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GUIDELINE FOR THE UNIFORM LABELING OF BLOOD AND BLOOD COMPONENTS

Prepared by
Food and Drug Administration
Center for Drugs and Biologics
Office of Biologics Research and Review
in cooperation with
The American Blood Commission

August 1985

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SECTION V. TECHNICAL SPECIFICATIONS FOR LABELS AND SYMBOLS

SECTION I. UNIFORM LABELING

A. Introduction

The information in this guideline is intended for any persons with responsibility for blood component labeling. The technical information contained in Section V should be of particular interest to label producers and designers of electronic data processing (EDP) systems used in a blood banking environment.

This guideline supersedes all previous publications on the subject of Uniform Labeling, including "Guideline(s) for the Uniform Labeling of Blood and Blood Components" issued in July 1980 and August 1984 (draft), and "Uniform Labeling of Blood and Blood Components; Users Guide, September 1982."

Label illustrations in this document should not be used as print masters, since the readability of the bar codes would be severely impaired and fall outside the symbol specifications.

The labels shown in Section IV of this guideline have been reviewed and approved by the Food and Drug Administration (FDA) as consistent with current regulations on good manufacturing practices for blood and blood components (21 CFR Part 606). Other labels which are printed in accordance with the specifications contained herein may be used without prior review and FDA approval. However, licensed establishments are required to submit all final label samples concurrent with use to the Director, Office of Biologics Research and Review (OBRR), (HFN-825), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20205. Note that some blood components listed in this guideline are not currently approved by the FDA; these are footnoted in the tables.

A major part of blood component labeling is the instruction circular. An FDA-approved circular, such as the "Circular of Information for the Use of Human Blood and Blood Components" produced by the American Red Cross (ARC), the Council of Community Blood Centers (CCBC), and the American Association of Blood Banks (AABB), must be available to all involved in the transfusion of blood and blood components.

Comments on this guideline (identified with Docket No. 80N-0120) should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

B. History of CCBBA

The Committee of Commonality in Blood Banking Automation (CCBBA) was established in June 1974 under the joint sponsorship of the AABB, the ARC, and the CCBC. The CCBBA came under the aegis of the American Blood Commission (ABC) in June 1975. It was subsequently funded by the National Heart, Lung and Blood

Institute and, from its inception, received the cooperation of the FDA.

In July 1979, ABC/CCBBA submitted its final report to the FDA, which accepted and approved its recommendations. The published regulations based on the CCBBA report directly affect all licensed and unlicensed blood banks through current good manufacturing practices for blood and blood components (21 CFR Part 606).

C. Purpose of the Label

The objective of the uniform blood component label is to reduce the danger of incompatible transfusions caused through human errors by presenting important information in a clear, logical and easily recognizable format. Although the use of machine-readable symbols on blood component labels is not required by the FDA, the CCBBA format provides for such a symbol (bar code) to promote accurate transfer of information and ease in tracking the blood through all steps from donor to patient when used in carefully designed EDP systems.

An adaptation of Codabar was chosen as the ABC bar code or symbol because it meets rigid standards for readability and low error potential. The ABC symbol is currently the only FDA-approved machine-readable symbol for use in blood component labeling. Other symbols, such as Code 39 and UPC which are also used in medical facilities, can easily co-exist with Codabar when electronic readers have appropriate decoders.

D. Use of Uniform Labeling in EDP Systems

Implementation of EDP systems designed to fully utilize the security and format features of the label can reduce the chance for human errors. Many of the bar codes are interdependent for information exchange and security checks. EDP systems designed to defeat or circumvent certain features of the labels could result in error prone procedures. FDA's regulations on current good manufacturing practices for blood and blood components (21 CFR Part 606) assume that a secure and error-free system will be utilized when automation is introduced into a blood banking service.

The ABC provides referrals to inquiries for assistance in EDP system design. (Contact The American Blood Commission, 1117 N. 19th Street, Suite 501, Arlington, VA 22209, 703/522-8414.) The ABC also coordinates its work on standardization of the uniform blood label with the International Society of Blood Transfusion's (ISBT) Standing Committee on Automation and Data Processing.

SECTION II. THE UNIFORM BLOOD LABEL AS AN EYE- AND MACHINE-READABLE LABEL

A. Introduction

This section shows the types of labels and how they fit on primary and satellite bags.

Manufacturers of blood bags state on the label the anticoagulant and its composition, the name and address of manufacturer or distributor, lot number, and other information to help in the label placement procedures. Bag manufacturers may also bar-code information such as the anticoagulant type, bag set configuration (single, double, triple, etc.), and type of plastic used in satellite bags (see Section II, D, 3, i & ii).

Bag manufacturers may prelabel the primary bag of a multiple set, "Red Blood Cells" and the single bag, "Whole Blood." When the blood component actually released for transfusion is not as is shown on the label, then the correct component over-label must be applied (for example, when the component in the primary bag of a multiple set becomes "Whole Blood, Cryoprecipitate Removed").

B. Bar Codes and Transmission of Information from the Label

Numbers are often used to represent the information encoded in machine-readable symbols. For example in the CCBBA format, 51 represents group O positive while 040 represents Red Blood Cells. Unique control codes are used to distinguish the numeric code representations, such as between a blood group code and a component name code.

The simplest and most accurately transmitted machine-readable symbols are bar codes. They are composed of wide and narrow vertical lines separated by wide and narrow spaces. A pattern of bars and spaces makes up a character in the bar code alphabet. (The technical specifications for the ABC symbol can be found in Section V, C.)

A scanner (light pen or laser) shines light over the bar code. Lines are black and absorb light while spaces reflect light back to the scanner. The pattern of absorbance and reflectance is converted by the scanner's reader into electrical impulses which are decoded into numeric code representations for computer display on a terminal and/or storage into memory files.

The numeric code can be translated by a computer back to the original non-encoded form (such as translating "040" to "Red Blood Cells"). To do this the computer fits the coded information received by the scanner with master information (look-up tables) stored in its memory. When information is found that matches the code, the computer displays it on a terminal.

The accuracy of the information transfer to the computer depends highly on the quality of the printed bar code. Two types

of errors can occur with poor quality symbols. Substitution errors are very serious because inaccurate information might be transmitted. The second type of error in reading results in a non-translatable message. The danger in this type of error results when a label reading failure requires the less secure manual keyboard entry of data.

Most on-site printing devices currently do not produce labels of the quality of professionally printed labels. Several on-site label printing devices under development (i.e., laser and thermal) may approach or meet the specifications in Section V and yield acceptable test results under protocols in Appendix A. No matter what the source of the label, however, the consumer should request that the supplier of the printing device or label show how his or her product will consistently meet the specifications and quality control measures contained in this guideline. Products failing to meet these criteria may compromise the secure transfer of data.

C. Information on the Uniform Blood Component Label

The information most prominently displayed on the CCBBA label, in both eye-readable and in machine-readable form, are: blood donor grouping results (ABO and Rh); the component name with appropriate qualifiers; the unique donation (or unit) number; the blood collection date (if used); and identification of the center collecting and processing the blood using the FDA registration number. In eye-readable form only are other FDA-required label statements, such as indicating that the blood came from a volunteer or paid donor, the expiration date of the blood component, referring the user to an instruction circular, and the infectious diseases and prescription warnings.

Most information formerly required by the FDA to be on blood component labels, and optional information added by the blood bank or center, must now be transferred to the instruction circular provided to the transfusion service by the blood bank or center.

D. Structure of Bar-Coded Messages

The encoded information is grouped into three separate message areas (see Section II, Figures 1-3). The first is a combination of the collection date (when used), the donation number, and the blood group or special information. This message area is situated across the top of the label. The second area is the blood component information located near the middle of the label. The third is the collection/processing center identification area located in the lower right corner.

1. Collection and Expiration Dating

a. Collection Date Label

The use of a collection date on a blood component requires in-house capabilities to produce such labels or a sufficient supply of predated professionally printed labels.

Most EDP systems currently in use are based on the manual entry of a collection date to cover a series of donation numbers for blood units collected on a particular day. However, the collection date label can be used in EDP systems to generate expiration dates for the various components produced when used in conjunction with anticoagulant and plastic codes (see 3, a, following), and the blood component label code (see 4).

The collection date field consists of seven characters. The first represents a collection date label identifying start code. The following five characters are the collection date represented in five digits (month, month, day, day, and the last digit of the year). For example, the date February 12, 1985 or 2/12/85, is displayed as 02125. The last or seventh character is a pause code that permits the combining of collection date code with the donation number and grouping or special message information. (See Section II, Figure 4 for an example and Section III, Table 1 for code assignments.)

b. Bar-Coded Expiration Dating

No allowance for the bar-coding of the expiration date of a blood component was made by the CCBBA. It was felt that the collection date combined with component and anticoagulant codes was sufficient to generate expiration dates for each component. However, such labels are in use in several blood centers. The labels are produced using on-site printers.

The character field for the expiration date is the same as that noted for the collection date except for the identifying start and stop codes. (See Section III, Table 1.)

2. Blood Donation (Unit) Number Label

a. Seven Digit Numbers

Each unit of blood collected by a facility (or within a region) must have a unique number assigned to identify it

with its donor. Up to seven digits may be used in this donation number (also called the unit or whole blood number).

The field for the blood donation code has nine-characters, a unique seven-digit number preceded and followed by pause codes. Special decoding rules apply for secure linking of the donation number with blood grouping and special message information (see Section V, C, 5.).

b. Alpha-Numeric Combinations

A large blood center may wish to use the first two digits of the donation number to represent alphabetic characters for identifying different mobile and fixed collection facilities within a blood service region. The alpha prefix is then followed by a five digit unique donation number. Section II, Figures 6 & 7 show different options for alpha-numeric combinations. The chart in Figure 7 shows how to identify up to 100 collection sites within a region; each site having up to 99,000 donations uniquely identified before starting over. The signal to the EDP system as to whether the first two numbers in the code remain as digits, or represent alphas, is contained in the start code of the collection/processing center identification label (see 5., following).

c. Regional Blood Center Prefix Codes

At least one organization (American Red Cross) adds a two-digit prefix to the seven character alpha-numeric combination for identifying its regions in the donation number. These prefix digits are not encoded in the donation number but can be generated from a look-up table in the EDP system when the region is identified by a scanning of the Federal Registration Number code in the center identification label.

3. Blood Grouping/Special Information Code Areas

This five character field transmits a variety of information. The first character is a pause code followed by a two-digit message code and ending with a two-character stop code. Different stop codes distinguish the type of information contained in the two-digit message. (See Section III, Table 1.)

a. Codes for Anticoagulants and Package and Plastic Types

i. The Primary Bag

In the upper right corner of a primary bag label is an area

encoded with information of the packaging type -- single, double, triple, quad (see Section II, Fig. 2 and Section III, Table 10) plus a code for the anticoagulant type (see Section III, Table 6). The anticoagulant codes can be used in an EDP system to generate expiration dates for various blood components. The package codes can be used to set up a file of components for inventory control (eg. a triple bag code will set up a file for three components). This code (and a similar one on satellite bags - see following) is usually covered by a blood group or special message label before the component leaves the processing center (see Section II, Figs. 7 & 8).

ii. Satellite and Transfer Bags

These bags have codes in the upper right corner (See Section II, Fig. 3) which refer to the volume capacity of the bag and the plastic film from which the bag has been made (see Section III, Table 11). The plastic type may have a bearing on the shelf-life of the components that are to be stored in the bag. This code can be used in an EDP system to differentiate, for example, between seven-day and three-day platelet plastics when generating expiration dates at the time of labeling.

b. Blood Group Labels

The FDA requires that all blood components prepared for transfusion have the blood group indicated on the component container. Two sets of codes exist to indicate ABO group with or without Rh (D) types (see Section III, Table 12).

If color is used to distinguish ABO group, then the right half of the label is tinted with the following color scheme (see Section V, A, 2. for exact color specifications):

Group O:	Blue
Group A:	Yellow
Group B:	Pink
Group AB:	White

Blood group labels may be produced in a variety of styles as illustrated in Section II, Figure 8. The style variations relate as to when and how an expiration date is generated on the component container, and as to whether the collection/processing identification label is part of, or separate from, the blood group label. Under labeling schemes used by most blood centers, the blood group label is not applied until all blood group, infectious diseases, and appropriate antibody testing has been performed and the components are satisfactory for transfusion. (Also see

1,b. above regarding expiration dating.)

c. Special Message Labels

Several color-coded special message labels have been devised (See Section II, Figure 8).

i. Hold for Further Processing (tan) -- used within a blood center to indicate that preliminary typing or testing results, such as for Rh or HBsAg, warrant further or repeat testing before the component can be released for transfusion.

ii. For Emergency Use Only By.....(orange) -- used to identify components which need to be released to a transfusing facility prior to completion of all test results, as prescribed in 21 CFR 640.2[f]. Results of tests completed are filled in, or an indication such as, "not done" or, "pending" is used.

iii. For Autologous Use Only (green) -- used on components collected for autologous transfusion from donors/patients who do not meet donor suitability criteria or whose blood is being reserved only for autologous indication. If autologous components are made from patients with an infectious disease, such a notation is usually placed on the component in addition to the autologous label (eg: use of a Biohazard label).

iv. Not For Transfusion (gray) -- used for blood components that are not to be used for transfusion purposes (for other than biohazard reasons), such as research and reagent production. This label need not be used on noninjectable components for further manufacturing if a noninjectable component label is used, (See Section IV, Fig. 11)

v. Irradiated (purple) -- used to indicate a component irradiated to suppress immune function by white blood cells carried in the component. The FDA has ruled that an irradiated blood component may be used only in patients at risk from graft vs. host response.

vi. Biohazard (red) -- used to alert handlers of blood components of a known or suspect risk (such as blood from a donor or patient which is reactive for HBsAg or HTLV-III antibody) or undocumented risk (such as blood from a subsequently infected or suspect donor). Biohazard components should be sterilized, such as by autoclaving, before disposal.

vii. From a Therapeutic Phlebotomy (chartreuse) -- used on blood components obtained through therapeutic phlebotomy, but determined by the medical director of a blood center to be safe for transfusion. The label is used to inform physicians attending the prospective recipient.

viii. Other Special Messages -- components which have been screened for special factors (such as for HLA type or CMV antibody) are usually best handled by using a tie-tag rather than indication of the results of these tests on the label itself.

4. Blood Component (Product) Label

Blood component (or product) labels are for overlay or placement on primary or satellite bags. Examples of these labels can be seen in Section IV, C-H. Included on this label both eye- and machine-readable form are: the proper name of blood component (such as "Red Blood Cells"); qualifiers for the component (such as "Frozen"); component contents either as standard contents [1] or written on the label, such as the volume of plasma components; temperature (in degrees Celsius) at which the component must be stored [2]; and the name of the source material, as applicable (for example, from 450 mL of Whole Blood).

The blood component code field consists of nine characters. The first two make up the start code and the last two, a stop code. The middle five characters contain the numeric message which provides information about the blood component; the first three identify the blood component (Section III, Tables 3, 4, and 5), the fourth digit indicates the anticoagulant (for Whole Blood and Red Blood Cells - Section III, Tables 6 and 7) or method of preparation for other blood components (Section III, Table 8), and the fifth digit indicates component contents.

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1. The term "standard contents" is used when the product is prepared according to the label and as described in the instruction circular. For example, Red Blood Cells, from 450 mL of Whole Blood prepared as described in the instruction circular, has standard contents. A component such as Platelets, from 450 mL of Whole Blood may have standard contents, however, the volume of the component must also appear on the label in eye-readable form.

2. Degree symbol may be deleted on label.

An example of how the code is derived is shown below (see Section III for table references):

Component: Red Blood Cells, Frozen
From 450 mL of CPDA-1 Whole Blood

Component Code (Table 4)	Method of Preparation (Table 8)	Content Code (Table 9)
062	0	0

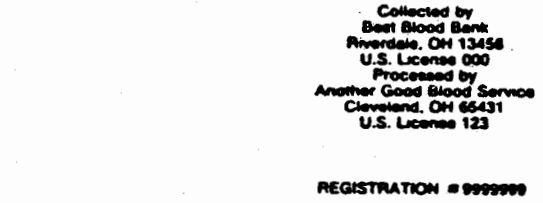
Thus the component code is 06200

5. Collection/Processing Center Identification Label

The FDA assigns each registered blood drawing site a seven-digit registration number; a unique five-digit number preceded by a two-digit FDA regional code (other countries assign a two-digit "national code"). The seven-digit message has start and stop codes, each containing two characters, making up an eleven-character field. As mentioned above (2. Blood Donation Number Label), the start code of the center identification label can indicate to an EDP system whether the first two characters of the donation number are to remain as numbers or become alphabetic prefixes. (See Section III, Table 1.)

If alphabetic characters are used within a blood service region to consistently identify the different mobiles or fixed sites, the registration number of the primary blood processing location within that region need be the only FDA registration number to appear on the region's label.

When blood is collected by one facility and processsed by a different manufacturer (eg., two blood banks operating under different FDA licenses), the names and addresses of both facilities must appear on the label. The registration number of only the processing location, however, need appear on such labels in machine-readable form.



E. Blood Derivative Codes

The ABC and the ISBT, in cooperation with the Health Industry Bar Code Council, recommend that blood products obtained through fractionation processes (blood derivatives) be identified with an FDA approved National Drug Code (NDC). The recommended machine-readable symbols for an NDC are either Code 39 or UPC bar codes. If you wish more information please contact the ABC.

F. New Component Codes

New components which become recognized by the blood banking community will be assigned codes by the FDA. If a blood bank produces a component not listed in the accompanying tables, it should direct inquiries for assignment of codes to the FDA. The FDA will periodically publish new codes.

FIG 1

PLACEMENT OF MACHINE-READABLE INFORMATION ON BLOOD BAGS

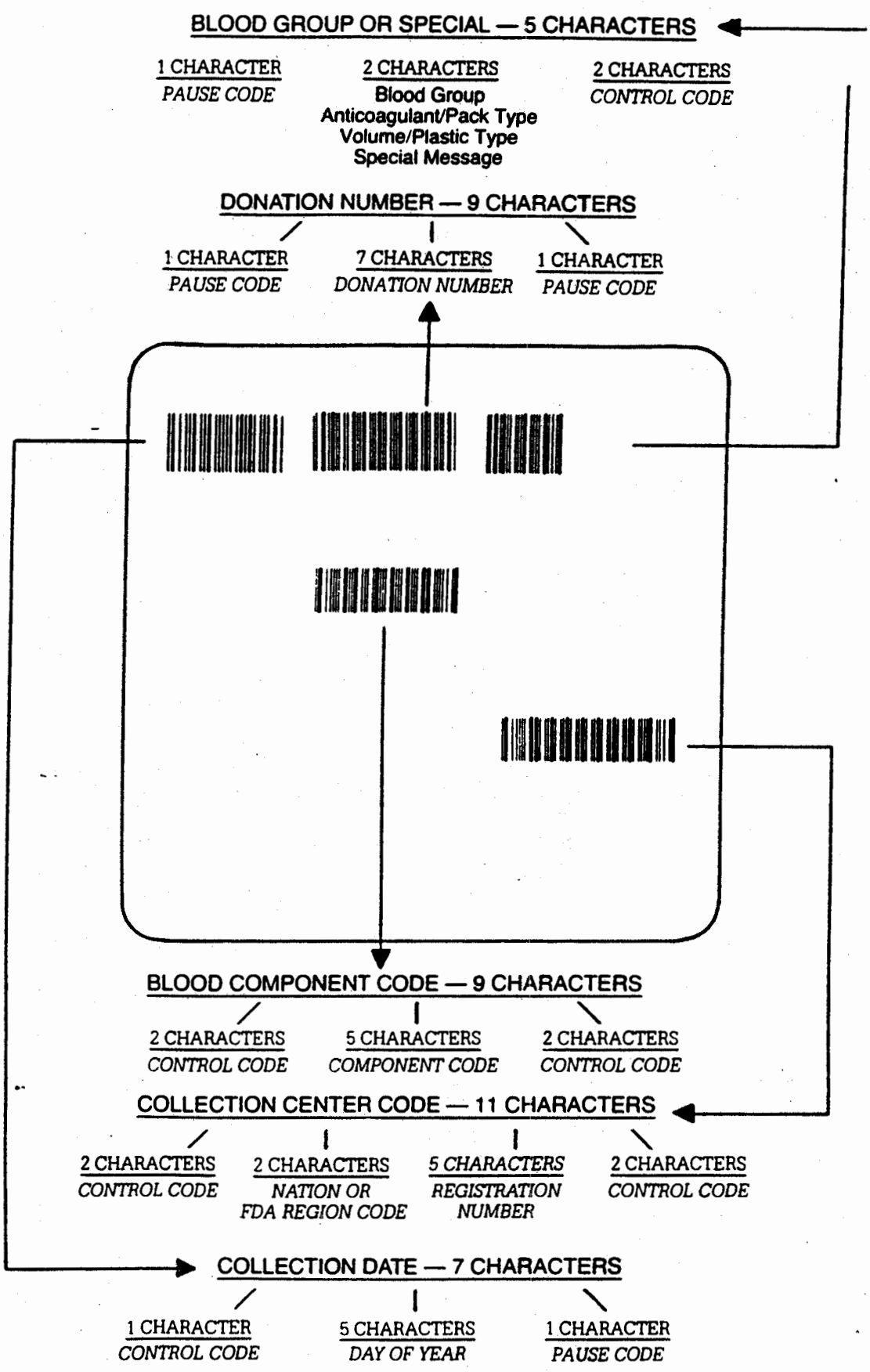


FIG 2

Primary Bag of Multiple Set

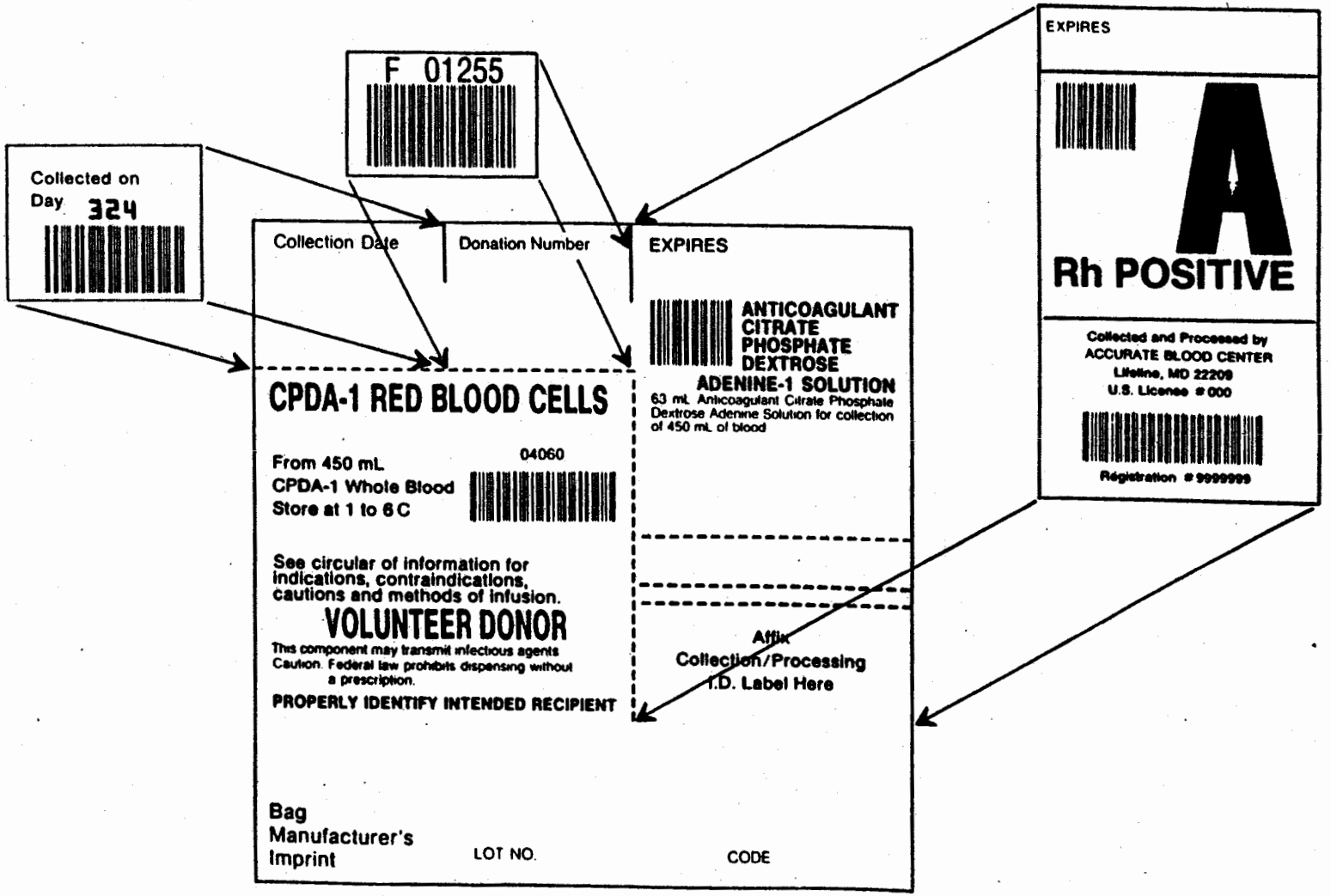
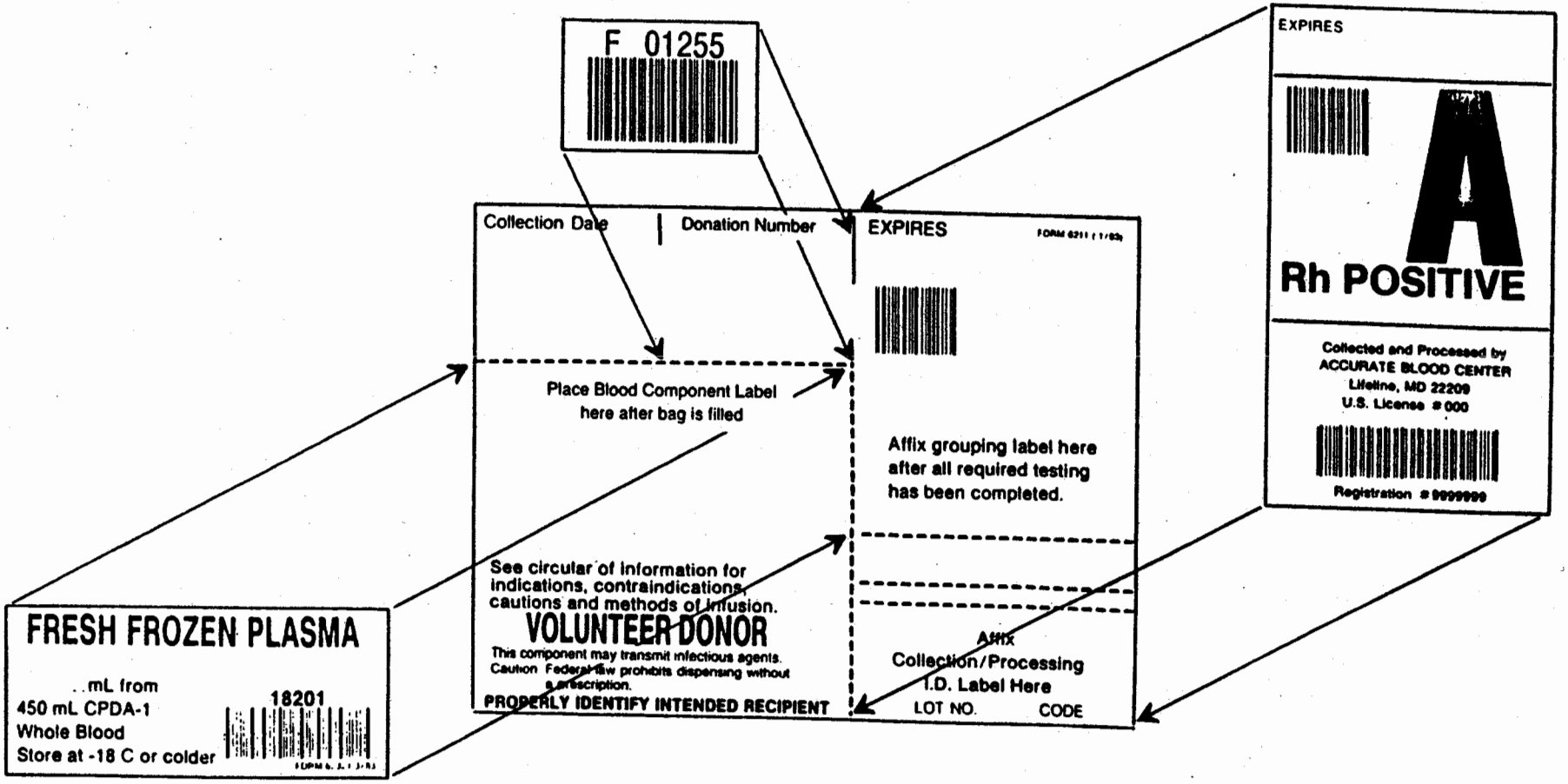


FIG 3

Satellite or Transfer Bag Label



COLLECTION DATE LABEL
(OPTIONAL)

MONTH,MONTH, DAY ,DAY,YEAR DATING

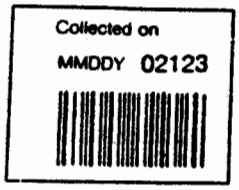
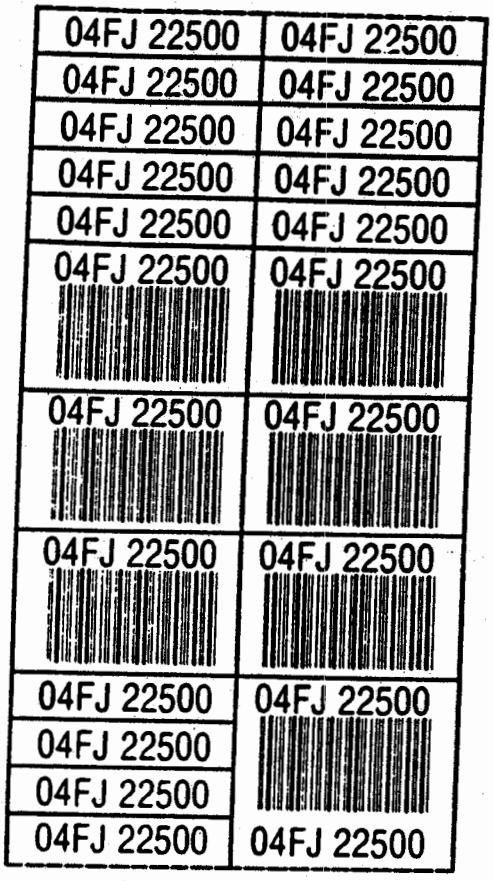


FIG 5

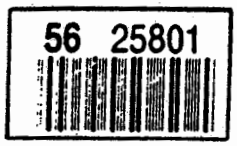
THERE ARE MANY OPTIONAL FORMATS FOR DONATION NUMBER SETS

TYPICAL DONATION NUMBER SET:



NUMBERING ROUTINE OPTIONS FOR DONATION NUMBER LABELS

Full numbers for larger centers



Alpha characters to conform with existing systems

SINGLE ALPHA

Initial two numbers identify different centers that operate under one license

SINGLE ALPHA

Initial zeros suppressed for smaller centers

DOUBLE ALPHA

DOUBLE ALPHA

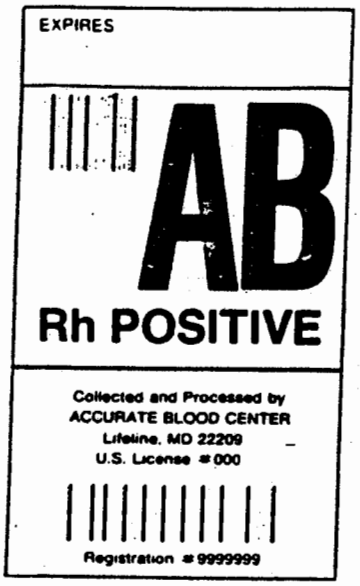
ALPHABETIC UNIT NUMBER PREFIX TABLE

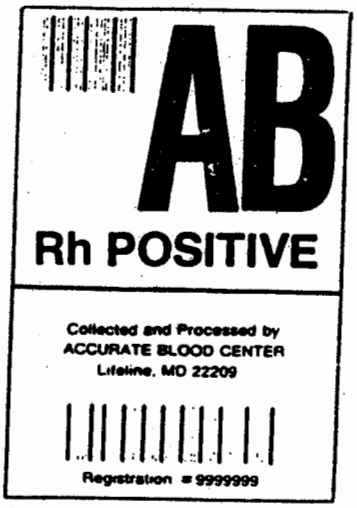
First Letter Of Double Alpha Primarily Used To Designate Centers In A Region	Single Letter (Or Second Letter If Double Alpha Used) Primarily Used To Designate Mobiles From A Given Center																			
	C	E	F	G	H	J	K	L	M	N	P	Q	R	S	T	V	W	X	Y	Z
BLANK	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	16	17	18	19
F	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39
G	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59
K	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79
L	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99

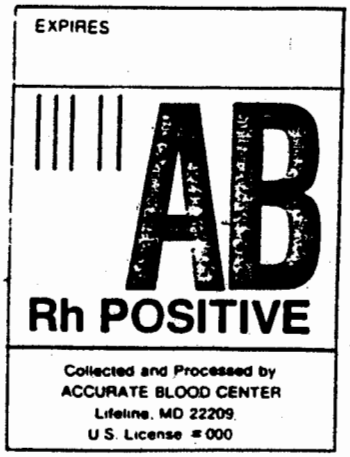
In this example, KC21749 translates to 6021749

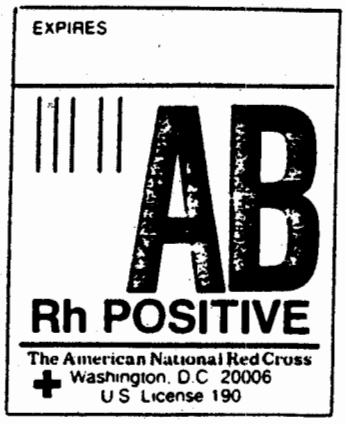
In this example, 13F01258 translates to 0201258. 13 is a Center prefix (eye readable only) with no bar code equivale

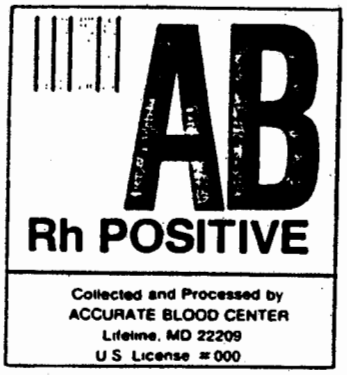
FIG 7
OPTIONS FOR GROUPING LABELS

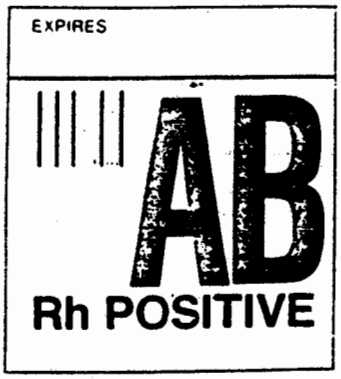












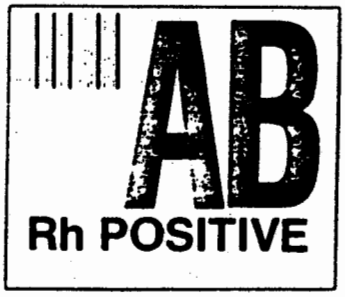
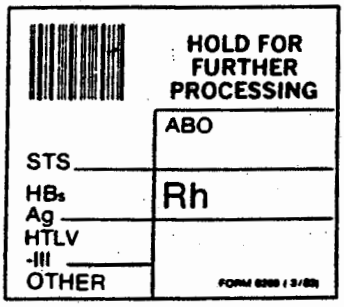
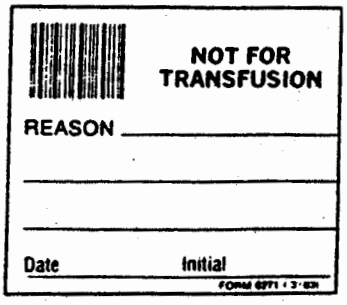


FIG 8

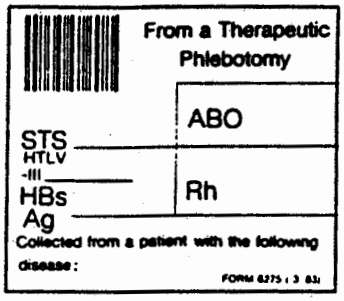
SPECIAL MESSAGE LABELS*



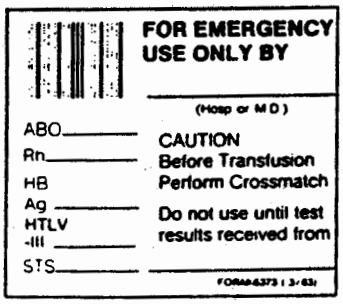
TAN**



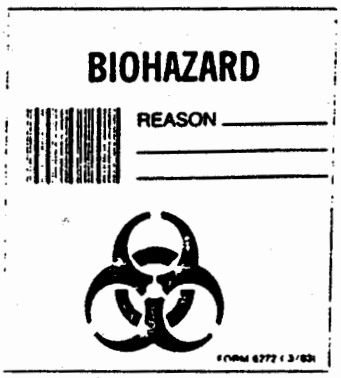
GRAY



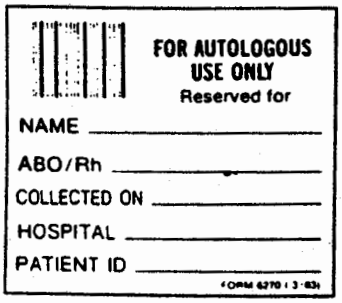
CHARTREUSE



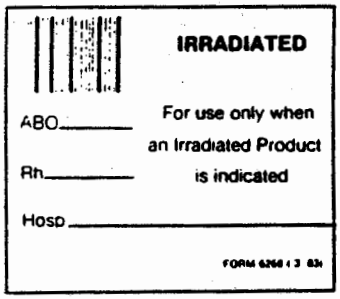
ORANGE



RED



GREEN



PURPLE

* SEE SEC III TABLE 12 FOR BAR CODING
** SEE SEC V-2 FOR PMS REFERENCE

SECTION III. CODE ASSIGNMENTS

Table 1

CONTROL (START AND STOP) CODES ASSIGNMENTS [1]

(START) LEFT CONTROL	DATA	(STOP) RIGHT CONTROL	USE
a0	7 Digit FDA Reg. #	1b	With Numeric Donation Number On Center ID Label
a1	7 Digit FDA Reg. #	1b	With Alphanumeric Donation Number On Center ID Label
c	5 Digit Date *	d	Collection Date Label
a	5 Digit Date *	c	Expiration Date Label
a0	5 Digit Blood Component Code	3b	Blood Component Label
d	xx [2]	$b	Primary Collection Bag
d	yy [3]	+b	Satellite/Transfer Bags
d	zz [4]	0b	Grouping & Special Message Labels
d	7 Digit Donation Number	d	Identification of Blood Bags & Sample Tubes

[1] Control codes are printed in machine-readable form only (not eye-readable).

[2] xx = 2 digits: the first digit indicates the anticoagulant code (Section III, Table 6) and the second digit indicates the package code (see Section III, Table 10).

[3] yy = 2 digits: indicate volume capacity of bag and product storage limitation dependent upon packaging materials (see Section III, Table 11).

[4] zz = 2 digit codes for Blood Group and Special Message Labels (see Section III, Table 12).

* Month, month, day, day, and last digit of year

Table 2

BLOOD COMPONENT CODE ASSIGNMENT LOGIC

The blood component code has five digits with information assigned as indicated below. The codes for Whole Blood and Red Blood Cells may be preprinted on primary collection bags by blood bag manufacturers. See Section II, Figure 1, for location of code on fully labeled bag.

	DIGIT 1-3	DIGIT 4	DIGIT 5
Whole Blood & Red Blood Cells Labels	Proper Name (Table 3)	Anticoagulant (Tables 6 & 7)	Contents (Table 9)
Other Component Labels	Proper Name (Tables 4 & 5)	Method of Preparation (Table 8)	Contents (Table 9)

Table 3

WHOLE BLOOD AND RED BLOOD CELLS PREPARED FOR TRANSFUSION

Code [1]	Proper Name and Qualifier [2,3]	Storage
001	*Whole Blood	1 to 6 C
009	*Whole Blood Cryoprecipitate Removed	1 to 6 C
014	*Whole Blood Leukocytes Removed	1 to 6 C
040	*Red Blood Cells	1 to 6 C
042	*Red Blood Cells Adenine-Saline Added[4]	1 to 6 C
043	*Red Blood Cells Leukocytes Removed By Filtration	1 to 6 C
044	*Red Blood Cells Leukocytes Removed By Centrifugation	1 to 6 C
046	*Red Blood Cells Adenine-Saline Added Leukocytes Removed By Centrifugation	1 to 6 C

* Anticoagulant/Preservative name precedes component name (e.g., CPDA-1 Red Blood Cells).

[1] Codes between 271 and 295 are available for local use (only).
[2] See Table 6 for fourth-digit and Table 9 for fifth-digit codes.
[3] The qualifier "Divided Unit" may be used to indicate when a unit of blood has been split into smaller aliquots (such as for pediatric use). Divided units have no unique code but the volume of the component (in mL) must be specified on label. (See examples in label copy.)
[4] See Table 7 for fourth-digit codes.

Table 4

OTHER BLOOD COMPONENTS PREPARED FOR TRANSFUSION

Code	Proper Name and Qualifier [1,2]	Storage
048	Red Blood Cells Leukocytes Removed By Washing	1 to 6 C
062	Red Blood Cells Frozen	-65 C or colder
063	Red Blood Cells Frozen Rejuvenated	-65 C or colder
064	Red Blood Cells -Deglycerolized	1 to 6 C
065	Red Blood Cells Rejuvenated Deglycerolized	1 to 6 C
066	Red Blood Cells Rejuvenated	1 to 6 C
101	Cryoprecipitated AHF	-18 C or colder
120	Platelets [3] 20 to 24 C	20 to 24 C
121	Platelets [3]	1 to 6 C
123	Platelet Rich Plasma	20 to 24 C
125	Platelets Frozen	-18 C or colder
164	Granulocytes [3,4]	(optional 1 to 24 C)
165	Granulocytes [4] Frozen	-18 C or colder
167	Granulocytes-Platelets [3,4]	(optional 1 to 24 C)
181	Resevered for Plasma subclasses	-18 C or colder
182	Fresh Frozen Plasma	-18 C or colder
184	Plasma	-18 C or colder
185	Liquid Plasma	1 to 6 C

[1] See Table 8 for fourth-digit and Table 9 for fifth-digit codes.
[2] The qualifiers "Divided Unit" (see Table 3, Note 3) and "Pooled" may be used as required.
[3] The qualifier "Pheresis" is used for components (excluding plasma) collected through automated methods.
[4] Components not currently approved for licensure by FDA.

Table 5

BLOOD COMPONENTS PREPARED FOR FURTHER MANUFACTURING ONLY

Code	Proper Name and Qualifier [1,2,3]	Storage
190	Source Plasma Liquid	10 C or colder
197	Source Plasma	-20 C or colder
193	Source Plasma Salvaged	between -20 and 10 C (shipped 4 to 10 C)
192	Recovered Plasma (noninjectable) [4]	37 C or colder
194	Therapeutic Exchange Plasma	37 C or colder
195	Recovered Plasma Liquid [5,6]	37 C or colder
196	Recovered Plasma [6]	-18 C or colder
198	Recovered Plasma [6,7] Fresh Frozen	-18 C or colder
200	Recovered Serum (noninjectable) [4]	37 C or colder
201	Source Leukocytes	between 1 to 10 C
220	Platelets (noninjectable) [4]	(optional 1 to 24 C)
240	Red Blood Cells (noninjectable) [4]	between 1 to 6 C

[1] See Table 8 for fourth-digit and Table 9 for fifth-digit codes.
[2] The qualifier "Pooled" may be used as applies.
[3] Source Plasma components are subject to the full labeling requirement of 21 CFR 640.70. Other components for further manufacturing may require additional label statements. The use of the CCBBA label format for these components is optional. Labels shown in Section IV are consistent with all applicable regulations.
[4] For production of diagnostic reagents only. Must carry required statement. One-half of the label is color-coded gray to distinguish the component from those for injectable use.
[5] Storage temperature range is optional below 37 C (10 C or colder is recommended).
[6] Products not subject to licensure but shipped under the "short supply" provisions of 21 CFR 601.22.
[7] Same preparation as Fresh Frozen Plasma for transfusion. However, does not need blood group label.

Table 6

FOURTH DIGIT CODES

ANTICOAGULANT

(USED WITH WHOLE BLOOD AND RED BLOOD CELL COMPONENTS FROM SECTION III TABLE 3) *

Code	Printed as First Part of Component Name	Full Name or Comments
0		No anticoagulant
1	Heparin	Heparin
2	ACD-A	Citrate Dextrose Formula A
3	ACD-B	Citrate Dextrose Formula B
4		Reserved
5	CPD	Citrate Phosphate Dextrose
6	CPDA-1	Citrate Phosphate Dextrose Adenine - Formula 1
7	CPDA-2	Citrate Phosphate Dextrose Adenine - Formula 2
8	CP2D	Citrate Phosphate Double Dextrose
9	Sodium Citrate	Sodium Citrate

* Also used as first digit in primary bag code (on upper right hand section of label). See Section III, Table 1, dxx$b and Table 10.

Table 7

FOURTH DIGIT CODES

PRESERVATIVE/ANTICOAGULANT

(USED ONLY WITH ADENINE-SALINE ADDED COMPONENTS, CODES 042 and 046)

CODE	Printed as First Part of Component Name	Full Name or Contents
0		Not Assigned
1	AS-1	Additive Solution Formula 1 with CPD Anticoagulant
2	AS-2	Additive Solution Formula 2 with CP2D Anticoagulant
3	AS-3	Additive Solution Formula 3 with CP2D Anticoagulant
4-9		Reserved

Table 8

FOURTH DIGIT CODES

METHOD OF PREPARATION

(USED ONLY WITH SECTION III, TABLES 4 AND 5)

Code	Meaning
0	Derived from one unit of whole blood (single draw)
1	Obtained by automated pheresis (centrifugation, filtration)
2	Derived from one unit of whole blood (multiple draw, "manual pheresis")
3-8	Reserved
9	Pooled unit from multiple donors

Table 9

FIFTH DIGIT CODES

COMPONENT CONTENTS

(USED WITH SECTION III TABLES 3, 4, AND 5)

Code	Meaning
0	Standard Contents *
1	Variable Contents to be Written (or Preprinted) on Label
2	Approx. 225 mL
3	Approx. 275 mL
4-9	Reserved

* Prepared as described on the label and in the instruction circular.

Table 10

PACKAGE_CODE_FOR_PRIMARY_COLLECTION_BAG *

Code	Meaning
0	Reserved
1	Single plastic collection bag
2	Double plastic collection bag
3	Triple plastic collection bag
4	Quadruple plastic collection bag
5	Quintuple plastic collection bag
6-9	Reserved

* Used as second digit in primary bag code. See Section III, Table 1, dxx$b for use, and Section II, Figure 2, for location of bar code in upper right section of label.

Table 11

PACKAGE CODE FOR SATELLITE OR TRANSFER BAG *

Code**	Bag Capacity	Storage Restrictions RBC & Plasma Components	Platelets (days)
01	300 mL	RBC & Plasma Components max. dating	3
02	400 mL	RBC & Plasma Components max. dating	3
03	Other than 300/400 mL	RBC & Plasma Components max. dating	3
04	300 to 400 mL	RBC limited dating Plasma Components max. dating	5
05	300 to 400 mL	RBC prohibited Plasma Components max. dating	5
06	300 to 400 mL	RBC & Plasma Products max. dating	5
09	Pooled Plasma Bottle		
10	Other than 300/400 mL	Same as 04	5
11	Other than 300/400 mL	Same as 05	5
12	Other than 300/400 mL	Same as 06	5
13	300 to 400 mL	Same as 04	7
14	300 to 400 mL	Same as 05	7
15	300 to 400 mL	Same as 06	7
17	300 to 400 mL	RBC prohibited Plamsa Products max. dating	Prohibited

* See Section III, Table 1, dyy+b for use, and Section II, Figure 3 for location of bar code in upper right section of label.

** Codes 00, 07, 08, & 16 are reserved.

Table 12

BLOOD GROUPS AND SPECIAL LABELS

Code	
51	O Positive
62	A Positive
73	B Positive
84	AB Positive
95	O Negative
06	A Negative
17	B Negative
28	AB Negative
55	O
66	A
77	B
88	AB
39	Hold for further processing
40	For autologous use only
47 (4-)	Not for Transfusion *
58 (5$)	Biohazard *
71 (7+)	For Emergency Use Only By ... *
44	Irradiated
21	From a Therapeutic Phlebotomy

* New labels be should be printed with the second character representing a digit rather than a symbol. Software (decoding) should be modified to accept either code until the transition to all numeric codes is complete.

Table 13

CONTROL CODE ASSIGNMENTS FOR OTHER APPLICATIONS IN BLOOD BANKING AUTOMATION *

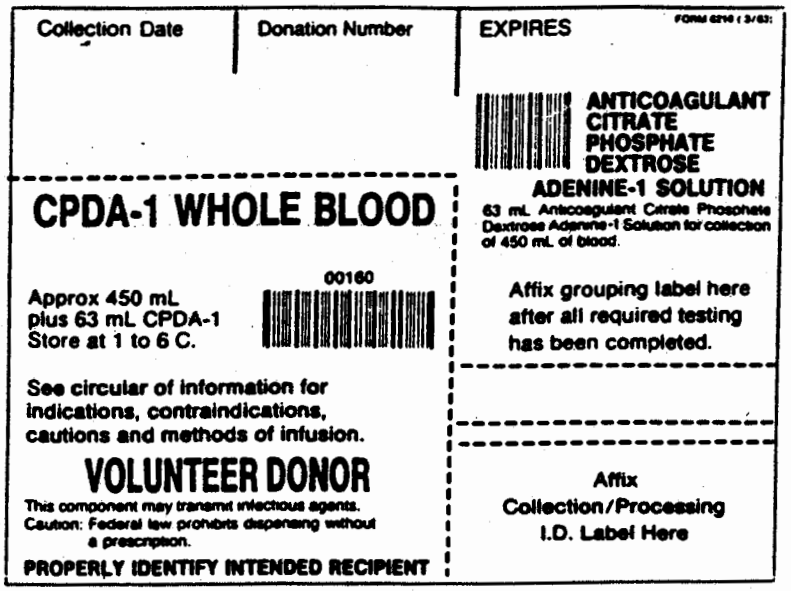
LEFT CONTROL CODE	DATA	RIGHT CONTROL CODE	USED ON
b0	7-Digit Patient ID#	0a	Patient ID Wristband
b1	7-Digit Patient ID#	0a	Identification of Patient Blood Sample Tube
b2	7-Digit Patient ID#	0a	Blood Bag of Cross-Matched or Designated Components
a9	Program ID#	$b	Program Identification at Scanner Terminals
a9	Personnel ID#	0b	Personnel I.D. Cards
a9	Hospital #	1b	Hospital Identification at Scanner Terminals

* Institutions interested in using Code 39 for these applications should contact the American Blood Commission. (See Section I, D for address.)

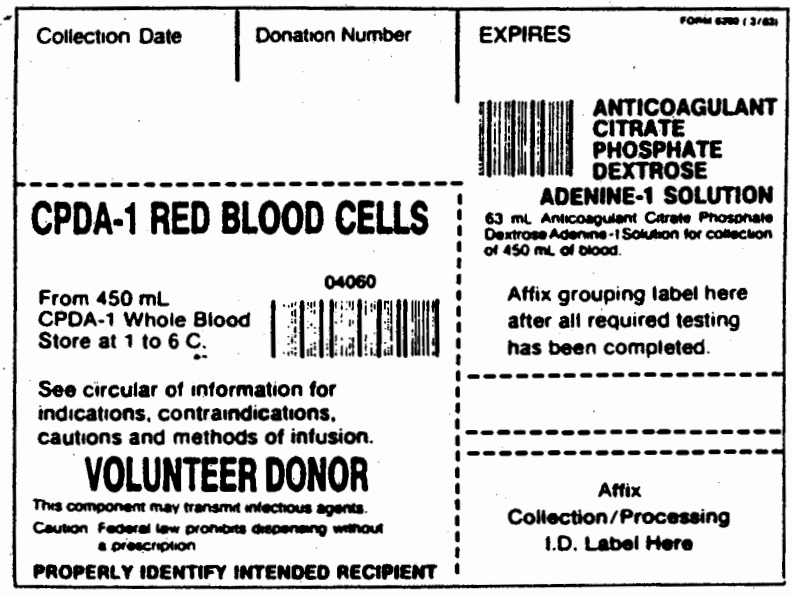
SECTION IV. EXAMPLES OF UNIFORM LABELS

A. BASE LABELS

Used as overlabels or pre-printed by the container manufacturer *



Single Unit Label

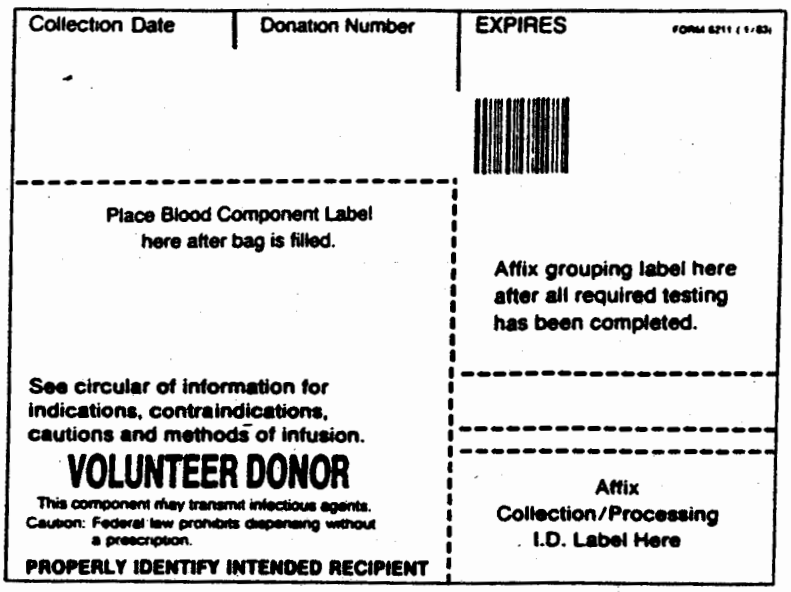


Multiple Unit
Primary Bag Label

Actual base labels are 1 inch longer.

* Additional information is required on labels produced by container manufacturers (See Sec. II Fig. 2).

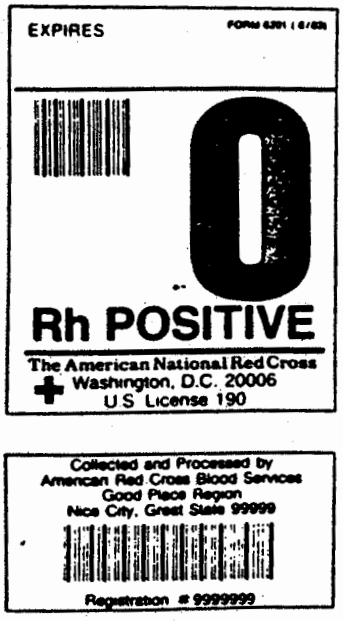
A. BASE LABELS
(continued)

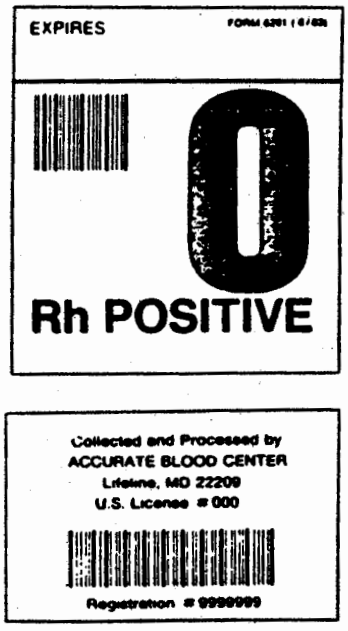


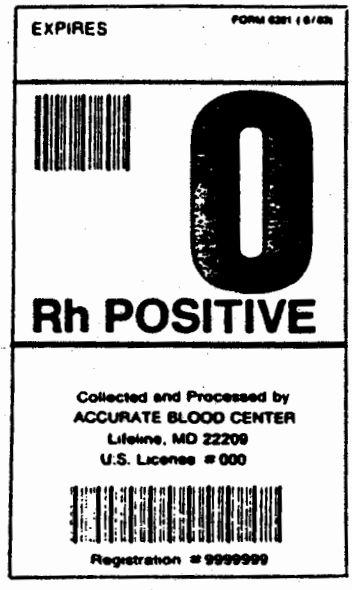
Base label on satellite bag or transfer pack

Satellite or Transfer bag

B. GROUPING AND COLLECTION/PROCESSING CENTER IDENTIFICATION







C. WHOLE BLOOD AND RED BLOOD CELLS

CPDA-1 WHOLE BLOOD

Approx 450 mL
plus 63 mL CPDA-1
Store at 1 to 6 C.

00160

Option

CPDA-1 WHOLE BLOOD

Approx 450 mL
plus 63 mL CPDA-1
Store at 1 to 6 C.
U.S. License No. 000

00160

CPDA-1 WHOLE BLOOD
DIVIDED UNIT

Approx _____mL
from 450 mL CPDA-1
Whole Blood
Store at 1 to 6 C.

00161

Option

CPDA-1 WHOLE BLOOD

Approx _____mL
from 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C.

00161

CPDA-1 WHOLE BLOOD

Approx _____mL
plus _____mL CPDA-1
Store at 1 to 6 C.

00161

Less than 450 mL collection

CPDA-1 WHOLE BLOOD
CRYOPRECIPITATE REMOVED

From 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C.

00960

CPDA-1 WHOLE BLOOD
LEUKOCYTES REMOVED

From 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C.

01460

C. WHOLE BLOOD AND RED BLOOD CELLS

(continued)

CPDA-1 RED BLOOD CELLS

From 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C.

04060

CPDA-1 RED BLOOD CELLS

Approx _____mL
from 450mL CPDA-1
Whole Blood
Store at 1 to 6 C.

04061

Option

CPDA-1 RED BLOOD CELLS
DIVIDED UNIT

Approx _____mL
from 450 mL CPDA-1
Whole Blood
Store at 1 to 6 C.

04061

AS-1 RED BLOOD CELLS
ADENINE - SALINE ADDED
LEUKOCYTES REMOVED BY CENTRIFUGATION

15.4 mEq Sodium added.
From 450 mL CPD
Whole Blood.
Store at 1 to 6 C.

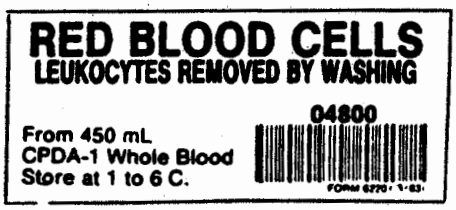
04610

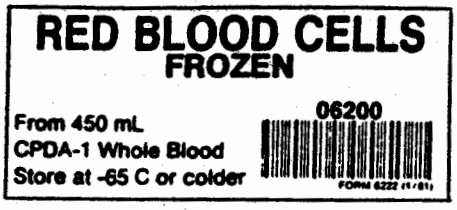
CPDA-1 RED BLOOD CELLS
LEUKOCYTES REMOVED BY CENTRIFUGATION

From 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C.

04460

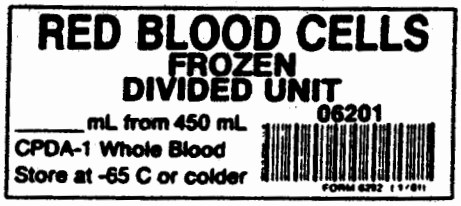
D. RED BLOOD CELL COMPONENTS

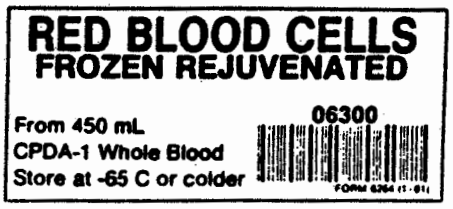


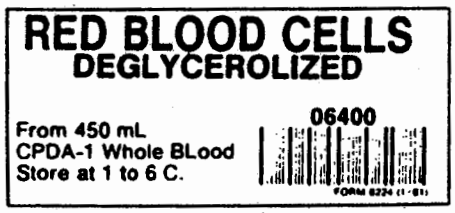


Standard contents

Divided from standard RBC unit

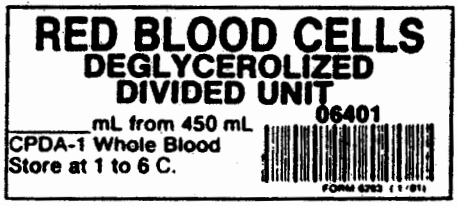


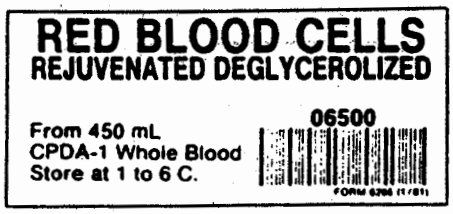


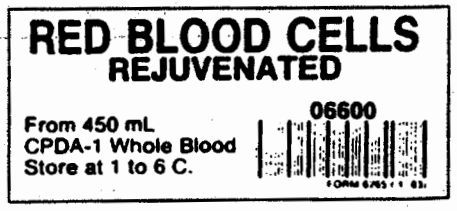


Standard contents

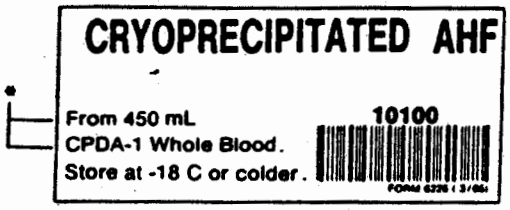
Divided from standard RBC unit

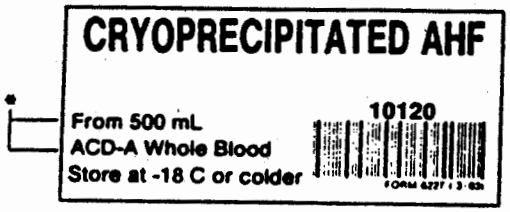




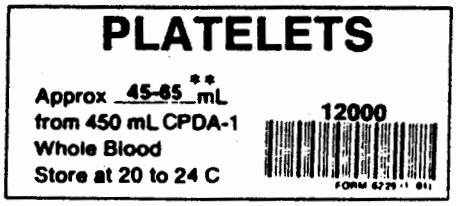


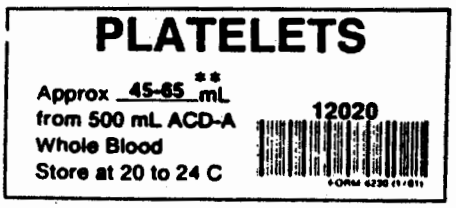
E. COMPONENTS

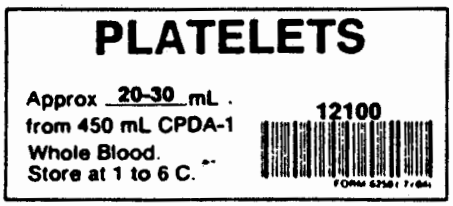




* This information optional







** Volume ranges up to 20 mL may be preprinted on Platelets labels

E. COMPONENTS
(continued)

FRESH FROZEN PLASMA

_____mL from
450 mL CPDA-1
Whole Blood
Store at -18 C or colder

18201

PLATELET RICH PLASMA

_____mL from
450 mL CPDA-1
Whole Blood
Store at 20 to 24 C.

12301

FRESH FROZEN PLASMA

_____mL from
500 mL ACD-A
Whole Blood
Store at -18 C or colder

18221

LIQUID PLASMA

_____mL from
450 mL CPDA-1
Whole Blood
Store at 1 to 6 C.

18501

PLASMA

_____mL from
450 mL CPDA-1
Whole Blood
Store at -18 C or colder

18401

PLASMA

_____mL from
500 mL ACD-A
Whole Blood
Store at -18 C or colder

18421

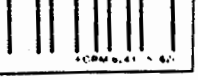
F. COMPONENTS, AUTOMATED PHERESIS

GRANULOCYTES
PHERESIS
_____mL containing approx.
_____mL of Tri-sodium Citrate in 6% Hydroxyethyl Starch solution
Store at _____C
16411

GRANULOCYTES-PLATELETS
PHERESIS
_____mL containing approx.
_____mL of Trisodium Citrate in 6% Hydroxyethyl Starch solution.
Store at _____ C
16711

PLATELETS
PHERESIS
_____mL containing approx _____mL of _____Anticoagulant
Store at 20 to 24 C
12010

PLATELETS
PHERESIS
_____mL containing approx.
_____mL of Tri-sodium Citrate in 6% Hydroxyethyl Starch solution.
Store at 20 to 24 C
12210



G. COMPONENTS FOR MANUFACTURING USE ONLY

To be used with a Satellite/Transfer pack label only.

SOURCE PLASMA
CAUTION: FOR MANUFACTURING USE ONLY
19721
_____mL from
500 mL Whole Blood
plus 75 mL ACD-A Store at -20 C or colder
Collected from a donor immunized with:
_____
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Expires:
The American National Red Cross
Washington D.C. 20006
U.S. License 190
_____ FORM 6279 (7-82)

SOURCE PLASMA
CAUTION: FOR MANUFACTURING USE ONLY
19721
_____mL from
500 mL Whole Blood
plus 75 mL ACD-A Store at -20 C or colder
Collected from a normal donor.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Expires:
The American National Red Cross
Washington D.C. 20006
U.S. License 190
_____ FORM 6257 (7-82)

SOURCE PLASMA
CAUTION: FOR MANUFACTURING USE ONLY
19721
_____mL from
_____mL Whole Blood
plus _____mL _____ Anticoagulant.
Store at –20 C or colder.
Collected from a normal donor.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Expires:
The American National Red Cross
Washington, D.C. 20006
U.S. License 190
_____ FORM 6280 (3-85)

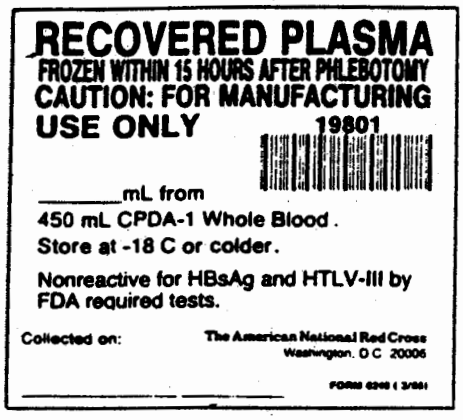
SOURCE LEUKOCYTES
PLATELETPHERESIS RESIDUES
CAUTION: FOR MANUFACTURING USE ONLY
20111
_____mL Prepared by Automated Platelet Pheresis Containing approx _____mL of _____ Anticoagulant Store at 1 to 10 C.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on:
The American National Red Cross
Washington D.C. 20006
U.S. License 190
_____ FORM 6283 (2-82)

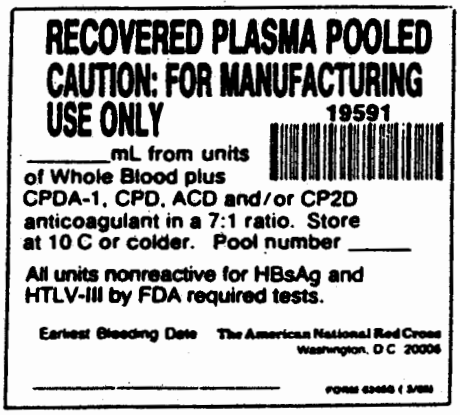
SOURCE LEUKOCYTES
CAUTION: FOR MANUFACTURING USE ONLY
20101
_____mL from 450 mL Whole Blood plus
63 mL CPDA-1. Store at 1 to 10 C.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on:
The American National Red Cross
Washington D.C. 20006
U.S. License 190
_____ FORM 6254 (7-84)

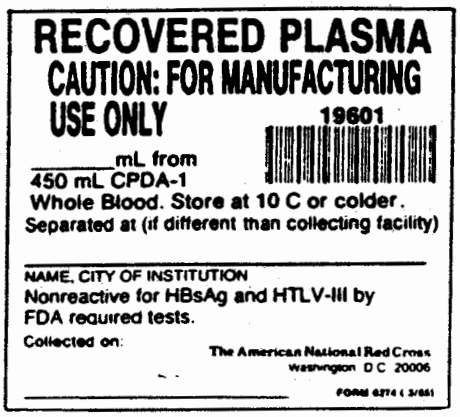
SOURCE LEUKOCYTES
CAUTION: FOR MANUFACTURING USE ONLY
20121
_____mL from 500 mL Whole Blood plus
75 mL ACD-A Store at 1 to 10 C.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on:
The American National Red Cross
Washington D.C. 20006
U.S. License 190
_____ FORM 6295 (3-83)

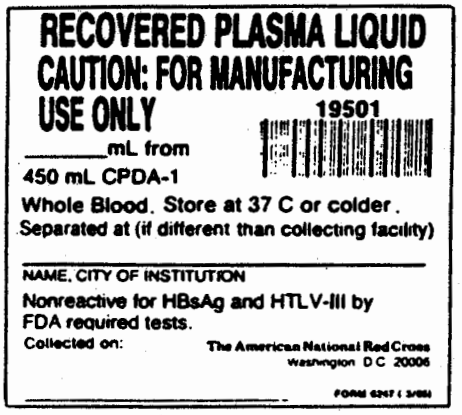
G. COMPONENTS FOR MANUFACTURING USE ONLY

(continued)









H. COMPONENTS FOR FURTHER MANUFACTURING OF NON-INJECTABLES

•Printed with gray tint area to distinguish from injectable products.

RECOVERED PLASMA
CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY
19201
Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act
_____mL from 450 mL CPDA-1 Whole Blood. Store at 37 C or colder.
Separated at (If different than collecting facility)
_____
NAME, CITY OF INSTITUTION
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on: _____
The American National Red Cross Washington, D C 20006
FORM 6251 (3 87)

PLATELETS
CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY
22001
Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act.
_____mL from _____mL Whole Blood plus _____mL _____ anticoagulant. Store at 37 C or colder.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on: _____
The American National Red Cross Washington, D C 20006
FORM 6250 (3/88)

RECOVERED SERUM POOLED
CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY
20091
Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act.
_____mL pooled from clotted donor samples.
Store at 37 C or colder.
Pool No. _____
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Earliest Bleeding Date: _____
The American National Red Cross Washington, D C 20006
FORM 6252G (3/88)

RED BLOOD CELLS
CAUTION: FOR USE IN MANUFACTURING NONINJECTABLE PRODUCTS ONLY
24001
Not For Use in Products Subject to License Under Section 351 of the Public Health Service Act
_____mL from _____mL Whole Blood plus _____mL _____ anticoagulant.
Store at 1 to 10 C.
Nonreactive for HBsAg and HTLV-III by FDA required tests.
Collected on: _____
The American National Red Cross Washington, D C 20006
FORM 6257G (3/88)

SECTION V. TECHNICAL SPECIFICATIONS FOR LABELS AND SYMBOLS

A. Character Size, Color and Typeface Specifications

1. Guidelines for Print Characters

TYPE FACE *	POINT SIZE	COLOR	COMMENTS
1. Helvetica Regular, Caps and lower case	8	Black	
2. Helvetica Regular Caps	8	Black	
3. Helvetica Medium Condensed, Caps	12	Red	Centered, condensed to fit
4. Helvetica Medium Condensed, Caps	18	Red	Centered, condensed to fit
5. Helvetica Regular, Caps and lower case	6	Black	Anticoagulant contents reduced to fit 9 Pica width x 4 Pica depth
8. Helvetica Medium, Caps	8	Red	
9. Helvetica Regular, Caps and lower case	6	Black	
10. Helvetica Regular, Caps	6	Black	
11. Helvetica Regular, Caps and lower case	16	Black	Donation numbers, caps only
12. Helvetica Medium, Caps and lower case	16	Black	
13. Helvetica Medium, Caps and lower case	16	White	Photographically reverse
14. Helvetica Bold,Caps	1"	Black	A,B,O Positive
15. Helvetica Bold Condensed,Caps	1"	Black	AB Positive
16. Helvetica Bold, Caps	1"	White	A,B,O Negative;hand reinforced black outline
17. Helvetica Bold, Condensed, Caps	1"	White	AB Negative; hand reinforced black outline
18. Helvetica Medium,Caps	10	Black	
19. Helvetica Medium, Caps and lower case	8	Black	Follow sample format; set 1/2 pt rule, align as indicated
20. Helvetica Regular, Caps and lower case	8	Red	8 Red
21. Bag Manufacture Imprint **			1.7 x 1.1", Satellite bag 0.5 x 4.0", Primary bag
22. Bag Manufacture Lot Number			0.25 x 4", Primary Bag 0.25 x 2.3", Satellite Bag

* Numbers refer to key on Examples 1-4, Section V. Print as specified, or a visual match. Use examples for format.

** Imprint of manufacturer's name may not be more prominent than blood component name or donor type (18 PTS.). Manufacturers' logo symbols should not be used.

2. Colors for Print Characters

The ABO blood group shall be printed in black
Rh positive: Black print on a white background
Rh negative: White print on a black background
Red lettering should be a visual match to PMS-485
(Pantone Matching System, Pantone Inc., Moonachie, NJ)

3. Colors for Blood Grouping and Special Message Labels

a. Use of colors for blood grouping labels is optional. When used, the right half of the label should be a visual match to:

White:	Group AB
Blue, PMS-305	Group O
Yellow, PMS-102:	Group A
Pink, PMS-182:	Group B

b. Colors should always be used on the right half of special message labels (Section II, Figure 9) and be a visual match to:

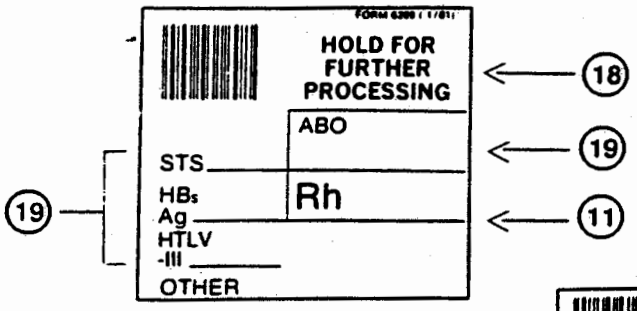
Tan, PMS-155:	HOLD FOR FURTHER PROCESSING
Green, PMS-358:	FOR AUTOLOGOUS USE ONLY
Gray, PMS-435:	NOT FOR TRANSFUSION
Orange, PMS-137:	FOR EMERGENCY USE ONLY BY ...
Purple, PMS-529:	IRRADIATED
Red, PMS-485:	BIOHAZARD
Chartreuse, PMS-388:	FROM A THERAPEUTIC PHLEBOTOMY

EXAMPLE 1

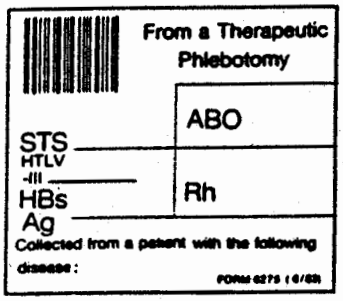
BLOOD GROUPING LABELS

EXAMPLE 2

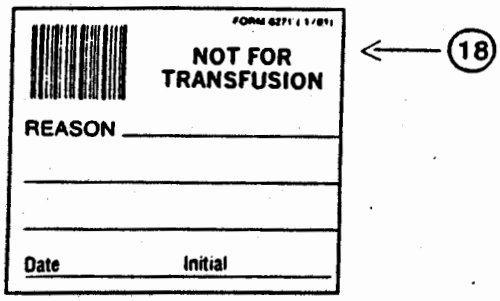
SPECIAL MESSAGE LABELS



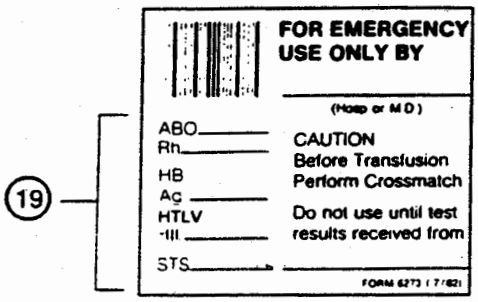
TAN



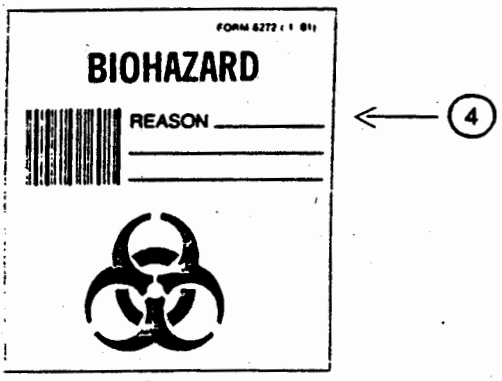
CHARTREUSE



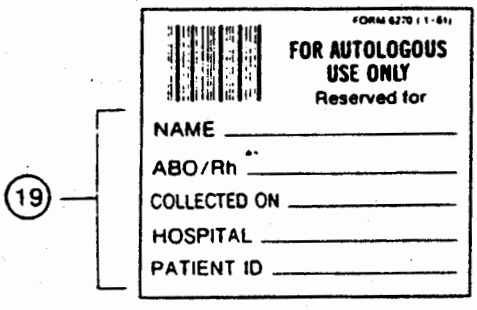
GRAY



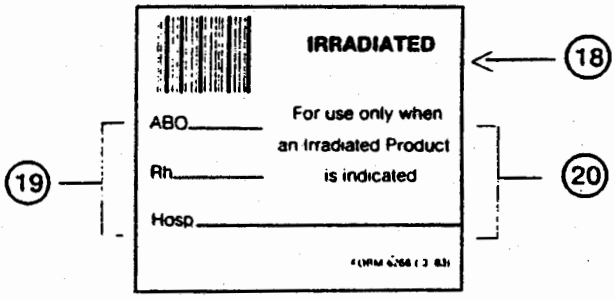
ORANGE



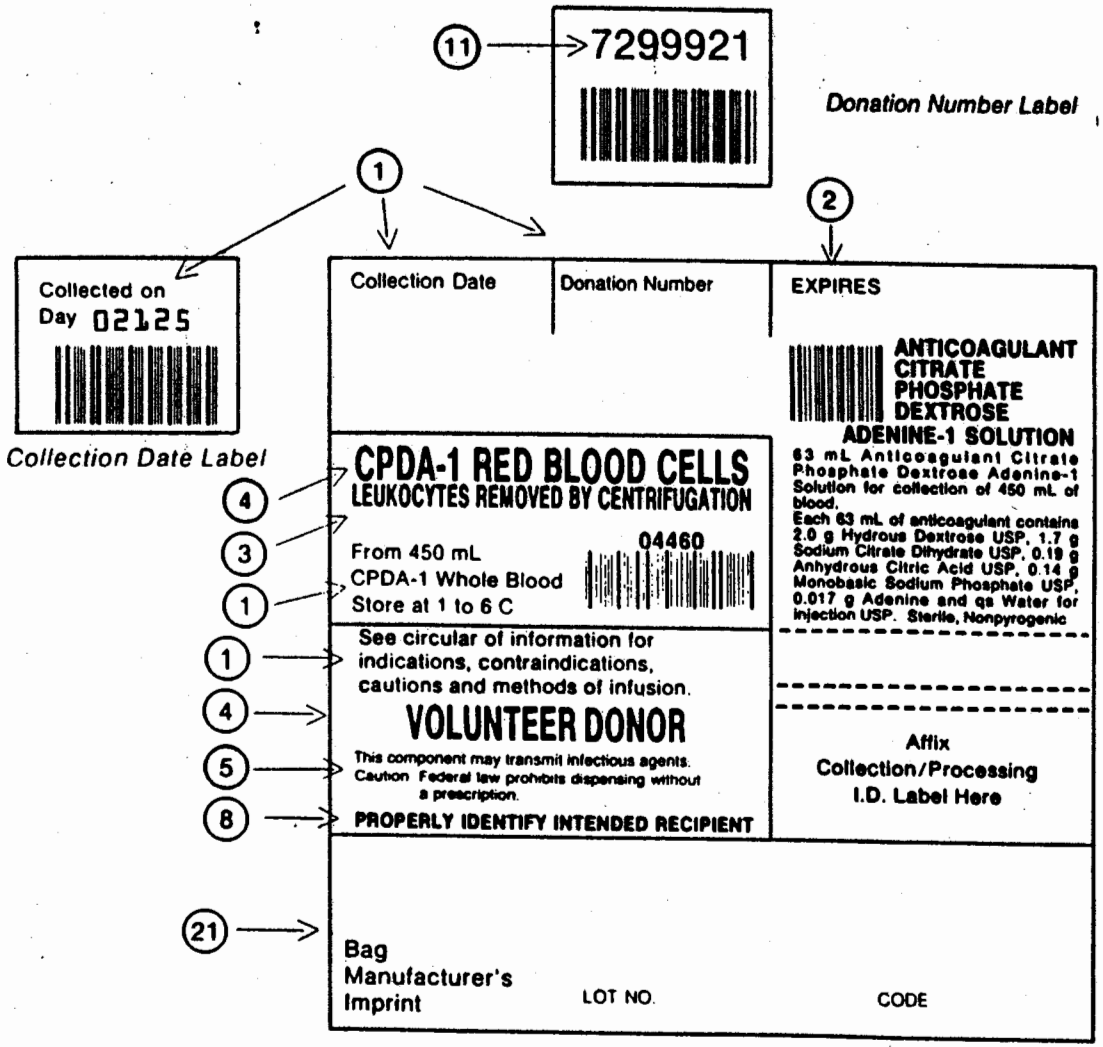
RED

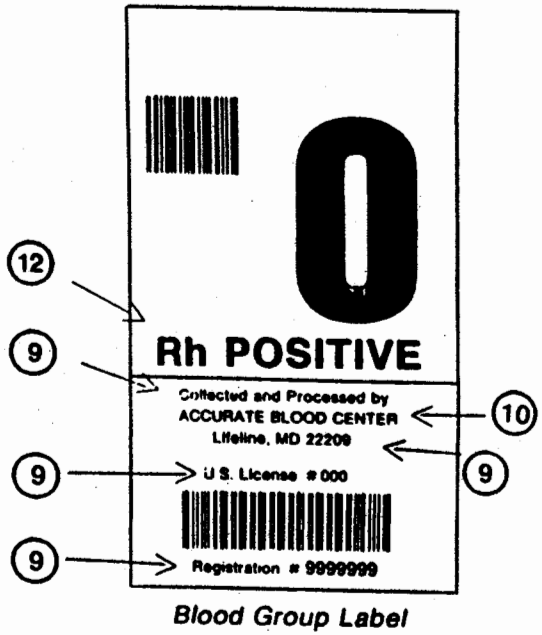


GREEN



PURPLE


11
7299921
Donation Number Label
1
2
Collected on
Day 02125
Collection Date Label
Collection Date
Donation Number
EXPIRES
ANTICOAGULANT
CITRATE
PHOSPHATE
DEXTROSE
ADENINE-1 SOLUTION
63 mL Anticoagulant Citrate Phosphate Dextrose Adenine-1 Solution for collection of 450 mL of blood.
Each 63 mL of anticoagulant contains 2.0 g Hydrous Dextrose USP, 1.7 g Sodium Citrate Dihydrate USP, 0.19 g Anhydrous Citric Acid USP, 0.14 g Monobasic Sodium Phosphate USP, 0.017 g Adenine and qs Water for Injection USP. Sterile, Nonpyrogenic
4
3
1
CPDA-1 RED BLOOD CELLS
LEUKOCYTES REMOVED BY CENTRIFUGATION
From 450 mL
CPDA-1 Whole Blood
Store at 1 to 6 C
04460
1
See circular of information for indications, contraindications, cautions and methods of infusion.
4
VOLUNTEER DONOR
5
This component may transmit infectious agents. Caution Federal law prohibits dispensing without a prescription.
8
PROPERLY IDENTIFY INTENDED RECIPIENT
Affix
Collection/Processing
I.D. Label Here
21
Bag
Manufacturer's
Imprint
LOT NO.
CODE
Primary Bag Label


12
9
O
Rh POSITIVE
Collected and Processed by
ACCURATE BLOOD CENTER
Lifeline, MD 22209
10
9
9
U.S. License # 000
9
Registration # 9999999
Blood Group Label

7299921

Donation Number Label

PLATELETS

Approx 45-65 mL
from 450 mL CPDA-1
Whole Blood
Store at 20 to 24 C

12000

Blood Component Label

Collection Date	Donation Number	EXPIRES

Place Blood Component Label here after bag is filled

Bag Manufacturer's Imprint

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR

This component may transmit infectious agents
Caution Federal law prohibits dispensing without a prescription

PROPERLY IDENTIFY INTENDED RECIPIENT

Processing Center name if different from collection center

Affix Collection/Processing I.D. Label Here

Lot Number ABC 12345

(16)

O

Rh NEGATIVE (13)

Collected and Processed by
ACCURATE BLOOD CENTER
Lifeline, MD 22209

U.S. License # 000

Registration # 09999999

Blood Group Label

(21)

(22)

B. Label Dimensions (Figures 1-5)

Note that metric equivalents for the dimensions provided in figures may be determined by conversion (metric equivalent of one inch is 2.54 centimeters).

The following constraints should be observed:

1. All label dimensions must be within tolerances of plus or minus 0.02 inch (0.5 mm).

2. All bar codes, lines, and words must be aligned parallel or perpendicular to the top edge of the label, as appropriate.

3. Lines will appear in black.

C. Technical Specifications for the ABC Symbol and Label Materials

All bar code images must be in accordance with the specifications outlined in this section.

1. ABC Symbol Definition

The ABC symbol, a subset of the bar code Codabar, is a two-level, seven-bit binary encoding system. The two levels are the optical reflectance from a dark pattern printed on a light background. Binary (zeros and ones) encoding takes place in both levels for maximum utilization of space. The symbol is represented by a linear sequence of wide and narrow bars and spaces. When a bar/space is compared to an adjacent bar/space, narrow bars/spaces represent binary "zeros," and wide bars/spaces represent binary "ones."

Each ABC symbol character is made up of four bars and three spaces, for a total of seven bits of information per character. The ABC symbol utilizes the 20 characters shown in Section V, Figure 6. Each character is decoded individually, independent of adjacent characters.

The ABC symbol code patterns being used are bidirectional, i.e., they can be read from right to left, or left to right.

2. Printing the ABC Symbol

The following specifications describe the dimensional parameters for the ABC symbol. Any firm preparing to print the symbol for the first time or to distribute a new imaging device for the symbol should consult the ABC.

The standard density of encoded characters is 10 per inch (or 0.4 per millimeter).

Each character is represented by seven elements consisting of four dark bars and three light spaces. A wide dark bar or a wide light space represents a binary "1." A narrow dark bar or a narrow light space represents a binary "0." The ratio between the narrow bar or space and the wide bar or space has been designated to yield adequate differentiation while allowing for varying character densities. Table 1 contains the printing tolerances and specifications for theses bars and spaces. Application for exception to these specifications should be made to the ABC.[1]

For the ABC symbol,the narrow (or wide) bars and spaces can be different widths, however, the nominal ratio between narrow and wide bars (spaces) remains the same. An adjustment from the nominal ratio has been made in the dimensional set shown to achieve a fixed character pitch and to improve decoding by allowing additional printing tolerance with a minimum cost of space.

a. Symbol Height

Character bar heights may vary depending on the type of reader and message length (in accordance with ASCII [2] specifications). To accommodate contact scanners, however, the minimum height should be 0.320 inch (8.13 mm).

b. Intercharacter Spacing

Intercharacter gaps must be a minimum of 0.008 inch (0.2 mm) to provide adequate resolution between characters. However, gap dimensions are not critical because each character is read independently of those preceding or following it, and gaps have no information content.

---

1. The specifications contained in this guideline are for so-called "traditional Codabar." Consideration is being given to adopt USS-Codabar (Uniform Symbology Specifications specifications) as recommended by the Automated Identification Manufacturers (AIM) Technical Symbology Committee. Should AIM membership approve currently proposed USS-Codabar specifications, this guideline will be revised accordingly

2. American Standard Code for Information Interchange.

c. Symbol Alignment

The linear bar code is a series of straight parallel lines nominally perpendicular to a base or reference line. Individual characters should not be misaligned more than five degrees from adjacent characters. However, the center line of the entire printed code need not be aligned to a guide edge of the media, and there is no angular tolerance requirement. Encoded messages can be read in any orientation within the scanning plane, since the code can be read bidirectionally.

d. Encoded Message Borders

The minimum border dimensions are 0.1 inch (2.54 mm) at each end of the message. The border dimension above and below the encoded message is not critical. The area above the encoded message should include the human-readable digits associated with the code; printing should not touch the bar code.

e. Embossment

Maximum depression or embossment of the printed symbol should not exceed 0.002 inch (0.05 mm).

f. Surface Curvature

The radius of curvature of the symbol is not critical as long as a proper viewing angle (as specified below) can be maintained when contact scanners are used.

3. Optical Parameters

a. Substrate

The symbol system is insensitive to the light-scattering properties of the substrate, except to the extent to which background reflectance is affected.

b. Background

Background diffuse reflectance is integral in the definition of contrast which is discussed below. However, a background diffuse reflectance of at least 70 percent

(optical density, 0.1) is necessary in the 500- through 950-nm range.[3] For this application, bar code images must be black on a white background.

c. Printing Quality Factors

i. Contrast.

The contrast, defined as the nominal difference in the diffuse reflectance between the background and and the printed image, should be at least 50 percent as measured over the range specified in 3.b. above. Measurements should be averaged over an area equivalent to an 0.008-inch (0.20-mm) diameter circle.

ii. Voids and Extraneous Image.

The missing image coverage ("white" spots) within bars or the extraneous dark specs between bars should not exceed 0.002-inch (0.05-mm) diameter, or subtend more than 25 percent of the area within a 0.004-inch (0.10-mm) diameter circle, as illustrated in Section V, Figure 7. Overall minimum contrast, as specified earlier, should be maintained.

iii. Edge Roughness.

The maximum area of edge irregularities subtending a 0.004-inch (0.10-mm) diameter circle should not exceed 25 percent of the area of that circle, as shown in Section V, Figure 8. The area of the irregularity is to be measured with respect to the nominal bar edge.

iv. Uniformity of Image.

Variation in image intensity reflectance across the symbol should not exceed five percent within the same character.

v. Image Fill-In.

Image fill-in should not expand individual bars within characters to dimensions exceeding the tolerance specified for the dimensional parameters.

vi. Show-Through.

---

3. Consideration is being given to allow for a narrowing of this to the visible light range. Should that occur, this guideline will be revised accordingly.

Images on the reverse side of the label surface, the reflectance of the substrate, or the color of the contents within a container may affect the background characteristic of the symbol. Labels should be properly designed and placed upon articles so that the contrast specifications are maintained.

4. Other Physical Properties

a. Scuff and Scratch Resistance

Scuffs and scratches reduce readability of the label and therefore need to be held to a minimum.

b. Wrinkles

Surface smoothness is necessary for effective reading. Wrinkles in applied labels should be held to an absolute minimum.

c. Stain Film

Stains or colored contamination of the label surface may be tolerated by the reader if the minimum contrast ratio is maintained.

d. Environmental Conditions

The label should maintain the characteristics mentioned after exposure to the conditions outlined in Appendix A.

e. Image Chemical Composition

The image should maintain characteristics after exposure to conditions outlined in Appendix A. Chemical residues of image and image medium should be non-toxic to handlers of labels and should not be able to leach through the blood bag.

f. Adhesives and Coatings

Adhesives and coatings used should be demonstrated as effective after exposure to conditions outlined in Appendix A. Generally, only those substances FDA-approved as "Indirect Food Additives" may be used in adhesives and coating components (21 CFR Part 175) for labels placed over the base label. The FDA has additional standards for labels that are applied directly on plastic blood containers and should be contacted regarding this or for other related questions.

5. ABC Symbol Decoding

a. Symbol Character Set

The set of characters which comprise Codabar was chosen for their wide print tolerance, high character densities, and reliability in the decoding operation. It is believed that this symbol, when printed in accordance with the print specifications contained herein, can be decoded with a statistically calculated character substitution error rate of no greater than 1 in 1,000,000. It will be the responsibility of the equipment manufacturers to supply decoding equipment which will maintain at least this level of security in decoding. In actual operation, this 1,000,000 level can be increased by mechanisms built into the software which will question numbers not in current use or possible duplicates.

b. Special Decoding Rules

i. Symbol length should be a minimum of five characters (eg., two start/stop characters and three data characters); equipment should be designed for a maximum symbol length of at least 32 characters.

ii. The first encountered start/stop character is to be decoded as a start character; the second is to be decoded as a stop character (Section V, Table 4).

iii. Special restrictions are placed on decoding when the start/stop character "d" is encountered as a stop character.

Messages utilizing overlays require an additional special decoding rule to assure that the high level of security is maintained and that the first-pass read rate remains high.

When "d" is encountered as a stop character (the second of two start/stop characters), the decoding system is to decide within about 30 milliseconds that this is a stop code unless a "d" start character has subsequently been decoded. The 30 milliseconds is roughly the time it takes the reader to pass across the distance of approximately 0.3 inch and decode the second "d." Further, the direction of the decoded "d's" must be the same. And the pair of "d's" must be removed from the message before it is transmitted to the host computer. See Fig. 9 for one possible flow diagram using these constraints.

iv. The start/stop and other control characters of the message contain information and should be transmitted to

the host computer along with the rest of the message. It is important to note that the pair of "d's" used in overlay messages are exempt from this rule. The pair of "d's" are to be removed before transmission.

v. Messages will be transmitted to the host computer as if they had been read from left to right.

vi. Decoding should allow variable size symbols to be decoded. Any complete character or set of characters can vary within the symbol from nominal character density to 1/2 nominal character density.

6. Symbol Security

Because there is a strong need to achieve the maximum security and information transfer from this symbol, several controls on the symbol are specified.

a. Format Control

The first relates to the fact that the symbol is often read by the utilization of hand movement. Because the hand motion relative to the symbol is not controlled, the scanner can be easily moved out of, and back into, the symbol field without the operator's knowledge, and still obtain a "good decode" if no format control is used. To control format, characters are defined within the symbol to identify the specific symbol being read. The start/stop characters can be used in any combination providing 4 (start) x 3 (stop) = 12 possible combinations. To increase the number of unique identifiers, start/stop combinations are used in conjunction with two additional message characters to convey identification of the label being read. The format is that of pairs--one numeric or control character is associated with the start character and one numeric or control character with the stop character. The general assignments made to the start/stop character pairs are shown in Tables 2 and 4. This arrangement typically provides a symbol of the form--a1XXXXX$b--where the X's represent the encoded data.

Specific assignments for control codes used in the blood service community are maintained by the ABC.

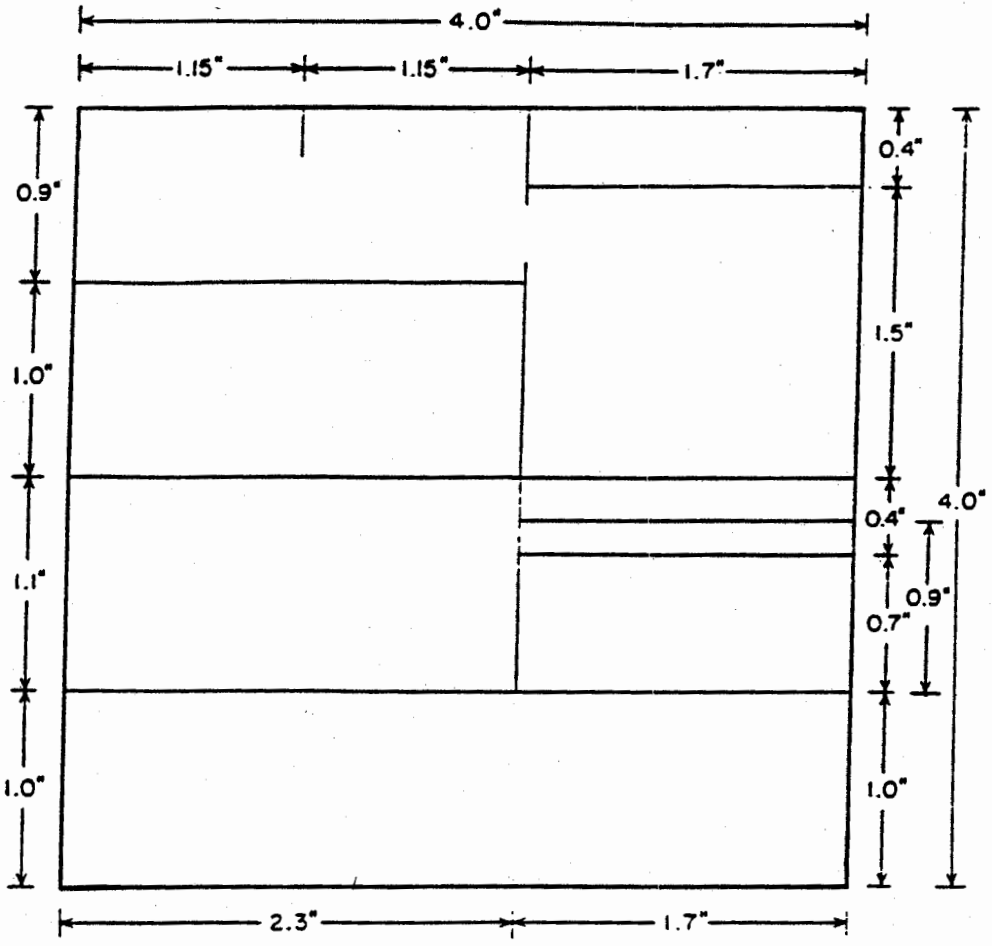
b. Two-Digit Redundancy Control

The security of the blood type code needs to be maintained at the highest possible level and thus a two-digit redundancy code is used. (See Section III, Table 12.)

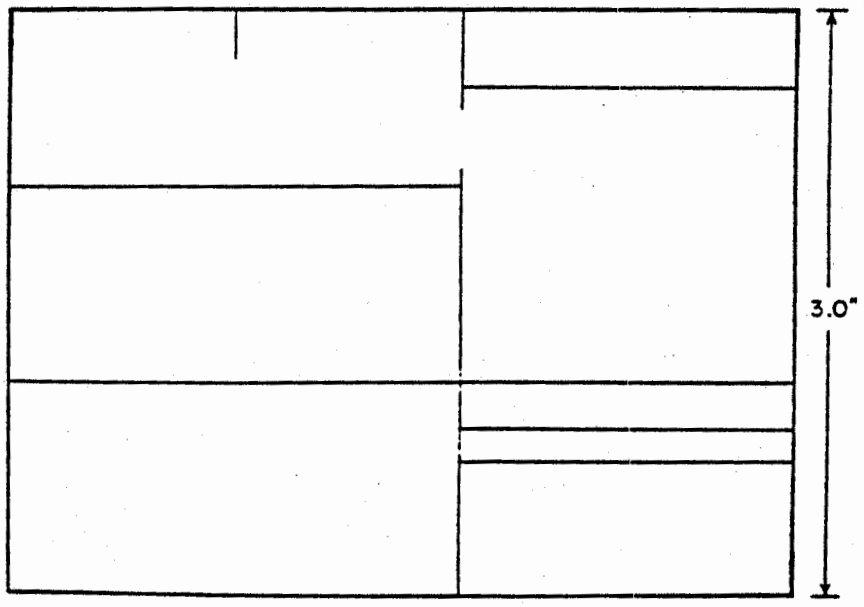
FIG 1

Overall dimensions * of the Base Labels

PRIMARY LABEL



SATELLITE LABEL



* The metric equivalent of one inch is 2.54 cm.

FIG 2

Dimensions and * placement of bar codes on Primary and Satellite Bag Labels

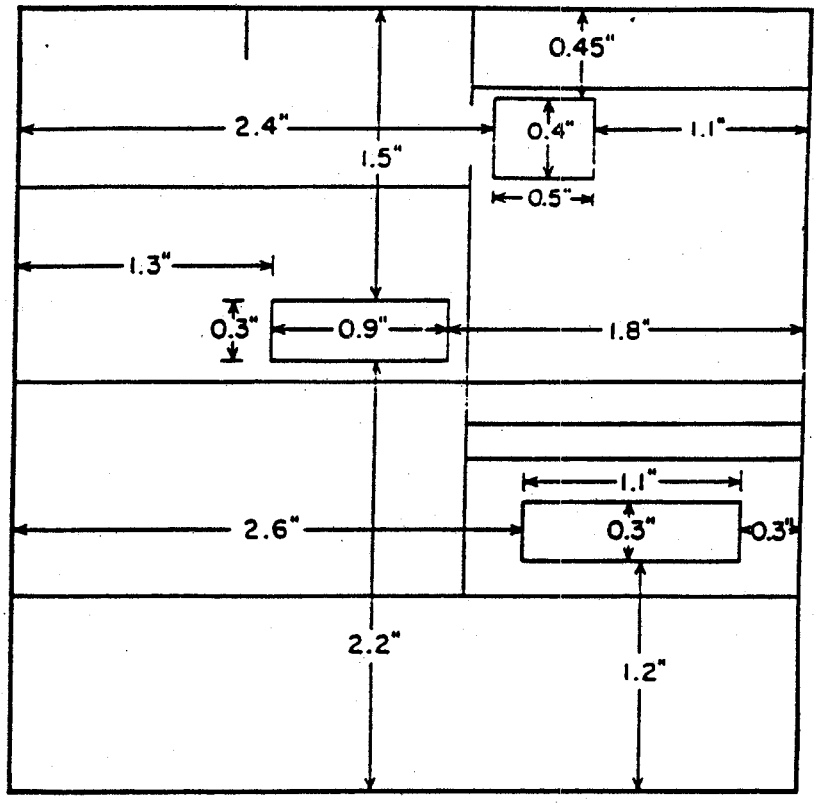
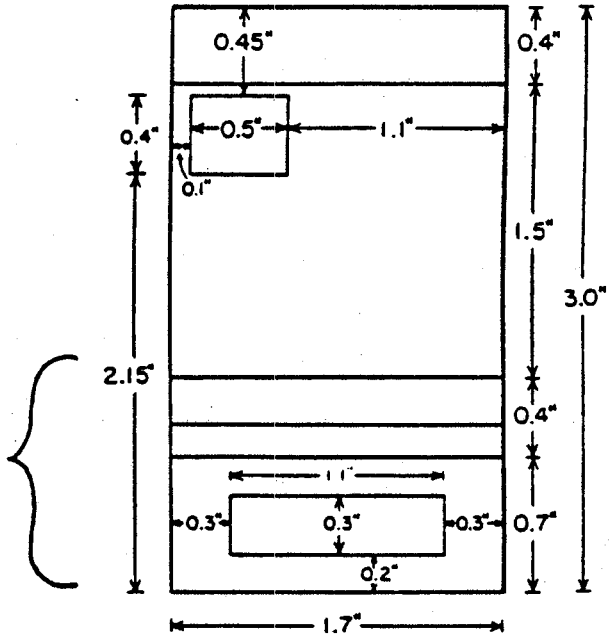


FIG 3

Overall dimensions * of Grouping, Special, and Center Labels -- Bar code dimensions and placement



This portion of label may be printed as a seperate label if desired.

* The metric equivalent of one inch is 2.54 cm.

FIG 4

Overall dimensions *of Unit Number
Labels -- Bar Code dimensions and placement

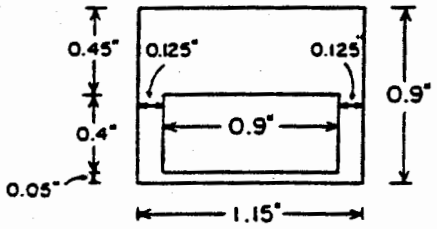
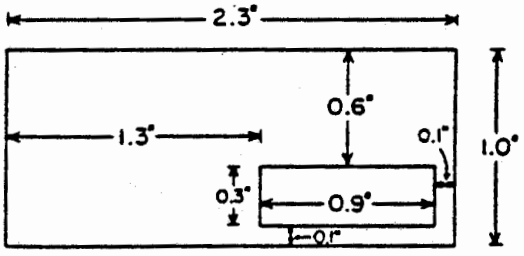


FIG 5

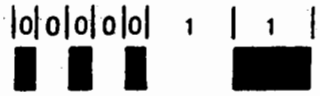
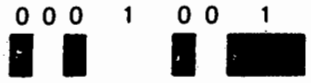
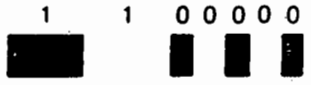
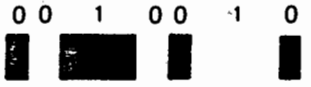
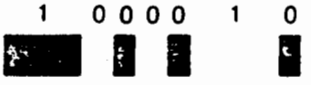
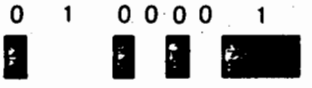
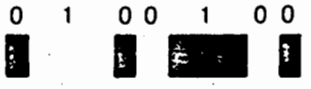
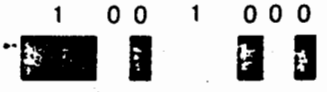
Overall dimensions * of Product
Labels -- Bar Code dimensions and placement

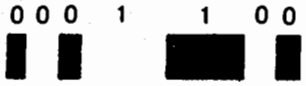
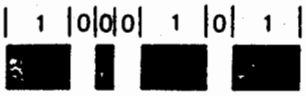
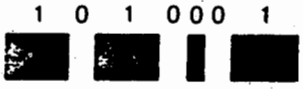
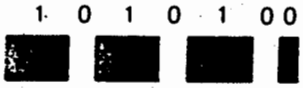
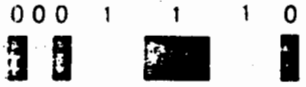


* The metric equivalent of one inch is 2.54 cm.

FIG 6

AMERICAN BLOOD COMMISSION
CODABAR CHARACTER SET ASSIGNMENTS

Character	7-bit code	Bar pattern
10 Numeric Characters		
0	0000011	
1	0000110	
2	0001001	
3	1100000	
4	0010010	
5	1000010	
6	0100001	
7	0100100	
8	0110000	
9	1001000	

Character	7-bit code	Bar pattern
6 Control Characters		
–	0001100	
$	0011000	
:	1000101	
/	1010001	
.	1010100	
+	0010101	
3 Start/Stop Characters		
a	0011010	
b	0101001	
c	0001011	
1 Start/Pause or Stop Characters		
d	0001110	

Note: Printed with permission of Welch Allyn Inc.

Fig. 7 Void Tolerance

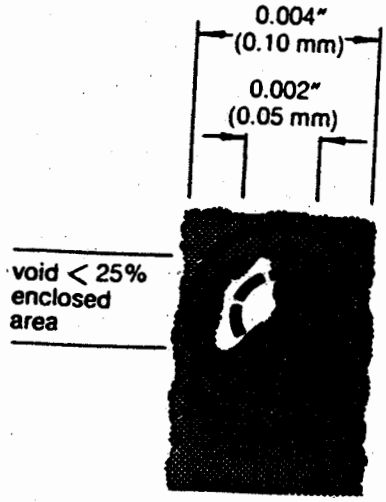
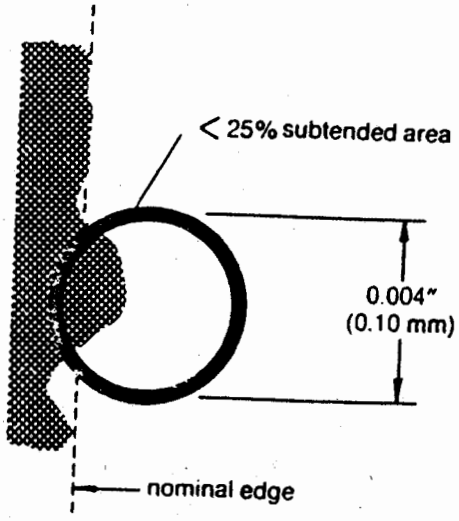


Fig. 8 Edge Roughness Tolerance



Note: Printed with permission of Welch Allyn Inc.

FIG 9

FLOW DIAGRAM FOR DECODING WITH SPECIAL CONDITIONS

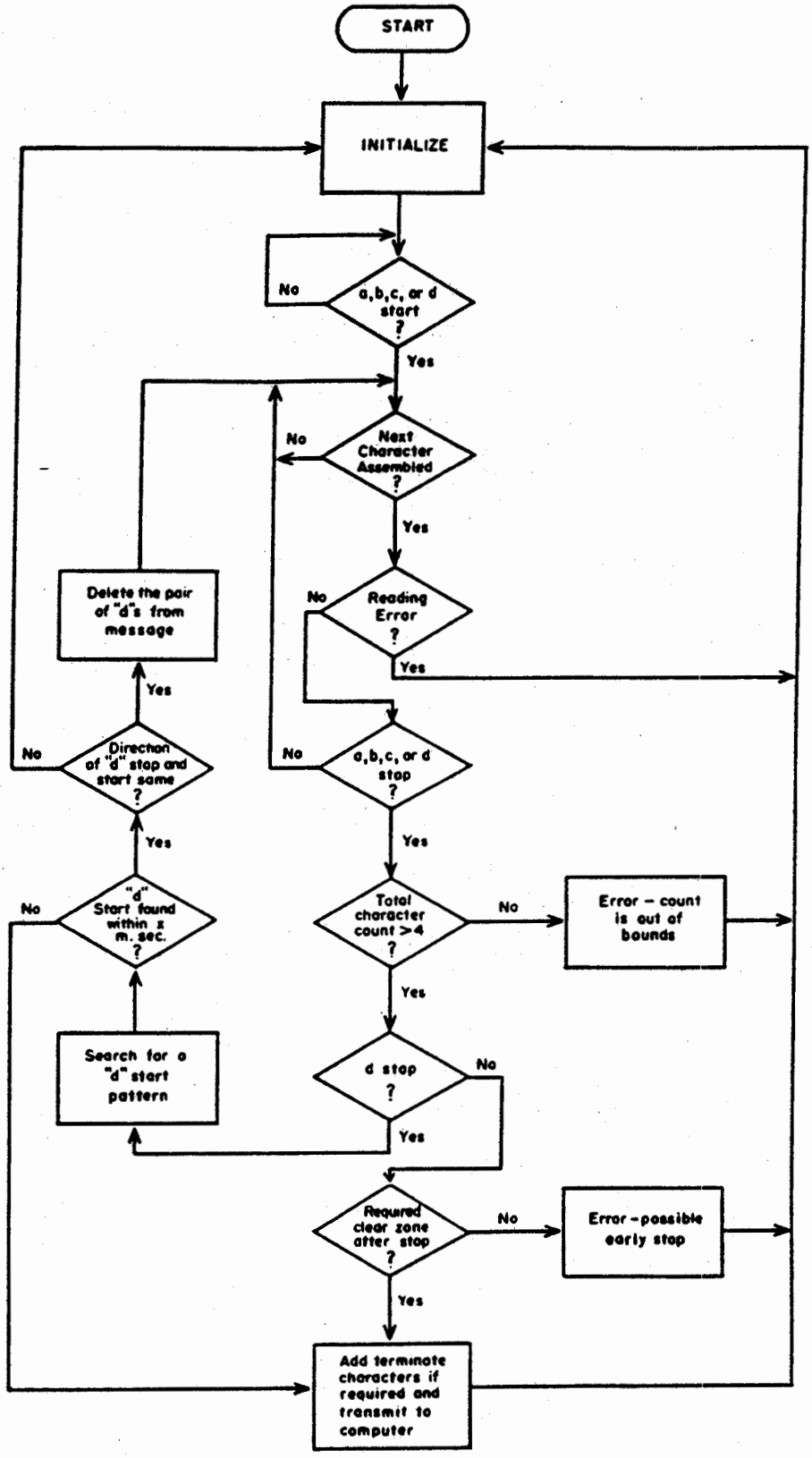


TABLE 1

AMERICAN BLOOD COMMISSION CODABAR PRINT SPECIFICATIONS

(10 Characters per Inch)

Character	Bar 1	Space 1	Bar 2	Space 2	Bar 3	Space 3	Bar 4
1	.0065	.0104	.0065	.0104	.0179	.0243	.0065
2	.0065	.0100	.0065	.0244	.0065	.0100	.0186
3	.0179	.0243	.0065	.0104	.0065	.0104	.0065
4	.0065	.0104	.0179	.0104	.0065	.0243	.0065
5	.0179	.0104	.0065	.0104	.0065	.0243	.0065
6	.0065	.0243	.0065	.0104	.0065	.0104	.0179
7	.0065	.0243	.0065	.0104	.0179	.0104	.0065
8	.0065	.0243	.0179	.0104	.0065	.0104	.0065
9	.0186	.0100	.0065	.0244	.0065	.0100	.0065
0	.0065	.0104	.0065	.0104	.0065	.0243	.0179
$	.0065	.0100	.0186	.0244	.0065	.0100	.0065
–	.0065	.0100	.0065	.0244	.0186	.0100	.0065
:	.0167	.0093	.0065	.0093	.0167	.0093	.0147
/	.0147	.0093	.0167	.0093	.0065	.0093	.0167
.	.0136	.0101	.0149	.0101	.0172	.0101	.0065
+	.0065	.0101	.0172	.0101	.0149	.0101	.0136
a	.0065	.0080	.0196	.0194	.0065	.0161	.0065
b	.0065	.0161	.0065	.0194	.0065	.0080	.0196
c	.0065	.0080	.0065	.0194	.0065	.0161	.0196
d	.0065	.0080	.0065	.0194	.0196	.0161	.0065

METRIC EQUIVALENTS

(Print Character Spacing = 2.54 mm)

Character	Bar 1	Space 1	Bar 2	Space 2	Bar 3	Space 3	Bar 4
1	.165	.264	.165	.264	.455	.617	.165
2	.165	.254	.165	.620	.165	.254	.472
3	.455	.617	.165	.264	.165	.264	.165
4	.165	.264	.455	.264	.165	.617	.165
5	.455	.264	.165	.264	.165	.617	.165
6	.165	.617	.165	.264	.165	.264	.455
7	.165	.617	.165	.264	.455	.264	.165
8	.165	.617	.455	.264	.165	.264	.165
9	.472	.254	.165	.620	.165	.254	.165
0	.165	.264	.165	.264	.165	.617	.455
$	.165	.254	.472	.620	.165	.254	.165
–	.165	.254	.165	.620	.472	.254	.165
:	.424	.236	.165	.236	.424	.236	.373
/	.373	.236	.424	.236	.165	.236	.424
.	.345	.257	.379	.257	.437	.257	.165
+	.165	.257	.437	.257	.379	.257	.345
a	.165	.203	.498	.493	.165	.409	.165
b	.165	.409	.165	.493	.165	.203	.498
c	.165	.203	.165	.493	.165	.409	.498
d	.165	.203	.165	.493	.498	.409	.165

Printing at these dimensions will result in a character pitch of 0.1 inch (10 to the inch or 2.54 mm). Printing tolerance on all bars is –.002 inch, +.004 inch (– 0.05 mm, + 0.10 mm). On all spaces, the printing tolerance is +.004 inch, +.002 inch (+ 0.10 mm, + 0.05 mm).

The application of these tolerances is predicated on the assumption that there will be "uniform ink spread." Uniform ink spread requires that if one of the four bars in a character grows in width (growth includes both ink spread and edge raggedness), then the remaining three bars must also grow in width. Furthermore, the amount of growth shall be consistent within +.002 inch (±0.05 mm) for all bars. The same rule will apply for shrinkage of bar widths as well as growth and shrinkage of space widths.

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Section V - Table 2
CONTROL CODE ASSIGNMENTS

	START	NUMERIC CONTROL	NUMERIC CONTROL	STOP	ASSIGNMENTS
	a	Any	Any	b,c	Designations already made or reserved for future use.*
	b	Any	Any	a,b,c	
	c	Any	Any Except O	c	
	d	None	Any	a,b,c	For use when this message and the preceding one are read as one message.*
	a,b,c	Any	None	d	For use when this message and the following one are read as one message.*
ENCODED MESSAGE	c	None	None	d	
	d	None	None	d	For use when this message, the preceding one and the following one are read as one message.
	a	Any	Any	a	For internal use within an organization.
	c	None	3 = 3,..., 9 = 9; - = 10; $ = 11; .= 12; + = 13; : = 14; / =15	b	Numeric control indicates length of field between start and stop characters.
	c	None	0 = 16,...,9=25; $ = 26; . = 27; + = 28; : = 29; / = 30	a	
	:	UPC Designation	0	c	UPC encoded symbol information.**

*The ABC will maintain and control this group of assignments. Requests should be directed to the American Blood Commission.

** This code is used when the information is already in the UPC format, i.e., one digit to indicate the type of item (0 = Grocery, 3 = National Drug Code, 4 = National Health Related Items Code, etc.), five digits to indicate the manufacturer, five digits to indicate the product name and the UPC check digit.

Table 3

AMERICAN BLOOD COMMISSION
SYMBOL CHARACTER SET AND CONTROL CODES

CHARACTER SET	DESCRIPTION
0-9	Zero through Nine
:	Colon *
+	Plus Sign *
$	Dollar Sign *
-	Minus Sign *
.	Period *
/	Slash *

NOTE: All above characters are ASCII equivalent.

CONTROL CODE	DESCRIPTION
a	Start or Stop Code *
b	Start or Stop Code *
c	Start or Stop Code *
d	Start or Stop or Pause Code *,**

NOTE: a, b, c and d ASCII equivalents are DC1, DC2, DC3, and DC4, respectively.

* Normally not eye-readable.

** When a "d" is encountered at the end of a message the scanner logic will pause. If another "d" is encountered, the message will continue; otherwise the "d" will be interpreted as a stop code.

Table 4

START AND STOP CONTROL CODES
FOR USE IN BLOOD BANKING AUTOMATION

START CONTROL CODE	ACCOMPANYING* CHARACTER		PRECEDING* CHARACTER	STOP CONTROL CODE
a	x		x	b
a	None		None	c
a	x		x	c
a	x	ENCODED MESSAGE	None	d
b	x		x	a
b	x		x	b
b	x		x	c
b	x		None	d
c	x		x (except 0)	c
c	x		None	d
c	None		None	d
d	None		x	a
d	None		x	b
d	None		x	c
d	None		None	d

* x can be any of the 16 characters indicated in Table 3 under Character Set.

Appendix A

SUGGESTED EVALUATION PROTOCOL FOR BAR-CODED PRESSURE SENSITIVE LABELS

Printers of bar-coded labels intended for blood banking use are requested to read and understand the technical standards in Section V and then to follow the attached protocols in order to determine the acceptability of their products from the user's perspective.

Questions or problems should be reported to the American Blood Commission.

INDEX

I. OBJECTIVE

The objective of this testing protocol is to present test methods which approximate conditions labels will encounter under actual use. Labels which can meet the test standards contained herein will likely be acceptable in use by the blood banking community.

Generally, the labels produced must adhere to the appropriate substrates under varying conditions; the first pass read rate of messages must be high under ideal conditions (greater than or equal to 99%) at all commonly used wavelengths; substitution error rate must be less than 1 in 1,000,000 characters scanned; the image must not deteriorate during up to one year at constant light and -150 C; and the labels should not be subject to degradation caused by environmental factors or contact scanners.

Labels are subject to temperature extremes from -150 to 56 C and 0 to 100 % humidity conditions. The tests outlined in this protocol are under rigorous but not extreme conditions. The label supplier should understand the conditions which the user will subject the labels.

II. DONATION (UNIT) NUMBER LABEL SET

Each label set contains multiple, but identical, "peel off" numbers in both bar-coded and nonbar-coded form. No two sets should have the same number within at least a one year period. Depending upon the user, the label set may be a multilayered composite; for example, a set with the three layers may have a printed layer with adhesive backing, an unprinted layer with adhesive backing, and a backing layer with no adhesive.

Numbers from this label set are applied to various paper substrates (forms and other labels), glass and plastic test tubes, and plastic blood storage bags. When a three layer set, as described above, is used a section of the labels may be applied directly to the back of a 600 mL primary blood collection bag.[4] These numbers are later used by transfusion services during blood compatibility testing procedures.

The silicon liner used in label set construction should allow relatively easy removal of labels. However, if a section of labels is placed on the back of the blood bag the labels should not slide-off the liner during centrifugation (see D. following).

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4. See Section V.C.4.f., regarding adhesives of such labels

A. Basic Label Readability and Verification

A representative random samples of donation number label sets (but not less than 0.01% of each lot produced) should be verified and tested for readability. Using scanning equipment designated to measure bars and spaces at all commonly used wavelengths, verify that the symbol meets ABC/Codabar specifications. When a laser, infrared, or visible light scanner is user, the label must have a first pass read rate of greater than 99%.

A system of quality control should be established that verifies the consistency of each bar-coded number within a label set, and that no number is repeated from set to set. There should also be a system which can assure that the human readable information is consistent with the bar-coded data.

B. Adhesion and Readability on Test Tubes

Typically 13 x 100 mm siliconized glass test tubes are used to collect blood samples for laboratory analysis. Once applied, the donation numbers should adhere to these tubes at various temperatures and humidity conditions. Also, since non-professional staff are often used to apply these labels, specialized application methods are not practical.

1. After allowing test tubes to equilibrate for 15 minutes at room temperature (18 to 24 C) and normal humidity (30-60%), a donation number test label should be applied to each tube (longitudinally) near the top. A recommended method of application may be specified, such as, "After label is initially applied, rub thumb over label twice to promote adhesion."

2. After 24 hours of refrigeration, determine curl back as the maximum linear distance of the label not adhering to the tube. Curl back should not exceed 0.1 inch at any label edge. Centrifuge tube at 400 g for 20 minutes and reexamine.

3. Read the labels at all commonly used wavelengths; the first pass read rate using laser and light scanners should be greater than or equal to 90%.

This protocol should be repeated when a new lot of adhesive backed label stock is used.

C. Adhesion and Readability to Labels on Plastic Blood Bags

Blood bags produced for sale in the US have a base label on one face. Other labels must adhere to the base label. Filled primary bags are stored at 1 to 6 C for up to 42 days. In the case of satellite bags, certain products may be maintained for

years at -65 to -20 C and thawed at 37 C prior to clinical use. Other products are stored at 20 to 24 C for up to 7 days.

1. Remove the blood bag(s) from the outer container (foil pouch) and detach the satellite bags. Immediately apply bar-coded number labels to the appropriate area on the base labels of the primary and satellite bags.

2. Fill the primary bag with water to a final volume of about 550 mL. Fill one satellite bag with 250 mL of water and a second with 50 mL water.

3. Refrigerate the primary bag at 4 C for 24 hours. Remove to ambient temperature and determine the amount of curl back. There should be none. The first pass read rate should be greater than or equal to 90% with no damage to the label.

4. Place the satellite bag containing 250 mL in a -20 C or colder freezer for 24 hours. If other labels are to be tested (see IIIE), remove the frozen bag, apply additional labels, and return the bag to the freezer for an additional 24 hours before proceeding. Place this bag in a 37 C water bath until completely thawed (about 15 minutes), "blot" dry, and perform read rate testing. Again, the rate should be greater than or equal to 90% with no label damage.

   Labels must be examined for deterimental effects caused by algicides used in waterbaths.

5. Leave the satellite bag containing 50 mL at ambient conditions for 24 hours and evaluate as in 3 above.

This protocol should be repeated for each lot of labels produced.

D. Adhesion and Readability on Plastic Blood Bags

As noted above, many blood centers and transfusion services place a portion of the donation number label set directly on the plastic surface of primary (600 mL) blood bags for subsequent use. (In these instances, the whole blood number label set is a three-layered product, as previously described.) Polyvinyl chloride of differing formulations is the plastic in current use. Label printers should obtain currently produced blood bags from the end users or blood bag suppliers for these tests.

At the time of use, blood bags are removed from a foil pouch and are damp (100 % humidity). In use, they are stored between 1 and 10 C at normal humidity for up to 56 days. Therefore, the donation numbers and label sets must adhere to the damp base label and plastic surface and must not curl back from either the plastic bag or intermediate substrate during storage.

1. Remove blood bag(s) from the storage container and immediately apply the appropriate portion of the donation number label set directly to the plastic surface of the primary (600 mL) bag. Specify a recommended method of label application.

2. Proceed as outlined in Section C 2 and 3 above concurrently with other testing, and then centrifuge primary bag at 3000 g for 10 minutes and reexamine label adhesion.

III. OTHER BLOOD BAG LABELS (OVERLABELS)

In general, the evaluation of other blood bag labels for adhesion and readability can be carried out concurrently with Section II. These include collection date, blood group, product, special and collection center registration labels which are placed on blood bag "base" labels. The protocol should be repeated for each lot of labels produced.

A. Basic Label Readability and Verification

A representative sample of labels from each lot should be subject to evaluation as outlined in Section IIA.

B. Date Stamp and Ink Pen Application

Labels, such as base, blood group, and special, which require date stamping or pen notation, by the laboratory must be tested for drying rate and ink retention.

Stamp the date on the label under evaluation and rub across the label after 30 seconds. The date must still be legible with no noticeable smearing and must not bleed excessively when submersed in a 37 C water bath. The same conditions should apply to ink pen notations. (Specify an ink or pen if necessary.)

C. Primary Bag Labels (Refrigerated Storage)

Apply a representative sample of these labels after Section IIC2 and follow instructions for Section IIC3.

D. Satellite Bag Labels (Room Temperature Storage)

Apply a representative sample of these labels after Section IIC2 and follow instructions for Section IIC5.

E. Blood Group/Special Message Labels on Frozen Bags

Apply a representative sample of this type of label after the bag has been frozen for 24 hours and proceed with the evaluation as outlined in Section IIC4.

F. Other Labels for Miscellaneous Storage

Labels are occasionally subject to extreme environmental conditions such as storage at -80 C, or even -150 C (in liquid nitrogen). In these instances, manufacturers should discuss appropriate test protocols with the end users.

Art preparation and printing provided by a grant from Computype, Inc. St. Paul, Minnesota