc)
UCC	Uniform Code Council
UN	United Nations
WPADP	(ISBT) Working Party on Automation and Data Processing

Acknowledgment

This page acknowledges with thanks the selfless individuals who voluntarily gave many hours of their time and who through tireless discussion and compromise forged this document

Abstract

Labeling of blood components is one of the oldest applications for bar codes. National blood labeling guidelines, commonly based on the use of a variant of the Codabar bar code symbology (*American Blood Commission (ABC) Codabar*), exist in many countries throughout the world.

The Working Party on Automation and Data Processing (WPADP), a task force established by the International Society of Blood Transfusion (ISBT), has developed a new specification for the bar code labeling of whole blood and blood components (blood products). This is intended to replace the many national bar code guidelines now in use.

This specification has been developed over the last five years by the ISBT WPADP. It recommends:

- Conversion to "*ISBT 128*," a variant of Code 128;
- A system for the unique identification of all blood collection and processing centers worldwide ("Country/Collection Facility Identification Number" [CCFIN]);
- Use of unique, *ISBT 128*-specified data identifiers and *ISBT 128*-specified data structures for each key bar code.

Changeover to *ISBT 128* by 4 July 1998 was recommended by the ISBT Council at the 23rd ISBT World Congress in Amsterdam, The Netherlands, when they approved *ISBT 128* on 3 July 1994. The unique design of *ISBT 128* permits it to coexist with most existing national guidelines. This permits earlier implementation of *ISBT 128* **on a national basis** if desired, and avoids relabeling of long-lived frozen blood products labeled before the changeover to *ISBT 128*.

This document:

- Defines the technical requirements and characteristics of the *ISBT 128* variant of the Code 128 symbology;
- Describes the *ISBT 128*-specified bar codes, including the required data identifiers and data structures;

- Specifies the Country/Collection Facility Identification Number allocations and ranges for each country;

- Explains the key issues, considerations and decisions that went into the development of this specification.

1 Background to the *ISBT 128* Specification for the Labeling of Blood Products

The International Society of Blood Transfusion Working Party on Automation and Data Processing (ISBT WPADP) has been entrusted by its member national blood banking organizations to develop a single worldwide specification for bar code labeling of whole blood and blood components (blood products).

The development of a worldwide specification is motivated by several considerations, including:

- Increased international shipment of blood;

- Use of blood from many countries in international disaster relief efforts (International Red Cross, UN, *etc*) and multinational military operations (*eg*, NATO, Desert Storm);

- Incompatibility among the various current national bar code guidelines (both data structures and bar code symbologies) and occasionally within a single country (*eg*, United States);

- Technical inadequacy of the American Blood Commission variant of Codabar (*ABC Codabar*) to meet current needs.

This new bar code labeling specification for blood products has been developed over the last five years by the ISBT WPADP. This specification was approved for implementation by the ISBT Council at the 23rd ISBT World Congress in Amsterdam, The Netherlands, on 3 July 1994. The approved specification recommends:

- Use of ANSI/FACT-1 Category 0 (non-alphanumeric) data identifiers[1,2] **for each data structure** (*see* Section 3), which serve the functions of:

  - Uniquely identifying blood products under the FACT-1 Revision Data Application Identifier Standard,[1] with possible future extension to tissues and organs;

  - Distinguishing *ISBT 128* data streams from *ABC Codabar* data streams from the data content only, independent of the use of symbology identifiers (*see* Section 5).

- Conversion to *"ISBT 128"*, a variant of Code 128 that has a bar code concatenation capability that parallels *ABC Codabar* (requirements specified in Section 4);
- A system for the unique identification of all blood collection and processing centers

worldwide that perform collection, processing or distribution of blood products (*see* Section 6 and Appendix A);

- Transition to "*ISBT 128*" specification be initiated no later than July 1997 **with full implementation no later than July 1998.** Earlier implementation is a **national** prerogative.

2 Key *ISBT 128* Technical Objectives for the Labeling of Blood Products

Please refer to Figure 1, “Example of Bar Codes on a Typically Labeled Blood Container”, for a general overview of the labeling of blood products and bar code usage. In Figure 1, all bar codes are shown to scale as *per* their definitions in Section 3.

There were several key technical problems. These technical issues included the definition and selection of data identifiers and the definition of the *ISBT 128* symbology variant of Code 128 for use in blood banking. Comments here refer to the *ABC Codabar*-based system used in the United States, but apply generically to most other national blood labeling systems.

Technical Objective 1: **To permit both *ABC Codabar* and *ISBT 128* labeling systems to coexist as long as needed** (an estimate of at least twenty years to accommodate frozen blood products was applied).

Problem: **Make the *ISBT 128* bar codes autodiscriminating**, both from each other and from their *ABC Codabar* equivalents.

Solution: The use of **data identifiers** based on characters which do not exist in Codabar.

- These should be data identifiers which are reserved for blood, organ and tissue products, and not confused with other medical or non-medical products.

Technical Objective 2: ***ISBT 128* must satisfy existing national requirements in several ISBT Member Countries that require concatenation of the Donation Identification Number and the ABO/Rh (D) Blood Groups** bar codes be performed to ensure accurate blood group labeling.

Problem: **Develop a concatenation capability for *ISBT 128*** that performs the same function as the use of Start and Stop code “D” in *ABC Codabar (also known as pause code “D”)* to provide time and/or spatially-dependent restricted concatenation of two bar codes, the Donation Identification Number and the ABO/Rh (D) Blood Groups.

- The use of restricted bar code concatenation is mandated by several national blood labeling guidelines.

Figure 1 Example of Bar Codes on a Typically Labeled Blood Container

Note: Dotted lines are for illustration only; they do not appear on the label.

Note: Box indicates actual size of bar code when printed to ISBT 128 specification.

- Comité Européen de Normalisation (CEN)[4] Code 128 symbology specifications provides only unrestricted bar code concatenation and does not perform the required function.

- This specification describes the required bar code reader methodology supporting restricted bar code concatenation in the *ISBT 128* symbology variant and specifies which bar codes can be concatenated.

Solution: **Seek approval for a satisfactory concatenation procedure** through FACT, AIM and CEN.

Technical Objective 3: **Provide a method for encoding non-English characters in *ISBT 128*.**

Problem: Provide for the **future use** of additional or **accented Latin alphabets** or, alternatively, the use of **non-Latin alphabets.**

Solution:

- Full 8-bit encoding in Code 128 permits use of ASCII 128–255 values in *ISBT 128*. This became available in 1993 through the redefined use of function code **f4** in the updated AIM USA[3] and CEN Code 128[4] symbology standards.

- ISO/IEC 8859 Parts 1–9 provides for single-byte encoding of nearly all Latin alphabet-based languages, and the Cyrillic, Arabic, Greek, and Hebrew alphabets.

- In addition, Japanese, Chinese, Korean, *etc*, can now be encoded by use of 1 or more 8-bit bytes/character.

- ISO 10646 *(development recently completed)* is intended to provide a true international character encoding standard for **all** languages.

Technical Objective 4: **Unique identification of every unit collected anywhere in the world with a traceability lifespan of 100 years.**

Problem: **Devise a method to provide for a unique "Blood Unit" or "Donation Number."**

Solution: Include in the Donation Identification Number a unique alphanumeric sequence that identifies the country, center and year of collection.

- Under the *ISBT 128* specification, every blood collection and processing agency worldwide will receive one or more unique alphanumeric identification number(s) that will be included in the Donation Identification Number[5] (*see* Section 6 and Appendix A).

- Collection year (two digits) forms part of the Donation Identification Number, together with a six-digit serial number.

- The system developed for whole blood and blood components (blood products) has the potential to be expanded to handle tissue and organ donations in the future.

Technical Objective 5: **Fit additional data in limited label space** on blood containers.

Solution: **Take full advantage of the Code 128 symbology**, while maintaining compatibility with as much of the installed base of bar code readers and automatic sample processing equipment as possible.

3 Definition of the *ISBT 128* Bar Codes

ISBT 128 bar codes each contain a specific type of data, encoded in a predefined format. The purpose of Section 3 is to define each *ISBT 128* bar code in terms of its four attributes:

- **Data identifier**: Means by which the bar code is uniquely recognized.
- **Data structure**: The data content of the bar code, including the data identifier.
- **Bar Code Encodation**: How the data content is represented using *ISBT 128* symbology.
- **Eye-Readable Text**: How the bar code data characters are presented.

3.1 Definition of Data Identifiers

Data identifier **characters** will be used in *ISBT 128* as part of each data structure to identify the data structure and data content. This allows the bar codes on a label to be scanned in any order.

Blood banking was one of the earliest bar code applications. Data identifiers (as we know them today) were not widely used at that time, and not standardized. In order to discriminate among the various bar codes on a blood container label, unique patterns of *ABC Codabar* Start/Stop characters “A,” “B,” “C” and “D” were used (in place of data identifiers encoded as part of the data structure itself). The Start and Stop patterns were read out along with the data content and appeared in the data stream sent to the host computer.

Codabar is unique as a symbology in that the four Start and four Stop characters serve the dual function of carrying user information as well as the normal functions of:

1) identifying the beginning and ending of the bar code;

2) carrying details of the encodation method used.

Code 128 symbology has three Start and one Stop patterns that are used internally only to control the reader. They are not used as part of the data content. The *ISBT 128* version of AIM USA/CEN Code 128 symbology, as in most bar code symbologies, will therefore use one or more data identifiers added as a prefix to the data to identify each data structure.

3.1.1 Requirements for *ISBT 128* Data Identifiers

Each *ISBT 128* data identifier must satisfy **three distinct requirements:**

1) Autodiscriminate among all *ISBT 128* bar codes on a blood container label;

2) Autodiscriminate among *ISBT 128* bar codes and their *ABC Codabar* equivalents;

3) Provide unique identification such that each *ISBT 128* bar code describes only one blood product.

The **first requirement** is easily met by making the data identifiers for each *ISBT 128* data structure different and unique.

The **second requirement** is more subtle. In practice, many bar code readers can autodiscriminate and are capable of reading both Codabar and Code 128 bar codes (and others). Technical Objective 1 requires that *ABC Codabar* (also the more rarely used Code 39 or Interleaved 2 of 5 bar code symbologies) and *ISBT 128* must be able to coexist in the same blood center or transfusion service during the transition from *ABC Codabar* to *ISBT 128*. Therefore a method must be developed to enable the host computer to be able to interpret the data coming to it from the bar code reader as belonging to a bar code from older national guidelines or as a bar code defined under the *ISBT 128* specification.

- There is now an alternative means to determine which symbology was read by the bar code reader, called the **symbology identifier prefix**. The AIM USA and CEN bar code symbology standards provide a uniform method for reporting the actual symbology read by the bar code reader. When the symbology identifier capability is both available and enabled in a bar code reader, a three-character symbology identifier prefix is added by the reader, and precedes the data (including the data identifiers) read from that symbol (*see* Section 5 for more information).

- Since blood banking was one of the earliest bar code applications many older bar code readers do not produce “symbology identifiers” to identify the bar code symbology read.

  Autodiscrimination of *ISBT 128* from Codabar (and also from Code 39 and Interleaved 2 of 5) can, however, be easily met by proper selection of the characters used as data identifiers in *ISBT 128*.

- This was done by selection of data identifiers that are characters in Code 128 but that do not exist in Codabar (or Code 39, or Interleaved 2 of 5) symbology.

- When a bar code reader capable of reading multiple symbologies is used, the output data from the bar code reading process is examined. The presence of *ISBT 128* data structures is then determined from the presence of *ISBT 128* data identifier characters, since they exist only in Code 128 and not in Codabar (or Code 39, or Interleaved 2 of 5) symbology.

The **third requirement** demands that the characters selected as data identifiers also identify a class of products as well as the bar code. For example, use of "+" as the first or **primary** data identifier character is reserved under the ANSI/FACT "Data Application Identifier Standard"[1] to signify bar codes defined as specified by HIBCC/EHIBCC standards.

- Due to the exacting requirements imposed by the use of blood products, **it is the recommendation of the ISBT WPADP that blood products should have a unique, internationally-recognized set of data identifiers**, so that hospital software can recognize blood products (and potentially organ and tissue donations) as distinct from all other products.

- Submission to and approval of the selected primary data identifiers used in *ISBT 128* in the ANSI/FACT-1 Revision "Data Application Identifier Standard"[1] was the chosen method to achieve this goal.[2]

3.1.2 Future Use of Other Symbologies

The choice of data identifier characters should be from the full 96-character ASCII set. (This character set is formally known as subset G0 of ISO/IEC Standard 4873-1991[6]). This permits the potential encoding of *ISBT 128* data structures in any other full-ASCII symbology.

Thus the data identifiers and data content defined in *ISBT 128* may also be encoded directly in:

- High density two-dimensional symbologies such as PDF-417;

- ANSI X.12 or UN/EDIFACT transaction sets for electronic data interchange (EDI).

The data identifiers and data content defined here transcend the current linear bar code technology and provide a basis for continued use in future machine-readable and electronic data storage technologies.

3.2 *ISBT 128* Data Identifiers

Two data identifiers, denoted as *ISBT 128* **primary** and **secondary** data identifiers were developed. They are used immediately following the Start character of each *ISBT 128* bar code.

3.2.1 Primary and Secondary Data Identifiers

The **primary data identifier** consists of one non-reserved FACT[1] Category 0 (non-alphanumeric) character per structure, always in the left-most position.

- Only non-alphanumeric characters which exist in Code 128 subset B (*see* Appendix B) but not in *ABC Codabar*, Code 39, and Interleaved 2 of 5 symbologies will be used (avoid use of ":" and "$" characters).

- Existing Category 0 special characters currently assigned under FACT, or currently requested by other organizations in the FACT-1 Revision[6], such as "+", "-", and "/" were excluded from consideration as **primary** data identifiers.

- "=" and "&" special characters have been approved as primary data identifiers (*see* Subsection 3.2.4 and Reference 1). They meet the requirements of Subsection 3.1.1, this Section and Subsection 3.2.2.

Secondary data identifiers immediately follow the primary data identifier in the data string, and denote the specific data structure and data content of each data structure.

- Normally used upper case alphanumeric characters, denoted by the set $\alpha = \{A\text{–}Z, 0\text{–}9\}$, form secondary data identifiers for the **Donation Identification Number** only. In this particular case "α" is the first character of the Country/Collection Facility Identification Number, as allocated by ICCBBA, Inc[7] (*see* Section 6 and Appendix A for details regarding assignment).

- By mutual agreement with the Health Industry Business Communications Council (HIBCC) the "+" symbol was not used as a secondary data identifier to avoid any potential for confusion with medical products labeled according to HIBCC specifications.

- Special characters # @ [\ ] ^ ` { | } ~ which have ISO standard language-specific substitutions for their ASCII values were excluded because of specific language usage (*eg*, ASCII 93 is "]" in English, but "Å" in Swedish, "é" in Italian, *etc*).

- Other non-alphanumeric special characters ! " $ % & ' ( ) * , - . / : ; < = > ? and _ may be used for secondary data identifiers in all other blood product label data structures.

Note: Blood container and test tube label space limitations (ie, meeting Technical Objective 5) prohibited use of the 3-data identifier structure of the HIBCC Provider Applications Standard developed by the Health Industry Business Communications Council. HIBCC has agreed to support the ISBT 128 standard for the labeling of blood products.

3.2.2 The Need for Two Kinds (“=” and “&”) of Primary Data Identifiers

Two primary data identifiers were selected for use in *ISBT 128* for two different but compatible reasons.

The **first reason** is technical. For example, there are two optional forms of the Expiration Date data structure in use, each of which is mandated by one or more national guidelines. These pairs must continue to coexist in *ISBT 128*.

The **second reason** is a need for both coexistence with existing national systems and transition overlap which requires the definition of two parallel systems, ***ISBT 128*-specified** and **non-*ISBT 128*-specified**, with separate data identifiers to meet the two following requirements.

1) Some countries wish to adopt the *ISBT 128* symbology and label bar codes but add special information in locally- or nationally-specified structures. **There needs to be a mechanism to distinguish *ISBT 128*-specified from non-*ISBT 128*-specified bar codes.**

2) Blood product codes are not yet standardized internationally. National systems for blood product coding will need to be supported during the transition to approved, common *ISBT 128* product codes over several years. **Separate data identifiers for *ISBT 128*-specified (“=<”) and interim national product codes (“&<”) product codes must coexist during the transition period to prevent errors in product code interpretation.**

This parallel system of “=” and “&” primary data identifiers greatly simplifies the transition process to the new *ISBT 128* data structures because:

- It permits countries now implementing the bar code labeling of blood products to begin using the *ISBT 128* data structures immediately, with national systems of product codes, with later transition to full *ISBT 128* product codes with no confusion as to which product code system is in use, or whether a given code is *ISBT 128*-compliant;

- It preserves the capability to accommodate special product codes, testing results and other additional information outside the *ISBT 128* specification to meet local and national needs, and still be *ISBT 128*-compliant for other key data structures.

3.2.3 Usage Rules for "=" and "&" Primary Data Identifiers

The following rules apply in the use of the "=" and "&" primary data identifiers:

Rule 1. Only one type (*ISBT 128*- or non-*ISBT 128*-specified) is permitted for each data structure on each blood product label:

- **Transition from nationally-specified to *ISBT 128*-specified bar codes should be completed by the recommended start date for each *ISBT 128*-specified bar code.**

Rule 2. **All bar codes beginning with "=" will be *ISBT 128*-specified** and data structure, content, and interpretation will be unique, and as specified by this document:

- The "=" primary identifier is **never** to be used unless the bar code is ***ISBT 128*- specified** since this would be in violation of the FACT agreement (*see* Subsection 3.2.4);

- All *ISBT 128*-specified bar codes must have data identifiers and data content that are fully compliant with this specification document.

Rule 3. Some bar codes starting with the "&" primary data identifier **may be now or in the future** completely or partially *ISBT 128*-specified.

3.2.4 ANSI/FACT Standardization of Data Identifiers

The American National Standards Institute Material Handling Group 10 Subcommittee 9 Working Group (ANSI MH10.9) is the principal standards agency in the world codifying data identifiers. By default, their ANSI/FACT-1 (1991) Data Application Identifier Standard, in effect today as an ANSI Standard in the United States, is used throughout the world.

The following formal requests[2] were made on 12 August 1992 for two FACT Category 0, "Special Characters that are Not Assigned or Controlled by FACT", were accepted and incorporated into the ANSI/FACT-1 Revision "Data Application Identifier Standard"[1] for primary identifiers:

- **"=" for *ISBT 128*-specified and -assigned bar codes** (formally requested in the FACT-1 Revision by the ISBT WPADP) and assignments administered by ICCBBA, Inc.

- **"&" for nationally-specified and -assigned bar codes** (formally requested in the FACT-1 Revision by the American Association of Blood Banks on behalf of blood centers and transfusion services worldwide). Administration of the use of "&" as a primary data identifier would be on a **national** basis, subject to the overriding requirements of the ISBT WPADP.

These primary data identifier requests were accepted in the US ANSI/FACT-1 Revision 1 document:[1]

American National Standard:
"Data Application Identifiers for Material Handling"
ANSI/MH 10.9 FACT - 1994
Working Draft (revision 1)
10 April 1993.

This document was accepted by a vote of the full ANSI MH-10 SBC-9 Working Group by balloting completed 31 August 1993. Specific ballot items of relevance include:

- Acceptance of all proposed data identifiers (*this includes the allocation of "=" and "&"*);

- Submission of the approved document to ISO *(the FACT-1 Revision 1 would then serve the purpose intended by the original FACT-2 document for international specifications such as ISBT 128)*.

Acceptance of the data identifiers in the ANSI/FACT-1 Revision 1 standard implies that **every bar code** starting with a "&" or "=" will by definition be reserved for blood products today, and potentially for other donated human products (organs and other tissues) in the future. Since the ANSI/FACT-1 Revision 1 is already a *de facto* international data identifier standard, submission of this standard by ANSI to ISO only reinforces this position.

3.2.5 *ISBT 128* Bar Code Data Identifiers

The **approved** *ISBT 128* data identifiers are shown in Table 1A, Page 3-9, "*ISBT 128* Data Identifiers for Bar Codes for the Labeling of Blood Products." Table 1B, Page 3-10 depicts **approved** "Interim and Nationally-Specified Bar Code Data Identifiers**.**"

3.3 *ISBT 128* Data Encodation

Code 128 offers many features and alternative methods for bar code data encodation. Three different encodation subsets, known as Subsets A, B and C are defined, and are detailed in Appendix B. The purpose of Subsection 3.3 is to specify the general rules to be followed in data encodation, and thus lay the framework for the designs of the data structures in Subsection 3.4.

3.3.1 Use of Code 128 Subsets A and B

Because alphanumeric data identifiers are used, **all bar codes are to be started in Code 128 subset B**. Subset B contains the upper and lower case English alphabet, digits, and the non-alphanumeric characters used as data identifiers in *ISBT 128*.

Subset A is not required by the *ISBT 128* data structures defined in Subsection 3.4. It may, however, be used in special cases (*see* Subsection 3.5 for conditions of use).

3.3.2 Use of Code 128 Subset C

Code shifts from Code 128 subset B to subset C may be used when long strings of digits appear in the data structure, as in the Donation Identification Number. Subset C encodes two numeric digits in one bar code symbol character. Spatial efficiency of this method increases when an even number of consecutive digits are encoded.

Therefore, under Technical Objective 5, the definition of all *ISBT 128*-specified bar codes will use subset C whenever a bar code can either be made physically shorter or contain more data in the same length symbol. The Expiration Date (*see* Subsection 3.4.3) is an example of both of these respective usages.

Use of subset C in nationally-specified data structures **is highly recommended where it results in a clear technical advantage** through packing more data into a smaller space.

An additional reason for using subset C is that some bar code printers automatically switch to Code 128 subset C when they determine that it is possible to print a shorter Code 128 symbol. Subset C may be used by these printers in applications where other printers would continue to encode data in subsets B or A. By defining the use of subset C whenever such a length advantage exists, any internal decision-making logic of the bar code printer is preempted and this ensures that *ISBT 128* bar codes are always printed in the same shortest possible way.

Table 1A *ISBT 128* Data Identifiers for Bar Codes for the Labeling of Blood Products

Data Identifier	Data Content and Additional Information
=α	Donation Identification Number, where the character α represents any alphanumeric in the set {A–Z, 0–9}. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.1). Bar code can be concatenated.
=%	Blood Groups [(A, B, AB, O) and Rh(D) (positive or negative)], extended to include additional routine testing information. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.2). Bar code can be concatenated.
=>	Expiration (Julian) Date. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.3).
&>	Expiration (Julian) Date and Time. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.3).
=*	Donation Collection Date. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.4).
&*	Donation Collection Date and Time. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.4).
=<	Product Code. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.5).
=)	Manufacturer's Identity and Container Information. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.6.2).
&)	Manufacturer's Lot Number. **Data structure meets *ISBT 128* specification** (*see* Subsection 3.4.6.3).
=&	Concatenation programming bar code. **Data structure meets *ISBT 128* specification**. Bar code can not be concatenated (*see* Subsection 4.8).

Table 1B Interim and Nationally-Specified Bar Code Data Identifiers

Data Identifier	Data Content and Additional Information
&<	Nationally-specified Product Code (encoded otherwise according to *ISBT 128* specification) **used only during transition from current symbology to *ISBT 128***. Data structure does **not** meet *ISBT 128* specification (*see* Subsection 3.4.5.5).
&(	Nationally-specified Special Testing. Data structure does **not** meet *ISBT 128* specification (*see* Subsection 3.4.7).
&β	National use bar codes. Here β represents the set of 26 lower case alpha characters {a, b, c, ..., z}. These may be assigned without review by ICCBBA, Inc by **recognized National Groups** with authority to make such designations. Data structure does **not** meet *ISBT 128* specification (*see* Subsection 3.4.8). Bar codes may be concatenated.
&!	Nationally-specified Confidential Unit Exclusion Status bar code. Data structure does **not** meet *ISBT 128* specification. Bar codes may be concatenated (*see* Subsections 3.4.9.1 and 4.1.3).
&;	Nationally-specified **Donor** (*note: not **Donation***) Identification Number. Data structure does **not** meet *ISBT 128* specification. Bar code may be concatenated (*see* Subsections 3.4.9.2 and 4.1.4).

3.3.3 Reading Bar Codes Using Mixed Subsets

The use of more than one subset for bar code data encodation does not result in any problems in reading *ISBT 128*, as these code change and code shift characters are entirely internal to the bar code, and control the bar code decoding itself. Bar code readers automatically switch between subsets according to the subset control characters within the bar code, to recover the data correctly no matter how printed.

The subset Start, Code Change, Code Shift, and ASCII Shift (**f4**) control characters used for data encodation are not output in the data string from the bar code reader. The recovered data structure is therefore unaffected by the actual subset mix used in printing any *ISBT 128* bar code.

This one-symbol character code shift to the double density numeric mode (subset C) is denoted by **shift C** in the text and Table 6, Page 3-40. Subsequent digit pairs are also shadowed to denote their representation as a single symbol character in the bar code.

3.4 *ISBT 128*-Specified Bar Codes

3.4.1 Donation Identification Number

A major goal (Technical Objective 4) of the ISBT WPADP was to provide for the unique identification of each unit of whole blood (or apheresis unit) collected anywhere in the world over a one hundred year period.

It is the recommendation of the ISBT WPADP that all **data** characters appearing in the Donation Identification Number must be presented in both machine-readable (symbol) and eye-readable text. Non-data characters, including data identifiers, need appear only in symbol form. This recommendation and the differentiation between data and non-data characters should be kept in mind in reading the sub-paragraphs of Subsection 3.4.1.

3.4.1.1 Donation Identification Number Data Structure

A single type of Donation Identification Number data structure was agreed upon, *viz*:

=a **shift C pp pp yy nn nn nn ff K**

It has the following substructure:

- Primary and secondary data identifiers, "=a" (*see* Subsection 3.4.1.2);

- A five-character (one alphanumeric plus four digits) Country/Collection Facility Identification Number, “a**pppp**” (*see* Section 6);

- A two-digit year of collection, “**yy**”;

- A six-digit unit serial number, “**nnnnnn**”;

- A two-digit flag, “**ff**” (*see* Table 2, Page 3-18);

- A manual data entry check character, “**K**”.

Under the *ISBT 128* specification, every blood collection and processing agency worldwide will be assigned a unique five-character alphanumeric **Country/Collection Facility Identification Number** “a**pppp**” which will be part of the Donation Identification Number (*see* Section 6 for details on how these assignments were made and Appendix A for the Country/Collection Facility Identification Number block assignments for each country).

The collection year, “**yy**” is the last two digits of the International Standard Year that starts on January 1, with a maximum time tolerance of plus or minus one (±1) month (*see* Subsection 3.4.1.4 for details).

The specific usage of the two *ISBT 128*-specified special (non-data) flag characters “**ff**” must conform to national guidelines. There are two general types of usage, where the two digits are to be interpreted as either:

- Two-digit special flag characters used for process control (*see* Subsection 3.4.1.5), or

- A weighted modulo 37,2 check digit on the entire thirteen character unit number (*see* Appendix C for method of calculation).

A method for calculating an alphanumeric check character for the eye-readable text representation of the Donation Identification Number for use in manual data entry is given in Subsection 3.4.1.5.

The Donation Identification Number system has the potential for expansion to handle organ and other tissue donations in the future.

3.4.1.2 Primary and Secondary Data Identifiers

The **primary data identifier** of the Donation Identification Number is always to be “**=**”.

Two special accommodations were made in the design of this bar code and its encodation to minimize the physical length of the bar code.

- The **secondary data identifier** of the Donation Identification Number was set equal to the alphanumeric first character "**a**" of the Country/Collection Facility Identification Number. Note that "**a**" is defined as one of thirty-six (36) characters in the range A–Z or 0–9.

- All the alphabetic and numeric characters were grouped together, and the numeric portion of the data structure encoded as two digits per bar code character through use of Code 128 subset C.

3.4.1.3 Fixed-Length Test Tube Label

The design of blood sample testing equipment used in blood centers effectively limits the maximum label length for Donation Identification Number bar code labels to the current 29 mm (1.14 in).

Unlike the relatively "open," uncontrolled environment of bar code reading on **blood containers**, where a wide variety of reading technology is used, test tube reading on automated analyzers is a tightly controlled process. Therefore, the minimum width of the smallest bar or space (the X dimension) may be decreased, and the necessary depth of field of the bar code scanner accommodated in the design of the analyzer.

After consultation with equipment manufacturers, the ISBT WPADP adopted a 29 mm (1.14 in) long test tube label with a practical X dimension of 0.167 mm (0.0066 in) (width of the narrowest bar or space). This was made possible by two special accommodations in the data structure and its encodation.

By use of 0.167 mm (0.0066 in) X dimension Code 128 and mixed symbology subsets B and C, fifteen characters of unique Donation Identification Number in *ISBT 128* can be put in the same physical space as formerly occupied by the non-unique seven-digit *ABC Codabar* Donation Identification Number on an existing 29 mm test tube label.

Note that the 0.167 mm (0.0066 in) X dimension in *ISBT 128* is **for use on test tubes only.** The **Donation Identification Number and all other bar codes** used on blood containers are to use 0.25 mm (0.010 in) X dimension bar codes (*see* Subsection 3.5 for additional recommendations for printing bar codes).

3.4.1.4 Donation Identification Number Collection Year

The collection year, "**yy**" is the last two digits of the International Standard Year that starts on January 1. For example, the collection year “1994" would be represented by “**94**” and the collection year “2002” by “**02**” in the Donation Identification Number. Note that the year 2000 will be “00.”

In order to enable cost-effective use of preprinted label inventories, the maximum time tolerance permitted is recommended as no more than the actual collection year plus or minus one (±1) month, *ie*:

- It is permissible to use Donation Identification Number labels dated for the subsequent collection year on or after December 1 of a given collection year;

- Similarly, Donation Identification Number labels dated for the prior collection year may be used through January 31 of the current collection year.

Thus a unit of blood collected and labeled with a Donation Identification Number having a collection year “**97**” could have been physically collected within the time interval between December 1, 1996 through January 31, 1998. If more precise collection date information is required, the Donation Collection Date data structure (*see* Subsection 3.4.4) should be used.

National organizations are free to set and require narrower ranges of time tolerance than plus or minus one (±1) month for blood collected within their own boundaries.

3.4.1.5 Donation Identification Number Flag Digits

The flag digits “**ff**” are **non-data** characters in the Donation Identification Number data structure. They are used to convey specific information other than the unique identification of the blood product.

Three types of flag digits are provided:

Type 1: Process control, with *ISBT 128*-defined meaning;

Type 2: Process control, with local blood center-defined meaning;

Type 3: Data transmission check.

Use of specific values of the *ISBT 128*-specified flag digits “**ff**” in the Donation Identification Number may be determined within each national guideline, provided that the following two rules are observed:

- When not used or not specified, the value of "**ff**" is to be set to "**00**";

- When used, the selected values of "**ff**" must conform to Table 2, Page 3-18.

When Type 1 or Type 2 process control flag digits are used (*ie*, encoded value of "**ff**" is non-zero, and in the range 01–59) they must be represented in a nationally-specified eye-readable text representation as a numeric, icon, or other graphical symbol as noted below.

1. Numeric Presentation.
   Printing of the numeric value of "**ff**" in the eye-readable text line is optional on a **national** basis. When the two-digit values of flags "**ff**" are printed, however, they should be rotated 90º clockwise to make them visually different from the other data characters in the Donation Identification Number. An example of rotated flag digits appears in Figure 1.

2. Non-numeric Presentation.
   Instead of printing the two-digit value rotated 90°, a graphical icon or other representation of the **value of "ff"** rather than the **actual value of "ff"** may be preferable, *eg*:

   - Instead of adding "**03**" to the end of the Donation Identification Number interpretation line, printing the phrase "**Container 3**" on the label may be more useful to the person handling the unit;

   - Instead of adding "**07**" to the end of the Donation Identification Number interpretation line, printing an icon showing a small test tube may be preferable.

Type 3 flag digits encode the value of the ISO 7064 modulo 37,2 check character defined in Subsection 3.4.1.5 above within the Donation Identification Number bar code. Since this check character acts on the entire data portion of the Donation Identification Number, encoding the check character in the bar code data acts as both a secondary check within the bar code itself, further improving the already excellent scanning error resistance of the *ISBT 128* symbology. More importantly, encoding the check character within the Donation Identification Number bar code can provide a data transmission check character to ensure accurate communication of the scanned bar code to the host computer.

The ISO 7064 modulo 37,2 check character is encoded in the Type 3 flag digits by adding 60 to the value of the check character resulting from applying the ISO 7064 modulo 37,2 method. Since the check character eye-readable text is already present on the printed label (*see* Section 3), it is recommended that the values of the Type 3 flag digits themselves (range 60–96) **not** be printed as part of the eye-readable text of the Donation Identification Number.

3.4.1.6 Check Character for Manual Data Entry

The check character "**K**" was established to provide for the perceived need for a check for manual data entry of that portion of the eye-readable text that specifically identifies a unit of blood, namely the alphanumeric Country/Collection Facility Identification Number, year of collection and the six-digit unit serial number. The Donation Identification Number check character is a **non-data character.** The value of "**K**" appears **only** in the eye-readable text and is **not** in the bar code, since its sole purpose is to support accurate manual data entry.

The eye-readable text representation of the data characters within the Donation Identification Number is an alphanumeric string, and therefore the value of "**K**" is an alphanumeric character. The value of "**K**" is calculated at the time of printing, using the ISO 7064 modulo 37,2 method (*see* Reference 8 and Appendix C).

- The primary data identifier "**=**" and flag digits "**ff**" are non-data characters, and thus are excluded from the calculation of the check digit, "**K**."
- "**K**" is calculated on the entire thirteen (13)-**data character** string "a**ppppyynnnnnn**."
- The ISO 7064 modulo 37,2 checksum calculation method is to be used so that "**K**" is calculated as the modulo 37 remainder of the weighted sum of the data character string (*see* Appendix C).
- This ISO method assumes values of 0–9 for the digits 0–9, and 10–35 for the English upper case alphabet A–Z, respectively.
- The character "*****" is used to represent the value 36 in the modulo 37 calculation.

It is recommended that the alphanumeric character value of "**K**" be printed enclosed in a box to indicate that it is a check character. It is also strongly recommended that the six-digit unit serial numbers and/or the check digits be printed in larger or more prominent type, for example:

W1234 95 123456 00 $\boxed{K}$

The enlarged unit serial number adds readability for manual data entry. Optional additional eye-readable-only identification of the check character (*such as the use of the printed* *abbreviation "ck" near the enclosing box*) may be used.

During manual data entry, the entire data string concluding with the check character "**K**" is to be entered. It is noted that "hot keys" (preprogrammed function keys on the keyboard) may be used for static portions of the data string such as "**appppyy**" which are often constant for many transfusion services, or perhaps as a limited menu. Due to the nature of the check character calculation, any variations from the correct Donation Identification Number caused by incorrect use of a hot key will be detected in the check digit calculation in the same manner as had the data been entered entirely by individual key strokes.

When the Donation Identification Number is printed only as an eye-readable text representation, such as on manifests, it is recommended that the check character "**K**" be printed as well. It can either be calculated or manually transcribed, depending on whether the list is machine-generated or manually written.

3.4.2 ABO/Rh (D) Blood Groups

The data structure for this bar code:

- Maintains the current *ABC Codabar* values encoding ABO and Rh (D) to avoid confusion during the transition to *ISBT 128*;
- Allows for the capture of additional data for autologous collections and directed donations;
- Supports encoding Rh and Kell phenotypes.

3.4.2.1 Default ABO/Rh (D) Blood Groups Encodation

Default two-digit values for encoding ABO/Rh (D) blood groups are those defined in the 1985 United States FDA *Guideline for the Uniform Labeling of Blood and Blood Components*, Table 12, Page III-12.[9] These **default values** are shown in Table 3A, Page 3-22.

3.4.2.2 Autologous Collections

Several major national guidelines had previously utilized only the ABO/Rh (D) blood groups bar code to encode "autologous donor" information. The tacit assumption was that ABO/Rh (D) blood groups-matching was a non-issue in autologous transfusion, since:

- The **ABO/Rh (D) blood groups** are the most important clinical information for

Table 2 *ISBT 128*-Specified Values for Donation Identification Number Flag Digits, "ff"

Value of "ff"	Meaning When Used in the Donation Identification Number
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) "demand-printed" label
06	Pilot tube label
07	Test tube label
08	Donor record label
09–39	Reserved for future assignment
40–59	Reserved for assignment and use by each local blood center. Therefore the meaning and interpretation of flag values 40–59 may differ with each Country/Collection Facility Identification Number (*see* Subsection 3.4.1.1 and Section 6) and should not be interpreted at any other site
60–96	ISO 7064 modulo 37,2 check character on the preceding thirteen (13) data characters, "**appppyynnnnnn**" including the Country/Collection Facility Identification Number, year and the unit serial number. Value is assigned as 60 + (modulo 37,2 checksum)
97–99	Reserved for future assignment

homologous (allogeneic) and **directed** donations;

- **Donor name** or identification is the most important information in **autologous** collection and transfusion.

The view that ABO/Rh (D) blood groups information was unimportant in the case of autologous collections has changed since the publication of the 1985 United States FDA *Guideline for the Uniform Labeling of Blood and Blood Components*,[9] in which the ABO/Rh (D) blood groups label was replaced by the special message label "For Autologous Use" with code value 40.

- Autologous collections (and directed donations) are now a significant percentage of total collections, particularly at hospital collection centers in Western countries. This trend may increase in areas where patients and their families have concerns about the safety of the local blood supply.

- Autologous collections which are actually or potentially biohazardous (for example, those collected from patients with diagnosed or high risk factors for HIV or HBsAg) need to be specially labeled. The US FDA-approved *Guideline*[9] calls for an **additional** "Biohazard" label to be applied, with the ABO/Rh (D) blood groups bar code carrying only the "autologous donor" information. This is not as desirable as the use of a data structure that carries both the "autologous" and "biohazard" information in both a bar code and in graphical or other eye-readable format.

- When blood collected for autologous transfusion **meets all requirements for homologous (allogeneic) blood donation** but is not used by the donor/patient it may be eligible for use in homologous (allogeneic) transfusion. Good practice requires that the unit be relabeled with an ABO/Rh (D) blood groups label (in the space previously used for the "autologous" information). Depending on national practice, this may also require that the unit be retested.

Thus a system was devised to encode the type of donation and the ABO/Rh (D) blood groups information **simultaneously** in the ABO/Rh (D) Blood Groups bar code.

3.4.2.3 ABO/Rh (D) Blood Groups Data Structure

The *ISBT 128* ABO/Rh (D) Blood Groups data structure and encodation is as follows:

= % gg re (all in subset B)

where:

"**=%**" is the data identifier;
"**gg**" and "**re**" encode blood group data as specified below.

Note that "**g**," "**r**," and "**e**" represent **alphanumeric** characters from the set {A–Z, 0–9, a–z} The values of "**gg**" are the two-characters shown in Tables 3A and 3B, Pages 3-22 and 3-23 for each pair of ABO/Rh (D) blood groups or the ABO blood group.

Table 4, Page 3-26 is used for the optional encoding of Rh, Kell and Miltenberger Mi-III phenotypes in symbol character "**r**." Symbol character "**e**" is reserved for future extension of this data structure.

Default values of zero are to be used when no data are present (the null value) for the ABO and Rh (D) blood groups or the Rh, Kell and Miltenberger Mi-III phenotypes.

3.4.2.4 ABO/Rh (D) Blood Groups Data Encodation

The former two-digit ABO/Rh (D) blood groups values encoded in the *ABC Codabar* bar code and as bar code text on in the ABO/Rh (D) Blood Groups label were revised to show, by a two-character **alphanumeric** code in "**gg**" the status of **all** the following information:

- ABO blood group (including Bombay and para-Bombay phenotypes);
- Rh (D) blood group (positive or negative);
- Homologous (allogeneic) donation, autologous collection, or directed donation type;
- Biohazard status, especially if either a biohazardous autologous collection or directed donation (such as a mother-child directed donation);
- If an autologous collection or a directed donation, the eligibility of the unit for crossover for use in homologous (allogeneic) transfusion;
- If the unit is intended for emergency transfusion only.

In Tables 3A and 3B, Pages 3-22 and 3-23, each single default value "n" for the eight ABO/Rh (D) blood groups pairs and the four Bombay/para/Bombay phenotypes is expanded into a set of seven values, within the range:

{n-3, n-2, n-1, n, n+1, n+2, n+3}

in which the default value "n" is modified according to the intended use, *viz*:

Value	**Intended Use**
n	Default: Not Specified
n-1	Directed Donation/Eligible for Crossover
n-2	Directed Donation/Biohazardous
n-3	For Emergency Use Only
n+1	For Autologous Use/Eligible for Crossover
n+2	For Autologous Use Only
n+3	For Autologous Use/Biohazardous

A directed donation and an autologous collection eligible for homologous (allogeneic) transfusion carries the value (n-1) or (n+1), respectively. The set of encoded values {(n-1), n, (n+1)}represents all units eligible for use in homologous (allogeneic) transfusion.

Separate values for each entry in Tables 3A and 3B, Pages 3-22 and 2-23 permit special graphics and bar code text regarding intended use to be placed in the ABO/Rh (D) Blood Groups bar code **in addition** to the ABO/Rh (D) blood groups or Bombay/para-Bombay phenotype. Unique values for each intended use also facilitates tracking of both autologous collections and directed donations.

Encoding of the four ABO blood groups with no Rh (D) blood group information was more complex. In order to maintain the same default values for O, A, B and AB (55, 66, 77 and 88, respectively) as specified in the 1985 US FDA-approved *Guideline*,[9] a new coding scheme was needed. This is because the scheme used above in which default value n is expanded into {n-3, n-2, n-1, n, n+1, n+2, n+3}results in an unacceptable overlap between the ranges of the four ABO blood groups and the eight ABO/Rh (D) blood groups pairs (*eg*, a Directed Donation unit of blood group O with no Rh (D) blood group information would have the value 55-1 = 54, and an Autologous/Biohazardous collection of blood groups O, Rh (D) positive would have the **same value**, 51+3 = 54).

Therefore, blood groups O, A, B, AB with no Rh(D) blood group information were coded in a mixed way:

- The default (***collection type not specified***) values of 55, 66, 77, 88 as *per* the 1985 *Guideline*[9] were retained;

Table 3A Encodation of Intended Use Information in ABO/Rh (D) Blood Groups Data Structure, With and With No Rh (D) Blood Group Information

ABO/Rh (D) Blood Groups	For Emergency Use Only	Directed Donation/ Biohazardous	Directed Donation/ Eligible for Crossover	**Default: Intended Use Not Specified**	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
	(n-3)	(n-2)	(n-1)	**(n)**	(n+1)	(n+2)	(n+3)
O Rh negative	92	93	94	**95**	96	97	98
O Rh positive	48	49	50	**51**	52	53	54
A Rh negative	03	04	05	**06**	07	08	09
A Rh positive	59	60	61	**62**	63	64	65
B Rh negative	14	15	16	**17**	18	19	20
B Rh Positive	70	71	72	**73**	74	75	76
AB Rh negative	25	26	27	**28**	29	30	31
AB Rh positive	81	82	83	**84**	85	86	87
O	P3	P4	P5	**55**	P7	P8	P9
A	A3	A4	A5	**66**	A7	A8	A9
B	B3	B4	B5	**77**	B7	B8	B9
AB	C3	C4	C5	**88**	C7	C8	C9

Table 3B Encodation of Intended Use Information and H-deficient Bombay and para-Bombay Phenotypes

ABO/Rh (D) Blood Groups	For Emergency Use Only	Directed Donation/ Biohazardous	Directed Donation/ Eligible for Crossover	**Default: Intended Use Not Specified**	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
	(n-3)	(n-2)	(n-1)	**(n)**	(n+1)	(n+2)	(n+3)
para-Bombay Rh negative	D3	D4	D5	**D6**	D7	D8	D9
para-Bombay Rh positive	E3	E4	E5	**E6**	E7	E8	E9
Bombay Rh negative	G3	G4	G5	**G6**	G7	G8	G9
Bombay Rh positive	H3	H4	H5	**H6**	H7	H8	H9

- Other ABO/Rh (D) blood groups/collection-type values were encoded similarly to those of the Bombay/para-Bombay phenotypes, *viz*

O:	P3, P4, P5,	**55**,	P7, P8, P9	with default of 55;
A:	A3, A4, A5,	**66**,	A7, A8, A9	with default of 66;
B:	B3, B4, B5,	**77**,	B7, B8, B9	with default of 77;
AB:	C3, C4, C5,	**88**,	C7, C8, C9	with default of 88.

Encodation of the blood groups O, A, B and AB with no Rh (D) blood group information is also shown in Table 3A, Page 3-22.

3.4.2.5 Encodation of Kell and Rhesus Phenotypes

The optional encodation of Kell and Rhesus phenotype information utilizes character "**r**" [*see* Table 4, Page 3-26]. The default value for "**r**" is zero.

3.4.2.6 Special Messages in the ABO/Rh (D) Blood Groups Data Structure

In the 1985 *Guideline*[9] a number of special messages were defined to be used in place of the ABO/Rh (D) blood groups bar code when the unit collected was intended:

- for autologous transfusion;
- for emergency use only;
- not to be used for transfusion.

The three possible cases for autologous use, and the case of emergency use when the ABO/Rh (D) blood groups are known, are covered in the assignment of values for "**gg**" in Subsection 3.4.2.4. What remains are special messages that have been used in various national systems **instead** of ABO and Rh (D) blood group when labeling units.

These special messages fall into two groups:

Group 1: Restricted use or not acceptable for homologous (allogeneic) transfusion.

Group 2: For alternative uses other than transfusion.

Special messages are to be coded in "**gg**" with the first letter as "M" and the second letter as a lower case alphabetic character, to differentiate them from blood groups and phenotypes.

The following Group 1 special messages have been designated:

Ma Autologous collection;
Mb Biohazardous;
Md Discard (to be destroyed);
Mq Quarantine/hold for further testing or processing;
Mx Not for transfusion based on test results.

Group 2 special messages that have been designated are:

Mf For fractionation use only;
Mr For research use only.

3.4.3 Expiration Date (and Time)

A 100-year expiration date method is used in the two *ISBT 128*-specified data structures encoding the expiration date. The first structure is:

= > shift C cy yj jj

where:

"**=>**" is the data identifier;
"**c**" is the century;
"**yy**" is the year;
"**jjj**" is the Julian day number of the year (*see Definitions for This Document*).

The second structure, that may be used for short-lived products, extends the bar code by four digits (two symbol characters in Code 128 subset C) to include the hour and minute of expiration:

& > shift C cy yj jj hh mm

where:

"**&>**" is the data identifier;
"**c**" is the century;
"**yy**" is the year;
"**jjj**" is the Julian day number of the year, as above;
"**hh**" is the hour (00 to 23) and "**mm**" the minute (00 to 59) of product expiration. A day is

Table 4 Encodation of Rhesus, Kell, and Miltenberger (Mi-III) Phenotypes

Values of "**r**" {0–9, A–T} are used to encode the results of testing with anti-K, anti-C, anti-c, anti-E, and anti-e as shown in this table. (For example, if the value of "**r**" is "E", then the red blood cells are K-negative, C-negative, c-positive, E-positive and e-positive). Values U and V encode Miltenberger Mi-III antigen test results.

Results with Anti-Kell:			**Results with:**			
Not tested	**Negative**	**Positive**	**Anti-C**	**Anti-c**	**Anti-E**	**Anti-e**
0	S	T	not tested	not tested	not tested	not tested
1	A	J	negative	positive	negative	positive
2	B	K	positive	positive	negative	positive
3	C	L	positive	positive	positive	positive
4	D	M	positive	positive	positive	negative
5	E	N	negative	positive	positive	positive
6	F	O	negative	positive	positive	negative
7	G	P	positive	negative	negative	positive
8	H	Q	positive	negative	positive	positive
9	I	R	positive	negative	positive	negative
U			Mi-III negative			
V			Mi-III positive			
W			Special Testing bar code present and must be interpreted (*see* Subsection 3.4.7)			

defined as beginning at midnight (00 hours, 00 minutes) and ending at 23:59.

3.4.4 Donation Collection Date (and Time)

The two forms of this *ISBT 128*-specified data structure are similar in their encodation to the Expiration Date (and Time) data structures defined in Subsection 3.4.3. The first structure is:

= * shift C cy yj jj

where:

“**=***” is the data identifier;
“**c**” is the century;
“**yy**” is the year;
"**jjj**" is the Julian day number of the year (*see Definitions for This Document*).

The second data structure extends the bar code by four digits (two symbol characters in Code 128 Subset C) to include the hour and minute of collection:

& * shift C cy yj jj hh mm

where:

“**&***” is the data identifier;
“**c**” is the century:
“**yy**” is the year;
“**jjj**” is the Julian day number of the year, as above;
“**hh**” is the hour (00 to 23) and "**mm**" the minute (00–59) of donation collection. A day is defined as beginning at midnight (00 hours, 00 minutes) and ending at 23:59.

3.4.5 Product Code

Product coding represents the most complex issue for the *ISBT 128* specification and its implementation because:

- Virtually every country has a different method for product coding;
- There is not always international agreement on what constitutes a “product;”
- Products widely used in one country may not be used at all in other countries. Product

codes need to be “rationalized”; that is, there should be only minor variations in product characteristics or in the processing steps that occur between two similar products that have the same product code.

3.4.5.1 Product Code Assignment

Most current product coding schemes utilize either serial assignment of product code numbers or systems in which each digit or position in the product code is “significant” and represents one attribute of the particular product. These latter schemes, while conceptually attractive, result in long product codes (ten or more characters) in which **less than one per cent (<1%)** of the possible code combinations are actually assigned.

As a compromise, the ISBT WPADP has recommended that five alphanumeric characters should be capable of encoding all conceivable blood products used now and in the future if they are randomly assigned in a non-structured manner. Note that if both upper and lower case English alphabetic characters (52) and numeric digits (10) are used, a five character scheme could theoretically encode 62^5 (over 916 million) products.

The question of how ISBT product codes are to be assigned has been addressed by several members of the ISBT WPADP. Several schemes have been suggested, including, but not limited to:

- Central assignment of product codes by the ISBT WPADP Secretariat, ICCBBA, Inc or other appointed organization;

- Formula-based assignment of product codes by national blood agencies utilizing formulae approved by the ISBT. This would probably take the form of a computer database program which would be maintained and distributed by the ISBT WPADP. Assigned product codes would then be reported by the assigning national agency to the ISBT WPADP Secretariat, ICCBBA, Inc or other appointed organization.

It has been agreed that the most satisfactory method of assignment is a single office world wide and the ICCBBA, Inc office has been chosen for this purpose.

3.4.5.2 Product Code Data Structure

The *ISBT 128*-specified data structure for the product code is:

= < a **o o o o t d s** (all in subset B)

where:

“=<” is the *ISBT-128* data identifier;

"a" is a character in the set {–Z}(*see* Subsection 3.4.5.5 for reasoning);
"**o**" is a character in the set {A–Z, a–z, 0–9}
"**t**" is a type of donation character from Table 5, Page 3-31;
"**d**" is a 1st level division character in the set {A–Z} or 0 (zero: default);
"**s**" is a 2nd level division character in the set {a–z} or 0 (zero: default).

The length of the *ISBT-128* product code is therefore ten (10) data characters, including the data identifier.

Note: The length of the product code bar code is almost the same physical length as the Donation Identification Number bar code defined in Subsection 3.4.1).

3.4.5.3 Inclusion of Type of Donation

Units which are obtained for reasons other than "voluntary" or "altruistic" reasons for homologous (allogeneic) transfusion (such as autologous collections and directed donations) may be thought of as **special products.** Inclusion of this type of donation information on the blood container label is mandated by many national regulatory agencies.

The **6th character** in the product code is used to carry this type of donation information. This is either in **addition to** or **instead of** the information encoded in the ABO/Rh (D) Blood Groups bar code. 6th character assignments are shown in Table 5, Page 3-31.

3.4.5.4 Coding of Products That Have Been Divided

Units made by the division of a single container of a finished product into two or more parts that are identical except for volume are "divided units." Such units have the same Donation Identification Number and may have the same first six data characters of the product code. The objective is to provide a means to identify each division.

Note: The first six characters of the product code may differ if system integrity has changed. Refer to the document "ISBT 128: Product Code Database — Structure and Definitions" for examples using actual product codes).

- The (undivided) primary collection unit will be encoded as "**00**" (two zeros). This is the default value.

- The **right-most** of the two alphanumeric characters **ds** of the six-character product code will encode the first division.

- First level divisions (up to 26) of the primary collection will be encoded using capital letters followed by a zero, *viz*: A0, B0, C0, D0, E0, F0, G0, H0, *etc*.

- Second level subdivisions (up to 26) of the first level divisions will be encoded using the letter of the first level division followed by a lower-case letter indicating the subdivision, *eg*:

  A0 would be subdivided as Aa, Ab, Ac, *etc*.
  Q0 would be subdivided as Qa, Qb, Qc, *etc*.

- Third level subdivisions (and beyond) are not encoded.

Note: Divisions need not be equal and that this nomenclature does not require this.

As a specific example of this scheme in practice, consider a 300 ml unit of AS-1 Red Blood Cells divided into two 150 ml subunits (that are denoted by A0 and B0). One of these 150 ml subunits, B0, is then divided into one 100 ml subunit (denoted by Ba) and two 25 ml subunits (denoted by Bb and Bc) such as for pediatric/neonatal use. The division level characters **ds** in the data structure and eye-readable text representation of the product codes for the for the resulting subunits are:

```
Primary (300 ml) 00 $))))))))))))))))))$ A0 (150 ml)
                    *
                    *     B0 (150 ml)
                    .))))))$)))))))))))))$ Ba (100 ml)
                          *
                          *
                          /)))))))))))))$ Bb  (25 ml)
                          *
                          *
                          .)))))))))))))$ Bc  (25 ml)
```

Note that the rest of the product code **aoooot** is the same for all divided units of this product (A0, Ba, Bb, and Bc). Note also that although B0 was divided into subunits of different sizes; the nomenclature is independent of the volume.

3.4.5.5 Transition from Nationally-Specified to *ISBT 128-Specified* Product Codes

Transition from **national** product codes to *ISBT 128* product codes is thought to be the most difficult implementation issue in converting from *ABC Codabar* to *ISBT 128*. For this reason, several accommodations have been made in the design of *ISBT 128*.

Table 5 Type of Donation Codes in the 6th Position in the Product Code Data Structure

Character	Type of Donation
0 (zero)	Not specified (null value)
V	**Volunteer homologous (allogeneic) donor (default)**
R	Volunteer research donor
S	Volunteer source donor
T	Volunteer therapeutic collection
P	Paid homologous (allogeneic) collection
r	Paid research collection
s	Paid source collection
A	Autologous collection, eligible for crossover
1 (one)	For autologous use only
X	For autologous use only, biohazardous
D	Volunteer directed donation, eligible for crossover
d	Paid directed collection, eligible for crossover
2 (two)	For directed donor use only
L	For directed donor use only, limited exposure
E	For directed donor use only, medical exception

- An interim **national** product code data identifier, “**&<**”, has been assigned for use until an equivalent *ISBT 128* product code is available. This is to be used only on a product-by-product basis. Therefore, **national** product codes and *ISBT 128* product codes for the **same products** may coexist with **different** bar codes in any given country for some period (determined by the actual product life cycle) during transition.

- It was agreed that the alphabetic character “**E**” should be used for the initial assignments for *ISBT 128* product codes. “A,” “B,” “C” and “D” are not used as the **first character** of any *ISBT 128* product code in order to avoid confusion with *ABC Codabar* Start/Stop characters and minimize problems during transition.

- The *ISBT 128* product code maximum length should be used to ensure adequate label space is allocated in designing new national blood container labels for use with *ISBT 128* (*see* Table 7, Page 4-11).

3.4.6 Manufacturer's Identity and Container Information and Manufacturer’s Lot Number

This Subsection specifies the data structures used to carry the manufacturer's identity, product type, catalog number, lot number, and expiration date on the containers as received by the collection center.

3.4.6.1 Packaging and Shipping Containers

Blood container manufacturers will bar code shipping containers and other outer packaging *per* the HIBCC (Health Industry Business Communications Council) Standard. Both primary and secondary symbols as described in the standard will be utilized such that the following are contained in the data structures:

- Manufacturer's identity;

- Catalog number;

- Level of packaging;

- Lot number;

- Expiration date;

- Packaged quantity (optional).

Container label size and design will be defined on a national basis. Container manufacturers will label blood containers with two bar codes, a Manufacturer's Identity and Container Information bar code, and a Manufacturer's Lot Number bar code. All manufacturer's bar coded and eye-readable text should be placed as shown in Figure 2.

3.4.6.2 Manufacturer's Identity and Container Information Data Structure

To provide blood collection facilities with information to aid them in process control, a Manufacturer's Identity and Container Information bar code will be printed by the manufacturer on each container label.

The contents and data structure of this bar code are as follows:

=) b q q w w w w w w w (all in subset B)

where:

"**=)**" is the data identifier;
"**b**" is the container number of the set;
"**qq**" is the manufacturer's identity code;
"**wwwwwww**" is the manufacturer's catalog number.

Manufacturers will define the standardized container number assignment system to be used. As a minimum, "0" will be assigned to single empty transfer packs and "1" will always be assigned to containers intended as the primary collection container for whole blood in standard blood pack systems. The primary collection container in apheresis sets should use a character different from "1" to clearly distinguish them from whole blood collection containers.

The manufacturer's identification code is to be assigned using the first two letters of the English-language form of the company name (unless this letter pair is already in use, in which case the manufacturer should choose an acceptable letter pair). Manufacturer identity assignments shall be *ISBT 128*-specified according to the listing below. Additional assignments will be made upon request.

BA	Baxter/Fenwal
CH	Chartermed
CO	Cobe
DI	Dideco
FR	Fresenius
GR	Green Cross

GC	Green Cross Medical
HA	Haemonetics
KA	Kawasumi
MA	Macopharma
MI	Miles/Cutter
NI	Nissho
NP	NPBI
PA	Pall
ST	Stericon
TE	Terumo
TU	Tuta

The manufacturer's catalog number "**wwwwwww**" will be seven (7) alphanumeric characters in length, with leading space or zero fill as needed.

3.4.6.3 Manufacturer's Lot Number Data Structure

To provide collection facilities with information of use in tracing blood containers, a Manufacturer's Lot Number bar code will be printed on each container label by the manufacturer. The data structure for the Manufacturer's Lot Number bar code is:

&) x x x x x x x x x x (all in subset B)

where:

"**&)**" is the data identifier;
"**xxxxxxxxxx**" is the manufacturer's lot number.

The lot number will be ten (10) alphanumeric characters in length, with leading space or zero fill as needed.

To enable container identification and assist in problem resolution, the eye-readable text of the Manufacturer's Lot Number bar code must **never** be overlabeled.

The *ISBT128*-specified placement of these two manufacturer's bar codes and eye-readable text is shown in Figure 2.

3.4.7 Special Testing

If desired, an *ISBT 128*-specified, five (5) alphanumeric character, **structured** bar code has been defined to contain the results of special testing. The data structure is:

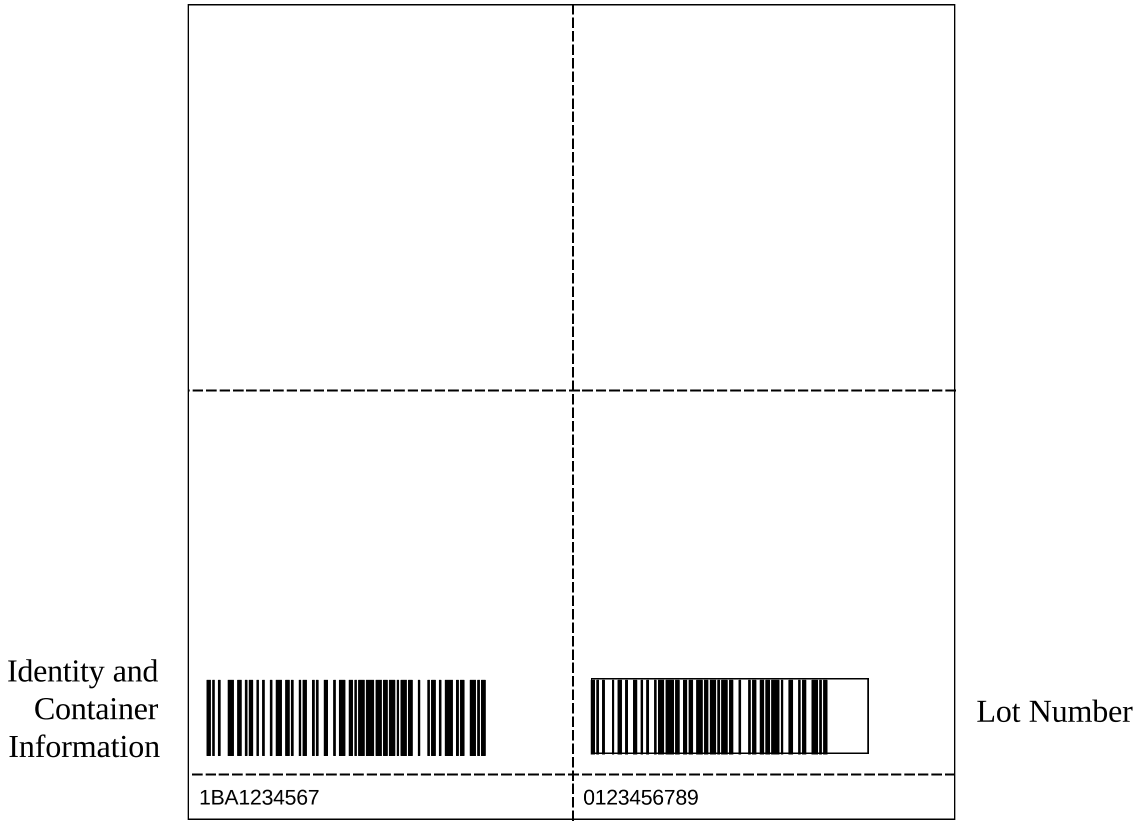

Figure 2 Placement of Manufacturer's Information Bar Codes

*Note: When applying labels the eye-readable text associated with the Manufacturer's Information bar codes **must not be covered up**.*

Note: Dotted lines are for illustration only; they do not appear on the label.

Note: Box indicates actual size of bar code when printed to ISBT 128 specification.

& (z z z z z (all in subset B)

where:

"**&(**" is the data identifier;
"**zzzzz**" specifies information according to **nationally-defined** tables.

The structure of the data encodation in "**zzzzz**," including any translation tables and interpretation, must be nationally-defined and -specified to meet the special needs and

The structure of the data encodation in "**zzzzz**," including any translation tables and interpretation, must be nationally-defined and -specified to meet the special needs and requirements determined by each national organization before this data structure is used.

3.4.8 National Use Bar Code Data Identifiers

Twenty-six bar code data identifiers for use with nationally or locally defined data structures are provided. Before use, the data structure must be defined on a **national** basis. However, each national organization is encouraged to allocate at least some of these data identifiers for local definition and assignment by collection and processing centers to meet their special needs.

The data identifier set for these 26 bar codes is:

& b (in subset B)

where:

"**b**" is in the set {a, b, c,...,z} (t*he lower-case alphabet*).

Potential uses include identification of the human-readable language in use on the label in officially multilingual countries, materials handling (*eg, shipping containers and manifests*) and special processing or applications-related information.

3.4.9 Rules for Non-Specified Data Structures for Bar Codes in Common Use

3.4.9.1 Confidential Unit Exclusion Status Data Structure

If desired, a **nationally**-specified structured bar code may be defined to contain the results of a confidential donor decision to request that a donated unit be either accepted for testing and processing, or discarded.

The data identifier will be "**&!**" and the structure of the data encodation will be **nationally-defined** to meet the special requirements determined by each national organization before this data structure is used.

The definition of this bar code is included here because of a potential requirement for its concatenation with the Donation Identification Number (*see* Section 4).

3.4.9.2 Donor Identification Number Data Structure

If desired, a **nationally-specified** structured bar code may be defined to contain a unique **donor** (not **donation**) identification number.

The data identifier will be "**&;**" and the structure of the data encodation will be **nationally-defined** to meet the special requirements determined by each national organization before this data structure is used.

The definition of this bar code is included here because of a potential requirement for its concatenation with the Donation Identification Number (*see* Section 4).

3.5 Printing *ISBT 128*-Specified Bar Codes

3.5.1 Eye-Readable Text

Every bar code, with the exception of the Donation Identification Number, should be accompanied by an **exact** eye-readable representation of the **data characters** in the bar code. This representation should be in at least 8-point *sans serif* type (2.8 mm or 0.011 in) [for example, This is 8-POINT sans serif type], be beneath the bar code, and begin at the left edge of the bar code as illustrated in Figures 1 and 2.

Similarly, the Donation Identification Number requires that the eye-readable text be restricted to the data characters (the second character in the data identifier is a data character in this instance) and emphasize the serial number. Unlike other bar codes, this representation is the sole means for presenting the data content as eye-readable text. **A box is to be drawn around the manual entry check digit to clearly distinguish it from the remainder of the number** (*see* Subsection 3.4.1.6 for details). The example in Figure 1 indicates the proper manner to present this information.

Note that bar code **data identifiers** are non-data characters and therefore should appear only in the bar codes, not in the eye-readable text. This avoids confusion during prompted manual entry procedures.

3.5.2 Requirement for Displaying All Characters in *ISBT 128* Bar Codes

All users of *ISBT 128* bar codes must have access to a system to display or print an exact representation of **all characters** in the bar code, including the data identifier and the modulo 103 check digit, and must be able to confirm, independently of the bar code scanner used, that the modulo 103 check digit is in agreement with that calculated for the data stream according to the AIM specification for Code 128. **Purchasers of scanning equipment should insist that this capability be present as part of the purchase order**.

Note: It is not intended that this program be in daily or even frequent use but that it be part of the resolution of any error condition].

3.5.3 Nominal X Dimension in Printing Bar Codes

All ***ISBT-128*** **specified bar codes** used on a blood container label are to use a nominal X dimension of 0.25 mm (0.010 in) to conform to the bar code industry practice of not using a smaller X dimension than this in product labeling.

Use of a nominal X dimension of 0.25 mm (0.010 in) for **non-*ISBT 128*-specified bar codes** (such as national use bar codes) used on a blood container label is **strongly recommended**.

A nominal X dimension of 0.167 mm (0.0066 in) is specified for **test tube Donation Identification Number labels only** for space reasons (as discussed in Subsection 3.4.1.3).

3.5.4 Bar Code Quiet Zones

A “quiet zone” is the clear, unprinted space preceding the Start character of the bar code, and that following the Stop character. This unprinted space is **part of the bar code symbol**.

Minimum width of the quiet zones for Code 128 (and thus for *ISBT 128*) is ten times the nominal X dimension. Although 10X is adequate for most laser and CCD-based bar code scanners, a wider quiet zone is often preferable for use with handheld bar code wands. As a general rule, quiet zones should be as large as compatible with the available label space but never less than 2.54 mm (0.10 in) for all bar codes except the Donation Identification Number bar code where it should be not less the 1.67 mm (0.066 in).

Quiet zones are to be free of all printing and marks, such as:

- Preprinted or on-demand printed information;
- Machine-readable symbols or eye-readable, bar code or label text;
- Direct marks made on the label with any kind of pen.

When overlabeling, care must be exercised to ensure that overlabels are placed in a manner which does not block the quiet zones of existing bar code labels.

3.5.5 Bar Code Height

Printed *ISBT 128* bar codes shall be of a minimum bar height in order to be reliably scanned using the available laser, wand and CCD scanner technologies. The specification for Code 128 symbology[3] recommends a bar height of a minimum of 15% of the **total** bar code symbol length.

Recommendations for *ISBT 128* are as follows:

- For bar codes intended to be read as a single bar code (*ie*, not concatenated) the bar height shall be a minimum of 10 mm (0.39 in);
- For bar codes intended to be read and concatenated, the bar height shall be a minimum of 15% of the nominal distance between the first Start bar of the left bar code and the last Stop bar of the right bar code of the concatenation pair, but in any case not less than 10 mm (0.39 in) (*see* Subsection 4.6 for additional explanation).

3.5.6 Examples of Printed *ISBT 128* Bar Codes

Table 6, Page 3-40, "Printed *ISBT 128*-Specified Data Identifiers and Data Structures for the Labeling of Blood Products," contains examples of *ISBT 128*-specified bar codes using the data identifiers in Table 1A, Page 3-9.

The examples shown use a corner around the bar code to establish the edges of the minimum required quiet zones. This is to demonstrate the full width of the symbol including quiet zones.

(Original editor's note: *Boxing of the bar code symbol is* ***not*** *a recommended labeling practice. A box around either the Donation Identification Number or other concatenable bar code may inhibit or abort concatenation).*

The bar code examples shown in Table 6, Page 3-40 are printed actual size. Minimum quiet zones of 10X are allowed within each containing box. The actual data structures (including data identifiers) are printed below each bar code, with the common meaning above it.

Table 6 Examples of *ISBT 128*-Specified Data Identifiers and Data Structures for the Labeling of Blood Products[a]

(ICCBBA, Inc thanks Zebra Technologies and Dr Clive Hohberger for these examples)

Data ID	Data Content and Additional Meaning	Data Structure[b]	Example[c]
=α	Donation Identification Number with ISO 7064 modulo 37,2 check digit encoded in flag characters Human readable ISO 7064 modulo 37,2 check digit is shown	**=αshift Cppppyynnnnnnff**	
=%	ABO/Rh (D) Blood Groups, Rh and Kell phenotypes	**=%ggre**	Examples not available in this Adobe Acrobat version of this document
=>	Blood product expiration date and time	**=>shift Ccyyjjjhhmm**	
=*	Donation collection date (Julian date only)	**=*shift Ccyyjjj**	
=<	*ISBT 128* blood product code	**=<αooootds**	

NOTES: a. Nominal X of .25 mm is to be used on all blood container labels.
b. Here α represents alphanumerics in the set {A–Z (product code E–Z), 0–9} and c, d, e, f, g, h, j, m, n, o, p, r, s, t, y are digits in the set{0–9}.
c. Actual size bar codes, including minimum required quiet zones, shown in each box; the actual data structure (including data identifier) in the bar code is printed below each bar code example.

4 *ISBT 128* Concatenation Requirement and Methods

The methods to support restricted bar code concatenation (denoted by the mathematical symbol "⊕") in the *ISBT 128* symbology variant are now described. Existing national standards in several ISBT WPADP member countries mandate the provision and use of a concatenation function to permit reading the Donation Identification Number and a second bar code within a single operation, with a concatenated data string as output **from the bar code reader**. Other uses for concatenation are to ensure labeling accuracy, support donor identification and donor self-exclusion.

4.1 Bar Codes That May Be Concatenated

Please refer to Figure 1. Note that it is an actual-size drawing of a typical blood container label with its *ISBT 128* Donation Identification Number and ABO/Rh (D) Blood Groups bar codes in proper relative placement on the label.

Any two *ISBT 128* bar codes can be concatenated (*see* Subsection 4.8.1). Several pairs of bar codes may be used at different stages of blood collection, processing and labeling, such as:

- Donation Identification Number (data identifier "**=a**", where a is defined as being in the set {A–Z, 0–9}) with ABO/Rh (D) Blood Groups (data identifier "**=%**");
- Donation Identification Number with Donor Identification Number (data identifier "**&;**");
- Donation Identification Number with Confidential Unit Exclusion Status (data identifier "**&!**");
- Product Code (data identifier "=<" or "**&<**") with Expiration Date (data identifier "=>" or "**&>**").

Placement of concatenable bar codes on the blood container label is done such that a single straight-line laser beam or wand scan can pass completely through both symbols.

4.1.1 Donation Identification Number Å ABO/Rh (D) Blood Groups

Recall that Technical Objective 2, bar code concatenation in blood labeling, is to support those national standards which use concatenation to ensure that the correct ABO/Rh (D) blood groups label is always associated with the correct unit of blood. This is critical to safe blood administration. Therefore, it is essential to define a concatenation method to ensure that only the data of the two correct bar codes on the same blood container label can be concatenated.

- Only two bar codes are concatenated: For example, the Donation Identification Number and the ABO/Rh (D) Blood Groups.

- Both spatial and/or temporal restrictions on relative location and reading of the two bar codes are required (*see* Subsection 4.6.1).

4.1.2 Donation Identification Number Å Donor Identification Number

This is used, for example, when donors have identification cards to associate a particular collected unit with a specifically identified donor for automatic entry into a computer database.

The Donor identification Number is a **nationally**-defined structure, having the data identifier "**&(**" and a data length and structure appropriate to its national use.

4.1.3 Donation Identification Number Å Confidential Unit Exclusion Status

Concatenation of these two bar codes is used to determine if an individual has requested confidentially that a collected unit is not to be used for transfusion. Confidential Unit Exclusion Status is a **nationally**-defined bar code, having the data identifier "**&;**" and a data structure and encodation appropriate to its national use (*see* Subsection 3.4.8).

- The donor selects a bar coded label corresponding to the "use" or "don't use" decision and places it on a card or form next to a Donation Identification Number bar code from the set used for collection of the blood unit.

- It is intended that both bar codes are placed near one another within spatial limit as discussed in Subsection 4.6.1.

The card or form is read, and the concatenated data tested. The appropriate notation for the "use"/"don't use" decision is then entered into the database under that Donation Identification Number.

4.1.4 Product Code Å Expiration Date

It is recommended that when this concatenation is used to validate that the labeled product is within the specified expiration date that either form of the Expiration Date bar code may be used (Julian day number only, data identifier “**=>**”; Julian day number with hour and minute of expiration, data identifier “**&>**”). Both the *ISBT 128* Product Code (*see* Subsection 3.4.5.1) and the interim national product code (*see* Subsection 3.4.5.5) should be supported.

4.2 Inadequacy of the Standard Code 128 Method of Bar Code Concatenation

Existing *ABC Codabar* standards that provide this capability are based on the use of Start and Stop Code “D” in *ABC Codabar* to provide **time and/or spatially-dependent** restricted concatenation of two specific bar codes.

Standard AIM USA[3] and CEN[4] Code 128 symbology supports a form of bar code concatenation in which function code **f2** is encoded in the data string. However, the definition of function code **f2** in AIM USA and CEN Code 128 provides only unrestricted concatenation of bar codes and is not adequate to meet the required objective described in Technical Objective 2 because:

- The data of any number of bar codes containing function code **f2** will be concatenated, in the order the bar codes are read, until and including the data read from a bar code **not** containing an **f2**;

- There is no temporal or spatial restriction on the bar codes so concatenated. In fact the bar codes could be on one or more blood containers, or include data from bar codes not on the blood container.

Clearly, the standard Code 128 method of bar code concatenation does not meet required Technical Objective 2 in Section 2. A new method was defined for *ISBT 128*.

4.3 *ISBT 128* Method of Bar Code Concatenation

ISBT 128 data identifiers can also be used for concatenation control and are the basis of the method used in *ISBT 128*.

Therefore, the definitions of data identifiers given in Section 3 is part of the definition of the concatenation feature of the *ISBT 128* symbology itself.

4.4 Definition of *ISBT 128* Concatenation Result

ISBT 128 concatenation results in a **single output data string** containing the Donation Identification Number (or the Product Code) data followed by the data from the second concatenated bar code **regardless of the order of scanning**, as long as the spatial-temporal restrictions of Subsection 4.6 are met.

The output data string is to contain all data appearing in each bar code between (but not including) the Start character and the Code 128 Modulo 103 Check Digit in each bar code, including the data identifiers. Since the Confidential Unit Exclusion Status and Donor Identification Number bar codes are nationally defined, bar code readers must accommodate to the actual bar code data length used. Bar code data, including the data identifiers, is always to be output by the reader in left-to-right byte order (*ie*, starting with the primary data identifier) regardless of the direction in which the bar code is scanned. Internal Code 128 control characters, such as those that cause a shift to subset C, are non-data characters and thus do not appear in the output string (*see* Subsection 3.3.3).

4.5 Order of Scanning of the Concatenable Bar Codes

4.5.1 Order of Physically Scanning the Bar Codes

Since scanning of concatenable bar codes (*eg*, Donation Identification Number and ABO/Rh (D) Blood Groups) can take place in any order (especially with laser scanners), the concatenation method must deal equally with either reading order of the two bar codes.

In defining the concatenation process in terms of the **outputs** of the scanning and decoding process within the bar code reader:

- The term **first bar code** shall refer to the first valid read of either concatenable bar code;
- The term **second bar code** shall refer to the reading of the second concatenable bar code.

4.5.2 Order of Concatenated Data Output from the Bar Code Reader

The terms “left bar code” and “right bar code” shall refer to both the relative placement of the two bar codes on the label, card or form and the order of the data in the output data string from the reader when the two bar codes are scanned (primary data identifier of the “left” bar code leads; data order of both bar codes as in Subsection 4.4) regardless of whether the bar codes are physically scanned from left-to-right or right-to-left.

The selection of the bar code defined as “left” or “right” may be made by use of the bar code reader programming bar code (*see* Subsection 4.8). Generally, the Donation Identification Number and Product Code bar codes are designated as “left” data structures, and all other concatenated bar codes are “right” bar codes.

4.6 Required Spatial-Temporal Relationship of Concatenated Bar Codes

4.6.1 Label Assumptions for Concatenation

Key geometric assumptions of the **label** are shown in Figure 1 and Table 6, Page 3-40. To summarize:

- X-modulus for all bar codes = 0.25 mm (.010 in);
- Relative placement of each bar code label ±2 mm (± 0.08 in);
- Nominal gap between last Stop bar of the left bar code and the first Start bar of The right bar code = 9 ± 4 mm (0.35 ± 0.16 in);
- Other assumptions as shown in Table 7, Page 4-11.

4.6.2 Bar Code Reader Assumptions for Concatenation

Assumptions for the **bar code reader** are as follows:

- When scanning with wands, a minimum speed of $125 mm/sec ($5 in/sec);

Note: Laser scanner speeds are much faster, up to several meters/sec.

- Z_1 = average measured narrow element width of all the bars and spaces of the first bar code read by the scanner;

- Acceleration or deceleration of the wand or laser beam is allowed to distort the apparent value of Z_1 up to ±20%. This error is caused by acceleration of the wand or laser beam during scanning, and/or perspective distortion caused by the curved surfaces of a full blood container when scanned by a laser or CCD scanner.

4.6.3 Spatial and Temporal Requirements in Concatenation

The spatial-temporal requirements are as follows:

- Both concatenable bar codes **must be validly decoded on a single scan** (one pass of the wand or laser beam, or a single CCD read);

- **No other non-concatenable bar code must be decoded** on that same scan between the Stop codes of the two concatenable bar codes;

- The two concatenable **bar codes must be located within a maximum physical distance of each other**, as determined, for example, by one of the three methods in Subsection 4.6.4 appropriate for the bar code reader in use.

4.6.4 Methods for Determining a Valid Concatenation

All three spatial-temporal requirements listed in Subsection 4.6.3 must be met on a single scan for data concatenation to be performed. Three typical methods are suggested as guidance for bar code reader manufacturers.

Method 1: Alternate One measurement technique for CCD and/or laser scanners, and a preferred technique for wand scanners.

Corresponding points of the last bar on the Code 128 Stop codes on the two validly decoded concatenable bar codes must appear to be physically within a specific maximum distance of each other.

This is in practice measured by Z_1, the average narrow element width of the first data structure measured by the scanner, given that:

- The apparent distance in terms of Z_1 must be increased by 20% to allow for errors caused by acceleration or curvature;

- The maximum measured distance observed between corresponding final Stop bars (when scanned in either direction) must be less than shown in Table 7, Page 4-11.

Method 2: Alternate Two measurement technique for CCD and/or laser scanners, and a preferred technique for wand scanners.

Measured gap between last Stop bar of first concatenable bar code and first Start bar of the second concatenated bar code must appear to be physically within 13 mm (0.51 in) of each other.

This is in practice measured by Z_1, the average narrow element width of the first data structure measured by the scanner, given that:

- The apparent distance in terms of Z_1 must be increased by 20% to allow for errors caused by acceleration or curvature;

- The measured distance when scanned in either direction must be less than 1.2*(13 mm/0.25 mm) = 62 Z_1.

Method 3: Alternate (but not preferred) measurement technique for wand scanners

Corresponding points of the last bar on the Code 128 Stop codes on the two validly decoded concatenable bar codes must be detected within the limits shown in Table 7, Page 4-11.

Situations may exist in which the actual specifications of the label and/or bar code reader differ widely in practice from those above. This may be due to:

- National implementation considerations, or

- New bar code reading or decoding technologies, or

- Discovery of algorithms or techniques superior to those above.

Appropriate modifications to the methods should be made, or new methods devised, to reflect the actual situation, in keeping with the "spirit" of the three methods (shown in bold type above).

4.7 Initiation and Termination of the Concatenation Process

Concatenation is attempted on every scan in which a valid first bar code is read. The **concatenation process** is triggered by the valid reading of the first bar code, as defined in Subsection 4.6. It continues only until:

- Normal termination when the second bar code is correctly read within the correct spatial-temporal limits, or
- An event occurs which **aborts** the concatenation process.

Normal termination results in a single **concatenated output data string in left-to-right byte order** (as defined in Subsection 4.5.2). The concatenated output data string is to contain all data appearing in each bar code between the Start character and the Modulo 103 Check Digit in each bar code, including the data identifiers, in the following first-to-last byte order:

- First, the data of the “left” bar code;
  - Presented as the leading portion of the output data string;
  - Output characters in left-to-right byte order;
- Second, the data of the “right” bar code;
  - Presented as the trailing portion of the output data string;
  - Output characters in left-to-right byte order.

The **concatenation process is aborted** if either:

- No valid read of the second bar code occurs which meets all three spatial/temporal requirements of Subsection 4.6, or
- Any bar code other than the expected second bar code is validly read within the required spatial-temporal limits.

Under either occurrence the concatenation process will be assumed to have failed. The concatenation attempt is to be aborted, and the scanner/decoder is to immediately output the data of the correctly-read first bar code as if read without concatenation. Reading and output of data from any other bar codes scanned then continues as an independent operation, as if a new scan had been started.

4.8 Bar Code Reader Concatenation Programming

The use of concatenation in practice depends on both national standards and local requirements, as well as the guidelines set forth in this *ISBT 128* specification. To enable customization of the concatenation features for the decoder of the bar code reading device, an optional method is recommended for programming all allowed concatenations. This is a bar code that is used internally by the reader/decoder to set up the concatenation process.

4.8.1 Concatenation Programming Bar Code

Programming of the reader/decoder may be done by scanning a bar code with the *ISBT 128*-specified data structure:

= & func 3 L L R R m m t u v (all in subset B)

where:

"**=&**" are the primary and secondary data identifiers of the Concatenation Programming bar code;
"**func 3**" is the Code 128 reader programming command (*see* Reference 3);
"**LL**" are the primary and secondary data identifiers of the "left" bar code (first in order of data output of the concatenated data by the bar code reader; *see* Subsection 4.5.2 for additional definition);
"**RR**" are the primary and secondary data identifiers of the second bar code (in order of data output);
"**mmtu**" is either (depending on the value of **u**, the units for **mmt**). If

u = d

then **mmt** is interpreted as the nominal distance **mm** (in millimeters) between the last Stop bar in each of the first and second bar codes, and the label positioning tolerance ±**t** of that distance **mm**. However, if

u = t

then **mmt** is interpreted as the maximum time **mmt** in milliseconds for performance of the concatenation;

"**v**" is the control code for the programming. If

v = 0

deprogram the concatenation of the bar codes specified by **LL** and **RR**, but if

v = 1

program the single concatenation of the bar codes specified by **LL** and **RR**, using parameters **mmtu** to control the concatenation.

4.8.2 Factory Default Concatenation Setting

The factory default programming for the bar code decoder will be **no concatenation programmed**. The programming command in Subsection 4.8.1 will permit reprogramming of the factory default for activation of concatenation in those readers/decoders having the programmable concatenation feature.

Table 7 Spatial-Temporal Parameters for Concatenation of Some Key Bar codes

	Donation Identification Number	ABO/Rh (D) Blood Groups	Product Code	Expiration Date (with Julian day, hour and minute)	Expiration Date (Julian day only)
Data Identifier	=a	=%	=<	&>	=>
Maximum Bar Code Length, Excluding Required Quiet Zones (in millimeters)	36.3 mm	25.3 mm	36.3 mm	30.8 mm	25.3 mm
Maximum Gap Between Bar Codes (in millimeters)		13.0 mm		13.0 mm	13.0 mm
Nominal Distance Between Bar Codes Last Stop Bars (Assumes Bar code physically located to the left is either Donation Identification Number or Product Code) (in millimeters) (in units of Z_1)		 38.5 mm 154 Z_1		 43.8 mm 175 Z_1	 38.5 mm 154 Z_1
Maximum Distance Observed Between Last Stop Bars (Method 1) (in units of Z_1)		185 Z_1		210 Z_1	185 Z_1
Maximum Time Observed Between Last Stop Bars (Method 3); Assumes 125 mm/second scan (in milliseconds)		370 ms		420 ms	370 ms

5 *ISBT 128* Symbology Identifier

The AIM USA[3] and CEN[4] bar code symbology standards provide a uniform method for reporting both the actual symbology read by the bar code reader and any special features of the symbol encountered during reading. When the symbology identifier capability is both available and enabled in the bar code reader, a three-character **symbology identifier prefix** precedes the data read from that symbol:

] C m

where:

"**]**" is the symbology identifier flag (character with ASCII value 93);
"**C**" is symbology identification character for Code 128;
"**m**" is the hexadecimal modifier value specifying the option(s) in effect. All option values in use are summed to form the modifier value, **m**.

A request was made for a special symbology identifier option value to indicate that an *ISBT 128* concatenation has been performed in both the AIM USA and CEN bar code symbology standards. It was accepted by AIM USA in September 1992, and first issued in the AIM USA "Uniform Symbology Specification: Code 128" in June 1993.[3] It was approved and issued in the Final Draft (March 1993) of the CEN "European Standard: Code 128."[4]

Option Value	Option Interpretation
0	No function code **f1** in either the first or second symbol character position after the Start character
1	EAN/UCC data packet: **f1** in 1st symbol character position after the Start character
2	Function code **f1** in 2nd symbol character position after the Start character
4	***ISBT 128* concatenation has been performed; concatenated data follows**

Function code **f1** is never to be utilized in *ISBT 128*. Therefore, in reading an *ISBT 128* label on a blood product, the only valid modifier values for the symbology identifier (when read) are:

- **m = 0** implies that:
  - either standard AIM USA or CEN Code 128 is in use, or
  - *ISBT 128* is in use but concatenation is not enabled, or
  - a non-concatenated read of an *ISBT 128* bar code has been performed.
- **m = 4** if the *ISBT 128* concatenation feature is present, enabled and performed.

The symbology identification character for Code 128 (and *ISBT 128*) is **C**, for Codabar it is **F**, Code 39 is **A**, and Interleaved 2 of 5 is **I**. Use of the symbology identifier prefix thus provides an alternative way of discriminating between bar codes conforming to the new Code 128-based *ISBT 128* specification and those from existing national bar code standards based on Codabar, Code 39, or Interleaved 2 of 5.

Note: The symbology identifier feature is ***not*** *available on many older bar code readers.*

6 *ISBT 128* Country/Collection Facility Identification Number Assignments

The purpose of this Section is to summarize the system developed in Reference 2: "*ISBT128* Country Code Assignments," Issue 2.1, used for estimating block sizes and logically allocating the starting alphanumerics of all countries in order to allocate blocks of Country/Collection Facility Identification Numbers.

These allocations appear in Appendix A.

6.1 Assignment of Country/Collection Facility Identification Numbers

This document **only allocates** the starting alphanumeric and range of digits for each country based on a formula to ensure adequate numbers of center codes for each country.

Both the starting alphanumeric and the range of digits used for each country **will be assigned** by ICCBBA, Inc[7] upon written request by each national blood banking organization.

Either the national blood banking organization can assign specific numeric codes to each center within their country and report these specific assignments to ICCBBA, Inc or ICCBBA, Inc will make the assignments upon request. A world-wide list of Country/Collection Facility Identification Number assignments will be compiled and maintained in a database by ICCBBA, Inc.

6.2 Allocated Countries

Definition of an "allocated country" includes:

- All current members of the United Nations;
- Nonmembers which are sovereign states (*eg*, Switzerland);
- Countries formed from:
  - The Union of Soviet Socialist Republics;
  - Yugoslavia;

- Czechoslovakia;

- Semi-autonomous regions which are still formally territories of another country but have largely indigenous medical systems (*eg*, Hong Kong, French Guiana, Goa, Greenland).

6.3 Number of Centers for Each Country

Estimation of the number of centers to reserve for each country was done on a formula basis. Results correlated well with specific block size requests made by several ISBT WPADP members.

A. Number of centers (= ranges of digits) for each country was estimated:

   - Based on 1991 population and geography;
   - Assuming 1 hospital per 40,000 population;
   - Assuming 1 regional blood processing center per 1 million population;
   - Total: 26 centers/million population.

B. Initial recommended block assignments were made using the above formula, subject to both specific requests from ISBT WPADP members and some additional rules that follow:

   - A minimum of 100 center identification numbers was allocated per country;
   - At least 50% more than the calculated minimum number of centers were allocated as a reserve for expansion, up to a maximum initial allocation of 10,000/country, unless more were requested by the national organization of that country.

C. Two special cases resulted in extra center number allocations:

   - Large, geographically spread countries with low population densities over most of their area (*eg*, Australia, Russia, Canada, Micronesia) received extra allocations as there tend to be more, smaller hospitals and clinics spread over a large geography. This should allow enough numbers for unique identification of each center.
   - Countries with high intensity medical services (*eg*, France, Germany, United States, Switzerland, Japan).

6.4 Method of Allocation of Starting Alphanumeric Characters

Codes for 201 countries and semi-autonomous regions were allocated. Specific alphanumeric starting characters were allocated using the methods, rules, and special considerations set forth in the following paragraphs.

Since Code 128 is used, upper case Latin non-accented alphanumerics are denoted by α, where α = {A-Z, 0-9}, and forms the first character of the Country/Collection Facility Identification Number, followed by a four digit number. Note that α is also the secondary data identifier for the Donation Identification Number (*see* Subsection 3.4.1 for details).

6.4.1 Special Cases and Considerations

These include oriental languages, large block allocations, and a reserve of unallocated letters and digits for future use.

6.4.1.1 Oriental Language Countries

Countries which use pictographic (*ie*, non-alphabetic) languages received digits rather than Latin alphabet letters for their starting alphanumeric:

1 Japan;
2 Taiwan;
3 South Korea;
4 North Korea;
5 Mongolia;
9 China .

6.4.1.2 Large Block Allocations

Countries with at least 10,000 potential centers received all 10,000 numbers of a single starting alphanumeric code:

Q0000–Q9999	Republic of India;
W0000–W9999	United States of America;
70000–79999	Russian Federation;
90000–99999	People's Republic of China.

Special attention was given to the starting alphanumeric codes used in large block allocations (*see* Reference 5 for further details).

- "Q", used for India, was selected because it minimizes conflicts with starting letters of other country names.

- Similarly, “W” was selected for the USA. Note that “W” is also the starting radio station prefix for the USA allocated by the International Telecommunications Union.

- There were many country names starting with “R” (also “R” is not a character in the Cyrillic alphabet). To minimize conflicts “7” (the international telephone country code prefix for Russia) was used for its starting alphanumeric.

- China is similar to Russia, in that there are many countries also starting with “C”. The choice of “9" minimizes name conflicts and avoids the use of a Latin alphabet character (as discussed in Subsection 6.4.1.1).

6.4.2 Reserved Alphanumerics

Some starting letters and digits were reserved for future expansion, and to avoid confusion:

- Letter “O” and digit “0" both to avoid possible confusion and for potential expansion;
- Letter “X” for expansion;
- Digit “6” for potential expansion for Russia (7);
- Digit “8” for potential expansion for China (9).

6.4.3 Regional Allocation of Starting Alphanumerics

An obvious rule is that no two countries in the same defined **geographic region** should have the same starting alphanumeric to avoid local confusion. To achieve this, the countries were broken into the following geographic regions to facilitate assignment. Ten regions were defined with roughly an equal number of countries per region:

- Africa, Central (includes nearby island nations);
- Africa, Southern (includes nearby island nations);
- America, Northern and Central (includes Greenland, Caribbean);
- America, Southern (plus Antarctica);

- Asia, South Central and Southeast (includes China);
- Asia, Northern (includes most former states of the USSR);
- Europe, Eastern;
- Europe, Western;
- Middle East and North Africa (mostly Arabic-speaking nations);
- Pacific Ocean and Pacific Rim (includes Australia).

6.4.4 Global Rules for Assignment of Starting Alphanumerics

Three global rules were used:

Rule 1. No two countries in the same defined geographic region were assigned the same starting alphanumeric;

Rule 2. No two **major** trading, military or economic partners were assigned the same starting alphanumeric (*see* Reference 5 for details on how this was done).

Rule 3. Duplicate starting alphanumeric assignments were minimized within each trading, economic or military bloc (*see* also Reference 5).

With the exception of those full 10,000 center blocks (*see* Subsection 6.4.1.2), and the reserved letters and digits (*see* Subsection 6.4.2), most other starting alphanumerics were **split blocks,** where several countries shared the same starting alphanumeric but with different ranges of digits. For each split block, additional goals were:

- Total center allocations not more than 7500 numbers;
- At least two regions (*see* Subsection 6.4.3) with no allocation made.

This gives expansion capability for the future, as new countries are added.

6.5 Resulting Block Allocations

Please refer to Appendix A for the resulting allocations. Appendix A organizes allocations by the first letter/digit assignments to define more clearly any regional and trading partner conflicts. Initial block assignments are also given.

Each column is one geographic region. For each country, three numbers appear below the country name. In top-down order, these are:

- Recommended initial allocated block size;
- Recommended block starting number;
- Recommended block ending number.

Note that in most cases, the starting alphanumeric is either the first letter of the country name in its native language (if Latin alphabets are used in that country) or the Latin alphabetic of the phonetic country name in English (*eg*, Bulgaria is “B”, Kuwait is “K”).

6.6 Reserves for Future Use

Only 178,600 centers of a possible 360,000 or 49.6% of the maximum number available have been allocated. This number includes a generous over allocation for each country (approximately 50% for each country) so that there are plenty of unused numbers reserved for future use.

- There are only the four total block allocations (USA, Russia, India, China).
- Five blocks “O”, ”X”, “0”, “6” and “8” are totally unused.

The total number of centers initially allocated is shown for each alphanumeric starting character below that character in the left-most column.

In Appendix A, note that with split blocks center numbers were allocated with unallocated numbers between each country block. This allows each country to expand beyond the initial recommended block into a contiguous additional block.

- No more than two regions were allocated for each split block alphanumeric.
- All split-block alphanumerics have some expansion capability for future assignment to current or new countries. Only one letter, “I” with 7700 allocated centers, exceeds the target 7500 center limit (*see* Subsection 6.4.4).

The largest blocks of numbers were generally allocated at the top of the number ranges for each starting alphanumeric. This allows the most expansion capability in the future for the countries having the largest potential future need.

References

1. "*American National Standard*: *Data Application Identifiers for Material Handling*

   ANSI/MH 10.9 FACT - 199X, Working Draft (revision 1), 10 April 1993"
   c/o John Nofsinger, Secretariat
   The Material Handling Institute
   8720 Read Oak Boulevard, Suite 201
   Charlotte, NC 38217-3992
   USA

   Telephone: +(1) 704 522 8644
   Fax: +(1) 704 522 7826

2. Letter of 12 August 1992 from Clive Hohberger to:
   Craig Harmon, Chairman
   ANSI/MH-10 SBC 9 Working Group
   Federation of Automatic Coding Technologies
   (For a copy contact ICCBBA, Inc at the address in Reference 7)

3. "*Uniform Symbology Specification*: *Code 128*" (June 1993)

   Bar Code Symbology Coordinator
   AIM USA
   634 Alpha Drive
   Pittsburgh, PA 15238-2802
   USA

   Telephone: +(1) 412 963 8588
   Fax: +(1) 412 963 8753

4. "*European Standard*: *Code 128*" (prEN 799:1993)

   Final Draft March 1993
   Comité Européen de Normalisation
   Central Secretariat
   rue de Stassart 36
   B-1050 Bruxelles

Belgium

5. For a copy of "*ISBT 128 Country Code Assignments*", Issue 2.1, dated 15 October 1992 contact ICCBBA, Inc at the address in Reference 7.

6. "*Information Technology - ISO 8-bit code for information interchange - Structure and rules for implementation, ISO/IEC 4873*"

   Reference Number: ISO/IEC 4873 :1991 (E)
   Available from the International Organization for Standardization
   Case Postale 56
   CH-1211 Genéve 20
   Switzerland

7. ICCBBA, Inc

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   Telephone: +1 (717) 845-4790
   Fax: +1 (717) 845-9727
   E-mail: iccbba@iccbba.com

8. "*Check character systems for use in information interchange, and guidance on choice and methods of application*"

   ISO 7064-1983
   Available from the British Standards Institution as BSI 6541:1985 (ISBN 0 580 14031 8)
   The British Standards Institution
   2 Park Street
   London W1A 2BS
   United Kingdom

   Telephone: +(44) 01 629 900

9. "*Guideline for Uniform Labeling of Blood and Blood Components*"

   Prepared by:

The United States Food and Drug Administration
Center for Drugs and Biologics
Office of Biologics and Review
in cooperation with the American Blood Commission
August, 1985

Contact your national government liaison with the US FDA for complete information

Appendix A Country/Collection Facility Identification Number Assignments with Suggested Initial Block Size

Letter Code	Total Allocated	Western Europe	Eastern Europe	Northern Asia	Mideast & North Africa	Central Africa	Southern Africa	Central & SE Asia	Pacific & Pacific Rim	North & Central America	South America
A		**Austria**		**Armenia**	**Algeria**		**Angola**	**Afghanistan**	**Australia**	**Antigua & Barbuda**	**Argentina**
	5,700	300		200	1,000		300	600	2,000	100	1,200
	First #	0		500	1,000		4,600	2,300	5,000	800	3,000
	Last #	299		699	1,999		4,899	2,899	6,999	899	4,199
B		**Belgium**	**Bulgaria**		**Bahrain**	**Burkina Faso**	**Burundi**		**Brunei**	**Bahamas**	**Brazil**
	6,800	400	400		100	300	300		100	200	5,000
	First #	0	1,000		500	1,500	2,000		800	2,500	3,000
	Last #	399	1,399		599	1,799	2,299		899	2,699	7,999
C			**Czech. Republic**		**Cyprus**	**Cameroon**	**Madagascar**	**Cambodia**	**Tuvalu**	**Canada**	**Chile**
	4,000		500		100	500	500	300	100	1,500	500
	First #		2,000		4,800	3,300	4,000	2,700	5,800	0	5,000
	Last #		2,499		4,899	3,799	4,499	2,999	5,899	1,499	5,499
D		**Germany**		**Kyrgyztan**	**Tunisia**	**Ivory Coast**	**Botswana**		**Malaysia**	**Dominican Republic**	
	5,100	3,000		200	300	500	100		700	300	
	First #	0		3,400	6,000	4,000	3,700		5,000	4,600	
	Last #	2,999		3,599	6,299	4,499	3,799		5,699	4,899	
E		**Spain**	**Belarus**		**Egypt**		**Equatorial Guinea**		**Macao**	**El Salvador**	**Ecuador**
	4,700	1,500	400		2,000		100		100	200	400
	First #	0	3,000		4,000		2,600		2,800	3,700	2,000
	Last #	1,499	3,399		5,999		2,699		2,899	3,899	2,399
F		**France**		**Azerbaijan**		**Central African Republic**		**Bhutan**	**Fiji**	**Honduras**	**Guyana**
	3,500	2,500		300		200		100	100	200	100
	First #	0		5,000		5,500		4,400	4,600	4,000	5,800
	Last #	2,499		5,299		5,699		4,499	4,699	4,199	5,899

Letter Code	Total Allocated	Western Europe	Eastern Europe	Northern Asia	Mideast & North Africa	Central Africa	Southern Africa	Central & SE Asia	Pacific & Pacific Rim	North & Central America	South America
G		**United Kingdom**		**Georgia**	**Eritrea**	**Ghana**		**Goa**	**Western Samoa**	**Guatemala**	
	4,000	2,500		200	100	600		100	100	400	
	First #	0		6,000	6400	4,000		5,600	5,800	5,000	
	Last #	2,499		6,199	6499	4,599		5,699	5,899	5,399	
H		**Switzerland**	**Estonia**		**Saudi Arabia**	**Benin**	**Zambia**	**Bangladesh**	**Hong Kong**	**Haiti**	
	6,000	300	100		600	200	300	4,000	200	300	
	First #	0	500		1,000	700	2,000	3,000	1,700	2,500	
	Last #	299	599		1,599	899	2,299	6,999	1,899	2,799	
I		**Italy**				**Cape Verde**	**Comoros Islands**		**Indonesia**		
	7,700	2,500				100	100		5,000		
	First #	0				3,500	3,700		4,000		
	Last #	2,499				3,599	3,799		8,999		
J		**Norway**	**Yugoslavia (Serbia)**		**Jordan**	**Djibouti**	**Gabon**	**Pakistan**		**Jamaica**	**Bolivia**
	5,600	300	500		200	100	100	4,000		100	300
	First #	0	1,000		1,700	800	2,800	3,000		2,600	2,000
	Last #	299	1,499		1,899	899	2,899	6,999		2,699	2,299
K			**Kosovo**	**Kazakhstan**	**Kuwait**	**Kenya**			**Kiribati**	**USA**	
	7,000		100	700	100	1,000			100	5,000	
	First #		5300	7,300	5,500	6,000			5,800	0	
	Last #		5399	7,999	5,599	6,999			5,899	4,999	
L		**Luxembourg**	**Lithuania**		**Lebanon**	**Ethiopia**	**Lesotho**	**Laos**	**Marshall Islands**		**Columbia**
	4,400	100	200		200	2,000	100	200	200		1,400
	First #	0	300		700	4,000	3,500	3,000	2,700		1,000
	Last #	99	499		899	5,999	3,599	3,199	2,899		2,399
M		**Greece**	**Hungary**		**Morocco**	**Mali**	**Mozambique**	**Maldives**	**Micronesia**	**Mexico**	
	6,600	400	400		1,000	400	600	100	200	3,500	
	First #	0	1,000		2,000	1,500	3,300	800	500	4,000	
	Last #	399	1,399		2,999	1,899	3,899	899	699	7,499	
N		**The Netherlands**	**Moldova**		**Oman**	**Nigeria**	**Namibia**	**Nepal**	**Papua New Guinea**	**Nicaragua**	
	7,100	600	200		100	5,000	100	700	200	200	
	First #	0	3,000		3,500	4,000	2,800	1,000	2,400	2,000	
	Last #	599	3,199		3,599	8,999	2,899	1,699	2,599	2,199	

Letter Code	Total Allocated	Western Europe	Eastern Europe	Northern Asia	Mideast & North Africa	Central Africa	Southern Africa	Central & SE Asia	Pacific & Pacific Rim	North & Central America	South America
O	Reserved										
	0										
	First #										
	Last #										
P		**Portugal**	**Latvia**	**Turkmenistan**	**Yemen**	**Liberia**			**Philippines**	**Panama**	**Peru**
	5,300	400	200	200	500	100			3,000	100	800
	First #	0	700	3,000	2,000	3,500			4,000	2,700	1,000
	Last #	399	899	3,199	2,499	3,599			6,999	2,799	1,799
Q								**India**			
	10,000							0,000			
	First #							0			
	Last #							9,999			
R		**Ireland**	**Romania**		**Iraq**	**Sierra Leone**	**Rwanda**		**Nauru**	**Costa Rica**	**French Guiana**
	3,100	200	1,000		1,000	200	300		100	200	100
	First #	0	1,000		3,000	700	2,400		2,800	400	2,200
	Last #	199	1,999		3,999	899	2,699		2,899	599	2,299
S		**Sweden**	**Slovenia**		**Syria**	**Sudan**	**South Africa**	**Sri Lanka**	**Singapore**		**Surinam**
	5,000	400	100		500	1,000	2,000	700	200		100
	First #	0	2,800		2,000	3,000	5,000	1,000	2,700		4,500
	Last #	399	2,899		2,499	3,999	6,999	1,699	2,899		4,599
T				**Tajikistan**	**Turkey**	**Togo**	**Tanzania**	**Thailand**	**Tonga**	**Trinidad & Tobago**	
	5,600			200	2,000	200	1,000	2,000	100	100	
	First #			4,400	0	2,400	3,000	5,000	2,800	4,800	
	Last #			4,599	1,999	2,599	3,999	6,999	2,899	4,899	
U		**Iceland**	**Albania**	**Ukraine**	**United Arab Emirates**	**The Gambia**	**Uganda**			**Cuba**	**Uruguay**
	3,900	100	200	2,000	200	100	700			400	200
	First #	0	2,700	3,000	2,400	1,800	1,000			400	2,000
	Last #	99	2,899	4,999	2,599	1,899	1,699			799	2,199
V		**Denmark**	**Slovakia**		**Iran**	**Chad**		**Vietnam**	**Vanuatu**	**St Vincent Grenadines**	**Venezuela**
	6,700	200	300		2,000	200		3,000	100	100	800
	First #	0	4,500		2,000	4,400		5,000	800	400	1,000
	Last #	199	4,799		3,999	4,599		7,999	899	499	1,799

Letter Code	Total Allocated	Western Europe	Eastern Europe	Northern Asia	Mideast & North Africa	Central Africa	Southern Africa	Central & SE Asia	Pacific & Pacific Rim	North & Central America	South America
W										**USA**	
	10,000									10,000	
	First #									0	
	Last #									9,999	
X	Reserved										
	0										
	First #										
	Last #										
Y		**Finland**		**Uzbekistan**	**Israel**	**Senegal**	**Zimbabwe**	**Myanmar**	**Solomon Islands**	**Greenland**	
	3,900	200		800	300	300	400	1,500	200	200	
	First #	0		1,000	2,000	2,500	3,000	4,000	3,700	400	
	Last #	199		1,799	2,299	2,799	3,399	5,499	3,899	599	
Z			**Poland**		**Libya**	**Guinea**	**Zaire**		**New Zealand**	**Belize**	**Paraguay**
	4,000		1,500		200	300	1,500		200	100	200
	First #		4,000		3,500	500	1,000		0	2,800	3,000
	Last #		5,499		3,699	799	2,499		199	2,899	3,199
0	Reserved										
	0										
	First #										
	Last #										
1		**Liechtenstein**	**Moldova**	**Tatarstan**	**Malta**	**Sao Tome & Principe**	**Swaziland**		**Japan**	**St Kitts & Nevis**	
	5,900	100	200	200	100	100	100		5,000	100	
	First #	800	9700	9400	400	600	200		1,000	0	
	Last #	899	9899	9599	499	699	299		5,999	99	
2		**San Marino**	**Croatia**		**Qatar**	**Somalia**	**Mauritius**		**Taiwan**	**Grenada**	
	1,700	100	200		100	300	100		1,000	100	
	First #	0	1,000		200	1,500	400		2,000	600	
	Last #	99	1,199		299	1,799	499		2,999	699	
3		**Monaco**	**Bosnia-Herzgovina**		**Western Sahara**	**Guinea-Bissau**	**Congo**		**South Korea**	**St Lucia**	
	2,200	100	200		100	100	100		1,500	100	
	First #	0	1,000		200	400	600		2,000	800	
	Last #	99	1,199		299	499	699		3,499	899	

Letter Code	Total Allocated	Western Europe	Eastern Europe	Northern Asia	Mideast & North Africa	Central Africa	Southern Africa	Central & SE Asia	Pacific & Pacific Rim	North & Central America	South America
4		**Andorra**	**Macedonia**		**Palestine**	**Niger**	**Seychelles**		**North Korea**	**Barbados**	
	2,100	100	100		200	300	100		1,000	100	
	First #	0	1,000		1500	600	1,300		2,000	200	
	Last #	99	1,099		1699	899	1,399		2,999	299	
5		**Vatican**	**Montenegro**			**Mauritania**	**Malawi**	**Mongolia**		**Dominica**	**Antarctica**
	1,200	100	100			100	300	200		100	300
	First #	0	1,000			200	500	1,200		1,700	2,000
	Last #	99	1,099			299	799	1,399		1,799	2,299
6	Reserved										
	0										
	First #										
	Last #										
7				**Russia**							
	10,000			10,000							
	First #			0							
	Last #			9,999							
8	Reserved										
	0										
	First #										
	Last #										
9								**China**			
	10,000							10,000			
	First #							0			
	Last #							9,999			
Assigned/Region:		16,400	6,900	15,000	13,000	14,200	9,200	37,500	31,500	23,600	11,500
World Total:		178,800									

Appendix B Code 128 Character Encodation Table

The table on the next page of this Appendix is reproduced with the permission of the publisher. For the address to obtain the full text of the *Code 128 Specification see* Reference 3.

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Appendix C (*Informative*) Algorithms for Calculation of Check Characters *per* ISO 7064, Mod 37,2 Pure Check Character Specification

This is an *informative* Appendix designed to assist programmers by giving two representative methods for the calculation of the Donation Identification Number ISO 7064 modulo 37,2 check character. Both use the "*Pure system recursive method*"for calculation of the check character as documented in Subsection 6.1 of the ISO 7064 specification: "*Check character systems for use in information interchange, and guidance on choice of methods of application*." This is performed by summing the products of the multiplication of each character-value by 2^i, where *I* is the character's ordinal position in the string starting at the rightmost character. The value of check character is the smallest value that, when added to that sum, produces a value with a modulus 37 result equal to 1.

Programmers must validate that their programs and algorithms comply with the *normative* ISO 7064 1983 specification and good programming practice. Programs to generate the check character should also contain sufficient error checking to verify that the first character of the input Donation Identification Number is either an uppercase A–Z or a digit 0–9 and that all subsequent characters in the input Donation Identification Number are digits.

The following PASCAL language function **ISOmod37_2** calculates and/or validates the ISO 7064 Mod 37,2 pure check character using the above-described method:

```
function ISOmod37_2(DonationInfo:string; K:integer) : char;
   (Calculate or validate ISO mode 37,2 pure check character}
   function ISOvalue(InputString:string; I:integer) : integer;
   begin  {Convert ASCII character value to ISO 7064 value in range 0...36}
      case InputString[I] of
         '0' .. '9':    ISOValue := (ord(InputString[I]) - 48);
         'A' .. 'Z':    ISOValue := (ord(InputString[I]) - 55);
         '*':           ISOValue := 36;
      end;
   end {function ISOvalue};
var
   J,Sum,CharValue,CheckValue : integer;
```

```
const
    ISOCharTable : string[37] = '0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*';
begin
    Sum := 0;
    for J:= 1 to K do
    begin
        CharValue := ISOvalue(DonationInfo,J);
        Sum := ((Sum + CharValue)*2) mod 37;
    end;
    {Check character value is defined to be congruent to 1 mod 37}
    CheckValue := (38 - Sum) mod 37;
    ISOmod37_2 := ISOCharTable[CheckValue + 1];
end {function ISOmod 37_2};
```

The following ‘C’ language function **CalculateMod37_2** also implements the “*Pure system recursive method*” documented in Subsection 6.1 the of ISO 7064 specification.

```
int CalculateISO7064Mod37_2(char *inputString)
{
    int ch, sum, charValue, isDigit, isUpperAlpha;
    static char iso7064ValueToCharTable[] =
                                    "0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*";
        // Read the characters from left to right.
    for (sum = 0; ch = *inputString; inputString++)
    {
            // Ignore invalid characters as per ISO 7064.
        isDigit = ((ch >= '0') && (ch <= '9'));
        isUpperAlpha = ((ch >= 'A') && (ch <= 'Z'));
        if (isDigit || isUpperAlpha)
        {
                // Convert the character to its ISO 7064 value.
            if (isDigit)
                charValue = ch - '0';
            else
                charValue = ch - 'A' + 10;
                // Add the character value to the accumulating sum,
                // multiply by two, and do an intermediate modulus to
                // prevent integer overflow.
```

```
            sum = ((sum + charValue) * 2) % 37;
        }
    }
        // Find the value, that when added to the result of the above
        // calculation, would result in a number who's modulus 37
        // result is equal to 1.
    charValue = (38 - sum) % 37;
        // Convert the value to a character and return it.
    return (iso7064ValueToCharTable[charValue]);
}
```

Examples of Usage

Calculation of a Check Character

Assume that you have the thirteen (13)-character Donation Identification Number "X600097123456" (*excluding the primary data identifier "=" and the flag characters "ff"*) as input data.

Either of the above program functions may be employed to calculate the ISO mod 37,2 pure check character for the input thirteen (13)-character Donation Identification Number "X600097123456." After either function call, the character "`checkCharacter`" will be equal to 'H'.

In PASCAL:

```
checkCharacter := ISOmod37_2('X600097123456',13);
```

In C:

```
checkCharacter = CalculateISO7064Mod37_2("X600097123456");
```

Validation of a Checked String

It is an inherent characteristic of the ISO 7064 check character computation that, if you calculate a check character for a string that already has a correct trailing check character, the result will always be the '*' character. This fact can be used to verify that a Donation Identification Number string is both correct and has been entered correctly.

Assume that you have a fourteen (14)-character string that consists of the same thirteen (13)-

character Donation Identification Number used above, appended with the single (correct) check character ‘H'. To verify the check character is correct, use either of the above functions:

In PASCAL:

```
checkCharacter := ISOmod37_2(‘X600097123456H’,14);
```

In C:

```
checkCharacter = CalculateISO7064Mod37_2("X600097123456H");
```

After either function call, `checkCharacter` will be equal to '*' indicating that the data and the check character are valid. Any other `checkCharacter` would indicate either that a data entry error was made, or that the input Donation Identification Number had an incorrect check character.

ICCBBA, Inc thanks Dr Clive Hohberger, VP of Technology Development at Zebra Technologies Corporation, Vernon Hills, Illinois, USA, for providing the PASCAL function ISOmod37_2, and Mr Harold Boe, VP of Software Development at Seagull Scientific Systems, Inc, Bellevue, Washington, USA, for providing the C-language function CalculateISO7064Mod37_2.

Appendix D New Data Structures

Two new data structures are being added to the *ISBT 128 Application Specification* in Version 1.2.0, a Donor Identification Number and a Staff Member Identification Number. Descriptions of these two new data structures follow.

D.1 Donor Identification Number Data Structure

The *ISBT 128* Donor Identification Number data structure and encodation is as follows:

= ; a **shift C pp pp vv vv vv vv vv vv vv vv K**

where:

"**=;**" is the data identifier;
"a**pppp**"is the Country/Collection Facility Identification Number;
"**vvvvvvvvvvvv**" is the *numerical* donor identification number.
"**K**" is an ISO 7064 modulo 37,2 check digit for keyboard entry, calculated for the entire data string "αppppvvvvvvvvvvvvvvvv" (*see* Subsection 3.4.1.6 and Appendix C).

Note: The check digit "K" should be enclosed in a box as for the Donation Identification Number (see Subsection 3.1.4.6).

D.1.1 Rationale for the Choice of a Sixteen (16)-Digit Numerical Donor Identification Number

Since many facilities already use nationally-assigned identification numbers for the purpose of identifying donors, the ICCBBA, Inc European Technical Advisory Group (ETAG) and North American Technical Advisory Group (NATAG) decided to standardize on a string that would encompass the longest such number of which they were aware [fifteen (15) digits]. To permit the use of double density encodation in subset C of Code 128 a sixteen (16)-digit data string is necessary.

Note that when the number used is less than sixteen (16) digits it should be padded with zeros at the beginning of the actual number. It would require specific knowledge of the actual length of the number being encoded if the padding is placed at the end, since the actual number could end in one or more zeros. If desired, software developers can routinely strip off padding, and present the actual number when displaying the number on a screen or printing it. For example:

in Denmark, a possible data string would be

000000 080656 1665

a ten (10)-digit number with six (6) leading zeroes as padding;

in France, it might be

0 1 56 05 18 033 087 78

a fifteen (15)-digit number with a single (1) leading zero as padding;

and in the US, where the Social Security Number is nine (9)-digits long

0000000 413 22 1853

nine (9) digits plus seven (7) zeroes as padding.

D.1.2 Use of a National Identification Number in Place of a Country/Collection Facility Identification Number

Since some countries assign their Donor Identification Numbers centrally through a national protocol, ICCBBA, Inc proposed that the last number in a country block be reserved for this purpose. To avoid confusion with α0000 occurrences, the last number in the block is the preferable choice. For example, The Netherlands block is N0000 through N0599. N0599 will not, therefore, identify a blood collection facility in The Netherlands, but will be reserved should The Netherlands issue national Donor Identification Numbers. Should the US decide to use centrally-assigned Donor Identification Numbers then each number would begin with W9999.

D.2 Staff Member Identification Number Data Structure

The *ISBT 128* Staff Member Identification Number data structure and encodation is as follows:

= ’ a **pp pp uu uu uu** (all in subset B) where:

“**=’**” is the data identifier;
“a**pppp**” is the Country/Collection Facility Identification Number);
“**uuuuuu**” is the *numerical or alpha-numerical* staff member identification number.

Appendix E Alternative Data Structures

E.1 Date of Production

The two *ISBT 128* Date of Production data structures and their encodation are as follows:

= } shift C cy yj jj

& } shift C cy yj jj hh mm

where:

"**=}**" and "**&}**" are the data identifiers;
"**c**" is the century;
"**yy**" is the year;
"**jjj**" is the Julian day number of the year (*see ISBT 128 Application Specification* "*Definitions for This Document*");
"**hh**" is the hour (00 to 23) and "mm" the minute (00–59) of production. A day is defined as beginning at midnight (00 hours, 00 minutes) and ending at 23:59.

These data structures may be used instead of either of the alternative forms of the Date of Collection data structures and should be applied to the upper left quadrant of the label underneath the Donation Identification Number. If a Date of Collection bar code has been previously applied, the Date of Production bar code should be applied as an overlabel, covering the Date of Collection bar code.

Note: To avoid any confusion with the Expiration Date (and Time), the text interpretation of the Collection Date (and Time) or the Production Date (and Time), if used, should be printed in a smaller typeface.

E.2 Special Testing — Alternative Data Structure One — Red Blood Cell Antigens

This alternative form of the Special Testing data structure (*see* Subsection 3.4.7) may be used when more information with respect to red blood cell antigen testing is desired.

Note: It is anticipated that other alternative encodations of this data structure will be developed.

The data structure is:

= { shift C aa aa aa aa aa aa aa aa ii K

where:

"**={**" is the data identifier;
"**aaaaaaaaaaaaaaaa**" is a sixteen (16)-character numeric string that is interpreted as indicated in Table E1, Pages E-4 and E-5;
"**ii**" is a two (2)-character numeric string that is interpreted as indicated in Tables E2 and E3, Pages E-6 and E-7;
"**K**" is an ISO 7064 modulo 37,2 check digit for keyboard entry, calculated for the entire data string "aaaaaaaaaaaaaaaaii" (*see* Subsection 3.4.1.6 and Appendix C).

Note: The check digit "K" should be enclosed in a box as for the Donation Identification Number (see Subsection 3.1.4.6).

Since Table E1, Pages E-4 and E-5, is based on a simple, yet complex, algorithm, specific examples of the decoding of (and by careful inspection of the examples, the encoding of) the sixteen (16)-character "aaaaaaaaaaaaaaaa"data string is perhaps the best way to clarify the use of Table E1, Pages E-4 and E-5.

Consider the following data string:

8800000000870000

this data string is decoded as follows:

C-c+E-e+, K+k+;
C^w, V/VS, A_1, M, N, S, s, U, Mi^a, P_1, Lu^a, Kp^a, Js^a, Wr^a, Le^a, Le^b not tested;
Fy(a+b+);
Jk(a+b-);
Di^a, Di^b, Do^a, Do^b, Co^a, Co^b, In^a, CMV antibody not tested.

Similarly:

6799999999999999

decodes as:

C+c-E-e+, K+k-; no other information.

And:

9999999999999991

indicates:

In^a not tested; CMV antibody negative; no other information.

Finally, an example of the encoding of a red blood cell antigen profile:

4862861395589999

that decodes as:

[C+]C^w +c+E+e+ K+ k+ M+N+S+s+ P_1- Lu(a-) Le(a-b+) Fy(a-b+) Jk(a+b+);
V/VS A_1 U Mi^a Kp^a not tested;
no information for other red blood cell antigens.

In contrast, the interpretation of the two (2)-character "ii" data string is quite simple. If the "ii" string is "99," then no information is provided by this data string (the default condition). If a number between "01" and "98" appears, then the antigen shown next to the value in Table E2, Page E-6 has been tested for and found to be negative. If the value is "00" then Table E3, Page E-7 should be consulted.

In Table E3, Page E-7,a specific antigen of importance to the recipient, has been demonstrated to be negative.

Table E1a Decoding Special Testing Alternative Data Structure One; Positions 1 through 9

Position	**1**	**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**	
Antibody																	
Antigen / Value	**Rh**	**K**	**k**	**C^w**	**VS/V**	**A1**	**M**	**N**	**S**	**s**	**U**	**Mi^a†**	**P1**	**Lu^a**	**Kp^a**	**Js^a**	**Wr^a**
0	C+c-E+e-	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	C+c+E+e-	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	C-c+E+e-	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	C+c-E+e+	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	C+c+E+e+	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	C-c+E+e+	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	C+c-E-e+	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	C+c+E-e+	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	C-c+E-e+	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: † aka Mur, Mi.III and GP.Mur; nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table E1b Decoding Special Testing Alternative Data Structure One (continued); Positions 10 through 16

Position	**10**		**11**		**12**		**13**		**14**		**15**		**16**	
Antibody														**CMV**
Antigen / Value	**Le^a**	**Le^b**	**Fy^a**	**Fy^b**	**Jk^a**	**Jk^b**	**Di^a**	**Di^b**	**Do^a**	**Do^b**	**Co^a**	**Co^b**	**In^a**	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: † aka Mur, Mi.III and GP.Mur; nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table E2 Decoding Special Testing Alternative Data Structure One; Erythrocyte Antigens Coded as Negative in Position "*ii*"

Value	Antigen	Value	Antigen	Value	Antigen	Value	Antigen
00	*see* Table E3	25	Kp^b	50	Au^a	75	An^a
01	En^a	26	Kp^c	51	Au^b	76	Dh^a
02	'N'	27	Js^b	52	Fy4	77	Cr^a
03	V^w	28	Ul^a	53	Fy5	78	IFC
04	Mur	29	K11	54	Fy6	79	Kn^a
05	Hut	30	K12	55	removed	80	In^b
06	Hil	31	K13	56	Sd^a	81	Cs^a
07	P	32	K14	57	Wr^b	82	I
08	PP_1P^k	33	K17	58	Yt^b	83	Er^a
09	hr^S	34	K18	59	Xg^a	84	Vel
10	hr^B	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At^a
12	Ce	37	K23	62	Sc3	87	Jr^a
13	G	38	K24	63	Jo^a	88	Ok^a
14	Hr_o	39	Lu^b	64	Do^b	89	reserved for future use
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	cE	41	Lu4	66	Gy^a	91	reserved for future use
17	C^x	42	Lu5	67	Co3	92	reserved for future use
18	E^w	43	Lu6	68	LW^a	93	reserved for future use
19	D^w	44	Lu7	69	LW^b	94	reserved for future use
20	hr^H	45	Lu8	70	Kx	95	reserved for future use
21	Go^a	46	Lu11	71	Ge2	96	reserved for future use
22	Rh32	47	Lu12	72	Ge3	97	reserved for future use
23	Rh33	48	Lu13	73	Wb	98	IgA deficient
24	Tar	49	Lu20	74	Ls^a	99	default

Table E3 Decoding Special Testing Alternative Data Structure One; Erythrocyte Antigens Declared as Negative by “00” in Position “*ii*”

He, M^{c}, M^{g}, Vr, M^{e}, Mt^{a}, St^{a}, Ri^{a}, Cl^{a}, Ny^{a}, M^{v}, Far, s^{D}, Mit, Dantu, Hop, Nob, Or, DANE, TSEN, MINY, MUT, SAT, ERIK, Os^{a}
P^{k}, LKE
Hr, C^{G}, Rh26, Rh29, Hr^{B}, Rh35, Be^{a}, Evans, Rh39, Rh41, Craw, Riv, JAL, STEM, Nou, Sec, Dav, FPTT, MAR
Lu9, Lu14
K16, Km
Le^{c}, Le^{d}, Le^{x}
LW^{ab}
Ch1, Ch2, Ch3, Ch4, Ch5, Ch6,WH, Rg1, Rg2
Ge4
Tc^{a}, Tc^{b}, Tc^{c}, Dr^{a}, Es^{a}, WES^{a}, WES^{b}, UMC,
McC^{a}, Sl^{a}, Yk^{a}, Kn^{b}
Cs^{b}
I
Er^{b}
By, Chr^{a}, Sw^{a}, Bi, Bx^{a}, Tr^{a}, Bp^{a}, Wu, Jn^{a}, Rd, To^{a}, Pt^{a}, Re^{a}, Je^{a}, Mo^{a}, Fr^{a}, Rb^{a}, Li^{a}, Vg^{a}, Wd^{a}, Hg^{a}, NFLD, Milne, RASM, SWl, Ol^{a}, JFV,Kg, BOW, Jones, HJK, HOFM, ELO, SARA, LOCR, REIT, WARR
JMH, Emm, AnWj, MER 2, Sd^{a}, PEL, Duclos

Appendix F Modifications to Tables and Re-Definition of International and National Data Identifiers

Table 2 *ISBT 128*-Specified Values for Donation Identification Number Flag Digits, "ff"

Value of "ff"	**Meaning When Used in the Donation Identification Number**
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) "demand-printed" label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Samples for bacterial testing
11–14	Reserved for future assignment
15–19	Container 5 through 9 of a set
20–59	Reserved for assignment and use by each local blood center. Therefore the meaning and interpretation of flag values 20–59 may differ with each Country/Collection Facility Identification Number (*see* Subsection 3.4.1.1 and Section 6) and should not be interpreted at any other site
60–96	ISO 7064 modulo 37,2 check character on the preceding thirteen (13) data characters, "a**ppppyynnnnnn**" including the Country/Collection Facility Identification Number, year and serial number. Value is assigned as 60 + (modulo 37,2 checksum)
97–99	Reserved for future assignment

Table 5 Type of Donation Codes in the 6th Position in the Product Code Data Structure

Character	Type of Donation
0 (zero)	Not specified (null value)
V	**Volunteer homologous (allogeneic) donor (default)**
R	Volunteer research donor
S	Volunteer source donor
T	Volunteer therapeutic collection
P	Paid homologous (allogeneic) collection
r	Paid research collection
s	Paid source collection
A	Autologous collection, eligible for crossover
1 (one)	For autologous use only
X	For autologous use only, biohazardous
D	Volunteer directed donation, eligible for crossover
d	Paid directed collection, eligible for crossover
2 (two)	For directed donor use only
L	For directed donor use only, limited exposure
E	For directed donor use only, medical exception
Q	*See* (*ie*, read [scan]) Special Testing bar code
3 (three)	For directed donor use only, biohazardous
4 (four)	Designated donor
5 (five)	Dedicated donor

Definition of the Terms Directed, Designated and Dedicated in Table 5

Directed — A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide (a) blood product(s) to be used by that person in some future therapeutic procedure.

Designated — A unit collected from a donor called by the collecting facility to provide (a) blood product(s) to be used by a specific recipient in some future therapeutic procedure (for example, compatible with HLA antibodies that the recipient has, CMV antibody negative, *etc*).

Dedicated — Donations arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic blood products).

Table 4 Encodation of Rhesus, Kell, and Miltenberger (Mi-III) Phenotypes

Values of “**r**” {0–9, A–T, X–Z} are used to encode the results of testing with anti-K, anti-C, anti-c, anti-E, and anti-e as shown in this table. (For example, if the value of “**r**“ is “E”, then the red blood cells are K-negative, C-negative, c-positive, E-positive and e-positive). Values U and V encode Miltenberger Mi-III antigen test results.

Results with Anti-Kell			**Results with:**			
Not tested	**Negative**	**Positive**	**Anti-C**	**Anti-c**	**Anti-E**	**Anti-e**
0	S	T	not tested	not tested	negative	not tested
1	A	J	negative	positive	negative	positive
2	B	K	positive	positive	negative	positive
3	C	L	positive	positive	positive	positive
4	D	M	positive	positive	positive	negative
5	E	N	negative	positive	positive	positive
6	F	O	negative	positive	positive	negative
7	G	P	positive	negative	negative	positive
8	H	Q	positive	negative	positive	positive
9	I	R	positive	negative	positive	negative
X	Y	Z	negative	not tested	negative	not tested

U	Mi-III negative
V	Mi-III positive
W	Special Testing bar code present and must be interpreted (*see* Subsection 3.4.7)

Note: *Values X, Y and Z have been added.*

International and National Data Identifiers

In the original planning for *ISBT 128*, it was intended that “**=**” and “**&**” as primary data identifier characters would distinguish between internationally-specified and nationally-designed data structures. With the desire to keep the same basic data structure for date and date with time, this distinction was quickly abandoned. Nevertheless, the desire to clearly differentiate between internationally-specified and nationally-created data structures remains strong. Therefore, the following consensus has been adopted.

All data identifiers beginning with “**=**” as the primary character are internationally-specified.

All data identifiers beginning with “**&**” as the primary character are also internationally-specified unless the second character is A through Z, that is, bar codes beginning “**&A**,” “**&B**”...”**&Z**” are reserved for national use and should not be interpreted outside the country identified by the Country/Collection Facility Identification Number.

Care should be taken not to confuse the issue of nationally-designated data structures with nationally-assigned product codes. These latter begin with “**=<**“ and are followed by the letter A, B, C or D, *ie*, bar codes beginning with “**=<A**,” “**=<B**,” “**=<C**” and “**=<D**” are bar codes encoding nationally-assigned product codes. Again, they should not be interpreted outside the country identified by the Country/Collection Facility Identification Number.

Appendix G Labeling Pooled Platelets of Mixed ABO and Rh Blood Groups

In general, the pooling of platelets should be ABO and Rh-specific. That is, all the units in the pool should be of the same ABO and Rh blood groups. Occasionally, because of a lack of group-specific platelets, it becomes necessary to transfuse pools of platelets of different ABO and/or Rh blood groups. This usually occurs in one of two ways. An example best illustrates these two alternatives:

> Suppose a group O, Rh positive recipient is to be transfused with a pool of six Platelets, but the transfusion service has available only three O, Rh positive Platelets to satisfy the order, and three A, Rh positive Platelets are chosen to supplement the O, Rh positive units. One can either pool the three O, Rh positive units and the three A, Rh positive units into separate containers of Pooled Platelets and permit the mixing to occur in the recipient, or all six units can be pooled into the same container. In the first instance, the *ISBT 128 Application Specification* provides all necessary data structures and coding to label the final containers. In the second instance, no provision is available in the *ISBT 128 Application Specification*. The following labeling and coding provisions address this issue.

There are seven possibilities.

Pools can be prepared in which all the platelets are of the same ABO blood group but mixed as to Rh, *ie*, both positive and negative.

That is:	Group A, Pooled Rh	A000 code (*ggre*) to appear in bar code;
	Group B, Pooled Rh	B000 code (*ggre*) to appear in bar code;
	Group AB, Pooled Rh	C000 code (*ggre*) to appear in bar code;
	Group O, Pooled Rh	D000 code (*ggre*) to appear in bar code.

Note: ***By definition, Pooled Rh Platelets may contain Rh positive red blood cells*** *and the SOP used when transfusing any blood component that may contain Rh positive red blood cells to an Rh negative recipient should apply*.

Pools can be prepared in which all the platelets are of the same Rh blood group but mixed as to ABO blood group.

That is:	Pooled ABO, Rh Positive	E000 code (*ggre*) to appear in bar code;
	Pooled ABO, Rh Negative	F000 code (*ggre*) to appear in bar code.

Finally, pools can be prepared in which ABO and Rh are both mixed.

That is: Pooled ABO, Pooled Rh. G000 code (*ggre*) to appear in bar code.

The next two pages illustrate the labels that should be applied in the upper right quadrant of the final container. Note that in each case the left lower quadrant would bear the required Pooled Platelets label and product code (*see* illustration in the *US Consensus Standard*, Section 5, Page 5-21). In the upper left quadrant, the pool identification number bar code would appear as previously described (*see US Consensus Standard,* Section 4, Page 4-10).

Labels for Group A, B, AB and O Pooled Platelets of Mixed Rh Blood Groups

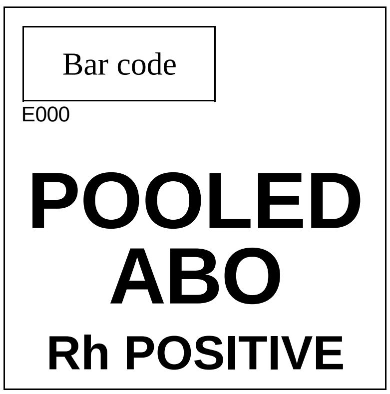
Bar code
A000
A
POOLED Rh

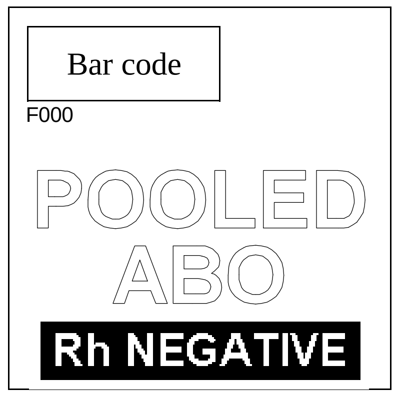
Bar code
B000
B
POOLED Rh

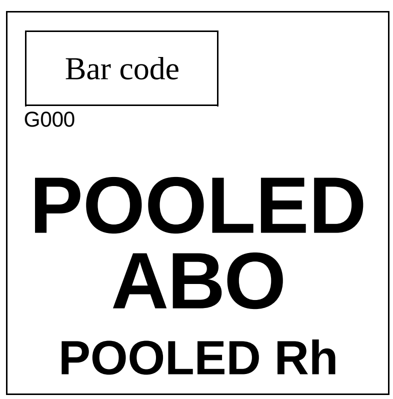
Bar code
C000
AB
POOLED Rh

Bar code
D000
O
POOLED Rh

Labels for Pooled Platelets of Mixed ABO Blood Group That Are Rh Positive, Rh Negative and Mixed Rh







Appendix H Special Testing — Alternative Data Structure Two — HLA and Platelet-Specific Antigens for Platelets

This alternative form of the Special Testing data structure (*see* Subsection 3.4.7) may be used when more information with respect to HLA and platelet-specific antigen testing for platelets is desired.

The data structure is:

& { shift C AA AA BB BB CC CC CC CC DD K

where:

"**&{**" is the data identifier;
"**AAAA**" is a four (4)-character numeric string that codes for HLA-A antigens and is interpreted as indicated in Table H1, Page H-3;
"**BBBB**" is a four (4)-character numeric string that codes for HLA-B antigens and is interpreted as indicated in Table H1, Page H-3;
"**CCCCCCCC**" is an eight (8)-character numeric string that codes for platelet-specific antigens (and IgA antigen and CMV antibody status) and is interpreted as indicated in Table H2, Page H-6;
"**DD**" is a two (2)-character numeric string reserved for future use — they should be set to a default value of 00 at this time;
"**K**" is an ISO 7064 modulo 37,2 check digit for keyboard entry, calculated for the entire data string "aaaaaaaaaaaaaaaaii" (*see* 3.4.1.6 and Appendix C).

Examples of Use

An individual of homozygous HLA-A2, B7 type would be coded as:

029907999999999900 (if only the phenotype is known)
020207079999999900 (if the genotype is known)

Note: These two examples indicate that no information is provided for platelet-specific antigens.

Remember, two AA values are always needed, followed by two BB values. To conform with practice the lower value should always be listed first.

An individual of HLA-A210, 24; B8, 2708 would be coded as:

022408279999999900

Again, no information is provided as to platelet-specific antigens.

A Pl^{A1} (HPA 1a)-negative individual would be coded as:

999999993999999900

if there was no information as to HLA type, and:

029908995999999900

if of HLA phenotype A2, B8.

An IgA-deficient, CMV-antibody negative individual would be coded as:

999999999999999400

providing no information about HLA type or platelet-specific antigen status.

And so on.

Table H1 Interpretation of HLA-A and HLA-B Antigen Codes

HLA-A	Value of AA	HLA-B	Value of BB
nt	00	nt	00
A1	01	B5	05
A2	02	B7	07
A203	02	B703	07
A210	02	B8	08
A3	03	B12	12
A9	09	B13	13
A10	10	B14	14
A11	11	B15	15
A19	19	B16	16
A23	23	B17	17
A24 A2403	24	B18	18
A25	25	B21	21
A26	26	B22	22
A28	28	B27 B2708	27
A29	29	B35	35
A30	30	B37	37
A31	31	B38	38
A32	32	B39	39
A33	33	B40 B4005	40

HLA-A	Value of AA	HLA-B	Value of BB
A34	34	B41	41
A36	36	B42	42
A43	43	B44	44
A66	66	B45	45
A68	68	B46	46
A69	69	B47	47
A74	74	B48	48
A80	80	B49	49
ni	99	B50	50
		B51	51
		B5102	
		B5103	
		B52	52
		B53	53
		B54	54
		B55	55
		B56	56
		B57	57
		B58	58
		B59	59
		B60	60
		B61	61
		B62	62
		B63	63
		B64	64
		B65	65

HLA-A	**Value of AA**	**HLA-B**	**Value of BB**
		B67	67
		B70	70
		B71	71
		B72	72
		B73	73
		B75	75
		B76	76
		B77	77
		B78	78
		B81	81
		ni	99

nt — not tested; ni — no information

Table H2 Interpretation of Platelet-Specific Antigen Codes; IgA Antigen and CMV Antibody Status

Position	**1**		**2**		**3**		**4**		**5**		**6**		**7**		**8**	
Antibody																**CMV**
Antigen / Value	**HPA 1a**	**HPA 1b**	**HPA 2a**	**HPA 2b**	**HPA 3a**	**HPA 3b**	**HPA 4a**	**HPA 4b**	**HPA 5a**	**HPA 5b**	**HPA 6a**	**HPA 6b**	**HPA 7a**	**HPA 7b**	**IgA**	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table H3 Common Names of Platelet-Specific Antigens (for Reference)

ISBT/ICSH Nomenclature	Old Nomenclature
HPA-1a HPA-1b	Zw^a, PL^{A1} Zw^b, PL^{A2}
HPA-2a HPA-2b	Ko^b Ko^a, Sib^a
HPA-3a HPA-3b	Bak^a, Lek^a Bak^b
HPA-4a HPA-4b	Pen^a, Yuk^b Pen^b, Yuk^a
HPA-5a HPA-5b	Br^b, Zav^b Br^a, Zav^a, Hc^a
HPA-6a	Tu, Ca
HPA-7a	Mo

Appendix I Special Testing Data Structure

In *ISBT 128*, a five (5)-character alphanumeric, structured bar code has been defined to encode the results of special testing. Special testing does not physically change the product, *ie*, the contents of the container, but influences the intended use of the product.

The codes reflect the status of: RBC phenotyping; red blood cell and other antibody(ies); HLA phenotyping; HPA phenotyping; CMV antibody, *etc*.

As a reminder, this data structure (as modified by this encodation procedure) is:

& (N z z z z (all in Subset B)

where:

"**&(**" are the primary and secondary *ISBT 128* data identifiers;
"**N**" is the first character indicating the encodation table from which the interpretation of the remaining four characters is obtained (CODES in the Special Testing database);
"**zzzz**" are four (4) alphanumeric characters in the set {A–Z, a–z, 0–9} encoding special testing, originally intended to be specified by nationally-defined tables, but with the publication of this Appendix are now internationally defined:
"**N0000**" is the default value, indicating no special testing information is provided.

The application of the Special Testing bar code is still optional. Note that it can take one of three formats: that covered by this Appendix, the data structure that codes for an extended red blood cell antigen phenotype (Appendix E) or that which codes for HLA and HPA antigens on Platelets (Appendix H).

The code table has been structured similarly to that used in the product code database, and will be similarly maintained and supplied in a Microsoft *Access*® database table. Table I1, Page I-2 lists the attributes currently defined.

Table I3, Page I-4 lists the translated nationally defined special testing codes and their interpretation as defined by the Dutch organization, Sanquin. The eye-readable text display of special testing information is not specified and should be nationally determined.

Table I1 Currently Defined Attributes

Group	Definition
a1	HLA phenotyped
a2	HLA antibody(ies) present
a3	HLA antibody absent
a4	HLA phenotyped; HLA antibody(ies) present
a5	HLA phenotyped; HLA antibody absent
b1	HPA phenotyped
b2	HPA antibody(ies) present
b3	HPA antibody absent
b4	HPA phenotyped; HPA antibody(ies) present
b5	HPA phenotyped; HPA antibody absent
c1	RBC phenotyped
c2	RBC antibody(ies) present
c3	RBC antibody absent
c4	RBC phenotyped; RBC antibody(ies) present
c5	RBC phenotyped; RBC antibody absent
c6	Specific antibody present
c7	Specific antibodies present
c8	RBC phenotyped; specific antibody present
c9	RBC antibody(ies) present; specific antibodies present
ca	RBC antibody absent; specific antibody present
d1	IgA deficient
d2	CMV seronegative
d3	CMV seropositive

Group	Definition
d4	IgA deficient; CMV seronegative
d5	IgA deficient; CMV seropositive
e1	CMV antibody present
e2	Anti-D present
e3	HAV antibody present
e4	HBV antibody present
e5	Tetanus antibody present
e6	Varicella Zoster antibody present
e7	CMV antibody present; anti-D present

Note: This table will be the ATTR table in the Special Testing database.

Note: The principle of mutual exclusivity of groups established for product coding will be used. Not all possible combinations have been defined. Some of those defined may not be used; they are examples of how the table will develop. This table is intended to indicate the layout of the ATTR table in the Special Testing database. Other combinations and new attributes and attribute groups will be assigned and defined as they are requested (ie, as with product codes).

Table I2 Abbreviations

CMV	cytomegalovirus
HAV	hepatitis A virus
HBV	hepatitis B virus
HLA	human leukocyte antigen
HPA	human platelet antigen
IgA	immunoglobulin A
RBC	red blood cell

Table I3 Currently Assigned Codes and Their Interpretation

Code	Interpretation	Formula
N0000	default	
N0001	HLA phenotyped	a1
N0002	HPA phenotyped	b1
N0003	IgA deficient	d1
N0004	RBC phenotyped	c1
N0005	RBC antibody(ies) present	c2
N0006	RBC antibody absent	c3
N0007	Specific antibody present	c6
N0008	CMV seronegative	d2
N0009	CMV seropositive	d3
N0010	HLA antibody(ies) present	a2
N0011	HLA antibody absent	a3
N0012	HPA antibody(ies) present	b2
N0013	HPA antibody absent	b3
N0014	HLA phenotyped HPA phenotyped	a1b1
N0015	HLA phenotyped IgA deficient	a1d1
N0016	HLA phenotyped RBC phenotyped	a1c1
N0017	HLA phenotyped RBC antibody(ies) present	a1c2
N0018	HLA phenotyped RBC antibody absent	a1c3

Code	Interpretation	Formula
N0019	HLA phenotyped CMV seropositive	a1d3
N0020	HLA phenotyped CMV seronegative	a1d2
N0021	HLA phenotyped HLA antibody(ies) present	a4
N0022	HLA phenotyped HLA antibody absent	a5
N0023	HLA phenotyped HPA antibody(ies) present	a1b2
N0024	HLA phenotyped HPA antibody absent	a1b3
N0025	HLA phenotyped HPA phenotyped RBC phenotyped	a1b1c1
N0026	HLA phenotyped HPA phenotyped RBC phenotyped CMV seronegative	a1b1c1d2
N0027	HLA phenotyped HPA phenotyped RBC phenotyped CMV seropositive	a1b1c1d3
N0028	HLA phenotyped RBC phenotyped RBC antibody(ies) present	a1c4
N0029	HLA phenotyped RBC phenotyped RBC antibody absent	a1c5
N0030	HLA phenotyped HLA antibody absent RBC phenotyped	a5c1

Code	**Interpretation**	**Formula**
N0031	HLA phenotyped HLA antibody absent RBC phenotyped CMV seronegative	a5c1d2
N0032	HPA phenotyped IgA deficient	b1d1
N0033	HPA phenotyped RBC phenotyped	b1c1
N0034	HPA phenotyped RBC antibody(ies) present	b1c2
N0035	HPA phenotyped RBC antibody absent	b1c3
N0036	HPA phenotyped CMV seronegative	b1d2
N0037	HPA phenotyped CMV seropositive	b1d3
N0038	HLA antibody(ies) present HPA phenotyped	a2b1
N0039	HLA antibody absent HPA phenotyped	a3b1
N0040	HPA phenotyped HPA antibody(ies) present	b4
N0041	HPA phenotyped HPA antibody absent	b5
N0042	RBC phenotyped IgA deficient	c1d1
N0043	IgA deficient CMV seronegative	d4
N0044	IgA deficient CMV seropositive	d5
N0045	RBC phenotyped RBC antibody(ies) present	c4

Code	Interpretation	Formula
N0046	RBC phenotyped RBC antibody absent	c5
N0047	RBC phenotyped Specific antibody present	c8
N0048	RBC phenotyped CMV seronegative	c1d2
N0049	RBC phenotyped CMV seropositive	c1d3
N0050	HLA antibody(ies) present RBC phenotyped	a2c1
N0051	HLA antibody absent RBC phenotyped	a3c1
N0052	HPA antibody(ies) present RBC phenotyped	b2c1
N0053	HPA antibody absent RBC phenotyped	b3c1
N0054	RBC phenotyped RBC antibody absent CMV seronegative	c5d2
N0055	RBC phenotyped RBC antibody absent CMV seropositive	c5d3
N0056	HLA antibody absent RBC phenotyped RBC antibody absent CMV seronegative	a3c5d2
N0057	HLA antibody absent RBC phenotyped RBC antibody absent CMV seropositive	a3c5d3

Code	Interpretation	Formula
N0058	HLA antibody absent HPA antibody absent RBC phenotyped RBC antibody absent CMV seronegative	a3b3c5d2
N0059	HLA antibody absent HPA antibody absent RBC phenotyped RBC antibody absent CMV seropositive	a3b3c5d3
N0060	RBC antibody(ies) present Specific antibody(ies) present	c9
N0061	RBC antibody(ies) present CMV seronegative	c2d2
N0062	RBC antibody(ies) present CMV seropositive	c2d3
N0063	HLA antibody(ies) present RBC antibody(ies) present	a2c2
N0064	HLA antibody absent RBC antibody(ies) present	a3c2
N0065	HPA antibody(ies) present RBC antibody(ies) present	b2c2
N0066	HPA antibody absent RBC antibody(ies) present	b3c2
N0067	RBC antibody absent Specific antibody present	ca
N0068	RBC antibody absent CMV seronegative	c3d2
N0069	RBC antibody absent CMV seropositive	c3d3
N0070	HLA antibody(ies) present RBC antibody absent	a2c3

Code	Interpretation	Formula
N0071	HLA antibody absent RBC antibody absent	a3c3
N0072	HPA antibody(ies) present RBC antibody absent	b2c3
N0073	HPA antibody absent RBC antibody absent	b3c3
N0074	CMV seronegative Specific antibody present	d2c6
N0075	CMV seropositive Specific antibody present	d3c6
N0076	HLA antibody(ies) present Specific antibody present	a2c6
N0077	HLA antibody absent Specific antibody present	a3c6
N0078	HPA antibody(ies) present Specific antibody present	b2c6
N0079	HPA antibody absent Specific antibody present	b3c6
N0080	HLA antibody(ies) present CMV seronegative	a2d2
N0081	HLA antibody absent CMV seronegative	a3d2
N0082	HPA antibody(ies) present CMV seronegative	b2d2
N0083	HPA antibody absent CMV seronegative	b3d2
N0084	HLA antibody(ies) present CMV seropositive	a2d3
N0085	HLA antibody absent CMV seropositive	a3d3
N0086	HPA antibody(ies) present CMV seropositive	b2d3

Code	Interpretation	Formula
N0087	HPA antibody absent CMV seropositive	b3d3
N0088	HLA antibody(ies) present HPA antibody(ies) present	a2b2
N0089	HLA antibody(ies) present HPA antibody absent	a2b3
N0090	HLA antibody absent HPA antibody(ies) present	a3b2
N0091	HLA antibody absent HPA antibody absent	a3b3
N0092		
N0093		
N0094		
N0095		
N0096		
N0097		
N0098		
N0099		
N0100	CMV antibody present	e2
N0101	Anti-D present	e3
N0102	HAV antibody present	e4
N0103	HBV antibody present	e5
N0104	Tetanus antibody present	e6
N0105	Varicella Zoster antibody present	e7

Note: This table will be the CODES table in the Special Testing database.

Appendix J Special Testing — Alternative Data Structure Three — Genomically-Determined (PCR) HLA Alleles for Hematopoietic Progenitor Cells and Tissues

The following two data structures should always be used as a pair:

= [shift C EE EE FF FF GG GG HH HH LM K

=] shift C II II JJ JJ MM MM MM MM MM K

where:

"**=[**" and "**=]**"are the primary and secondary *ISBT 128* data identifiers;
"**EEEE"** is a four (4)-character numeric string that codes for the first four digits of the first of the pair of HLA-A genomically-determined alleles and is interpreted using Table J1, Page J-5 ;
"**FFFF"** is a four (4)-character numeric string that codes for the first four digits of the second of the pair of HLA-A genomically-determined alleles and is interpreted using Table J1, Page J-5;
"**GGGG"** is a four (4)-character numeric string that codes for the first four digits of the first of the pair of HLA-B genomically-determined alleles and is interpreted using Table J2, Page J-15;
"**HHHH"** is a four (4)-character numeric string that codes for the first four digits of the second of the pair of HLA-B genomically-determined alleles and is interpreted using Table J2, Page J-15;
"**IIII"** is a four (4)-character numeric string that codes for the first four digits of the first of the pair of HLA-DRB1 genomically-determined alleles and is interpreted using Table J3, Page J-34;
"**JJJJ"** is a four (4)-character numeric string that codes for the first four digits of the second of the pair of HLA-DRB1 genomically-determined alleles and is interpreted using Table J3, Page J-34;
"**L**" is used for coding CMV antibody status (se*e* Table J4, Page J-46*)*;
"**M**" and "**MMMMMMMMMM**" are reserved for future use;
"**K**" is an ISO 7064 modulo 37,2 check digit for keyboard entry, calculated for the entire eighteen (18)-character data strings "**EEEEFFFFGGGGHHHHLM**" and "**IIIIJJJJMMMMMMMMMM**" (*see* Subsection 3.4.1.6 and Appendix C).

Note: *Only the first four digits of the HLA-A, -B and -DRB1alleles are significant for transfusion and transplantation, since the fifth and any subsequent characters describe synonymous mutations*.

Note: *For the interpretation of any characters that appear after the first four digits in the pairs of HLA alleles see Table J5, Page J-46. The bar code text allele numbers are preceded* *by an asterisk (*) to indicate their genomically-determined status.*

Note: 00 after the first two characters is meant to signify that tissue typing of the respective HLA-locus has been performed using a method that does not allow allele discrimination at higher resolution than 2 digits. This is usually the case using low resolution PCR-SSP/SSO or serology, whereas sequence-based typing (SBT) may allow higher resolution.

Note: Since null alleles do not result in an HLA molecule on the cell surface the value in the bar code for these alleles is 0000 and the bar code text is a — (dash).

Examples of Use

Remember, two EEEE values are always needed, followed by two FFFF values and two IIII values. To conform with practice the lower value of each pair should always be listed first.

A CMV antibody negative individual of with the genomic typing HLA-A*0103, 02011; B*0702, 27052 ; DRB1*1001, 15011 would be coded as:

0103 0201 0702 2705 19
1001 1501 9999 9999 99

and the bar code text would appear as:

HLA-A*0103, 0201; B*0702, 2705;
DRB1*1001, 1501
CMV antibody negative

The same individual typed by low resolution genomic typing would be coded as:

0100 0200 0700 2700 19
1000 1500 9999 9999 99

and the bar code text would appear as:

HLA-A*01, 02; B*07, 27;
DRB1*10, 15
CMV antibody negative

A CMV antibody negative individual with the serological HLA class I typing HLA-A2, 3; B7, 44 and the genomic typing HLA-DRB1*0301, 1501 would be coded as

0299 0399 0799 4499 19

0301 1501 9999 9999 99

and the bar code text would appear as:

HLA-A2, 3; B7, 44;
DRB1*0301, *1501
CMV antibody negative

The same individual typed by low resolution genomic typing would be coded as

0200 0300 0700 4400 19
0300 1500 9999 9999 99

and the bar code text would appear as:

HLA-A*02, 03; B*07, 44
DRB1*03, 15
CMV antibody negative

Null alleles are coded according to the phenotype, *ie*, a CMV antibody negative individual with the genomic typing HLA-A*0301, 2611N; B*07022, 0801; DRB1*03011, 1501 would be coded as:

0301 0000 0702 0801 19
0301 1501 9999 9999 99

and the bar code text would appear as:

HLA-A*0301; B*0702, 0801;
DRB1*0301, 1501
CMV antibody negative

A CMV antibody positive HLA homozygous individual with the genomic typing HLA-A*0101; B*0801; DRB1*0304 (confirmed by family typings) would be coded as:

0101 0101 0801 0801 29
0304 0304 9999 9999 99

but the bar code text would appear as:

HLA-A*0101; B*0801;
DRB1*0304
CMV antibody positive

in accordance with current reporting convention. And so on.

General Reference:

Nomenclature for factors of the HLA system

Compiled by Steven G. E. Marsh

for the

WHO Nomenclature Committee for Factors of the HLA System

http://www.anthonynolan.org.uk/HIG/nomenc.html

This reference is given because ICCBBA, Inc cannot possibly maintain Tables J1–J5, Pages J-5 to J-46 in a timely manner, and it is the official source for the latest data regarding genomically-determined HLA alleles. Those using this data structure pair should frequently check for updates to the table using the link given above (HIG must be capitalized) and populate the HLA-A, -B and -DRB1 tables that follow with any additions or changes. ICCBBA, Inc will publish updated tables at irregular intervals when deemed appropriate by the ICCBBA, Inc Technical Advisory Groups.

Table J1 Value of "EEEE" and "FFFF": HLA-A Alleles

Value in bar code	Bar code text	Allele(s)
0100	A*01	A*01 "low resolution"
0101	A*0101	A*01011
		A*01012
0102	A*0102	A*0102
0103	A*0103	A*0103
0000	—	A*0104N
0000	—	A*0105N
0106	A*0106	A*0106
0107	A*0107	A*0107
0108	A*0108	A*0108
0199	A1	A1 by serology
0200	A*02	A*02 "low resolution"
0201	A*0201	A*02011
		A*02012
		A*02013
		A*02014
0202	A*0202	A*0202
0203	A*0203	A*0203
0204	A*0204	A*0204
0205	A*0205	A*0205
0206	A*0206	A*0206
0207	A*0207	A*0207
0208	A*0208	A*0208

Value in bar code	Bar code text	Allele(s)
0209	A*0209	A*0209
0210	A*0210	A*0210
0211	A*0211	A*0211
0212	A*0212	A*0212
0213	A*0213	A*0213
0214	A*0214	A*0214
0000	—	A*0215N
0216	A*0216	A*0216
0217	A*0217	A*02171
		A*02172
0218	A*0218	A*0218
0219	A*0219	A*0219
0220	A*0220	A*02201
		A*02202
0221	A*0221	A*0221
0222	A*0222	A*0222
0224	A*0224	A*0224
0225	A*0225	A*0225
0226	A*0226	A*0226
0227	A*0227	A*0227
0228	A*0228	A*0228
0229	A*0229	A*0229
0230	A*0230	A*0230
0231	A*0231	A*0231
0000	—	A*0232N
0233	A*0233	A*0233

Value in bar code	Bar code text	Allele(s)
0234	A*0234	A*0234
0235	A*0235	A*0235
0236	A*0236	A*0236
0237	A*0237	A*0237
0238	A*0238	A*0238
0239	A*0239	A*0239
0240	A*0240	A*0240
0241	A*0241	A*0241
0242	A*0242	A*0242
0000	—	A*0243N
0244	A*0244	A*0244
0245	A*0245	A*0245
0246	A*0246	A*0246
0299	A2	A2 by serology
0300	A*03	A*03 “low resolution”
0301	A*0301	A*03011
		A*03012
		A*03013
0302	A*0302	A*0302
0000	—	A*0303N
0304	A*0304	A*0304
0305	A*0305	A*0305
0306	A*0306	A*0306
0307	A*0307	A*0307
0308	A*0308	A*0308
0399	A3	A3 by serology

Value in bar code	**Bar code text**	**Allele(s)**
1100	A*11	A*11 “low resolution”
1101	A*1101	A*11011
		A*11012
1102	A*1102	A*1102
1103	A*1103	A*1103
1104	A*1104	A*1104
1105	A*1105	A*1105
1106	A*1106	A*1106
1107	A*1107	A*1107
1109	A*1109	A*1109
1199	A11	A11 by serology
2300	A*23	A*23 “low resolution”
2301	A*2301	A*2301
2302	A*2302	A*2302
2303	A*2303	A*2303
2304	A*2304	A*2304
2305	A*2305	A*2305
2306	A*2306	A*2306
2399	A23	A23 by serology
2400	A*24	A*24 “low resolution”
2402	A*2402	A*2402101
		A*2402102L
		A*24022
2403	A*2403	A*24031
		A*24032
2404	A*2404	A*2404

Value in bar code	Bar code text	Allele(s)
2405	A*2405	A*2405
2406	A*2406	A*2406
2407	A*2407	A*2407
2408	A*2408	A*2408
0000	—	A*2409N
2410	A*2410	A*2410
0000	—	A*2411N
2413	A*2413	A*2413
2414	A*2414	A*2414
2415	A*2415	A*2415
2416	A*2416	A*2416
2417	A*2417	A*2417
2418	A*2418	A*2418
2420	A*2420	A*2420
2421	A*2421	A*2421
2422	A*2422	A*2422
2423	A*2423	A*2423
2424	A*2424	A*2424
2425	A*2425	A*2425
2426	A*2426	A*2426
2427	A*2427	A*2427
2428	A*2428	A*2428
2429	A*2429	A*2429
2430	A*22430	A*2430
2499	A24	A24 by serology
2500	A*25	A*25 “low resolution”

Value in bar code	Bar code text	Allele(s)
2501	A*2501	A*2501
2502	A*2502	A*2502
2503	A*2503	A*2503
2599	A25	A25 by serology
2600	A*26	A*26 “low resolution”
2601	A*2601	A*2601
2602	A*2602	A*2602
2603	A*2603	A*2603
2604	A*2604	A*2604
2605	A*2605	A*2605
2606	A*2606	A*2606
2607	A*2607	A*2607
2608	A*2608	A*2608
2609	A*2609	A*2609
2610	A*2610	A*2610
0000	—	A*2611N
2612	A*2612	A*2612
2613	A*2613	A*2613
2614	A*2614	A*2614
2615	A*2615	A*2615
2699	A26	A26 by serology
3900	A*29	A*29 “low resolution”
2901	A*2901	A*2901
2902	A*2902	A*2902
2903	A*2903	A*2903
2904	A*2904	A*2904

Value in bar code	**Bar code text**	**Allele(s)**
2999	A29	A29 by serology
3000	A*30	A*30 “low resolution”
3001	A*3001	A*3001
3002	A*3002	A*3002
3003	A*3003	A*3003
3004	A*3004	A*3004
3006	A*3006	A*3006
3007	A*3007	A*3007
3008	A*3008	A*3008
3009	A*3009	A*3009
3099	A30	A30 by serology
3100	A*31	A*31 “low resolution”
3101	A*3101	A*31012
3102	A*3102	A*3102
3103	A*3103	A*3103
3104	A*3104	A*3104
3105	A*3105	A*3105
3199	A31	A31 by serology
3200	A*32	A*32 “low resolution”
3201	A*3201	A*3201
3202	A*3202	A*3202
3203	A*3203	A*3203
3204	A*3204	A*3204
3205	A*3205	A*3205
3206	A*3206	A*3206
3299	A32	A32 by serology

Value in bar code	**Bar code text**	**Allele(s)**
3300	A*33	A*33 “low resolution”
3301	A*3301	A*3301
3303	A*3303	A*3303
3304	A*3304	A*3304
3305	A*3305	A*3305
3306	A*3306	A*3306
3399	A33	A33 by serology
3400	A*34	A*34 “low resolution”
3401	A*3401	A*3401
3402	A*3402	A*3402
3403	A*3403	A*3403
3499	A34	A34 by serology
3600	A*36	A*36 “low resolution”
3601	A*3601	A*3601
3602	A*3602	A*3602
3699	A36	A36 by serology
4300	A*43	A*43 “low resolution”
4301	A*4301	A*4301
4399	A43	A43 by serology
6600	A*66	A*66 “low resolution”
6601	A*6601	A*6601
6602	A*6602	A*6602
6603	A*6603	A*6603
6699	A66	A66 by serology
6800	A*68	A*68 “low resolution”

Value in bar code	Bar code text	Allele(s)
6801	A*6801	A*68011
		A*68012
6802	A*6802	A*6802
6803	A*6803	A*68031
		A*68032
6804	A*6804	A*6804
6805	A*6805	A*6805
6806	A*6806	A*6806
6807	A*6807	A*6807
6808	A*6808	A*6808
6809	A*6809	A*6809
6810	A*6810	A*6810
0000	—	A*6811N
6812	A*6812	A*6812
6813	A*6813	A*6813
6814	A*6814	A*6814
6815	A*6815	A*6815
6816	A*6816	A*6816
6817	A*6817	A*6817
0000	—	A*6818N
6819	A*6819	A*6819
6899	A68	A68 by serology
6900	A*69	A*69 “low resolution”
6901	A*6901	A*6901
6999	A69	A69 by serology
7400	A*74	A*74 “low resolution”

Value in bar code	Bar code text	Allele(s)
7401	A*7401	A*7401
7401	A*7402	A*7402
7403	A*7403	A*7403
7404	A*7404	A*7404
7499	A74	A74 by serology
8000	A*80	A*80 “low resolution”
8001	A*8001	A*8001
8099	A80	A80 by serology

Table J2 Value of "GGGG"and "HHHH": HLA-B Alleles

Value in bar code	Bar code text	Allele(s)
0700	B*07	B*07 "low resolution"
0702	B*0702	B*07021
		B*07022
		B*07023
0703	B*0703	B*0703
0704	B*0704	B*0704
0705	B*0705	B*0705
0706	B*0706	B*0706
0707	B*0707	B*0707
0708	B*0708	B*0708
0709	B*0709	B*0709
0710	B*0710	B*0710
0711	B*0711	B*0711
0712	B*0712	B*0712
0713	B*0713	B*0713
0714	B*0714	B*0714
0715	B*0715	B*0715
0716	B*0716	B*0716
0717	B*0717	B*0717
0718	B*0718	B*0718
0719	B*0719	B*0719
0720	B*0720	B*0720
0722	B*0722	B*0722

Value in bar code	Bar code text	Allele(s)
0723	B*0723	B*0723
0724	B*0724	B*0724
0799	B7	B7 by serology
0800	B*08	B*08 “low resolution”
0801	B*0801	B*0801
0802	B*0802	B*0802
0803	B*0803	B*0803
0804	B*0804	B*0804
0805	B*0805	B*0805
0806	B*0806	B*0806
0807	B*0807	B*0807
0000	—	B*0808N
0809	B*0809	B*0809
0810	B*0810	B*0810
0811	B*0811	B*0811
0812	B*0812	B*0812
0899	B8	B8 by serology
1300	B*13	B*13 “low resolution”
1301	B*1301	B*1301
1302	B*1302	B*1302
1303	B*1303	B*1303
1304	B*1304	B*1304
1306	B*1306	B*1306
0000	—	B*1307N
1399	B13	B13 by serology
1400	B*14	B*14 “low resolution”

Value in bar code	Bar code text	Allele(s)
1401	B*1401	B*1401
1402	B*1402	B*1402
1403	B*1403	B*1403
1404	B*1404	B*1404
1405	B*1405	B*1405
1406	B*1406	B*14061
		B*14062
1499	B14	B14 by serology
1500	B*15	B*15 “low resolution”
1501	B*1501	B*1501101
0000	—	B*1501102N
1501	B*1501	B*15012
		B*15013
1502	B*1502	B*1502
1503	B*1503	B*1503
1504	B*1504	B*1504
1505	B*1505	B*1505
1506	B*1506	B*1506
1507	B*1507	B*1507
1508	B*1508	B*1508
1509	B*1509	B*1509
1510	B*1510	B*1510
1511	B*1511	B*15111
		B*15112
1512	B*1512	B*1512
1513	B*1513	B*1513

Value in bar code	**Bar code text**	**Allele(s)**
1514	B*1514	B*1514
1515	B*1515	B*1515
1516	B*1516	B*1516
1517	B*1517	B*1517
1518	B*1518	B*1518
1519	B*1519	B*1519
1520	B*1520	B*1520
1521	B*1521	B*1521
1522	B*1522	B*1522
1523	B*1523	B*1523
1524	B*1524	B*1524
1525	B*1525	B*1525
0000	—	B*1526N
1527	B*1527	B*1527
1528	B*1528	B*1528
1529	B*1529	B*1529
1530	B*1530	B*1530
1531	B*1531	B*1531
1532	B*1532	B*1532
1533	B*1533	B*1533
1534	B*1534	B*1534
1535	B*1535	B*1535
1536	B*1536	B*1536
1537	B*1537	B*1537
1538	B*1538	B*1538
1539	B*1539	B*1539

Value in bar code	Bar code text	Allele(s)
1540	B*1540	B*1540
1542	B*1542	B*1542
1543	B*1543	B*1543
1544	B*1544	B*1544
1545	B*1545	B*1545
1546	B*1546	B*1546
1547	B*1547	B*1547
1548	B*1548	B*1548
1549	B*1549	B*1549
1550	B*1550	B*1550
1551	B*1551	B*1551
1552	B*1552	B*1552
1553	B*1553	B*1553
1554	B*1554	B*1554
1555	B*1555	B*1555
1556	B*1556	B*1556
1557	B*1557	B*1557
1558	B*1558	B*1558
1559	B*1559	B*1559
1560	B*1560	B*1560
1561	B*1561	B*1561
1562	B*1562	B*1562
1563	B*1563	B*1563
1564	B*1564	B*1564
1599	B15	B15 by serology
1800	B*18	B*18 “low resolution”

Value in bar code	Bar code text	Allele(s)
1801	B*1801	B*1801
1802	B*1802	B*1802
1803	B*1803	B*1803
1804	B*1804	B*1804
1805	B*1805	B*1805
1806	B*1806	B*1806
1807	B*1807	B*1807
1808	B*1808	B*1808
1809	B*1809	B*1809
1810	B*1810	B*1810
1811	B*1811	B*1811
1812	B*1812	B*1812
1899	B18	B18 by serology
2700	B*27	B*27 “low resolution”
2701	B*2701	B*2701
2702	B*2702	B*2702
2703	B*2703	B*2703
2704	B*2704	B*2704
2705	B*2705	B*27052
		B*27053
		B*27054
2706	B*2706	B*2706
2707	B*2707	B*2707
2708	B*2708	B*2708
2709	B*2709	B*2709
2710	B*2710	B*2710

Value in bar code	Bar code text	Allele(s)
2711	B*2711	B*2711
2712	B*2712	B*2712
2713	B*2713	B*2713
2714	B*2714	B*2714
2715	B*2715	B*2715
2716	B*2716	B*2716
2717	B*2717	B*2717
2718	B*2718	B*2718
2719	B*2719	B*2719
2720	B*2720	B*2720
2721	B*2721	B*2721
2722	B*2722	B*2722
2799	B27	B27 by serology
3500	B*35	B*35 “low resolution”
3501	B*3501	B*35011
		B*35012
3502	B*3502	B*3502
3503	B*3503	B*3503
3504	B*3504	B*3504
3505	B*3505	B*3505
3506	B*3506	B*3506
3507	B*3507	B*3507
3508	B*3508	B*3508
3509	B*3509	B*35091
		B*35092
3510	B*3510	B*3510

Value in bar code	Bar code text	Allele(s)
3511	B*3511	B*3511
3512	B*3512	B*3512
3513	B*3513	B*3513
3514	B*3514	B*3514
3515	B*3515	B*3515
3516	B*3516	B*3516
3517	B*3517	B*3517
3518	B*3518	B*3518
3519	B*3519	B*3519
3520	B*3520	B*3520
3521	B*3521	B*3521
3522	B*3522	B*3522
3523	B*3523	B*3523
3524	B*3524	B*3524
3525	B*3525	B*3525
3526	B*3526	B*3526
3527	B*3527	B*3527
3528	B*3528	B*3528
3529	B*3529	B*3529
3530	B*3530	B*3530
3531	B*3531	B*3531
3532	B*3532	B*3532
3533	B*3533	B*3533
3534	B*3534	B*3534
3535	B*3535	B*3535
3536	B*3536	B*3536

Value in bar code	Bar code text	Allele(s)
3537	B*3537	B*3537
3599	B35	B35 by serology
3700	B*37	B*37 “low resolution”
3701	B*3701	B*3701
3702	B*3702	B*3702
0000	—	B*3703N
3799	B37	B37 by serology
3800	B*38	B*38 “low resolution”
3801	B*3801	B*3801
3802	B*3802	B*38021
		B*38022
3803	B*3803	B*3803
3804	B*3804	B*3804
3805	B*3805	B*3805
3806	B*3806	B*3806
3899	B38	B38 by serology
3900	B*39	B*39 “low resolution”
3901	B*3901	B*39011
		B*39013
		B*39014
3902	B*3902	B*39021
		B*39022
3903	B*3903	B*3903
3904	B*3904	B*3904
3905	B*3905	B*3905

Value in bar code	Bar code text	Allele(s)
3906	B*3906	B*39061
		B*39062
3907	B*3907	B*3907
3908	B*3908	B*3908
3909	B*3909	B*3909
3910	B*3910	B*3910
3911	B*3911	B*3911
3912	B*3912	B*3912
3913	B*3913	B*3913
3914	B*3914	B*3914
3915	B*3915	B*3915
3916	B*3916	B*3916
3917	B*3917	B*3917
3918	B*3918	B*3918
3919	B*3919	B*3919
3920	B*3920	B*3920
3921	B*3921	B*3921
3922	B*3922	B*3922
3923	B*3923	B*3923
3924	B*3924	B*3924
3999	B39	B39 by serology
4000	B*40	B*40 “low resolution”
4001	B*4001	B*40011
		B*40012
4002	B*4002	B*4002
4003	B*4003	B*4003

Value in bar code	Bar code text	Allele(s)
4004	B*4004	B*4004
4005	B*4005	B*4005
4006	B*4006	B*4006
4007	B*4007	B*4007
4008	B*4008	B*4008
4009	B*4009	B*4009
4010	B*4010	B*4010
4011	B*4011	B*4011
4012	B*4012	B*4012
4013	B*4013	B*4013
4014	B*4014	B*4014
4015	B*4015	B*4015
4016	B*4016	B*4016
4018	B*4018	B*4018
4019	B*4019	B*4019
4020	B*4020	B*4020
4021	B*4021	B*4021
0000	—	B*4022N
4023	B*4023	B*4023
4024	B*4024	B*4024
4025	B*4025	B*4025
4026	B*4026	B*4026
4027	B*4027	B*4027
4028	B*4028	B*4028
4029	B*4029	B*4029
4030	B*4030	B*4030

Value in bar code	Bar code text	Allele(s)
4031	B*4031	B*4031
4032	B*4032	B*4032
4033	B*4033	B*4033
4034	B*4034	B*4034
4099	B40	B40 by serology
4100	B*41	B*41 “low resolution”
4101	B*4101	B*4101
4102	B*4102	B*4102
4103	B*4103	B*4103
4104	B*4104	B*4104
4105	B*4105	B*4105
4199	B41	B41 by serology
4200	B*42	B*42 “low resolution”
4201	B*4201	B*4201
4202	B*4202	B*4202
4299	B42	B42 by serology
4400	B*44	B*44 “low resolution”
4402	B*4402	B*44021
		B*44022
4403	B*4403	B*44031
		B*44032
4404	B*4404	B*4404
4405	B*4405	B*4405
4406	B*4406	B*4406
4407	B*4407	B*4407
4408	B*4408	B*4408

Value in bar code	Bar code text	Allele(s)
4409	B*4409	B*4409
4410	B*4410	B*4410
4411	B*4411	B*4411
4412	B*4412	B*4412
4413	B*4413	B*4413
4414	B*4414	B*4414
4415	B*4415	B*4415
4416	B*4416	B*4416
4417	B*4417	B*4417
4418	B*4418	B*4418
0000	—	B*4419N
4420	B*4420	B*4420
4421	B*4421	B*4421
4422	B*4422	B*4422
4499	B44	B44 by serology
4500	B*45	B*45 “low resolution”
4501	B*4501	B*4501
4502	B*4502	B*4502
4503	B*4503	B*4503
4599	B45	B45 by serology
4600	B*46	B*46 “low resolution”
4601	B*4601	B*4601
4602	B*4602	B*4602
4699	B46	B46 by serology
4700	B*47	B*47 “low resolution”
4701	B*4701	B*4701

Value in bar code	Bar code text	Allele(s)
4702	B*4702	B*4702
4703	B*4703	B*4703
4799	B47	B47 by serology
4800	B*48	B*48 “low resolution”
4801	B*4801	B*4801
4802	B*4802	B*4802
4803	B*4803	B*4803
4804	B*4804	B*4804
4805	B*4805	B*4805
4806	B*4806	B*4806
4807	B*4807	B*4807
4899	B48	B48 by serology
4900	B*49	B*49 “low resolution”
4901	B*4901	B*4901
4902	B*4902	B*4902
4903	B*4903	B*4903
4999	B49	B49 by serology
5000	B*50	B*50 “low resolution”
5001	B*5001	B*5001
5002	B*5002	B*5002
5004	B*5004	B*5004
5099	B50	B50 by serology
5100	B*51	B*51 “low resolution”

Value in bar code	**Bar code text**	**Allele(s)**
5101	B*5101	B*51011
		B*51012
		B*51013
		B*51014
5102	B*5102	B*51021
		B*51022
5103	B*5103	B*5103
5104	B*5104	B*5104
5105	B*5105	B*5105
5106	B*5106	B*5106
5107	B*5107	B*5107
5108	B*5108	B*5108
5109	B*5109	B*5109
5110	B*5110	B*5110
0000	—	B*5111N
5112	B*5112	B*5112
5113	B*5113	B*51131
		B*51132
5114	B*5114	B*5114
5115	B*5115	B*5115
5116	B*5116	B*5116
5117	B*5117	B*5117
5118	B*5118	B*5118
5119	B*5119	B*5119
5120	B*5120	B*5120
5121	B*5121	B*5121

Value in bar code	Bar code text	Allele(s)
5122	B*5122	B*5122
5123	B*5123	B*5123
5124	B*5124	B*5124
5199	B51	B51 by serology
5200	B*52	B*52 “low resolution”
5201	B*5201	B*52011
		B*52012
		B*52013
5202	B*5202	B*5202
5202	B*5203	B*5203
5299	B52	B52 by serology
5300	B*53	B*53 “low resolution”
5301	B*5301	B*5301
5302	B*5302	B*5302
5303	B*5303	B*5303
5304	B*5304	B*5304
5305	B*5305	B*5305
5306	B*5306	B*5306
5307	B5307	B*5307
5399	B53	B53 by serology
5400	B*54	B*54 “low resolution”
5401	B*5401	B*5401
5402	B*5402	B*5402
5499	B54	B54 by serology
5500	B*55	B*55 “low resolution”
5501	B*5501	B*5501

Value in bar code	Bar code text	Allele(s)
5502	B*5502	B*5502
5503	B*5503	B*5503
5504	B*5504	B*5504
5505	B*5505	B*5505
5507	B*5507	B*5507
5508	B*5508	B*5508
5509	B*5509	B*5509
5510	B*5510	B*5510
5599	B55	B55 by serology
5600	B*56	B*56 “low resolution”
5601	B*5601	B*5601
5602	B*5602	B*5602
5603	B*5603	B*5603
5604	B*5604	B*5604
5605	B*5605	B*5605
5606	B*5606	B*5606
5607	B*5607	B*5607
5699	B56	B56 by serology
5700	B*57	B*57 “low resolution”
5701	B*5701	B*5701
5702	B*5702	B*5702
5703	B*5703	B*57031
		B*57032
5704	B*5704	B*5704
5705	B*5705	B*5705
5706	B*5706	B*5706

Value in bar code	Bar code text	Allele(s)
5707	B*5707	B*5707
5799	B57	B57 by serology
5800	B*58	B*58 "low resolution"
5801	B*5801	B*5801
5802	B*5802	B*5802
5804	B*5804	B*5804
5805	B*5805	B*5805
5806	B*5806	B*5806
5899	B58	B58 by serology
5900	B*59	B*59 "low resolution"
5901	B*5901	B*5901
5999	B59	B59 by serology
6700	B*67	B*67 "low resolution"
6701	B*6701	B*67011
		B*67012
6799	B67	B67 by serology
7300	B*73	B*73 "low resolution"
7301	B*7301	B*7301
7399	B73	B73 by serology
7800	B*78	B*78 "low resolution"
7801	B*7801	B*7801
7802	B*7802	B*78021
		B*78022
7803	B*7803	B*7803
7804	B*7804	B*7804
7899	B78	B78 by serology

Value in bar code	Bar code text	Allele(s)
8100	B*81	B*81 “low resolution”
8101	B*8101	B*8101
8199	B81	B81 by serology
8200	B*82	B*82 “low resolution”
8201	B*8201	B*8201
8202	B*8202	B*8202
8299	B82	B82 by serology
8300	B*83	B*83 “low resolution”
8301	B*8301	B*8301
8399	B83	B83 by serology

Table J3 Value of "IIII" and "JJJJ": HLA-DRB1 Alleles

Value in bar code	Bar code text	Allele(s)
0100	DRB1*01	DRB1*01 "low resolution"
0101	DRB1*0101	DRB1*0101
0102	DRB1*0102	DRB1*01021
		DRB1*01022
0103	DRB1*0103	DRB1*0103
0104	DRB1*0104	DRB1*0104
0105	DRB1*0105	DRB1*0105
0106	DRB1*0106	DRB1*0106
0199	DR1	DR1 by serology
0299	DR2	DR2 by serology
0300	DRB1*03	DRB1*03 "low resolution"
0301	DRB1*0301	DRB1*03011
		DRB1*03012
0302	DRB1*0302	DRB1*03021
		DRB1*03022
0303	DRB1*0303	DRB1*0303
0304	DRB1*0304	DRB1*0304
0305	DRB1*0305	DRB1*0305
0306	DRB1*0306	DRB1*0306
0307	DRB1*0307	DRB1*0307
0308	DRB1*0308	DRB1*0308
0309	DRB1*0309	DRB1*0309
0310	DRB1*0310	DRB1*0310

Value in bar code	Bar code text	Allele(s)
0311	DRB1*0311	DRB1*0311
0312	DRB1*0312	DRB1*0312
0313	DRB1*0313	DRB1*0313
0314	DRB1*0314	DRB1*0314
0315	DRB1*0315	DRB1*0315
0316	DRB1*0316	DRB1*0316
0317	DRB1*0317	DRB1*0317
0399	DR3	DR3 by serology
0400	DRB1*04	DRB1*04 “low resolution”
0401	DRB1*0401	DRB1*04011
		DRB1*04012
0402	DRB1*0402	DRB1*0402
0403	DRB1*0403	DRB1*04031
		DRB1*04032
0404	DRB1*0404	DRB1*0404
0405	DRB1*0405	DRB1*04051
		DRB1*04052
0406	DRB1*0406	DRB1*0406
0407	DRB1*0407	DRB1*0407
0408	DRB1*0408	DRB1*0408
0409	DRB1*0409	DRB1*0409
0410	DRB1*0410	DRB1*0410
0411	DRB1*0411	DRB1*0411
0412	DRB1*0412	DRB1*0412
0413	DRB1*0413	DRB1*0413
0414	DRB1*0414	DRB1*0414

Value in bar code	**Bar code text**	**Allele(s)**
0415	DRB1*0415	DRB1*0415
0416	DRB1*0416	DRB1*0416
0417	DRB1*0417	DRB1*0417
0418	DRB1*0418	DRB1*0418
0419	DRB1*0419	DRB1*0419
0420	DRB1*0420	DRB1*0420
0421	DRB1*0421	DRB1*0421
0422	DRB1*0422	DRB1*0422
0423	DRB1*0423	DRB1*0423
0424	DRB1*0424	DRB1*0424
0425	DRB1*0425	DRB1*0425
0426	DRB1*0426	DRB1*0426
0427	DRB1*0427	DRB1*0427
0428	DRB1*0428	DRB1*0428
0429	DRB1*0429	DRB1*0429
0430	DRB1*0430	DRB1*0430
0431	DRB1*0431	DRB1*0431
0432	DRB1*0432	DRB1*0432
0433	DRB1*0433	DRB1*0433
0434	DRB1*0434	DRB1*0434
0435	DRB1*0435	DRB1*0435
0436	DRB1*0436	DRB1*0436
0599	DR5	DR5 by serology
0699	DR6	DR6 by serology
0700	DRB1*07	DRB1*07 “low resolution”

Value in bar code	**Bar code text**	**Allele(s)**
0701	DRB1*0701	DRB1*07011
		DRB1*07012
0703	DRB1*0703	DRB1*0703
0704	DRB1*0704	DRB1*0704
0799	DR7	DR7 by serology
0800	DRB1*08	DRB1*08 “low resolution”
0801	DRB1*0801	DRB1*0801
0802	DRB1*0802	DRB1*08021
		DRB1*08022
0803	DRB1*0803	DRB1*08032
0804	DRB1*0804	DRB1*08041
		DRB1*08042
		DRB1*08043
0805	DRB1*0805	DRB1*0805
0806	DRB1*0806	DRB1*0806
0807	DRB1*0807	DRB1*0807
0808	DRB1*0808	DRB1*0808
0809	DRB1*0809	DRB1*0809
0810	DRB1*0810	DRB1*0810
0811	DRB1*0811	DRB1*0811
0812	DRB1*0812	DRB1*0812
0813	DRB1*0813	DRB1*0813
0814	DRB1*0814	DRB1*0814
0815	DRB1*0815	DRB1*0815
0816	DRB1*0816	DRB1*0816
0817	DRB1*0817	DRB1*0817

Value in bar code	Bar code text	Allele(s)
0818	DRB1*0818	DRB1*0818
0819	DRB1*0819	DRB1*0819
0820	DRB1*0820	DRB1*0820
0821	DRB1*0821	DRB1*0821
0822	DRB1*0822	DRB1*0822
0899	DR8	DR8 by serology
0900	DRB1*09	DRB1*09 “low resolution”
0901	DRB1*0901	DRB1*09012
0999	DR9	DR9 by serology
1000	DRB1*10	DRB1*10 “low resolution”
1001	DRB1*1001	DRB1*10011
		DRB1*10012
1099	DR10	DR10 by serology
1100	DRB1*11	DRB1*11 “low resolution”
1101	DRB1*1101	DRB1*11011
		DRB1*11012
		DRB1*11013
1102	DRB1*1102	DRB1*1102
1103	DRB1*1103	DRB1*1103
1104	DRB1*1104	DRB1*11041
		DRB1*11042
1105	DRB1*1105	DRB1*1105
1106	DRB1*1106	DRB1*1106
1107	DRB1*1107	DRB1*1107
1108	DRB1*1108	DRB1*11081
		DRB1*11082

Value in bar code	Bar code text	Allele(s)
1109	DRB1*1109	DRB1*1109
1110	DRB1*1110	DRB1*1110
1111	DRB1*1111	DRB1*1111
1112	DRB1*1112	DRB1*1112
1113	DRB1*1113	DRB1*1113
1114	DRB1*1114	DRB1*1114
1115	DRB1*1115	DRB1*1115
1116	DRB1*1116	DRB1*1116
1117	DRB1*1117	DRB1*1117
1118	DRB1*1118	DRB1*1118
1119	DRB1*1119	DRB1*1119
1120	DRB1*1120	DRB1*1120
1121	DRB1*1121	DRB1*1121
1122	DRB1*1122	DRB1*1122
1123	DRB1*1123	DRB1*1123
1124	DRB1*1124	DRB1*1124
1125	DRB1*1125	DRB1*1125
1126	DRB1*1126	DRB1*1126
1127	DRB1*1127	DRB1*11271
		DRB1*11272
1128	DRB1*1128	DRB1*1128
1129	DRB1*1129	DRB1*1129
1130	DRB1*1130	DRB1*1130
1131	DRB1*1131	DRB1*1131
1132	DRB1*1132	DRB1*1132
1133	DRB1*1133	DRB1*1133

Value in bar code	Bar code text	Allele(s)
1134	DRB1*1134	DRB1*1134
1135	DRB1*1135	DRB1*1135
1136	DRB1*1136	DRB1*1136
1137	DRB1*1137	DRB1*1137
1138	DRB1*1138	DRB1*1138
1139	DRB1*1139	DRB1*1139
1140	DRB1*1140	DRB1*1140
1141	DRB1*1141	DRB1*1141
1199	DR11	DR11 by serology
1200	DRB1*12	DRB1*12 “low resolution”
1201	DRB1*1201	DRB1*1201
1202	DRB1*1202	DRB1*12021
		DRB1*12022
1203	DRB1*1203	DRB1*12032
1204	DRB1*1204	DRB1*1204
1205	DRB1*1205	DRB1*1205
1206	DRB1*1206	DRB1*1206
1299	DR12	DR12 by serology
1300	DRB1*13	DRB1*13 “low resolution”
1301	DRB1*1301	DRB1*13011
1302	DRB1*1302	DRB1*13021
		DRB1*13022
1202	DRB1*1303	DRB1*13031
		DRB1*13032
1304	DRB1*1304	DRB1*1304
1305	DRB1*1305	DRB1*1305

Value in bar code	Bar code text	Allele(s)
1306	DRB1*1306	DRB1*1306
1307	DRB1*1307	DRB1*13071
		DRB1*13072
1308	DRB1*1308	DRB1*1308
1309	DRB1*1309	DRB1*1309
1310	DRB1*1310	DRB1*1310
1311	DRB1*1311	DRB1*1311
1312	DRB1*1312	DRB1*1312
1313	DRB1*1313	DRB1*1313
1314	DRB1*1314	DRB1*13141
		DRB1*13142
1315	DRB1*1315	DRB1*1315
1316	DRB1*1316	DRB1*1316
1317	DRB1*1317	DRB1*1317
1318	DRB1*1318	DRB1*1318
1319	DRB1*1319	DRB1*1319
1320	DRB1*1320	DRB1*1320
1321	DRB1*1321	DRB1*1321
1322	DRB1*1322	DRB1*1322
1323	DRB1*1323	DRB1*1323
1324	DRB1*1324	DRB1*1324
1325	DRB1*1325	DRB1*1325
1326	DRB1*1326	DRB1*1326
1327	DRB1*1327	DRB1*1327
1328	DRB1*1328	DRB1*1328
1329	DRB1*1329	DRB1*1329

Value in bar code	**Bar code text**	**Allele(s)**
1330	DRB1*1330	DRB1*1330
1331	DRB1*1331	DRB1*1331
1332	DRB1*1332	DRB1*1332
1333	DRB1*1333	DRB1*1333
1334	DRB1*1334	DRB1*1334
1335	DRB1*1335	DRB1*1335
1336	DRB1*1336	DRB1*1336
1337	DRB1*1337	DRB1*1337
1338	DRB1*1338	DRB1*1338
1339	DRB1*1339	DRB1*1339
1340	DRB1*1340	DRB1*1340
1341	DRB1*1341	DRB1*1341
1342	DRB1*1342	DRB1*1342
1343	DRB1*1343	DRB1*1343
1344	DRB1*1344	DRB1*1344
1399	DR13	DR13 by serology
1400	DRB1*14	DRB1*14 “low resolution”
1401	DRB1*1401	DRB1*14011
		DRB1*14012
1402	DRB1*1402	DRB1*1402
1403	DRB1*1403	DRB1*1403
1404	DRB1*1404	DRB1*1404
1405	DRB1*1405	DRB1*1405
1406	DRB1*1406	DRB1*1406
1407	DRB1*1407	DRB1*1407
1408	DRB1*1408	DRB1*1408

Value in bar code	Bar code text	Allele(s)
1409	DRB1*1409	DRB1*1409
1410	DRB1*1410	DRB1*1410
1411	DRB1*1411	DRB1*1411
1412	DRB1*1412	DRB1*1412
1413	DRB1*1413	DRB1*1413
1414	DRB1*1414	DRB1*1414
1415	DRB1*1415	DRB1*1415
1416	DRB1*1416	DRB1*1416
1417	DRB1*1417	DRB1*1417
1418	DRB1*1418	DRB1*1418
1419	DRB1*1419	DRB1*1419
1420	DRB1*1420	DRB1*1420
1421	DRB1*1421	DRB1*1421
1422	DRB1*1422	DRB1*1422
1423	DRB1*1423	DRB1*1423
1424	DRB1*1424	DRB1*1424
1425	DRB1*1425	DRB1*1425
1426	DRB1*1426	DRB1*1426
1427	DRB1*1427	DRB1*1427
1428	DRB1*1428	DRB1*1428
1429	DRB1*1429	DRB1*1429
1430	DRB1*1430	DRB1*1430
1431	DRB1*1431	DRB1*1431
1432	DRB1*1432	DRB1*1432
1433	DRB1*1433	DRB1*1433
1434	DRB1*1434	DRB1*1434

Value in bar code	Bar code text	Allele(s)
1435	DRB1*1435	DRB1*1435
1436	DRB1*1436	DRB1*1436
1437	DRB1*1437	DRB1*1437
1499	DR14	DR14 by serology
1500	DRB1*15	DRB1*15 “low resolution”
1501	DRB1*1501	DRB1*15011
		DRB1*15012
1502	DRB1*1502	DRB1*15021
		DRB1*15022
		DRV1*15023
1503	DRB1*1503	DRB1*1503
1504	DRB1*1504	DRB1*1504
1505	DRB1*1505	DRB1*1505
1506	DRB1*1506	DRB1*1506
1507	DRB1*1507	DRB1*1507
1508	DRB1*1508	DRB1*1508
1509	DRB1*1509	DRB1*1509
1510	DRB1*1510	DRB1*1510
1599	DR15	DR15 by serology
1600	DRB1*16	DRB1*16 “low resolution”
1601	DRB1*1601	DRB1*16011
		DRB1*16012
1602	DRB1*102	DRB1*16021
		DRB1*16022
1603	DRB1*1603	DRB1*1603
1604	DRB1*1604	DRB1*1604

Value in bar code	**Bar code text**	**Allele(s)**
1605	DRB1*1605	DRB1*1605
1607	DRB1*1607	DRB1*1607
1608	DRB1*1608	DRB1*1608
1699	DR16	DR16 by serology

Table J4 Value of "L": Anti-CMV Status

Value	Anti-CMV Status
0	nt
1	neg
2	pos

Table J5 Interpretation of Characters Appearing After the First Four Numbers in Genomically-Determined HLA-A, -B and -DRB1 Alleles

Characters	Interpretation
N	a null allele
1	an allele that differs by a synonymous mutation in the coding region
2	an allele that differs by a synonymous mutation in the coding region
3	an allele that differs by a synonymous mutation in the coding region
4	an allele that differs by a synonymous mutation in the coding region
101	an allele that contains a mutation outside the coding region
102	an allele that contains a mutation outside the coding region
102L	an allele that contains a mutation outside the coding region, causing low allele expression
102N	a null allele that contains a mutation outside the coding region

J.1 Printing the Bar Codes in the Right Lower Quadrant

Since the expiration date of the product also appears in this quadrant, care should be taken in placing the two bar codes such that there is room for the bar code and label text for all three bar codes, and that the bar codes maintain the required quiet zone to facilitate accurate scanning. It is recommended that to achieve the appropriate compromise, the bar code height be reduced to 0.4" (10.2 mm). The illustration below indicates the space occupied by the bar codes and bar code text and the space available for label text using this recommendation.

Note: If these long bar codes are scanned using wands (“pens”) it will require extra care to ensure that the entire symbol is traversed.