APPENDIX F VISTA BLOOD BANK USER MANUAL INTENDED USES

Preface

Directions for Use

The Laboratory Planning and Implementation Guide Version 5.2 of the Laboratory software application provides detailed instructions on implementation of the software application and file setups.

The Blood Bank User Manual Version 5.2 provides detailed information and specific examples of data entry for each option. This manual is targeted toward the end users of the software and explanations are geared to the medical technologist, Blood Bank supervisory and/or Blood Bank Medical Director.

The Release Notes and Implementation Guide for Patch LR*5.2*72 includes an itemized listing of the data dictionary, option, and functionality changes, as well as instructions for implementation. Since Release Notes usually include information on other modules in addition to Blood Bank, the sections applicable to Blood Bank are also documented in Appendix D of the Blood Bank User Manual.

In addition, all patch messages for the Blood Bank module are prepared in a standardized format and include directions for the Blood Bank staff as well as for the Laboratory Information Manager and/or Information Resource Management (IRM) staff.

Intended Uses

The intended uses for the *VISTA* Blood Bank Software V. 5.2 are detailed in the following sections by major function, (i.e. donor, inventory and patient). For each major function, a descriptive listing of the data elements for the file is provided, followed by a detailed listing of software limitations and a table of intended uses.

Direction For Use

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VISTA Laboratory Blood Bank Version 5.2 Software Intended Uses

Introduction

The delivery of quality healthcare services to eligible veterans is one of the primary missions of the Department of Veterans Affairs (DVA). Within the DVA, the Veterans Health Administration (VHA) operates the largest centrally directed electronic healthcare information system in the United States. The electronic information systems provide vital support to the delivery of healthcare to veterans at 173 Veterans Administration Medical Centers (VAMCs), 389 outpatient clinics, 131 nursing homes, and 39 domiciliaries.

In 1982, VHA committed to building an electronic healthcare architecture titled Veterans Health Information Systems and Architecture (VISTA), formerly Decentralized Hospital Computer Program (DHCP). The focus of the program was the implementation of software modules that were easily integrated into a complete electronic hospital information system. By 1990, VHA had upgraded computer capacity at all VAMCs, and is now implementing software on a national scale that supports integrated healthcare delivery. All VA facilities have been integrated for the past eight years with a digital communications network. Through enhancement of its data transport utility, Patient Data Exchange (PDX), VA healthcare facilities can exchange health summaries containing relevant clinical data across the VA network. As VHA evolves into a managed care organization, the information network capabilities will provide support for health plan business elements in all operational and patient care support areas.

In developing **VISTA** software, VHA established the following criteria for design and integration:

- Software applications that are standardized and able to be exported to all VAMCs.
- Technical integration through the use of a common database, programming standards and conventions, and data administration functions.
- Functional integration through utilities such as order entry/results reporting and flexible healthcare summaries.
- · Standard data elements.
- Timely access to data.

- Equipment and software specifications that avoid dependence on a single vendor.
- A system that is easy to use for the information resources manager and the healthcare professional.
- System integrity and protection of data against loss and unauthorized change, access or disclosure.

Blood Banking involves many sophisticated analyses that, without automation/computerization, can only be performed by highly skilled persons. The human ability to "look for things" is more flexible than a computer's; but the ability to be flexible and intelligently search for and analyze information starts to break down as the quantity of information becomes larger. Computers, however, can handle vast amounts of information without suffering any deleterious effects. Therefore, a sophisticated computer system allows the highly trained technical staff to devote more time and energy to those problems and sophisticated analyses that are not yet within the realm of a computer.

The goals of the VISTA Blood Bank software are to:

- Improve the safety of blood/blood component transfusion by decreasing the number and severity of errors, through retrieval of previous records, verification of present results, detection of inconsistencies in data, bar code entry of unit ID, ABO/Rh, etc., and computer assisted donor labeling.
- Improve the quality of patient care through evaluation of transfusion appropriateness flags for specific components, and evaluation of transfusion increments.
- Decrease the clerical workload through bar code entry of unit information, printing of transfusion requests, transfer of information to multiple records and preparation of labels for specimens and unit tags.
- Improve resource management through statistics by location, physician, and/or treating specialty, through access of information by other medical staff and by optimizing inventory control.

While the computerizing of any system can require changes in that system, this module has been designed to impose no substantive changes in the actual workflow. With the exception of the actual worksheets for recording tests results and interpretations, the majority paper documents will be replaced by the computer.

Hardware Sizing Model

Platform size and disk capacity was chosen based on internal VA sizing algorithms which measure the mission, size, and complexity of all VHA facilities. Hardware was initially distributed from a centralized purchase which provided DEC Alpha systems for the largest 108 facilities and Intel based PC systems for the remaining (at that time) 64 hospitals. Local facilities are authorized to accommodate local needs or to improve performance as required.

In 1982, the Department of Medicine and Surgery within the Department of Veterans Affairs developed a planning tool for estimating resource requirements for *VISTA*. The planning tool is called the "sizing model". The "sizing model" is composed of algorithms for each software application that use workload data to calculate resource requirements for the VAMCs. All VAMCs were assigned a "Class" status based on the first sizing model results. Class I facilities were considered to have the largest resource needs and Class V were considered to have the smallest. Computing equipment to support the CORE applications, including the Laboratory software application was distributed with respect to class status. At that time, the Laboratory software application did not include Blood Bank software.

Over the following years, the scope of *VISTA* grew. The CORE applications were enhanced and new applications were added (both clinical and administrative). A second sizing model was developed in 1986 applying the same principals used for the first sizing model. However, the first sizing model addressed five applications, the second sizing model covered thirty. The first sizing model took into account a dozen input variables, the second employed nearly two hundred workload indicators. Application specific algorithms were developed using input from software application developers, subject matter experts, and hospital system managers who were already supporting these applications in a production environment. Each application is addressed separately with a computed expression for processing power, disk storage, video terminal, and printer requirements. Therefore, site specific requirements can reflect the particular mix of applications relevant to each unique setting.

The sizing model results are in terms of central processing through-put units (TUs), disk capacity, terminal and printer requirements. For the model, the PDP 11/44 processors are used as the benchmark for comparisons. One TU may be considered as equivalent to one quarter of the processing power of four networked PDP 11/44 processors. Estimates indicated that twenty users simultaneously accessing the central processing unit would use one TU. The Alpha equipment currently in use has a capacity approximately twenty times greater than the PDPs.

Information was collected from a variety of sources, including Automated Management Information System (AMIS) workload reports. In order to verify the accuracy of the input data, each site was given the opportunity to review and correct its own data profile. Corrections were made based on site input including supporting documentation and certification by the facility Director.

Accuracy of the sizing model predictions has been confirmed for applications that are in current production use. The sizing model process is inherently dynamic, with progressive refinement resulting from increasing understanding, continual change resulting from events at each site, and periodic revision by the Capacity Management and Planning group at the San Francisco Chief Information Officer Field Office (CIOFO).

The sizing model was again updated in 1995. The use of bar code readers were optional at that time and not included in this model. This issue will be revisited based on the upcoming conversion from Codabar to ISBT Code 128, which has a significant impact on the length and complexity of the unit ID numbers.

1. Blood Bank Data

- a) Total # crossmatches (taken from FY95 AMIS Segment H29)
- b) Total # blood donors (taken from FY95 AMIS Segment H29)
- c) Number of technicians working in the blood bank during the day

2. Blood Bank Equations

a) Blood Bank through-put units (TU) ((CRTs + PRTs)/25) + (Crossmatches/200,000)

b) Blood Bank Disk

Algorithm is based on # crossmatches and # donors. Each crossmatch test requires 2.5K of storage (considering both the BLOOD INVENTORY file (#65) and the LAB DATA file (#63)) and each blood donor requires 0.2K of storage. The result is divided by 1000 to indicate megabytes. A constant of 1MB is added.

c) Blood Bank CRTs

Algorithm is based on # crossmatches, # donors, and maximum # techs on duty in Blood Bank at one time

For sites with Blood Bank activity and less than 1800 donors, allow one CRT for every two techs, with a minimum of one CRT.

For sites with more than 1800 donors/year, an additional CRT is added.

NOTE: This is based on the type of data entry and the limitations detailed in Section IX Functional Requirements.

d) Blood Bank Printers Algorithm is based on the # crossmatches, with a minimum of one

NOTE: This assumes that Blood Bank is in close proximity to other laboratory sections and that label printers can be shared.

Since the Blood Bank software represents only one component of the much larger hospital system, hardware considerations must be viewed in context. Although a TU can be calculated for each facility based on an appropriate algorithm, the adequacy of this measure is better reflected in terms of response time and the availability of CRTs.

Number of Users

The number of users who can access the system simultaneously is controlled by the number of available CRTs. Since the Blood Bank software is part of an integrated hospital computer system involving over thirty software applications, the total number of CRTs and users is beyond the scope of control of Blood Bank or even the Pathology & Laboratory Medicine Service. However, the number of CRTs needed to support the Blood Bank software is provided by the sizing model as indicated above.

Response Time

The integrated system provides dynamic adjustments of resources that provide optimum response time to on-line users. Performance monitoring tools allow each individual site to monitor and review response time to provide less than two second average responses, with an optimum target of under one second for responses. System load is balanced to provide acceptable response for printing labels and reports for users.

Storage Capacity

VHA Directive 10-95-094, dated September 28, 1995, provides instructions for archiving and purging data to relieve current disk storage limitations. Health care facilities are instructed to ensure that the presence of historical data in the VISTA databases does not adversely impact the ability to store current patient and administrative data. Data elements not specifically detailed in this directive represent completed actions, are not otherwise subject to retention requirements and are considered purgeable after 90 days or the time established by the software. If disk storage limitations are particularly severe, this period may be shortened on a case by case basis at the discretion of the Chief, Information Resources Management Service (IRM) and the Chiefs of the respective using Services, with the approval of the medical center Director. Data for blood donors, blood inventory, and patients are specifically detailed in this directive, and therefore, are not subject to routine purging.

As noted in the sizing model, it is possible to predict the amount of disk space required to support the Blood Bank software on an annual basis. The tools available as part of the Statistical Analysis of Global Growth software provide data such as number of entries, number of blocks currently in use, percent change in a single day, percent change in the last 28 days, etc. The tools may be used by the sites to assist in evaluating current and future needs.

A variety of options exist which provide purge and archive capabilities, some of which are in the main Laboratory software application and some of which are specific to the blood bank software. Each of these options is discussed below. In general, data for the BLOOD INVENTORY file (#65) and the BLOOD DONOR file (#65.5) can be printed and purged as detailed below. However, patient data that is stored in the LAB DATA file (#63) is maintained on-line permanently. A listing of the data elements for each of these files is included in Section IX Functional Requirements.

The Purge Old Orders and Accessions [LROC] option is an interactive manual purge of the old data in the ACCESSION file (#68) and LAB ORDER ENTRY file (#69.9) within the Laboratory software application. No patient test data is purged with this option. The amount of data retained is site definable via the Grace Period For Orders field (#15), in the LAB ORDER ENTRY file (#69.9). Access to this option requires a higher level of security and is generally restricted to the IRM staff. This purge includes orders for blood bank tests; however, this is included in the limitations detailed in Section IX Functional Requirements.

The Laboratory Archiving enhancement provided in patch LR*5.2*59 provide archiving capability for the WKLD DATA file (#64.1) and the LAB MONTHLY WORKLOADS file (#67.9). Since this global/file can grow quite large as it holds data on each test performed within the lab, archiving/purging is necessary to control its growth.

The VA FileManager Extract Tool is used to move data from the source file to a destination (archive) file. After the data has been copied to external media, the data can then be purged from the source file. A variety of reporting capabilities is available for the archived data; however, the data cannot be restored to the source file. This purge includes blood bank workload; however, this data is collected for purely administrative/management purposes and has no relation to any safety critical functional requirements. The Purge Data Found in the Search [LR ARCHIVE PURGE] option is used to archive laboratory data for patients based on an algorithm and site defined parameters. Blood bank data is not included in this algorithm (i.e., only data for CH subscript tests is evaluated and included in the archive/purge).

The Purge the Cumulative File [LRAC PURGE] option is used to purge entries in the CUMULATIVE file (#64.7) based on an algorithm and site defined parameters for the grace period. Patient lab test data is not removed is stored in the LAB DATA file (#63). Blood bank data is not included in this algorithm (i.e., only CH and MI subscript tests are included in the cumulative report). Blood bank test reports are generated via a separate option and data is pulled directly from the LAB DATA file (#63).

The Remove inappropriate transfusion requests [LRBLSRI] option is used to purge inappropriate transfusion requests which are identified and flagged based on site defined audit criteria. Access to this option requires a higher level of security than the majority of the blood bank options. This option should be run periodically as necessary, usually on a monthly basis. Before running the Remove inappropriate transfusion requests [LRBLSRI] option, sites should generate the Inappropriate Transfusion Requests Report [LRBLPRIT] option. The removal of the listing of the inappropriate requests does not affect actual component request information.

The Remove units with final disposition [LRBLSER] option is used to remove data from the BLOOD INVENTORY file (#65) when a final disposition has been entered. Prior to using this option, the Print units with final disposition [LRBLRUF] option must be executed. This option identifies those units which meet the criteria (i.e., a final disposition has been entered to provide a hard copy document of all data in the BLOOD INVENTORY file (#65) for each unit sorted by unit number which can be retained in accordance with record retention requirements). Removing units from the BLOOD INVENTORY file (#65) does not affect a patient's transfusion record. Access to the Remove units with final disposition [LRBLSER] option requires a higher level of security than the majority of the blood bank options. The frequency by which this option is used is determined by the site. However, based on the minimal amount of space used by the LRD global where the data for the BLOOD INVENTORY file (#65) is stored, adequate storage capacity exists to provide on-line storage for many years, though not necessarily indefinitely. On-line storage is preferable in order to expedite access to data in the event that a unit is identified through 'look back' procedures. If so desired, the growth of this global can be monitored by the IRM at the site on a regular basis.

The Remove ex-donors [LRBLDK] option is used to remove donors from the BLOOD DONOR file (#65.5). Prior to using this option sites **must** execute the Print ex-donor [LRBLDEX] option. The Print ex-donor [LRBLDEX] option will identify donors who meet the remove ex-donors criteria, (i.e., no donations since the date specified by the site and to provide a hard copy document of all data in File (#65.5) for each donor sorted by donor which can be retained in accordance with record retention requirements). Access to the Remove ex-donors [LRBLDK] option requires a higher level of security than the majority of the blood bank options.

The frequency with which this option is run is determined by the site; however, based on the minimal amount of space used by the LRE global where the data for File (#65.5) is stored, adequate storage capacity exists to provide on-line storage for many years, though not necessarily indefinitely. On-line storage is preferable in order to expedite access to data in the event that a donor is identified through 'look back' procedures. If so desired, the growth of this global can be monitored by the IRM at the site on a regular basis.

The Remove data change audits [LRBLAR] option is used to remove the entries on the audit trail which are created based on algorithms included in the software for tracking changes in specific data.

NOTE: See Section IX Functional Requirements for a detailed listing of the fields for the BLOOD DONOR file (#65.5), BLOOD INVENTORY file (#65), and LAB DATA file (#63).

In some cases, the algorithm is part of the routine and in some cases, it is part of the input template. The entries for the audit trail are stored in the LAB SECTION PRINT file (#69.2), Data Change Date field (#999) is stored by ACCESSION AREA. Recommendations are for the Print data change audits [LRBLAD] option to be run on a regular basis as part of the supervisory review. The frequency by which the entries on the audit trail are removed is determined by the site and should be related to the procedures for retaining the hard copies of the audit trail report and the record retention policy at the site. Access to this option requires a higher level of security than the majority of the blood bank options. Deletion of the entries on the audit trail does not affect the appearance of comments automatically generated regarding changes in verified data for the patient test results entered through the Enter test data [LRBLPET] option, including ABO, Rh, antibody screening and direct antiglobulin testing. On the Blood Bank Tests Report, the comments will still appear indicating both the new result and the original result even after the entry on the audit trail has been deleted.

A. Blood Donor Functions

1. BLOOD DONOR file (#65.5) Description of Data Elements

| | Field | |
|--------------|---|---|
| _, , , , , , | Help Prompt | |
| | Description | Data Type (PM=Pattern Match) |
| .001 | IDENTIFICATION NUMBER TYPE A WHOLE NUMBER BETWEEN 1 AND 99999 This is a unique number assigned to the number cannot be assigned to a new donor. | blood donor. An existing |
| .01 | NAME NAME MUST BE 3-30 CHARACTERS, NOT NUMER Name of blood donor | FREE TEXT IC OR STARTING WITH PUNCTUATION |
| .02 | SEX | SET 'M' FOR MALE; 'F' FOR FEMALE; |
| | This is the sex of the blood donor. | |
| .03 | DOB | DATE (PM= Exact date (with month and day) required and echo the answer) |
| | This is the age of the donor. (Must be | |
| .031 | AGE This is the computed age of the donor. Algorithm: TODAY-DOB/365.25 (always 0 do | COMPUTED ecimal digits) |
| .04 | APHERESIS CODE | SET '1' FOR YES; '2' FOR NO; '1' FOR yes; '2' FOR no; |
| | If donor is willing donate plasma, plate 'YES' | |
| .05 | ABO GROUP | SET 'A' FOR A; 'B' FOR B; 'O' FOR O; 'AB' FOR AB; |
| | The ABO group of the donor is entered he | - · · · · · · · · · · · · · · · · · · · |
| .06 RH | TYPE SET | 'POS' FOR POSITIVE; |
| | The RH type of the donor is entered here | 'NEG' FOR NEGATIVE; |
| .07 | CUMULATIVE DONATIONS TYPE A WHOLE NUMBER BETWEEN 0 AND 99999 Total number of donation credits based of donation. | |

Blood Donor Functions

Field Name Help Prompt

Field# Description

Data Type

TOTAL AWARDS .08

NUMBER

TYPE A WHOLE NUMBER BETWEEN 1 AND 99999

Number of awards given based on 1 award for each gallon or equivalent (8 donation credits) donated

.085 GIVE NEW AWARD SET

'1' FOR YES;

To acknowledge giving award delete entry by entering '@'

DEMOG ENT/EDIT BY .09

POINTER TO NEW PERSON FILE (#200)

Person entering or editing donor demographic data

. 1 PERMANENT DEFERRAL SET

'1' FOR YES;
'0' FOR NO;

If the donor is to be permanently excluded from donation enter 'YES' Donor should be permanently deferred as a homologous blood donor based on donor history or test results.

.11 DATE REGISTERED/EDITED

DATE (PM= Exact date (with month and day) required, time

allowed and echo the answer)

DATE DONOR IS ENTERED/EDITED IN THE FILE

This is the date the donor was registered into this file.

DEFERRAL ENTER/EDIT BY . 12

POINTER TO NEW PERSON FILE (#200)

Person entering or editing permanent deferral of donor.

.13

FREE TEXT

ANSWER MUST BE 9-10 CHARACTERS IN LENGTH

This field contains the social security number of the donor.

NOTE: The entry for the FORUTH DEFAULT for DONOR in the LABORATORY SITE file (#69.9) controls whether this field is included in the input template.

.14 MILITARY RANK FREE TEXT

Answer must be 2-20 characters in length.

If this collection is being performed by a DOD site, the rank of the donor is entered in this field.

NOTE: The entry for the SECOND DEFAULT for DONOR in the LABORATORY SITE file (#69.9) controls whether this field is included in the input template.

PERMANENT DEFERRAL DATE CHANGE . 16

DATE (PM= Exact date (with month and day) required, time allowed and echo the answer)

If the deferral date is adjusted, the date is entered in this field.

| Field# | Field Name Help Prompt Description | Data Type |
|--------|---|--|
| 1.1 | ADDRESS LINE 1 ANSWER MUST BE 1-30 CHARACTERS IN LENGTH First line of donor address | FREE TEXT |
| 1.2 | ADDRESS LINE 2 ANSWER MUST BE 1-30 CHARACTERS IN LENGTH Second line of donor address (if necessary) | |
| 1.3 | ADDRESS LINE 3 ANSWER MUST BE 1-30 CHARACTERS IN LENGTH Third line of donor address (if necessar | |
| 1.4 | CITY ANSWER MUST BE 1-30 CHARACTERS IN LENGTH City of donor | FREE TEXT H |
| 1.5 | STATE State of donor residence | POINTER TO STATE FILE (#5) |
| 1.6 | ZIP CODE ANSWER MUST BE 5-9 CHARACTERS IN LENGTH Zip code of donor | FREE TEXT |
| 1.7 | HOME PHONE ANSWER MUST BE 3-15 CHARACTERS IN LENGTH Home phone of donor | FREE TEXT H |
| 1.8 | WORK PHONE ANSWER MUST BE 3-15 CHARACTERS IN LENGTH Phone where donor works so that the dono working hours if necessary | |
| 2 | GROUP AFFILIATION (Subfile 65.51) Multiple | POINTER |
| | .01 GROUP AFFILIATION | POINTER TO BLOOD BANK UTILITY FILE (#65.4) |
| | These are groups with which the don $.02$ FULL NAME | or may be associated. COMPUTED |
| 3 | DONOR SCHEDULING (Subfile 65.52) .01 BLOOD DONOR COMMENTS | Field Not in Use Field Not in Use |

| D' 7.1" | | Prompt | |
|---------|------|---|--|
| Field# | | ription OR SCHEDULING/RECALL (Subfile 65.53) | Data Type SET |
| 1 | | ciple | |
| | .01 | DONOR SCHEDULING/RECALL | SET '1' FOR JAN; '2' FOR FEB; '3' FOR MAR; '4' FOR APR; '5' FOR MAY; '6' FOR JUN; '7' FOR JUL; '8' FOR AUG; '9' FOR SEP; '10' FOR OCT; '11' FOR NOV; '12' FOR DEC; '13' FOR 7/4; |
| | | | '14' FOR LABOR DAY; '15' FOR XMAS; |
| | | se are donors placed on a specific reposes. | '16' FOR EMERGENCY; ecall list for recruitment |
| 5 | | ATION OR DEFERRAL DATE (Subfile 65.54 ciple | l) DATE |
| | .01 | DONATION OR DEFERRAL DATE These are the dates of donation or | DATE (PM = Exact date (with and day) required and echo the answer; allows dates up to and including the current date) |
| | | Date when a person appears for donat date is the deferral date; otherwise | tion. If no donation then this |
| | .011 | DONATION ENTERED/EDIT BY Person entering or editing donation | POINTER TO NEW PERSON FILE (#200) information. |
| | .02 | COLLECTION SITE | POINTER TO BLOOD BANK UTILITY FILE (#65.4) |
| | | Site at which a donation attempt is | |
| | .03 | DONATION GROUP | POINTER TO BLOOD BANK UTILITY FILE (#65.4) |
| | | Group affiliation for which a donat | · |
| | .13 | ARRIVAL/APPT TIME | DATE (PM = Exact date (with month and day) required and echo the answer; allows dates up to and including the current time) |
| | | Future date/time not allowed. This is the date/time the donor arradonate. | ives for an appointment to |

Field Help Prompt Field# Description Data Type .14 ENTRY VIA OLD RECORDS SET '1' FOR YES; '0' FOR NO; If data entry for donation/deferral date subfield is by way of the enter old records option, a 'YES' is entered in this field. DONATION/DEFERRAL CODE SET 'W' FOR WHOLE BLOOD; 'P' FOR PLASMAPHERESIS; 'C' FOR CYTAPHERESIS; 'N' FOR NO DONATION; This is the result of donation attempt. If donation successful, the type of donation is entered. 1.1 DONATION TYPE SET 'H' FOR HOMOLOGOUS; 'A' FOR AUTOLOGOUS; 'T' FOR THERAPEUTIC; 'D' FOR DIRECTED; This is the donation type. 1.2 RESTRICTED FOR FREE TEXT If autologous donation donor must be the same as the patient If autologous donor must also be the patient selected. If directed donation can be any patient selected. 2 DEFERRAL REASON (Subfile 65.55) POINTER Multiple .01 DEFERRAL REASON POINTER TO BLOOD BANK UTILITY FILE (#65.4) These are the reasons for which the donor is deferred. DONOR REACTION CODE POINTER TO BLOOD BANK UTILITY 3 FILE (#65.4) Any adverse reaction which the donor might have suffered during or immediately following the blood donation. FREE TEXT UNIQUE ID ASSIGNED TO PRIMARY UNIT Enter ID that component(s) prepared from donation will be labeled. This determines that the donor ID assigned to another donation within the past 5 years will not be allowed. 4.1 PRIMARY BAG '1' FOR SINGLE; '2' FOR DOUBLE; '3' FOR TRIPLE; '4' FOR QUADRUPLE; '5' FOR QUINTUPLE; This is the type of bag used for the collection of the donor

blood.

Field Help Prompt Field# Description

Data Type

4.11 ANTICOAGULANT/ADDITIVE

SET
'1' FOR CPD;
'2' FOR ACD;
'3' FOR CPDA-1;
'4' FOR ADSOL;

This is the type of anticoagulant in the collection bag.

4.15 BAG LOT #

FREE TEXT

ANSWER MUST BE 1-15 CHARACTERS IN LENGTH This is the lot number of the collection bag.

NOTE: The entry for the THIRD DEFAULT for DONOR in the LABORATORY SITE file (#69.9) controls whether this field is included in the input template.

4.2 DATE/TIME COLLECTION STARTED

DATE (PM=Exact date (with month and day) and time required and echo the answer)

Date AND time must be entered !!
This is the date and time the donation was started.

4.3 DATE/TIME COLLECTION COMPLETED

DATE (PM=Exact date (with month and day) and time required and echo the answer)

This is the date and time the donation was completed.

4.4 DATE/TIME PROCESSED

DATE (PM=Exact date (with month and day) and time required and echo the answer; allows dates up to and including the current time)

DATE AND TIME COLLECTION WAS PROCESSED Date/time at which the component preparation started.

- 4.5 COLLECTED PRIMARY UNIT WT (gm) NUMBER WEIGHT IN GRAMS OF COLLECTION INCLUDING CONTAINER TYPE A NUMBER BETWEEN 1 AND 9999

 This is the gross weight of the unit collected.
- 4.6 EMPTY PRIMARY UNIT WT (gm) NUMBER WEIGHT IN GRAMS OF COLLECTION CONTAINER TYPE A NUMBER BETWEEN 1 AND 1000 Weight of the empty donor bag (primary bag only).
- 4.7 COLLECTION VOL (ml) NUMBER

 TYPE A WHOLE NUMBER BETWEEN 1 AND 9999

 Volume of blood collected (ml)

 Algorithm: (Volume = collected primary unit wt (gm) minus empty primary unit wt (gm) divided by 1.06)

Field Help Prompt Field# Description Data Type 4.8 PROCESSING TECH POINTER TO NEW PERSON FILE (#200) Person performing the component preparation. PATIENT CREDIT Enter patient for donation credit Patient for whom a unit of blood was donated, i.e. to whom should the "replacement" be credited. 6 PHLEBOTOMIST FREE TEXT ANSWER MUST BE 2-30 CHARACTERS IN LENGTH Name of person performing the collection. 6.1 COLLECTION DISPOSITION SET '0' FOR PREPARE COMPONENT(S); '1' FOR QUARANTINE; '2' FOR DISCARD COLLECTION; Records what happened to the collection. 6.2 COLLECTION DISPOSITION COMMENT (Subfile 65.546) Multiple .01 COLLECTION DISPOSITION COMMENT FREE TEXT ANSWER MUST BE 2-80 CHARACTERS IN LENGTH These are comments regarding the collection disposition. RBC TYPING METHOD (Subfile 65.61) Field Not in Use RBC TYPING METHODField Not in Use .01 TECHNIQUE Field Not in Use TECHNOLOGIST Field Not in Use .02 .03 ANTISERUM (Subfile 65.62) Field Not in Use .01 ANTISERUM Field Not in Use .02 LOT# Field Not in Use .03 INTERPRETATION Field Not in Use .04 IS Field Not in Use Field Not in Use
Field Not in Use
Field Not in Use
Field Not in Use
Field Not in Use
Field Not in Use .05 37 C .06 AHG .00 ANG .07 CONTROL CELL .08 ROOM TEMP .09 12-18 C .1 4 C Field Not in Use 8.1 DONOR CELLS+ANTI A 8.2 DONOR CELLS+ANTIB Field Not in Use 8.3 DONOR CELLS+ANTIA,B Field Not in Use 8.4 DONOR PLASMA/SERUM+A1 CELLS Field Not in Use 8.5 DONOR PLASMA/SERUM+B CELLS Field Not in Use 9.1 DONOR CELLS+ANTI D Field Not in Use 9.2 DONOR CELLS+RH CONTROL Field Not in Use

| | Field Help | Prompt | |
|--------|-----------------------------------|--|--|
| Field# | Descr | iption | Data Type |
| | 9.3 I | DONOR CELLS+ ANTI D (37 C) | Field Not in Use |
| | 9.4 [| DONOR CELLS+RH CTRL (37 C) | Field Not in Use |
| | 9.5 I | DONOR CELLS+ANTI D (AHG) | Field Not in Use |
| | 9.6 I | DONOR CELLS+RH CTRL (AHG) | Field Not in Use |
| | | ABO INTERPRETATION INTERPRETATION OF ABO TESTING | SET 'A' FOR A; 'O' FOR O; 'B' FOR B; 'AB' FOR AB; 'ND' FOR NOT DONE; |
| | I | This is the interpretation of ABO gr | rouping results. |
| | 10.2 | TECH ENTERING-ABO INTERP This is the technologist entering | POINTER TO NEW PERSON FILE (#200) ABO interpretation. |
| | 10.3 | ABO TESTING COMMENT ANSWER MUST BE 1-80 CHARACTERS IN This is a comment concerning the A | |
| | 10.4 | ABO INTERPRETATION RECHECK | SET 'A' FOR A; 'O' FOR O; 'B' FOR B; 'AB' FOR AB; |
| | Recheck of ABO group interpretat. | | on. |
| | 10.5 | TECH ENTERING-ABO RECHECK Technologist entering ABO grouping | |
| | 10.6 | ABO RECHECK COMMENT ANSWER MUST BE 1-80 CHARACTERS IN ABO grouping recheck comment. | FREE TEXT LENGTH. |
| | 11 | RH INTERPRETATION | SET 'NEG' FOR NEGATIVE; 'POS' FOR POSITIVE; 'ND' FOR NOT DONE; |
| | | INTERPRETATION OF RH TESTING This is the interpretation of Rh t | yping results. |
| | 11.2 | TECH ENTERING-RH INTERP This is the technologist entering | POINTER TO NEW PERSON FILE (#200) Rh interpretation. |
| | 11.3 | RH TESTING COMMENT ANSWER MUST BE 1-80 CHARACTERS IN This is a comment concerning the R | |
| | 11.4 | RH INTERPRETATION RECHECK | SET 'NEG' FOR NEGATIVE; 'POS' FOR POSITIVE; |
| | | Rh interpretation recheck | |

Field Name Help Prompt Field# Description Data Type POINTER TO NEW PERSON TECH ENTERING-RH RECHECK 11.5 FILE (#200) Technologist entering Rh type recheck. 11.6 RH TESTING RECHECK COMMENT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH Rh testing recheck comment 12 SYPHILIS SEROLOGY SET '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; This is the results of syphilis serology test. 12.2 TECH-SYPHILIS SEROLOGY POINTER TO NEW PERSON FILE (#200) Technologist entering syphilis serology results. 12.3 SYPHILIS SEROLOGY COMMENT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH This is a comment concerning the syphilis serology test. SET 13 HBsAq '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; Hepatitis B surface antigen These are the results of hepatitis B surface antigen testing. 13.2 TECH-HBsAq POINTER TO NEW PERSON FILE (#200) Technologist entering Hepatitis B surface antigen test results. 13.3 HBsAg COMMENT FREE TEXT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH This is a comment concerning the HBsAg test. 14 HIV ANTIBODY '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; HUMAN IMMUNODEFICIENCY ANTIBODY These are results of HIV antibody testing. 14.2 TECH-HIV POINTER TO NEW PERSON FILE (#200) Technologist entering HTLV-III test results. 14.3 HIV TESTING COMMENT FREE TEXT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH

This is a comment concerning the HIV test.

| | Field Name Help Prompt | | |
|--------|---------------------------|--|---|
| Field# | _ | iption | Data Timo |
| rieiu# | 15 | ANTIBODY SCREEN RESULT | Data Type SET '0' FOR NEGATIVE; "1' FOR POSITIVE; 'ND' FOR NOT DONE; |
| | | These are the results of antibody | |
| | 15.2 | TECH-ANTIBODY SCREEN Technologist entering antibody scr | POINTER TO NEW PERSON FILE (#200) reening test results. |
| | 15.3 | ANTIBODY SCREEN COMMENT ANSWER MUST BE 1-80 CHARACTERS IN This is a comment concerning the a | |
| | 16 | HBcAb | SET '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; |
| | | These are the results of hepatitis | s core antibody testing. |
| | 16.2 | TECH-HBcAb This is the technologist entering results. | POINTER TO NEW PERSON FILE (#200) Hepatitis Core Antibody |
| | 16.3 | HBcAb TEST COMMENT ANSWER MUST BE 1-80 CHARACTERS IN This is a comment concerning the B | |
| | 17 | ALT | SET '1' FOR ELEVATED; '0' FOR NOT ELEVATED; 'ND' FOR NOT DONE; |
| | | ALANINE-AMINO TRANSFERASE These are the results of alanine-a NOTE: The entry for the FIFTH DEFA LABORATORY SITE file (#69.9) conta included in the input template. | AULT for DONOR in the |
| | 17.2 | TECH-ALT This is the technologist entering results. | POINTER TO NEW PERSON FILE (#200) alanine-amino transferase |
| | 17.3 | ALT TEST COMMENT ANSWER MUST BE 1-80 CHARACTERS IN This is a comment concerning the A | |
| | 18 | HTLV-I ANTIBODY | SET '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; |
| | | Results of HTLV-I antibody testing | |
| | 18.2 | TECH-HTLV-I | POINTER TO NEW PERSON FILE (#200) |
| | 18.3 | HTLV-I TESTING COMMENT ANSWER MUST BE 1-80 CHARACTERS IN | FREE TEXT LENGTH |

| | Field Name Help Prompt | | | |
|--------|--|-------|--|--|
| Field# | | | | Data Type |
| | | HCV | ANTIBODY alts of hepatitis C virus (HCV) | SET '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; antibody testing are entered |
| | 100 | | this field. | |
| | | | I-HCV ANTIBODY | POINTER TO NEW PERSON FILE (#200) |
| | 19.3 | | ANTIBODY TESTING COMMENT JER MUST BE 1-80 CHARACTERS IN | FREE TEXT LENGTH. |
| | 20 | | ANTIGEN | SET '1' FOR REACTIVE; '0' FOR NEGATIVE; 'ND' FOR NOT DONE; |
| | | (#69. | entry for the SIXTH DEFAULT fo 9) controls whether this field | r DONOR in the LABORATORY SITE I is included in the input |
| | 20.2 | _ | I-HIV ANTIGEN Inologist performing HIV antige | POINTER TO NEW PERSON FILE (#200) on testing. |
| | 20.3 | ANSW | ANTIGEN COMMENT JER MUST BE 1-80 CHARACTERS IN Ment related to HIV antigen tes | |
| | 66 | Mult | DD COMPONENT (Subfile 65.66) | |
| | These are blood components prepared from the collection. | | d from the collection. | |
| | | .01 | BLOOD COMPONENT | POINTER TO BLOOD PRODUCT FILE (#66) |
| | | | The selection must be a blood Blood component prepared from | |
| | | .02 | COMPONENT DISP DATE/TIME | DATE (PM=Exact date (with month and day), time allowed and echo the answer; allows dates up to and including the current time) |
| | | | DATE/TIME OF COMPONENT DISPOSED Date/time at which component a quarantined or discarded. | |
| | | .03 | DATE/TIME STORED | DATE (PM=Exact date (with month and day), time allowed and echo the answer; allows dates up to and including the current time) |
| | | | Date/time component stored. | |
| | | .04 | EXPIRATION DATE | DATE (PM=Exact date (with month and day), time allowed and echo the answer; allows dates including the current and future times) |

Field Name Help Prompt Field# Description

Data Type

Cannot enter expired components. Expiration date/time of component prepared.

- .05 COMPONENT VOL (ml) NUMBER
 TYPE A WHOLE NUMBER BETWEEN 0 AND 500
 Volume in milliliters (ml) of component prepared.
- .06 TECH LABELING POINTER TO NEW PERSON FILE (#200)

This is the person initially reviewing the donor results and, if appropriate, placing the correct labels on the component.

- .07 DISPOSITION TECH POINTER TO NEW PERSON FILE (#200)
 Person verifying that the donor results and the labeling are
 - Person verifying that the donor results and the labeling are acceptable and that the component can be released to inventory.
- .08 COMPONENT DISPOSITION

 SET
 '0' FOR RELEASE COMPONENT;
 '1' FOR QUARANTINE;
 '2' FOR DISCARD;
 - This is the disposition of component.
- 1 COMPONENT DISPOSITION COMMENT (Subfile 65.67) Multiple
 - .01 COMPONENT DISPOSITION FREE TEXT
 COMMENT
 ANSWER MUST BE 2-80 CHARACTERS IN LENGTH
 This is the reason component quarantined or discarded.

| 2 | SEDIMENTING AGENT | Field Not in Use |
|----|--------------------|--------------------------------------|
| 3 | DRUG | Field Not in Use |
| 70 | GENERAL APPEARANCE | Field Not in Use for Data Storage |
| 71 | VENIPUNCTURE SITE | Field Not in Use for Data Storage |
| 72 | ORAL TEMPERATURE | Field Not in Use for Data Storage |
| 73 | BLOOD PRESSURE | Field Not in Use for Data Storage |
| 74 | PULSE | Field Not in Use for Data Storage |

Field Name Help Prompt

| | Help Promp | | |
|--------|--|--|---|
| Field# | Description | | Data Type |
| | 74.3 | PULSE COMMENT | Field Not in Use |
| | 75 | WEIGHT (lb) | Storage Field Not in Use for Data |
| | 80 | HEMOGLOBIN | Storage Field Not in Use for Data Storage |
| | 81 | HEMATOCRIT | Field Not in Use for Data Storage |
| | 82 | TOTAL SERUM PROTEIN | Field Not in Use |
| | 83 | SERUM PROTEIN ELECTROPHORESI | S (Subfile 65.6) Field Not in Use |
| | | .01 SERUM PROTEIN ELECTROPHOR | RESIS |
| | 84 85 86 87 88 89 90 | | Field Not in Use |
| | 92 | PLATELET COUNT | Field Not in Use |
| | 500 | are entered here. .01 WORKLOAD TEST/PROCEDURE Tests or procedures containiare entered here. 1 COMPLETE DATE/TIME (Subfi | ng WKLD codes for donor workload POINTER TO LABORATORY TEST FILE (#60) ng WKLD codes for donor workload |
| | | Multiple .01 COMPLETE DATE/TIME Used for workload r workload needs to b | DATE (PM=Exact date (with month and day) and time required and echo the answer) ecording. If x-ref exists, se counted. |
| | | .02 TECH | POINTER TO NEW PERSON File (#200) |
| | | 1 WKLD CODE (Subfile 65.599 Multiple | 11) POINTER |
| | | .01 WKLD CODE | POINTER TO WKLD CODE file(#64) |
| | | .02 WKLD CODE COUNT Type a Number betwee | NUMBER en 0 and 999, 0 Decimal Digits |
| | | .03 CODE COUNTED | SET '1' FOR YES; '0' FOR NO; |

Blood Donor Functions

| | Field | | |
|--------|--|-----------------|---|
| Field# | Help Prompt Description | Data Type | |
| 6.1 | RBC ANTIGEN PRESENT (Subf Multiple | ile 65.56) | POINTER |
| | .01 RBC ANTIGEN PRESENT | | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | donor. SNOMED codes can be e | entered as well | ne red blood cells of the as the name of the antigen. re in the FUNCTION FIELD file |
| | 1 COMMENT | | Field Not in Use |
| 6.2 | RBC ANTIGEN ABSENT (Subfi Multiple for RBC Antigen | | POINTER |
| | .01 RBC ANTIGEN ABSENT | | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | 1 COMMENT | | Field Not in Use |
| 6.3 | HLA ANTIGEN PRESENT (Subf Multiple for HLA antigen | • | POINTER |
| | .01 HLA ANTIGEN PRESENT COMMENT | | POINTER TO FUNCTION FIELD FILE (#61.3) Field Not in Use |
| 6.4 | HLA ANTIGEN ABSENT (Subfi Multiple for HLA antigen | | POINTER |
| | .01 HLA ANTIGEN ABSENT | | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | 1 COMMENT | | Field Not in Use |
| 6.5 | CMV ANTIBODY | | SET '0' FOR NEG; '1' FOR POS; |
| | A negative or positive re | sult for the Cy | |
| 9 | BLOOD DONOR COMMENTS (Sub | file 65.52) | |
| 63 | .01 BLOOD DONOR COMMENTS WORD-PROCESSING This field contains comments about the donor not found elsewhere. LABORATORY REFERENCE Field Not in Use | | |
| 99 | PERMANENT DEFERRAL REASON | (Subfile 65.99 |) |
| | .01 PERMANENT DEFERRAL RE | | WORD-PROCESSING red. |

2. BLOOD DONOR file (#65.5) Data Copied/Enteredn BLOOD INVENTORY file (#65) Upon Labeling/Release of Unit

| File 65 Field# | Field Name | File 65.5 Field of Data Origin | Data Copied/Entered |
|-------------------|--------------------------------|--------------------------------|--|
| .01 | UNIT ID | Subfile 65.54,4 | Exact |
| .02 | SOURCE | NA | Assigns Self |
| .03 | INVOICE# | NA | Assigns 00 |
| .04 | COMPONENT | Subfile 65.66,.01 | Exact |
| .05 | DATE/TIME RECEIVED | Subfile 65.66,.02 | Exact |
| .06 | EXPIRATION DATE/TIME | Subfile 65.66,.04 | Exact |
| .07 | ABO GROUP | Subfile 65.54,10 | Exact |
| .08 | RH TYPE | Subfile 65.54,11 | Exact |
| .11 | VOLUME (ml) | Subfile 65.66,.05 | Exact |
| .16 | DIVISION | NA | Assigns based on division of user releasing unit |
| 8 | RESTRICTED FOR | Subfile 65.54,1.2 | Exact if data exists, i.e., directed or autologous unit |
| 8.1 | POS/INCOMPLETE SCREENING TESTS | NA | Assigns'YES' based on established algorithm |
| 10 | ABO INTERPRETATION | Subfile 65.54,10 | Exact IF recheck is designated for transfer based on site parameter File setup |
| 10.2 TE | CCH ENTERING-ABO INTERP | Subfile 65.54,10.2 | Exact IF recheck is designated for transfer based on site parameter File setup |
| 10.4 AE | 30 MOVED FROM DONOR FILE | NA | Assigns 'YES' if data is transferred |

Blood Donor Functions

| File (| | File 65.5 Field of Data Origin | Data Copied/Entered |
|--------------|--|--------------------------------|--|
| 11 reched | | Subfile 65.54,11 | Exact IF |
| | | | is designated for transfer based on site parameter File setup |
| 11.2 | TECH ENTERING-RH INTERP | Subfile 65.54,11.2 | Exact IF recheck is designated for transfer based on site parameter File setup |
| 11.4 | RH MOVED FROM DONOR FILE | NA | Assigns 'YES' if data is transferred |
| 60 | RBC ANTIGEN PRESENT (Subfile 65.04) .01 RBC ANTIGEN PRESENT | Subfile 65.56,.01 | Exact |
| 70 | RBC ANTIGEN ABSENT (Subfile 65.05) .01 RBC ANTIGEN ABSENT | Subfile 65.57,.01 | Exact |
| 80 | HLA ANTIGEN PRESENT (Subfile 65.08) .01 HLA ANTIGEN PRESENT | Subfile 65.58,.01 | Exact |
| 90 | HLA ANTIGEN ABSENT (Subfile 65.09) .01 HLA ANTIGEN ABSENT | Subfile 65.59,.01 | Exact |
| 91 | CMV ANTIBODY | Subfile 65.5,6.5 | Exact |

Software Limitations

| Functionality | Description of Software Limitations |
|---|--|
| Donor - Registration, Screening and Collection | No evaluation of donor screening responses. No evaluation of donor history/physical results. No evaluation of volume of blood drawn. No evaluation of frequency and timing of autologous donations. No automatic updating of deferral status. No automatic updating and evaluation of donor recruitment/recall information based on actual donation data. No evaluation of information regarding confidential self-exclusion. No provision of an electronic system of records for donor medical history information. No provision of an electronic system of records of therapeutic phlebotomy requests. Partial provision of an electronic system of records for |
| Donor - Component Preparation | apheresis procedures. No system of blood component quality control records. No evaluation of components which can be prepared bas on an evaluation of donation types. Partial system for evaluating mutually exclusive components. |
| Donor Processing/Transfusion Transmitted Disease Marker Testing | No evaluation of results to determine requirements for repeat and/or confirmatory testing. No evaluation of quality control results to validating runs. No provision for test result interpretation based on actual testing results, (e.g. evaluation of actual instrument readings or reactions of antisera). Manual entry of test result interpretations for all required testing, (i.e., no instrument interfaces). Manual entry of ABO/Rh confirmation testing (rechecks). No provision for donor notification of abnormal test results. No provision for notification of recipient's physician if test result is reactive for unit which was labelled/released with incomplete testing. No system for proficiency testing. |
| Donor Phenotyping | Manual entry of test result interpretations. |

| Functionality | Description of Software Limitations |
|------------------------|--|
| Donor Labeling/Release | No system for quarantining of in-date units based on |
| | donor look-back procedures. |
| | No provision for determining the suitability for |
| | subsequent transfusion of units prepared from |
| | therapeutic phlebotomy. |
| | No system for ensuring application of biohazard labels |
| | to autologous units when appropriate. |
| Donor Records | No provision of an electronic system of records for |
| | donor medical history information. |
| | No provision of an electronic system of records for |
| | confidential self-exclusion. |
| | No provision of an electronic system of records of |
| | therapeutic phlebotomy requests. |
| | Partial provision of an electronic system of records for |
| | apheresis procedures. |
| | No automatic updating of deferral status. |
| | No system of blood component quality control records. |
| | No provision system of records for actual test results, |
| | (i.e., manual entry of test result interpretations for all |
| | required testing). |
| | No system for tracking disposal of discarded units. |
| | No provision for documentation of indication for |
| | emergency issue of incompletely tested units. |

<u>Intended Uses</u>

| IU# | Functionality | Description of Intended Uses |
|-----|--|--|
| D1 | Donor-General | Provision of a unique cumulative donor record for each individual blood donor/patient based on data elements detailed above for the BLOOD DONOR file (#65.5). |
| D2 | Donor - General | Provision of a unique cumulative donation sub-record for each individual donation/deferral date. |
| D3 | Donor- General | Tracking of the donation type for each donation, i.e., homologous, autologous, therapeutic, or directed. |
| D4 | Donor - General | Record updates immediately upon data entry. |
| D5 | Donor - General | Tracking of the person performing various steps in the process, i.e., the person entering the data into the computer. |
| D6 | Donor - General | Accommodation of a bar code reader for entry of the unit ID. |
| D7 | Donor-General | Tracking of changes in verified data for specific data elements defined for the BLOOD DONOR file (#65.5) as detailed in Section IX under Functional Requirements |
| D8 | Donor-General | Maintenance of donor confidentiality by providing different levels of security access such that the type of data access can be defined by individual user. |
| D9 | Donor-General | Minimal potential for data entry errors based on control of the data type and the input format through the use of a highly structured data dictionary and input transforms. |
| D10 | Donor - General | Limited simultaneous access by multiple terminals/ users to the same donor record for purposes of data entry in specified options. |
| D11 | Donor-Old Records | Entry of historical donor information if deemed appropriate and identification of the specific donation dates for which data was entered via that option. |
| D12 | Donor-Old Records | Check of the unit IDs during data entry of each unit ID, to determine if that unit ID is already in existence in the BLOOD INVENTORY file (#65) in order to identify potential duplicates/inappropriate entries. |
| D13 | Donor-Old Records | Restricted access to donor through the 'Old records' option once the donor record has been created. |
| D14 | Donor-Registration, Screening and Collection | Check the existing entries in the BLOOD DONOR file (#65.5) during the registration of each blood donor, to identify potential duplicate donors. |
| D15 | Donor - Registration, Screening and Collection | Evaluation of the donation intervals for allogeneic (homologous) blood donors. |
| D16 | Donor-Registration, Screening and Collection | Calculation of the age of donor based on his/her date of birth and subsequent evaluation of the age of the donor to see if outside defined limits, (i.e., ≤17 or >65 years of age). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|--|
| D17 | Donor-Registration, Screening and Collection | Site specific control to edit the donor history questions at the discretion of the facility in order to meet changes in regulatory and accrediting agency requirements. (Requires higher security level). |
| D18 | Donor-Registration, Screening and Collection | Site specific control to edit the donor consent in order to meet changes in regulatory and accrediting agency requirements. (Requires higher security level) |
| D19 | Donor - Registration, Screening and Collection | Donor specific donor history form which contains the donor demographics, date of last donation and site specific donor history questions and site specific donor consents. |
| D20 | Donor - Registration, Screening and Collection | Identification of donors who have been placed in a 'permanent deferral' status and flagging of those donors when appropriate. |
| D21 | Donor - Registration, Screening and Collection | Provision of a report of permanently deferred donors for use at remote sites where the computer system is not accessible and/or preprinted donor history forms may not be available for all potential donors. |
| D22 | Donor - Registration, Screening and Collection | Entry of collection data through routinely used options restricted if allogeneic (homologous) donor is permanently deferred. |
| D23 | Donor-Registration, Screening and Collection | Warning message; if an autologous donor or therapeutic phlebotomy patient who is permanently deferred is selected for data entry. |
| D24 | Donor - Registration, Screening and Collection | Entry of special comments for future reference so that donors who require special handling can be identified and appropriate procedures can be implemented. |
| D25 | Donor - Registration, Screening and Collection | Provision of link between autologous donor/patient in an effort to ensure that autologous units are made available for a patient before allogeneic (homologous) blood is selected. |
| D26 | Donor - Registration, Screening and Collection | Identification of units collected in bags of a specific lot in case of potential recalls. |
| D27 | Donor - Registration, Screening and Collection | Calculation of collection volume based on the gross weight, the empty bag weight and the specific gravity of whole blood. |
| D28 | Donor-Registration, Screening and Collection | Evaluation of unit ID to prevent assignment of "duplicate" unit IDs based on a search of existing entries in the BLOOD DONOR file.(#65.5) |
| D29 | Donor-Registration, Screening and Collection | Free text special comments in the BLOOD DONOR COMMENTS field (#.01) for future reference |
| D30 | Donor-Registration, Screening and Collection | Tracking of whether the donor had a donor reaction, making information available through a variety of report and inquiry options. |
| D31 | Donor-Registration, Screening and Collection | Screen on entry of donation date/time to prevent entry of a future date. |
| D32 | Donor-Registration, Screening and Collection | Screen on the entry of the collection completion date/time to ensure it is not prior to the collection start date/time. |

| IU# | Functionality | Description of Intended Uses |
|------|-----------------------------|--|
| D33 | Donor - Component | Tracking of all collection dispositions and tracks |
| | Preparation | storage and disposition of all components prepared. |
| D34 | Donor - Component | Tracking of the person performing various steps in the |
| | Preparation | process, i.e. the person entering data into the |
| | | computer. |
| D35 | Donor-Component Preparation | Restricted access to the donor's most recent donation, |
| | | (i.e., user cannot specify a unit ID) which is from other |
| | | than the most recent donation. |
| D36 | Donor - Component | Evaluation of the component preparation time to |
| | Preparation | ensure that components are prepared within the |
| | | maximum time allowable for that specific component. |
| D37 | Donor - Component | Evaluation of the number of components prepared |
| Das | Preparation | versus type of collection bag. |
| D38 | Donor - Component | Exclusion of more than 1 RBC component for |
| Dao | Preparation | preparation from a donor unit. |
| D39 | Donor - Component | Exclusion of incompatible components based on the |
| | Preparation | anticoagulant of the donor unit and that of components being prepared. |
| D40 | Donor - Component | Calculation of the date portion of the expiration date |
| | Preparation | for each component based on the donation date and the |
| | | specific component. |
| D41 | Donor-Component Preparation | Tracking of data on the date/time stored for each |
| | | specific component of a specific unit ID. |
| D42 | Donor-Component Preparation | Evaluation of the elapsed time between the collection |
| | | time and the date/time stored for the specific |
| | | component to prevent entry of data for a component for |
| | | which the maximum allowable component preparation |
| D 49 | D D : //D/DD M 1 | time has been exceeded. |
| D43 | Donor-Processing/TTD Marker | Expedited data entry for donor IDs by incrementing |
| | Testing | the unit IDs and displaying that number as the default IF the next logical unit ID exists. |
| D44 | Donor-Processing/TTD Marker | Check of current ABO/Rh results for the specific donor |
| | Testing | unit against the donor's historical record. |
| D45 | Donor-Processing/TTD Marker | Comparison of the recheck information to original |
| | Testing | processing result interpretations if ABO/Rh unit |
| | | rechecks are performed prior to the release of the unit |
| | | to inventory, rather than after the unit is released to |
| | | inventory and data is entered. NOTE: the original |
| | | ABO/Rh are NOT displayed at the time of data entry. |
| D46 | Donor-Processing/TTD Marker | Comparison of the user identification and the entry in |
| | Testing | the tech field for the original results to prevent the |
| | | same tech from entering both original and recheck |
| D47 | Donor Proposition/PPD Made | results for ABO/Rh. |
| D41 | Donor-Processing/TTD Marker | Determination of whether ALT and HIV Ag testing is required, and specifically which of these fields should |
| | Testing | be accessible during data entry based on site specific |
| | | parameters. |
| D48 | Donor-Processing/TTD Marker | Entry of test result interpretations for each unit ID, for |
| 1010 | Testing | subsequent evaluation during labeling/release, i.e., no |
| | 1000000 | batch entry. |
| | | Savoir Citory. |

| IU# | Functionality | Description of Intended Uses |
|-----|--|---|
| D49 | Donor-Processing/TTD Marker Testing | Generation of worklists for any of the tests. These lists include any incomplete testing, i.e., unit IDs for which there are no test results or which were added back to the worklist pending completion of repeat and/or confirmatory testing. |
| D50 | Donor-Processing/TTD Marker Testing | Automatic generation of a bulletin detailing the test result sent to all holders of a specific security key. If the results of the transfusion transmitted disease marker testing are entered as anything other than "negative" or "non-reactive" for units that have already been released to inventory on an emergency basis, regardless of the donation type. |
| D51 | Donor-Processing/TTD Marker Testing | Restriction on the level of security access required to edit result interpretations after components have been released to inventory. |
| D52 | Donor-Processing/TTD Marker Testing | Reports of donor testing results to allow data review before the actual labeling of the donor units if so desired. |
| D53 | Donor Phenotyping | Use of a standardized coding system, i.e. SNOMED, for identifying both RBC and HLA antigens and antibodies |
| D54 | Donor Phenotyping | Prevention of data entry which makes the same antigen both 'present' and 'absent'. |
| D55 | Donor-Labeling/Release | No release of "duplicate" unit IDs to inventory. |
| D56 | Donor-Labeling/Release | Release of units to inventory prohibited if no current ABO/Rh results exist. |
| D57 | Donor-Labeling/Release | Transfer of selected data from the BLOOD DONOR file (#65.5) to the BLOOD INVENTORY file (#65) as detailed above. |
| D58 | Donor-Labeling/Release | Release of units to inventory prohibited if the check of the current ABO/Rh results for the specific donor unit against the donor's historical record indicate a discrepancy and the ABO/RH recheck data is to be transferred to the BLOOD INVENTORY file (#65) when the unit is released. |
| D59 | Donor-Labeling/Release | Automatic generation of a bulletin detailing the test result sent to all holders of a specific security key. If the check of the current ABO/Rh results for the specific donor unit against the donor's historical record indicate a discrepancy, but the ABO/RH recheck data is NOT to be transferred to the BLOOD INVENTORY file (#65) when the unit is released. |
| D60 | Donor-Labeling/Release | Detailed reports of donor's historical ABO/RH, permanent deferral (if appropriate), test results and component information for review prior to labeling and/or for hard copy documentation. |
| D61 | Donor-Labeling/Release | Evaluation of TTD marker testing results such that release of homologous, directed donor and therapeutic phlebotomy units with positive disease marker testing results is prevented. |

| IU# | Functionality | Description of Intended Uses |
|-----|------------------------|--|
| D62 | Donor-Labeling/Release | Automatic quarantine of components if an attempt is made to label/release a unit for which the results indicate that the unit is not suitable for release to inventory, i.e. are positive or reactive. |
| D63 | Donor-Labeling/Release | Requirement for a higher level of security access to make changes in the status of a component previously placed in 'quarantine'. |
| D64 | Donor-Labeling/Release | Verification of the accuracy of labeling of ABO/Rh via bar code reader by comparing the scanned ABO/RH label to the ABO/RH results for that unit ID. |
| D65 | Donor-Labeling/Release | Comparison of the identity of the user attempting to release the unit with the entry in the TECH LABELING field for that specific unit in order to prevent the same tech doing both labeling & verifying if labeling/release is done manually. |
| D66 | Donor-Labeling/Release | Assignment of a final disposition of RELEASE to each component in the BLOOD DONOR file (#65.5) and automatic creation of a new entry in the BLOOD INVENTORY file (#65) with specific associated data elements for each component which is labeled/released. |
| D67 | Donor-Labeling/Release | Assignment of the division of the user who is labeling/releasing the unit into inventory to the unit when the unit is assigned a final disposition in the BLOOD DONOR file (#65.5) and unit is entered into the BLOOD INVENTORY file (#65). |
| D68 | Donor-Labeling/Release | Tracking of both allogeneic (homologous) and autologous units which are released to inventory with incomplete transfusion transmitted disease marker testing such that those units are identified if subsequent attempts are made to modify the unit into another blood component or to ship the unit to another facility. |
| D69 | Donor-Labeling/Release | For autologous units released to inventory with positive/ incomplete testing, release of the unit for use by other patients or modification of the unit into other non-autologous components is prevented. |
| D70 | Donor-Labeling/Release | Transfer of ABO/Rh confirmatory testing results to the BLOOD INVENTORY file (#65) if appropriate based on the site parameters. |
| D71 | Donor-Labeling/Release | Inclusion of the unit in the queue for the Inventory ABO/Rh worklist if the unit contains red cells and data for ABO/Rh confirmatory testing is not transferred to the Inventory based on the site parameters. |
| D72 | Donor-Labeling/Release | For autologous and directed components, display of the name of the patient that the unit is 'RESTRICTED FOR' in an attempt to make sure that the unit is segregated appropriately. |
| D73 | Donor-Records | On-line storage of a unique cumulative donor history for look-back purposes. |

| IU# | Functionality | Description of Intended Use |
|-----|-------------------|---|
| D74 | Donor-Records | Generation of a hard copy printout of the cumulative donor history prior to removal of the donors from the computer system for those donors who have not donated since a specified date. |
| D75 | Donor-Records | Mechanism for merging data (donation sub-records) from two donor records in the event that a duplicate donor record was created in error. |
| D76 | Donor-Recruitment | Report of all donors who indicated a specific group affiliation to provide feedback to donor group chairpersons. Users can specify search criteria for the group affiliation and the range of donation/deferral dates to be included. Reports are sorted by group affiliation and include donor name, ABO/Rh, donation/deferral date, donation/deferral code, donor reaction code and deferral reason. |
| D77 | Donor-Recruitment | Entry of data regarding donation group and collection site such that activity reports can be generated to provide feedback to donor group chairpersons. Users can specify search criteria based on the specific report selected. Reports include donor group affiliation, donation group and or collection site in addition to donor name, ABO/Rh, donation/deferral date, donation/deferral code, donor reaction code and deferral reason. |
| D78 | Donor-Recruitment | Entry of standardized letters that can be generated, based on their group affiliation information, and used for specific targeted donor recruitment efforts. |
| D79 | Donor-Recruitment | Entry of standardized letters, which can be generated, based on a search of all donors who lack a specific RBC antigen, and used for specific targeted donor recruitment efforts. |
| D80 | Donor-Recruitment | Entry of standardized letters which can be generated based on a search of all donors who have not donated since a specified date to be used for specific targeted donor recruitment efforts. |
| D81 | Donor-Recruitment | Generation of post visit thank you letters for donors who attempted to donate based on the list of donors created when the donation/deferral data was entered through the Donor registration [LRBLDLG] option. |
| D82 | Donor-Recruitment | Generation of letters for various groupings of donors based on specified criteria and type of letter selected, inserting the donor name and address for the addressee for those donors identified in the search criteria. |
| D83 | Donor-Recruitment | Generation of labels including the donor name and address for various groupings of donors based on specified criteria. |
| D84 | Donor-Recruitment | Generation of a list of donors who have not donated since a specified date, including their name, date of last donation, group affiliation, home phone and work phone. |

| IU# | Functionality | Description of Intended Use |
|-----|-------------------|--|
| D85 | Donor-Recruitment | Report of all donors who have indicated their willingness to be called on an emergency basis, including their name, ABO/Rh, home phone, work phone, last donation date and donation/deferral code from the last donation date. NOTE: Users can specify ABO/Rh and date range for donations to be included on report. |
| D86 | Donor-Recruitment | Report of all donors who have indicated their willingness to be called on a regular basis for specified months and/or holidays, including their name, ABO/Rh, home phone, work phone, last donation date, and donation/deferral code from the last donation date. |
| D87 | Donor-Recruitment | Report of all donors who have indicated their willingness to be called to be apheresis donors or for which no data was entered regarded their apheresis interest, sorted by ABO/Rh, including their name, ABO/Rh, home phone, work phone, last donation date and donation/deferral code from the last donation date. |
| D88 | Donor-Recruitment | Calculation of cumulative donation totals based on user specific formula and previously entered donation data and provides reports to be used for donor awards. |
| D89 | Donor-Recruitment | Mechanism to enter the fact that a donor was given a gallon donor award and provides a report listing all donors who have received gallon donor awards. |
| D90 | Donor-Recruitment | Report of all first time donors for a specified period based on the entry in the date registered/edited field, including collection site, donation group, donor name, work phone, donation/deferral date, donation/deferral type and the deferral reason. |
| D91 | Donor-Recruitment | Report of patient credits in order to provide feedback as the effectiveness of any recruitment efforts directed at the friends/relatives of patients, including the patient name, the donor name, and the donation/deferral date. |
| D92 | Donor-Management | Report of short draw collections, (i.e., those whose collection volume is less than 405 ml, for a specified date range for supervisory review, sorted by donation date, including unit ID, collection volume, donor reaction code, phlebotomist, donation/deferral date, and collection site). |
| D93 | Donor-Management | Report on donor temporary deferrals for a designated period, sorted by collection site and donation date. This can be used for supervisory review in order to identify trends or problems with donor deferrals, including the collection site, the deferral date, the donation group, the donor name, and the deferral reason. |

| IU# | Functionality | Description of Intended Use |
|------|-------------------|---|
| D94 | Donor-Management | Report of units that are quarantined/discarded prior to component preparation for supervisory review. This includes specified data fields, (i.e., donation date, unit ID, collection site, collection time started and completed, collection volume, donor reaction code, phlebotomist, collection disposition, and collection disposition comment). |
| D95 | Donor-Management | Report of the collection and component preparation information, sorted by donation date, for supervisory review, including specified data fields, i.e., unit ID, type of donation, type of bag, anticoagulant, duration of collection in minutes, processing time in minutes, collection disposition, processing tech, blood components prepared, volume of components in ml, and storage time. |
| D96 | Donor-Management | Blood product rejection report for those units which are collected, have components prepared and have component dispositions of 'discard' or 'quarantine', sorted by donation/deferral date, including unit ID, collection time, collection volume, component preparation time, component preparation tech, component, date/time component stored, component net weight, component disposition and component disposition comment. |
| D97 | Donor-Management | Report of abnormal test results for a specified range of donor unit ID numbers to be used for supervisory review, including donation date, unit ID, donor internal file number and test(s) for which results were abnormal, i.e., did not meet the criteria for subsequent release for transfusion, and excluding the donor names for confidentiality purposes. |
| D98 | Donor -Statistics | Report of all donors who attempted to donate for a specified date range, sorted by donation group, including donor name, work phone, last attempt date, donation type, and cumulative donations. |
| D99 | Donor -Statistics | Report of scheduling information for specified date range for use in evaluating staffing needs, including donation/deferral date, arrival/appointment time, unit ID, donation/deferral code, donation type, and patient credit. |
| D100 | Donor -Statistics | Capture of workload information and transfer of data to non-BB laboratory files for use in a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. |

1. BLOOD INVENTORY file (#65) Description of Data Elements

| | Field Name | |
|--------|---|--|
| | Help Prompt | |
| Field# | Description | Data Type (PM=Pattern Match) |
| .01 | UNIT ID | FREE TEXT (PM=Any alphanumeric, upper or lower case, punctuation allowed) |
| | ANSWER MUST BE 2-12 CHARACTERS IN LENGT. The unit identification on the blood pro- | |
| .02 | SOURCE Entry must be one of the following: Collecting facility NOTE: Although this is stored as free to restricted to entries in the SUPPLIER fin the BLOOD PRODUCT file (#66). | |
| .03 | INVOICE# ANSWER MUST BE 2-10 CHARACTERS IN LENGT: Number on invoice accompanying unit. | FREE TEXT H |
| .04 | COMPONENT Name of blood product file (#66) | POINTER TO BLOOD PRODUCT |
| .05 | DATE/TIME RECEIVED | DATE/TIME (PM=Exact date(with month and day) and time required and echo the answer; allows dates up to the current time) |
| | Date/time component received. Allows curdisallows future times. | • |
| .06 | EXPIRATION DATE/TIME Expiration date/time of unit. time | DATE/TIME (PM=Exact date (with month and day) required, allowed and echo the answer) |
| .07 | ABO GROUP | SET 'A' FOR A; 'B' FOR B; 'O' FOR O; 'AB' FOR AB; 'NA' FOR N/A; |
| | ABO blood group of unit. If ABO group is component (ex. a mixed pool of compatible (not applicable). | s not applicable to the unit or |
| .08 | RH TYPE | SET 'POS' FOR POSITIVE; 'NEG' FOR NEGATIVE; 'NA' FOR N/A; |
| | Rh type of unit. If RH TYPE not applicate enter NA for N/A (not applicable or necessity) | ble to the unit or component |

| | Field Name Help Prompt | |
|--------|---|---|
| Field# | ± ± | Data Type (PM=Pattern Match) |
| .09 | LOG-IN PERSON | POINTER TO NEW PERSON file (#200) |
| | Person entering unit in file. | (" |
| .1 | COST | <pre>NUMERIC(PM=1 or more numeric; may have decimal followed by 2 numerics)</pre> |
| | TYPE A NUMBER BETWEEN 0 AND 99999 Cost of unit | |
| .11 | VOLUME (ml) | NUMERIC(PM=1 or more numerics) |
| | TYPE A WHOLE NUMBER BETWEEN 0 AND 9999 Volume of unit or component | |
| .12 | TYPING CHARGE | NUMERIC (PM=1 or more numeric; may have decimal followed by 2 numerics) |
| | TYPE A NUMBER BETWEEN 0 AND 999 Charge assigned by organization perform | |
| .13 | SHIPPING INVOICE# Enter RETURN invoice # to SUPPLIER (2-10) Invoice (order) number identified with in | · · · · · · · · · · · · · · · · · · · |
| .14 | RETURN CREDIT Entry must begin with a minus (-) then amount of credit (ex37.50) Credit given for returning unit to supplier or sending unit elsewhere | |
| .16 | DIVISION | POINTER TO INSTITUTION FILE (#4) |
| | The division where the unit resides. If to another division, enter the New divis | the unit is being transferred |
| 1.1 | BAG LOT # | FREE TEXT |
| | Answer must be $1-15$ characters in length You may enter the bag lot number if prepin inventory. | n. paring a component from a unit |
| .2 | PATIENT XMATCHED/ASSIGNED (Subfile 65.03 Multiple | l) FREE TEXT |
| | .01 PATIENT XMATCHED/ASSIGNED On the right of NAME is the last charact Enter patient name, SSN, or first letter digits of SSN. | |
| | NOTE: The data is stored as free text; he data entry routine allows only entrifile (#2). | |
| | .012 PARENT FILE | COMPUTED |

File where demographic data is stored for patient crossmatched.

Field Name Help Prompt Field# Description

.02 DATE/TIME UNIT ASSIGNED

Data Type (PM=Pattern Match)

DATE (PM=Exact date (with month and day) and time required and echo the answer; allows dates up to the current time)

Date/time unit is crossmatched for each patient. If unit is released from crossmatch for a specific patient the date/time is deleted.

.03 LAST SPECIMEN DATE XMATCHED

DATE/TIME (PM=Exact date (with month and day) required, time allowed and echo the answer)

Date/time of specimen unit was last xmatched with.

NOTE: Data not entered. Triggered by the DATE/TIME CROSSMATCHED field of the BLOOD SAMPLE DATE/TIME subfield of the PATIENT XMATCHED/ASSIGNED subfield of the BLOOD INVENTORY file.

- BLOOD SAMPLE DATE/TIME (Subfile 65.02)DATE
 Multiple
 - .01 BLOOD SAMPLE DATE/TIME

DATE (PM=Exact date (with month and day) required, time allowed/ and echo the answer; allows dates up to the current time)

Date/time of blood sample used for pretransfusion testing.

.02 TREATING SPECIALITY

FREE TEXT(PM=Any
 alphanumeric, upper or
lower case, punctuation
allowed - see note)

ANSWER MUST BE 3-30 CHARACTERS IN LENGTH Not numeric or starting with punctuation Medical specialty treating patient.

NOTE: During routine data entry, this data is pulled from the information associated with the entry for the REQUESTING PHYSICIAN during the specimen log-in process and is then stored as free text. It is unrelated to the entry for the individual component request.

.03 PHYSICIAN

FREE TEXT (PM -see note)

ANSWER MUST BE 3-30 CHARACTERS IN LENGTH Patient's physician

NOTE: During routine data entry, this data is pulled from the information associated with the entry for the REQUESTING PHYSICIAN during the specimen log-in process and is then stored as free text. It is unrelated to the entry for the individual component request.

| | Help Promp | t | |
|--------|------------|---|--|
| Field# | Descriptio | n | Data Type (PM=Pattern Match) |
| | .04 | XMATCH RESULT | <pre>SET 'C' FOR COMPATIBLE; 'I' FOR INCOMPATIBLE, UNSAFE TO TRANSFUSE; 'CD' FOR COMPATIBLE, DON'T TRANSFUSE; 'CF' FOR COMPATIBLE, FURTHER STUDY NEEDED; 'IG' FOR INCOMPATIBLE, GIVE WITH BB DIRECTOR APPROVAL</pre> |
| | | Interpretation of major cross | smatch. |
| | .05 | XMATCH TECH Person performing crossmatch | POINTER TO NEW PERSON FILE (#200) |
| | .06 | PATIENT SAMPLE ACC # ANSWER MUST BE 1-12 CHARACTER Blood bank accession number f | |
| | .07 | TREATING SPECIALTY NUMBER | POINTER TO FACILITY TREATING SPECIALTY FILE (#45.7) |
| | | Internal entry # in treating | specialty file. |
| | .08 | PROVIDER NUMBER Internal entry # in the NEW F If the physician is an entry number is stored here. | POINTER TO NEW PERSON FILE(#200) PERSON file in the NEW PERSON file the printer |
| | .09 | DATE/TIME CROSSMATCHED The date/time of the blood sa | DATE (PM=Exact date (with month and day) and time required and echo the answer) ample crossmatch |
| | .1 | RELEASE REASON ANSWER MUST BE 2-40 CHARACTER NOTE: In addition to free tex entries in the LAB DESCRIPTION RELEASE as the screen. | |
| | 1 | MAJOR XMATCH METHOD (Subfile .01 MAJOR XMATCH METHOD .02 TECHNIQUE .03 INTERPRETATION .04 IS .05 37 C .06 AHG .07 CONTROL CELL .08 ROOM TEMP .09 12-18 C .1 4 C | |

Field# Description Data Type (PM=Pattern Match)

MINOR XMATCH METHOD (Subfile 65.0912)

Field Not in Use

.01 MINOR XMATCH METHOD Field Not in Use
.02 TECHNIQUE Field Not in Use
.03 INTERPRETATION Field Not in Use
.04 IS Field Not in Use
.05 37 C Field Not in Use
.06 AHG Field Not in Use
.07 CONTROL CELL Field Not in Use
.08 ROOM TEMP Field Not in Use
.09 12-18 C Field Not in Use
.1 4 C

3 CROSSMATCH COMMENT (Subfile 65.0913) Multiple

These are comments relating to the crossmatch of the specific donor unit.

NOTE: These comments become part of the permanent transfusion record of the patient if the unit is subsequently transfused to the patient.

.01 CROSSMATCH COMMENT FREE TEXT
ANSWER MUST BE 2-80 CHARACTERS IN LENGTH

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB TESTING as the screen.

3 DATE/TIME UNIT RELOCATION (Subfile 65.03) DATE/TIME Multiple

These are dates/times the unit is relocated from one location to another.

EXAMPLE: From blood bank to surgery or from surgery to blood bank.

.01 DATE/TIME UNIT RELOCATION DATE (PM=Exact date

(with month and day) required, time allowed/ and echo the answer; allows dates up to the

current time)

Date/time the unit is relocated from one location to another, ex. from blood bank to surgery or from surgery to blood bank. This is a multiple entry field but only asked once

.02 INSPECTION SET

'S' FOR SATISFACTORY;
'U' FOR UNSATISFACTORY;

Interpretation of unit inspection for color and appearance immediately before issue/relocation.

.03 TECH INSPECTING POINTER TO NEW PERSON FILE (#200)
Person inspecting unit

Field Name Help Prompt Data Type (PM=Pattern Match) Field# Description FREE TEXT (PM=Any alphanumeric, .04 LOCATION upper or lower case, punctuation allowed) Entry must be 2-30 characters Location to which unit of blood is being relocated. .05 ISSUED TO/REC'D FROM FREE TEXT ANSWER MUST BE 2-30 CHARACTERS IN LENGTH Person taking unit from or returning unit to the blood bank. .06 FOR PATIENT FREE TEXT ANSWER MUST BE 2-30 CHARACTERS IN LENGTH The patient the unit of blood is being relocated for. .07 VA PATIENT NUMBER POINTER TO PATIENT FILE (#2) Internal entry # in the patient (#2) file If the patient is an entry in the PATIENT file (#2) the pointer number 4.1 DISPOSITION SET 'R' FOR RETURN TO SUPPLIER; 'T' FOR TRANSFUSE; 'D' FOR DISCARD; 'S' FOR SEND ELSEWHERE; 'M' FOR MICROBIOLOGY/ RESEARCH; 'MO' FOR MODIFY; 'SA' FOR SALVAGED Final disposition of the unit DATE/TIME (PM=Exact date (with 4.2 DISPOSITION DATE month and day) required, time allowed/ and echo the answer; allows dates up to the current time) Enter only past or present Date/time Date of final disposition DISPOSITION ENTERING PERSON 4.3 POINTER TO NEW PERSON FILE (#200) Person entering final disposition POOLED/DIVIDED UNITS 4.4 FREE TEXT (PM=1 or more numeric) Enter number of units in pool enclosed in parentheses; ex. (5). Number of units in pool OR number of aliquots into which a unit of blood/blood component has been divided

4.5 SHIP TO FREE TEXT

MUST BE 2-68 CHARACTERS IN LENGTH, CAN USE LAB DESCRIPTION FILE ENTRIES WITH BB DISP SCREEN.

If unit is returned to sender or shipped elsewhere enter name/location of facility where sent.

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB DISP as the screen.

Field# Description

Data Type (PM=Pattern Match)

DISPOSITION COMMENT (Subfile 65.06)

Multiple

These are final disposition comments.

.01 DISPOSITION COMMENT FREE TEXT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH, CAN USE LAB DESCRIPTION

FILE ENTRIES WITH BB DISP SCREEN Final disposition comments.

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB DISP as the screen.

PATIENT TRANSFUSED 6.1

FREE TEXT (see note)

Enter patient name

Name of patient transfused

NOTE: The data is stored as free text; however, the input template for the data entry routine allows only entries selected from the PATIENT file (#2).

PARENT FILE 6.12 COMPUTED

> This is the file whose demographic data is stored for the patient transfused.

TRANSFUSED PATIENT ABO 6.15 COMPUTED

This is the transfused patient's ABO.

6.16 TRANSFUSED PATIENT RH COMPUTED

This is the transfused patient's Rh type.

6.2 FREE TEXT

> ANSWER MUST BE 2-30 CHARACTERS IN LENGTH Physician of patient transfused

NOTE: The data is stored as free text; however, the data is generally pulled from the current entry in the PATIENT File (#2), field .104 and is displayed as the default. If no data exists, the user is required to enter data.

6.3 TREATING SPECIALTY FREE TEXT (PM=Any

> alphanumeric, upper or lower case, punctuation allowed; may not be all numeric or start with punctuation)

ANSWER MUST BE 3-30 CHARACTERS IN LENGTH

Treating specialty to which the patient is assigned at the time the unit was transfused.

NOTE: The data is stored as free text; however, the data is generally pulled from the current entry in the PATIENT file (#2), field .(#1043) and is displayed as the default. If no data exists the user is required to enter data.

Field Name Help Prompt

Field# Description Data Type (PM=Pattern Match)

6.4 TRANSFUSION RECORD NUMBER

NUMERIC (PM=contains 6 or

more numerics)

TYPE A NUMBER BETWEEN 1 AND 9999999

Internal number in subfile 63.085 TRANSFUSION RECORD

NOTE: This field is not editable. It is created by software.

6.5 TRANSFUSION REACTION

SET

'1' FOR YES;

'0' FOR NO;

If patient had a transfusion reaction enter 'Y'
Answer 'YES' if the patient experienced an adverse reaction as a result of transfusion of designated blood/blood component

6.6 PROVIDER NUMBER POINTER TO NEW PERSON FILE (#200) If the physician is an entry in the New Person file the pointer number is stored here.

6.7 TREATING SPECIALTY NUMBER

POINTER TO FACILITY TREATING

SPECIALTY FILE (#45.7)

Internal entry # in treating specialty file
If the treating specialty is an entry in the treating specialty file,
the pointer number is stored here.

6.8 TRANSFUSION REACTION TYPE

POINTER TO BLOOD BANK UTILITY

FILE (#65.4)

Indicates the type of transfusion reaction
Selects transfusion reaction type

NOTE: Choices are limited to those with the SCREEN = TRANSFUSION REACTION

7 TRANSFUSION COMMENT (Subfile 65.07)

Multiple

These are comments regarding the transfusion or specific unit, including whether only a part of the unit was transfused and the reason(s).

.01 TRANSFUSION COMMENT

FREE TEXT

Comments regarding the transfusion of the specific unit, including whether only a part of the unit was transfused and the reason(s).

ANSWER MUST BE 1-80 CHARACTERS IN LENGTH

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB TRANS as the screen.

8 RESTRICTED FOR

FREE TEXT

The patient indicated here is the only one who may be transfused with this unit.

NOTE: The data is stored as free text; however, the input template for the data entry routine allows only entries selected from the PATIENT file (#2).

Field# Description Data Type (PM=Pattern Match)

8.1 POS/INCOMPLETE SCREENING TESTS

SET

'1' FOR YES;
'0' FOR NO;

If autologous donor has a positive syphilis serology, HBsAg, or HIV antibody test YES is entered. This flag is intended to warn NOT to transfuse this unit to anyone other than the DONOR!

8.3 DONATION TYPE

SET

'A' FOR AUTOLOGOUS;
'D' FOR DIRECTED;

This field indicates which type of donation will be used to log this unit.

9 MODIFIED TO/FROM (Subfile 65.091)
Multiple

POINTER TO BLOOD PRODUCT

FILE (#66)

TYPE A NUMBER BETWEEN 0 AND 99999

If unit is modified identifies what products are made and what are the new unit ID's. If unit is a pool identifies what product was pooled and what units are in the pool.

.001 NUMBER

NUMBER(PM=1 or more numerics)

TYPE A WHOLE NUMBER BETWEEN 1 AND 20.

A number from 1 to 20.

.01 MODIFIED TO/FROM

POINTER TO BLOOD PRODUCT

FILE (#66)

If unit is modified, identifies what products are made and what are the new units by ID#. If unit is a pool, identifies what product was pooled and what units are in the pool. Products allowed to be made from inventory.

NOTE: Selections are limited based on the file setup in the BLOOD PRODUCT file (#66) in the MODIFIED TO/FROM field. For the specific component being modified.

.02 UNIT ID

FREE TEXT

ANSWER MUST BE 2-12 CHARACTERS IN LENGTH

If the unit is to be modified, the unit ID of the new unit is entered here. If the unit is a modified unit, the old unit ID's are entered.

.03 FROM/TO

SET

'1' FOR FROM;

'2' FOR TO;

If entry is from another unit, '1' is entered.

If entry is to become or be part of another unit, a '2' is entered. Several of the entries may have been entered to form a pool and each entry will have a '1' entered. Then the pool may be modified to another unit and then the entry will have a '2' entered.

NOTE: This data is routinely entered automatically by the software.

| | Field Name | |
|--------|---|--|
| | Help Prompt | |
| Field# | Description | Data Type (PM=Pattern Match) |
| 10 | ABO INTERPRETATION | SET 'A' FOR A; 'B' FOR B; 'O' FOR O; 'AB' FOR AB; 'ND' FOR NOT DONE; |
| | Interpretation of ABO testing | |
| 10.2 | TECH ENTERING-ABO INTERP Person performing ABO testing | POINTER TO NEW PERSON FILE (#200) |
| 10.3 | ABO TESTING COMMENT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH Comment related to ABO testing | FREE TEXT H |
| | NOTE: In addition to free text, the user the LAB DESCRIPTIONS file (#62.5) which | |
| 10.4 | ABO MOVED FROM DONOR FILE | SET '1' FOR YES; |
| 11 | RH INTERPRETATION Interpretation of Rh testing | SET 'NEG' FOR NEGATIVE; 'POS' FOR POSITIVE; 'ND' FOR NOT DONE; |
| 11.2 | TECH ENTERING-RH INTERP Person performing Rh testing | POINTER TO NEW PERSON FILE (#200) |
| 11.3 | RH TESTING COMMENT ANSWER MUST BE 1-80 CHARACTERS IN LENGTH Comment related to Rh testing | FREE TEXT H |
| | NOTE: In addition to free text, the user the LAB DESCRIPTIONS file (#62.5) which | can select from entries in have BB TESTING as the screen. |
| 11.4 | RH MOVED FROM DONOR FILE | SET 1' FOR YES; |
| 15 | DATE RE-ENTERED (Subfile 65.15) Multiple | |
| | Re-entry date of the unit in the file | |
| | NOTE: Data for this multiple is entered It is not editable. | automatically by the software. |

| | Field Name Help Prompt | | |
|--------|---------------------------|--|---|
| Field# | _ | cription | Data Type (PM=Pattern Match) |
| | | DATE RE-ENTERED | DATE/TIME (PM=Exact date (with month and day) required, time allowed and echo the answer) |
| | | Re-entry date of the unit in the fi entering the unit in the INVENTORY | |
| | .02 | PREVIOUS DISPOSITION The previous disposition | SET 'R' FOR RETURNED TO SUPPLIER; 'S' FOR SENT ELSEWHERE; |
| | .03 | PREVIOUS DISPOSITION DATE | DATE (PM=Exact date (with month and day) required, time allowed and echo the answer) |
| | | The date of the previous disposition | on. |
| | .04 | PREVIOUS DISP ENTERING PERSON The name of the person entering the | |
| | .05 | PREVIOUS SHIPPING INVOICE ANSWER MUST BE 2-10 CHARACTERS IN I The previous shipping invoice. | FREE TEXT ENGTH |
| | .06 | PREVIOUS RECEIVING INVOICE ANSWER MUST BE 2-10 CHARACTERS IN I The previous receiving invoice. | FREE TEXT ENGTH |
| | .07 | PREVIOUS LOG-IN PERSON The name of the previous log-in per | POINTER TO NEW PERSON FILE (#200) cson. |
| | .08 | PREVIOUS DATE LOGGED-IN Date of the previous log-in.month a and echo the answer) | DATE (PM=Exact date (with and day) required, time allowed |
| | .09 | PREVIOUS SHIP TO ANSWER MUST BE 2-68 CHARACTERS IN I The name of the previous ship. | FREE TEXT ENGTH |
| 16 | PED | IATRIC ALIQUOT MADE (Subfile 65.16) | |
| | .01 | PEDIATRIC ALIQUOT MADE | Field Not in Use |
| | .02 | VOLUME (ml) | Field Not in Use |

| | | d Name Prompt | |
|--------|------|---|--|
| Field# | Desc | cription | Data Type (PM=Pattern Match) |
| 60 | | ANTIGEN PRESENT (Subfile 65.04) | POINTER |
| | .01 | RBC ANTIGEN PRESENT | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | | RBC Antigen tested Enter ANTIGEN Antigen(s) present on red blood cell | ls of the unit (if applicable) |
| | | 3 . , 1 | , |
| | NOTE | E: Choices are restricted to those for | or which the SCREEN = AN |
| | .02 | RBC ANTIGEN PRESENT COMMENT | Field Not in Use |
| 70 | | ANTIGEN ABSENT (Subfile 65.05) ciple | |
| | .01 | RBC ANTIGEN ABSENT | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | | Antigen(s) absent on red blood cell: | |
| | | NOTE: Choices are restricted to tho | se for which the SCREEN = AN |
| | .02 | RBC ANTIGEN ABSENT COMMENT | Field Not in Use |
| 80 | Mult | ANTIGEN PRESENT (Subfile 65.08) Liple ECTS HLA ANTIGEN | POINTER |
| | .01 | HLA ANTIGEN PRESENT | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | | HLA antigen(s) present on the appropriate Selects HLA antigens | , |
| | | NOTE: Choices are restricted to tho | se for which the SCREEN = HL |
| | .02 | HLA ANTIGEN PRESENT COMMENT | Field Not in Use |
| 90 | HLA | ANTIGEN ABSENT (Subfile 65.09) Multiple | POINTER |
| | .01 | HLA ANTIGEN ABSENT | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | | HLA antigen(s) absent on the approp | · · · · · · · · · · · · · · · · · · · |
| | | NOTE: Choices are restricted to tho | se for which the SCREEN = HL |
| | .02 | HLA ANTIGEN ABSENT COMMENT | Field Not in Use |

| Field# | Description | Data Type (PM=Pattern Match) |
|--------|--|-------------------------------|
| 91 | CMV ANTIBODY | SET '0' FOR NEG; '1' FOR POS; |
| 121 | DONOR CELLS+ANTI D(slide rgt) | Field Not in Use |
| 122 | | |
| 123 | DONOR CELLS+ANTI D (37) | Field Not in Use |
| 124 | DONOR CELLS+RH CTRL (37) | Field Not in Use |
| 125 | DONOR CELLS+ANTI D (AHG) | Field Not in Use |
| 126 | DONOR CELLS+RH CTRL (AHG) | |
| 127 | | Field Not in Use |
| 128 | DONOR CELLS+RH CTRL CC | Field Not in Use |
| 141 | DONOR CELLS+ANTI A(slide) | Field Not in Use |
| 142 | DONOR CELLS+ANTI B(slide) | Field Not in Use |
| 143 | DONOR CELLS+ANTI A,B(slide) | Field Not in Use |
| 144 | DONOR PLASMA+A1 CELLS | Field Not in Use |
| 145 | DONOR PLASMA+B CELLS | Field Not in Use |
| 200 | DIRECT AHG(BS) | Field Not in Use |
| 500 | TEST/PROCEDURE (Subfile 65.3) Multiple | POINTER |

.01 TEST/PROCEDURE

POINTER TO LABORATORY TEST

FILE (#60)

This field contains the test performed on this unit. Used to keep track of TEST/PROCEDURES for WKLD workload. Selects only blood bank subscripted tests.

COMPLETE DATE/TIME (Subfile 65.31) DATE Multiple

The completion date/time of the test/procedure.

This field contains the test performed on this unit.

| .01 | COMPLETE DATE/TIME | DATE(PM=Exact date |
|-----|--------------------|--------------------------------|
| | | WKLD workload flag (with month |
| | | and day) and time |
| | | required and echo the answer; |
| | | allows dates up to the |
| | | current time) |

- POINTER TO NEW PERSON FILE (#200) .02 The name of the technician completing the test/procedure.
- INSTITUTION POINTER TO INSTITUTION FILE (#4) .03 The name of the institution from the Institution file.
- .04 MAJOR SECTION POINTER TO ACCESSION FILE (#68) The name of the major section from the Accession file.
- .05 POINTER TO ACCESSION FILE (#68) The name of the subsection from the Accession file

Field Name Help Prompt Data Type (PM=Pattern Match) Field# Description WKLD CODE (Subfile 65.311) POINTER 1 Multiple The name of the workload code from the WKLD code file .01 WKLD CODE POINTER TO WKLD CODE FILE (#64) .02 WKLD CODE COUNT NUMBER Type a Number between 0 and 999, 0 Decimal Digits. The count of the workload code entry. .03 WKLD CODE COUNTED SET '1' FOR YES;
'0' FOR NO; A set of code of yes or no, whether the workload was counted. 999 DATA CHANGE DATE (Subfile 65.099) Multiple Date the report value was changed .01 DATA CHANGE DATE DATE/TIME (PM=Exact date (with month and day) required, time allowed and echo the answer) This field contains the date the reported value was changed .02 PERSON CHANGING DATA FREE TEXT ANSWER MUST BE 2-30 CHARACTERS IN LENGTH This field contains the person that alter the reported value .03 DATA ELEMENT FREE TEXT ANSWER MUST BE 1-30 CHARACTERS IN LENGTH This field indicated what result name the data was altered. OLD VALUE FREE TEXT .04 ANSWER MUST BE 1-30 CHARACTERS IN LENGTH This field contains the value before it was altered. NEW VALUE FREE TEXT .05 ANSWER MUST BE 1-30 CHARACTERS IN LENGTH

This field contains the value after it was altered.

2. BLOOD INVENTORY file (#65) Data Copied from Original Unit

The BLOOD INVEVTORY file (#65) data are copied from Original Unit and entered in the BLOOD INVENTORY file (#65) for New Unit upon Unit Modification.

| File 65 Field# .02 .03 .07 .08 .1 | Field Name SOURCE INVOICE # ABO GROUP RH TYPE COST DIVISION | | | Data Copied/Entered Assigns Self Assigns 00 Exact Exact Exact Exact Exact |
|---|--|------------|-------------------------------|---|
| 2 | PATIE | ENT XMATCH | MED/ASSIGNED (Subfile 65.01) | NA |
| | .01 | PATIENT | XMATCHED/ASSIGNED | *Exact if unit is assigned |
| | .012 | PARENT F | TILE | NA- Computed field |
| | .02 | DATE/TIM | IE UNIT ASSIGNED | *Exact if unit is assigned |
| | .03 | LAST SPE | CIMEN DATE XMATCHED | *Exact if unit is assigned |
| | | 1 BLOOD | SAMPLE DATE/TIME (Subfile 65. | .02) NA |
| | | .01 | BLOOD SAMPLE DATE/TIME | *Exact if unit is assigned |
| | | .02 | TREATING SPECIALITY | *Exact if unit is assigned |
| | | .03 | PHYSICIAN* | Exact if unit is assigned |
| | | .04 | XMATCH RESULT* | Exact if unit is assigned |
| | | .05 | XMATCH TECH | *Exact if unit is assigned |
| | | .06 | PATIENT SAMPLE ACC # | *Exact if unit is assigned |
| | | .07 | TREATING SPECIALTY NUMBER | *Exact if unit is assigned |
| | | .08 | PROVIDER NUMBER | *Exact if unit is assigned |
| | | .09 | DATE/TIME CROSSMATCHED | *Exact if unit is assigned |

| File 65 Field# | Field Name | Data Copied/Entered |
|-------------------|--------------------------------------|----------------------------|
| 3 | CROSSMATCH COMMENT (Subfile 65.0913) | NA |
| | .01 CROSSMATCH COMMENT | *Exact if unit is assigned |
| 8 | RESTRICTED FOR | Exact |
| 8.1 | POS/INCOMPLETE SCREENING TESTS | Exact |
| 8.3 | DONATION TYPE | Exact |
| 60 | RBC ANTIGEN PRESENT (Subfile 65.04) | NA |
| | .01 RBC ANTIGEN PRESENT | Exact |
| 70 | RBC ANTIGEN ABSENT (Subfile 65.05) | NA |
| | .01 RBC ANTIGEN ABSENT | Exact |
| 80 | HLA ANTIGEN PRESENT (Subfile 65.08) | NA |
| | .01 HLA ANTIGEN PRESENT | Exact |
| 90 | HLA ANTIGEN ABSENT (Subfile 65.09) | NA |
| | .01 HLA ANTIGEN ABSENT | Exact |
| 91 | CMV ANTIBODY | Exact |

^{*}Exact if unit is "assigned" at the time the unit is modified and data exists for the original unit.

Software Limitations

| Functionality | Description of Software Limitations |
|---|---|
| Inventory- Receipt, Shipment and Discard of Units | No automatic quarantining of in-date units based on donor look back procedures. No provision for documenting approval of autologous products repeatedly reactive for HIV-1 Antigen. No provision for tracking specific method of disposal of discarded units. No provision for documenting receipt and storage of human tissue (other than blood and blood components) and derivatives. |
| Inventory- Confirmation testing of units | No provision for test result interpretation based on actual testing results, (e.g. evaluation of reactions of antisera). Manual entry of ABO/Rh confirmation testing interpretations (rechecks). |
| Inventory- Modification of units | No system of blood component quality control records. No provision for evaluation of ABO compatibility of units being modified into a pooled product. No system for recording of lot #s of filters used in the preparation of leukocyte reduced blood products and/or solutions used in the preparation of washed, frozen, deglycerolized and rejuvenated red blood cells. Partial system for evaluating mutually exclusive components. |
| Inventory - Issue/relocation of units for transfusion | Manual entry of test result interpretations for all required testing. Manual entry of ABO/Rh confirmation testing. No provision for generating the electronic equivalent of the Blood Component Requisition (SF518). Manual entry of pretransfusion compatibility testing interpretations. No provision of a separate methodology for emergency release of units. No provision for evaluation of time elapsed criteria for return/reissue of units. No electronic record created for relocation from the Blood Bank which is not completed because unit inspection is found to be unsatisfactory. No provision for documenting medical director approval for transfusion of units after the expiration date/time. No provision for documenting storage and issue of human tissue. |

| Functionality | Description of Software Limitations |
|--|---|
| Inventory - Phenotyping of units | Manual entry of test result interpretations. |
| Inventory- Release of units to stock/available inventory | No provision of an electronic donation record for those autologous units drawn on-site. No automatic provision for the release of units to stock after a specific time. |
| Inventory - Records | No system of blood component quality control records. No provision of system of records for actual test results, i.e. manual entry of test results interpretations for all required testing. No provision of indication for emergency issue of uncrossmatched blood. No provision for documenting approval for issue of components which are not ABO/Rh compatible. No provision for documenting approval for issue of components which have expired. |

<u>Intended Uses</u>

| IU# | Functionality | Description of Intended Uses |
|-----|--|---|
| I1 | Inventory - General | Provision of a unique cumulative unit history record for each individual blood component based on the data elements detailed above for the BLOOD INVENTORY file (#65). |
| I2 | | Maintenance of patient record confidentiality for test results/transfusion histories by providing different levels of security access such that the type of data access can be defined by individual user. |
| I3 | Inventory - General | Site specific control to set up the entries in the BLOOD PRODUCT file (#66) for component specific requirements and algorithms to reflect the facility operating procedures. See Section IX for a listing of the data elements and the descriptions of their use. |
| I4 | Inventory - General | Record updates immediately upon data entry. |
| I5 | Inventory - General | Limited simultaneous access by multiple terminals/ users to the same unit record for purposes of data entry in specified options. |
| I6 | Inventory - General | Accommodation of the use of a bar code reader for entry of the unit ID |
| 17 | Inventory - General | Accommodation of the use of a bar code reader for entry of the component (blood product code) |
| I8 | Inventory - General | Accommodation of the use of a bar code reader for entry of the expiration date |
| I9 | Inventory - General | Limited access to only units assigned to the same division as the user, based on a comparison of the division assigned to the unit and the division currently assigned to the user. |
| I10 | Inventory - General | Tracking of the person entering test results and/or performing various steps in the process, (i.e., the person entering the computer). |
| I11 | Inventory - General | Tracking of changes in verified data for specific data elements defined for the BLOOD INVENTORY file (#65)- see Section IX for listing by data element |
| I12 | Inventory - General | Tracking of verified data entered for specific data elements defined for the BLOOD INVENTORY file (#65) and LAB DATA file (#63) when data is entered/edited via the supervisory edit options requiring a higher level of security. |
| I13 | Inventory-Receipt, Shipment and Discard of Units | Entry of an exact date and time for the date/time received. |
| I14 | Inventory-Receipt, Shipment and Discard of Units | Check of the existing entries in BLOOD INVENTORY file (#65) during the entry of a unit ID to prevent entry of a duplicate unit ID of the same component. |

| IU# | Functionality | Description of Intended Uses |
|-----|---|--|
| I15 | Inventory-Receipt, Shipment and Discard of Units | Ability to designate the appropriate DONATION TYPE of the unit for autologous and directed donor units being entered. Component selected has an "A" or "D" in the AUTOLOGOUS/DIRECTED field (#.25) in the BLOOD PRODUCT file (#66). |
| I16 | Inventory-Receipt, Shipment and Discard of Units | For autologous and directed donor units being entered, required entry of a patient name in the RESTRICTED FOR field (#8) of the BLOOD PRODUCT file (#66). Component selected has an "A" or "D" in the AUTOLOGOUS/DIRECTED field (#.25) in the BLOOD PRODUCT file (#66). |
| I17 | Inventory-Receipt, Shipment and Discard of Units | For autologous and directed donor units being entered, ability to enter data in the POS/INCOMP. SCREENING TESTS field (#8.1) if appropriate based on the results of the required TTD marker testing. (Component selected has an "A" or "D" in the AUTOLOGOUS/DIRECTED field (#.25) in the BLOOD PRODUCT file (#66)). |
| I18 | Inventory-Receipt, Shipment and Discard of Units | Limited ability to re-enter units into inventory, i.e., only units which can be re-entered are those with dispositions of 'S' (sent elsewhere) or 'R' (returned to supplier). |
| I19 | Inventory-Receipt, Shipment and Discard of Units | For units that are re-entered, transfer of the original log-in and disposition data to appropriately designated fields to allow tracking of the original data Subfile (#65.15). |
| I20 | Inventory-Receipt, Shipment and Discard of Units | Ability to enter a time in the Expiration Date field (#.06). |
| I21 | Inventory-Receipt, Shipment and Discard of Units | Identification of potentially biohazardous units based on a notation on the shipping invoice for units which were released from the donor module with incomplete results, i.e., unit has a "YES" in the POS/INCOMP. SCREENING TESTS field (#8.1), in an effort to ensure appropriate handling. |
| I22 | Inventory - Receipt, Shipment and Discard of Units | Site specific control of the text that appears on the shipping invoice. (SHIPPING INVOICE entry in the LAB LETTER file (#65.9). |
| I23 | Inventory-Receipt, Shipment and Discard of Units | Inclusion of information on the shipping invoice to allow recording of information on shipping temperatures based on the wording entered in for in the LAB LETTER file (#65.9) for SHIPPING INVOICE. |
| I24 | Inventory-Receipt, Shipment and Discard of Units | Restricted selection of blood components to those in BLOOD PRODUCT file (#66)with suppliers, etc. |
| I25 | Inventory-Receipt, Shipment and Discard of Units | Evaluation of the validity of the expiration date based on the entry in the MAXIMUM STORAGE DAYS field for that blood component in the BLOOD PRODUCT file (#66). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|---|
| I26 | Inventory-Receipt, Shipment and Discard of Units | When editing data on a pooled product, restricted access to those units for which the component is defined as a pooled product based on the entry in the Pooled Product field (#.27) in the BLOOD PRODUCT file (#66) (i.e., requires a higher level of security access). |
| I27 | Inventory-Receipt, Shipment and Discard of Units | Use of an average volume for the component for the unit volume, based on the entry in the Volume field (#.1) in the BLOOD PRODUCT file (#66) for that specific blood component. |
| I28 | Inventory-Receipt, Shipment and Discard of Units | Use of the entry in the COST field (#.02) for the specific SUPPLIER for the specific component in the BLOOD PRODUCT file (#66) to record of the cost of the unit. |
| I29 | Inventory-Receipt, Shipment and Discard of Units | Adjustment in the cost of units which are "RETURNED TO SUPPLIER" by entering data into the RETURN CREDIT field (#.14) for the unit. |
| I30 | Inventory-Receipt, Shipment and Discard of Units | Transfer of a unit to a different DIVISION within a multidivisional facility, providing the numeric portion of the parent institution in the INSTITUTION file (#4) for the new DIVISION matches that of the existing entry in the DIVISION field (#.16). |
| I31 | Inventory-Receipt, Shipment and Discard of Units | No entry of future disposition dates. |
| 132 | Inventory - General | Site specific control of standardized canned comments which are accessible during the data entry of disposition information for units with a DISPOSITION 'TRANSFUSE' or 'MODIFY' (entries in the LABORATORY DESCRIPTIONS file (#62.5) for which the SCREEN = BB DISP). |
| I33 | Inventory-Receipt, Shipment and Discard of Units | Ability to edit verified information relating to the receipt (log-in) for a specific unit ID. (Requires a higher level of security access) |
| I34 | Inventory-Receipt, Shipment and Discard of Units | Ability to edit verified information relating to the disposition of a specific unit ID. (Requires a higher level of security access) |
| I35 | Inventory-Receipt, Shipment and Discard of Units | Ability to edit verified information relating to the contents of a pooled product for a specific unit ID. (Requires a higher level of security access) |
| I36 | Inventory - Confirmation testing of units | For units received from an outside facility or created through modification of other units, creation of a queue which includes units on the Inventory ABO/Rh testing worklist report if the blood component has a "yes" in the CONTAINS RED CELLS field (#.19) in the BLOOD PRODUCT file (#66). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|--|
| I37 | Inventory - Confirmation testing of units | Comparison of the confirmatory (recheck) test results to the unit log-in information and display of a warning message if results do not agree. |
| I38 | Inventory - Confirmation testing of units | Limited access to those units assigned to the same division as the user if data entry is done by unit (not if done by batch). |
| I39 | Inventory - Confirmation testing of units | Testing worksheet which includes unit #s of units to be tested for use in manually recording actual testresults. |
| I40 | Inventory - Confirmation testing of units | Site specific control of the text which appears on the Inventory ABO/Rh testing worksheet generated by the option [LRBLIW]. (INVENTORY WORKSHEET entry in the LAB LETTER file (#65.9)). |
| I41 | Inventory - Confirmation testing of units | Site specific control of standardized canned comments which are accessible during the data entry of confirmatory testing (rechecks) on units (entries in the LAB DESCRIPTIONS file (#62.5) for which the SCREEN = BB TESTING). |
| I42 | Inventory - Modification of Units | Creation of a new entry in the INVENTORY file (#65) for each new blood component created and assignment of a final disposition to the original unit being modified. |
| I43 | Inventory - Modification of Units | Attachment of appropriate pieces of data to the new unit created when a unit is modified - see Section V for a listing by data element |
| I44 | Inventory - Modification of Units | Determination as to whether the ABO/Rh confirmatory testing information should be attached to the new unit created based on the entry in the RETYPE AFTER PREPARATION field for the component in the BLOOD PRODUCT file (#66). |
| I45 | Inventory - Modification of Units | Placement of unit in queue for inclusion on the Inventory ABO/Rh testing worklist if the component created has a "YES" in the RETYPE AFTER PREPARATION field in the BLOOD PRODUCT file (#66). |
| I46 | Inventory - Modification of Units | Assignment of the ABO of a pool based on the ABO of the first unit in the pool. |
| I47 | Inventory - Modification of Units | Assignment of the Rh of a pool such that regardless of the order in which the units are pooled, the pool will be deemed Rh positive if any of the units in the pool were Rh positive. |
| I48 | Inventory - Modification of Units | If a product is divided, calculation of the number of aliquots into which the unit is divided and entry of the data in the POOLED/DIVIDED UNITS field (#4.4) for the original unit. |
| I49 | Inventory - Modification of Units | Exclusion of ability to modify an autologous component to a non autologous component if an entry exists in the POS/INCOMP. SCREENING TESTS field (#8.1) indicating that testing for transfusion transmitted disease markers is incomplete or positive. |

| IU# | Functionality | Description of Intended Uses |
|-----|--------------------------------------|---|
| I50 | Inventory - Modification of Units | Identification of units that are potentially unsuitable for modification based on an entry in the POS/INCOMP. SCREENING TESTS field (#8.1) indicating that the unit was released from the donor module with incomplete results. |
| I51 | Inventory - Modification of Units | Restricted selection of component choices to those defined in the MODIFIED TO/FROM field (#.01) in the BLOOD PRODUCT file (#66) for the specific component of the unit being modified. |
| I52 | Inventory - Modification of Units | Determination of whether more than one new unit can be created from a unit being modified based on the entry in the NOT ONLY ONE ALLOWED field (#.02) in the BLOOD PRODUCT file (#66) for the specific component of the unit being modified. |
| I53 | Inventory - Modification of Units | Prevents multiple modifications to the same unit by excluding selection of units which already have a disposition entered. |
| I54 | Inventory - Modification of Units | Requirement for a new unit ID for units being created. |
| I55 | Inventory - Modification of Units | If a unit is being divided/split into other components, evaluation of the sum of the new unit volumes to make sure the sum does not exceed the volume of the original unit. |
| I56 | Inventory - Modification of Units | Calculation of the expiration date of the unit being created based on the time of the data entry and the entry in the Days Left field (#.11) of the BLOOD PRODUCT file (#66). If the entry in the field is a whole number, the calculation will be a date only; whereas, if the entry is a decimal, the calculation will be in the format of a date and time. |
| I57 | Inventory - Modification of Units | Evaluation of the calculated expiration date of the new unit against the expiration date of the unit being modified and displays alert message. If the calculated expiration date of the new unit exceeds the original expiration date, or in the case of a pooled product, the original expiration date of any of the units in the pool. |
| I58 | Inventory - Modification of Units | No entry of future disposition dates. |
| I59 | Inventory - Modification of Units | If a pediatric component is being created, restricted unit selection to those of appropriate age based on the entry in the MAX AGE FOR PEDIATRIC USE field (#.21) in the BLOOD PRODUCT file (#66).for the component of the unit being modified. |
| I60 | Inventory - Modification of Units | If a pediatric component is being created, identification of low volume units, i.e., those with a volume < 150ml. and displays the volume. |
| I61 | Inventory - Modification of Units | For pediatric units, calculation of the volume of the unit being created using an algorithm based on the weight entered and the specific gravity of the component as defined in the BLOOD PRODUCT file (#66). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|---|
| I62 | Inventory - Modification of Units | If a pediatric unit is being created, assignment of a final disposition of 'MODIFIED' to units with 0ml remaining volume after the unit has been modified, (i.e., divided into aliquots). |
| I63 | Inventory - Modification of Units | Site specific control to determine whether the user should be asked for a bag lot number during data entry of unit modification information for use in future FileMan search requests. (Ask Bag Lot # field (#.28) in the BLOOD PRODUCT file (#66)). |
| I64 | Inventory - Issue/relocation of units for transfusion | Display of patient and unit information on the CRT for comparison with the label generated by the Unit Caution tag labels [LRBLILA] option after the necessary pretransfusion testing has been completed. |
| 165 | Inventory - Issue/relocation of units for transfusion | Display of an alert message for any patients selected who have autologous and/or directed components in inventory, based on a match with the name entered in the Restricted For field (#8) for the unit(s). |
| I66 | Inventory - Issue/relocation of units for transfusion | Display of a warning message if the unit selected has been double crossmatched and is still assigned to another patient at the time the unit is being issued for transfusion. |
| 167 | Inventory - Issue/relocation of units for transfusion | Display of an alert message for any patients selected who have an entry in either the ANTIBODIES IDENTIFIED or the BLOOD BANK COMMENTS field (#.01) in the LAB DATA file (#63). |
| I68 | Inventory - Issue/relocation of units for transfusion | Limited selection of units for issue to those units, which have a current status of 'assigned' and are assigned to the patient specified. |
| I69 | Inventory - Issue/relocation of units for transfusion | For patients with an entry in the ANTIBODIES IDENTIFIED field (#.075), evaluation of the unit phenotyping of allogeneic (homologous) units against each clinically significant patient antibody & prevents issue if unit phenotyping s not appropriate, i.e., for each entry in the ANTIBODIES IDENTIFIED field (#.076), there must be a corresponding entry in the RBC ANTIGEN ABSENT field (#.5) of the unit. |
| 170 | Inventory - Issue/relocation of units for transfusion | Prior to its issue for subsequent transfusion, evaluation of the crossmatch requirements in the BLOOD PRODUCT file (#66) for the specific component of the unit selected to determine whether crossmatch results must be entered and prevents issue if a crossmatch is required and no results have been entered for the unit. |
| I71 | Inventory - Issue/relocation of units for transfusion | Use of an algorithm to prevent issue if no recheck results are entered based on component specific parameters defined the BLOOD PRODUCT file (#66), (i.e., if CONTAINS RED CELLS = YES, an ABO recheck is required, and if unit is Rh negative, the Rh recheck is also required). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|--|
| I72 | Inventory - Issue/relocation of units for transfusion | Prevents issue of unit if the inspection is entered as unsatisfactory for that specific relocation from any previous relocations of that unit. |
| I73 | Inventory - Issue/relocation of units for transfusion | Evaluation of the expiration date of unit and displays a warning message if unit is expired when compared to the current time. |
| I74 | Inventory - Issue/relocation of units for transfusion | No issue of the unit if the component is one for which there is an entry of "YES" in the Modified Before Release field (#.14) in the BLOOD PRODUCT file (#66). |
| I75 | Inventory - Issue/relocation of units for transfusion | Data validation check to ensure that the unit relocation date/time is not prior to the date/time the unit was assigned to the patient. |
| I76 | Inventory - Issue/relocation of units for transfusion | Prevents entry of a future relocation date/time. |
| I77 | Inventory - Issue/relocation of units for transfusion | Restricted relocation of units to standard locations within the same associated division based on the entries in the HOSPITAL LOCATION file (#44) <i>unless</i> user enters a non-standard location and overrides the check. |
| I78 | Inventory - Issue/relocation of units for transfusion | Ability to edit verified information relating to the issue/relocation of a specific unit ID. (Requires a higher level of security access) |
| I79 | Inventory - Phenotyping of units | Use of a standardized coding system, i.e., SNOMED, for identifying both RBC and HLA antigen typings on units. |
| I80 | Inventory - Phenotyping of units | Ability for the site to define which entries in FUNCTION FIELD file (#61.3) are accessible during the data entry of unit RBC phenotyping results (entries in File #61.3 for which the SCREEN = AN). |
| I81 | Inventory - Phenotyping of units | Site specific control of the transfusion criteria regarding the RBC antigen phenotyping of units selected for patient(s) with clinically significant antibody(ies). (CORRESPONDING ANTIGEN entry in the FUNCTION FIELD file (#61.3)) |
| I82 | Inventory - Phenotyping of units | Report listing of all units in inventory which have been phenotyped, including all entries for RBC antigens present and absent, for a specified component of a specified ABO/Rh. |
| I83 | Inventory - Phenotyping of units | Data validation check to prevent entry of the same antigen in the RBC Antigen Present field (#.04) and the RBC Antigen Absent field (#.05) for a given unit ID. |
| I84 | Inventory - Phenotyping of units | Donor record in the BLOOD DONOR file (#65.5) updated to reflect any unit phenotyping performed and entered for the donor unit after the unit has been released to the BLOOD INVENTORY file (#65). |

| IU# | Functionality | Description of Intended Uses |
|-----|---|--|
| I85 | Inventory-Release of units to stock/available inventory | Restricted release of the autologous/directed donor units for allogeneic (homologous) use, i.e., deletion of RESTRICTED FOR information, for units with a 'YES' in the POS/INCOMP. SCREENING TESTS field (#8.1). |
| I86 | Inventory-Release of units to stock/available inventory | Restricted release of units from locations other than BLOOD BANK. |
| I87 | Inventory - Release of units to stock/available inventory | Site specific control of standardized canned comments that are accessible during the release of crossmatched/assigned units back to available inventory. (entries in the LABORATORY DESCRIPTIONS file (#62.5) for which the SCREEN = BB RELEASE). |
| I88 | Inventory- Records | Tracking of unit modification information for both the unit being modified and the unit(s) being created to include data on units MODIFIED TO or MODIFIED FROM as appropriate. |
| I89 | Inventory- Records | Use of an algorithm to search the BLOOD INVENTORY file (#65) to look for missing data. See Section IX for a listing of data elements being evaluated. |
| I90 | Inventory- Records | On-line storage of unit cumulative history for lookback purposes. |
| I91 | Inventory- Records | Ability to display/print a hard copy of the cumulative unit history. |
| I92 | Inventory- Records | Display of selected information on the current status of a unit, i.e., unit ID, component, expiration date, ABO/Rh, patient assigned if currently assigned, date assigned if currently assigned, current location and the date last relocated if unit has ever been relocated. |
| I93 | Inventory- Records | Ability to print a hard copy of the cumulative unit history for units entered into the BLOOD INVENTORY file (#65) within a specified date range for which have a final disposition has been entered for use as a permanent record prior to the removal of the unit from the computer system. |
| I94 | Inventory - Records | Requirement to use the Print units with final disposition [LRBLRUF] option to print a hard copy of the cumulative unit history in the BLOOD INVENTORY file (#65) in order to purge units for which a final disposition has been assigned. (NOTE: Higher level of security access also required.) |
| I95 | Inventory - Management | Report of units which have been tested for CMV antibody and for which results have been entered, allowing user to specify ABO/Rh and whether the report should include CMV Antibody positive or CMV Antibody negative units. |

| IU# | Functionality | Description of Intended Uses | |
|-----|------------------------|--|--|
| I96 | Inventory- Management | Report for a specified range of disposition dates for a specified disposition of units (as long as the disposition selected "TRANSFUSE") and can be used for supervisory or utilization review. The report is sorted by component and includes specified data fields; for most dispositions i.e., unit ID, disposition date, supplier (source), ABO/Rh, date received and disposition comment. If "MODIFY" is selected for the disposition, the report will include the unit ID, disposition date, the component into which the unit was modified and the new unit ID instead. | |
| I97 | Inventory - Management | Report for a specified component (or all components), for a specified ABO/Rh (or all groups), of units which are available, i.e., are in date and have no final disposition, sorted by component, by ABO/Rh and by expiration date within the ABO/Rh which can be used for checking available inventory or for supervisory or utilization review. Report includes ABO/Rh, unit ID, expiration date, current location, patient assigned is currently assigned, specimen date is appropriate and totals for each ABO/Rh for each component. In addition, if the units autologous or directed, the patient's name is included even if the unit is not currently in the assigned status. | |
| I98 | Inventory- Management | Report for a specified component (or all components), for a specified ABO/Rh (or all groups), of units which have no final disposition (both in date and outdated), sorted by component, by ABO/Rh and by expiration date within the ABO/Rh which can be used for checking inventory and data entry records. Report includes ABO/Rh, unit ID, expiration date, current location, patient assigned is currently assigned, specimen date is appropriate and totals for each ABO/Rh for each component. In addition, if the unit is autologous or directed, the patient's name is included even if the unit is not currently in the assigned status. | |
| I99 | Inventory- Management | Report of units in the "assigned" status in chronological order by date/time assigned for use evaluating which units should be canceled/released or for other types of supervisory/utilization review. Report includes the date/time crossmatched (or assigned if component does not require crossmatching), specimen date/time if appropriate, unit ID, ABO/Rh, current location, unit expiration date/time, component abbreviation and patient (name and SSN). | |

| IU# | Functionality | Description of Intended Uses | |
|------|-----------------------|--|--|
| I100 | Inventory- Management | Ability to edit supplier charges for individual units before generating costing reports by invoice number or by transaction. | |
| I101 | Inventory- Management | Ability to enter and/or edit supplier charges for special typing charges on individual units before generating costing reports for special typing charges. | |
| I102 | Inventory- Management | Report of units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by supplier and by invoice # within the supplier for use in verifying billing invoices received. Report includes the component, invoice #, date/time received, unit ID, expiration date, ABO/Rh, cost, disposition if already entered, counts, cost subtotals and cost totals. | |
| I103 | Inventory- Management | Report of units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by component, then by date received, then by ABO/Rh for use in verifying billing invoices received or for a review of transactions. Report includes the supplier, component, date/time received, invoice #, unit ID, ABO/Rh, expiration date, cost, disposition if already entered, counts, cost subtotals and cost totals. (NOTE: Report differs from the report by invoice number in both format and count as the report by transaction includes unit modifications done on-site.) | |
| I104 | Inventory- Management | Report of all special charges for units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by date/time received, for use in verifying billing invoices received. Report includes the unit ID, component, supplier (source), invoice #, date/time received, cost, log-in tech, ABO/Rh, volume and special typing charge. | |
| I105 | Inventory- Management | Report detailing the disposition of autologous units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by date received, which have a disposition = TRANSFUSE, for supervisory and/or utilization review. Report includes the patient information, unit ID, # days present in inventory (calculated from date received to disposition date), component treating specialty of the patient when transfused and totals by type of component. | |
| I106 | Inventory- Management | Report detailing the disposition of autologous units entered into the BLOOD INVENTORY file (#65) for a specified date range, sorted by patient, which have a disposition TRANSFUSE, for supervisory and/or utilization review. Report includes the patient information, component, disposition, unit ID, # days present in inventory (calculated from date received to disposition date) and totals by type of component. | |

| IU# | Functionality | Description of Intended Uses | |
|------|-----------------------|--|--|
| I107 | Inventory- Management | Report of all issues/relocations for a specified date range, sorted by date/time relocation, for use as a semi-permanent record/utilization review or as a quick reference in other clinical lab sections. Report includes the date/time relocation, unit ID, component abbreviation, inspection results, tech performing inspection, person issued to, patient name, location issued to, patient SSN, counts by location and by component, and totals by component. | |
| I108 | Inventory- Statistics | Report of tallies for ABO recheck and Rh rechecks entered for units are entered into the BLOOD INVENTORY file (#65) for a specified date range. | |
| I109 | Inventory- Statistics | Capture of workload information feeds data to non-BB laboratory files which is subsequently used for a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. | |

C. Patient Functions

1. LAB DATA file (#63) Description of Data Elements

| | Field Name | | | |
|--------|---|---|--|--|
| Field# | Help Prompt Description | Data Type (PM=Pattern Match) | | |
| .01 | LRDFN The internal file number of the patier Enter the application entry number. | NUMBER | | |
| .02 | | POINTER TO FILE (#1) File where the name of this entry may be found. To the appropriate parent you wish this entry associated with. | | |
| .03 | NAME The internal file number in the parent | NUMBER internal file number in the parent file for this entry. | | |
| .04 | DO NOT TRANSFUSE | Field Not in Use | | |
| .05 | ABO GROUP | SET 'A' FOR A; 'B' FOR B; 'AB' FOR AB; 'O' FOR O; | | |
| | ABO blood group of patient | | | |
| .06 | RH TYPE | SET 'POS' FOR POS; 'NEG' FOR NEG | | |
| | This is the patient's RH blood type. | NZO PON NZO | | |
| .07 | RBC ANTIGENS PRESENT(other) (Subfile 63.13) POINTER Multiple RBC antigens present other than ABO & Rho(D) NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identified. | | | |
| | .01 RBC ANTIGENS PRESENT These are red blood cell antiger Rho(D). | POINTER TO FUNCTION FIELD FILE (#61.3) as present other than ABO and | | |
| | NOTE: User can only select from entries in the FUNCTION FI file (#61.3) which have AN as the identifier. | | | |
| | .02 RBC ANTIGENS PRESENT COMMENT This is a comment on the red blo ANSWER MUST BE 2-80 CHARACTERS I | | | |

Field# Description

Data Type (PM=Pattern Match)

.75 ANTIBODIES IDENTIFIED (Subfile 63.075) POINTER

Multiple

These are the patient's identified antibodies. Selects only antibodies.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AB as the identifier.

.01 ANTIBODIES IDENTIFIED

POINTER TO FUNCTION FIELD

FILE (#61.3)

This is a pointer to an antibody identified on this patient.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AB as the identifier.

- .02 ANTIBODIES IDENTIFIED COMMENT FREE TEXT
 This is a comment on the antibodies identified.
 ANSWER MUST BE 2-80 CHARACTERS IN LENGTH
- .76 BLOOD BANK COMMENTS (Subfile 63.076)
 - .01 BLOOD BANK COMMENTS WORD-PROCESSING These are blood bank comments for this patient.
- .08 RBC ANTIGENS ABSENT(other) (Subfile 63.016) POINTER Multiple
 Red blood cell antigens absent other than ABO & Rho(D).

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier.

.01 RBC ANTIGENS ABSENT

POINTER TO FUNCTION FIELD

FILE (#61.3)

This is a red blood cell antigen absent for this patient. Selects only antigens.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier

- .02 RBC ANTIGENS ABSENT COMMENT FREE TEXT This is the comment on the absent antigen.
 ANSWER MUST BE 2-80 CHARACTERS IN LENGTH
- .84 BLOOD COMPONENT REQUEST (Subfile 63.084) POINTER Multiple
 These are blood component requests.
 Selects only components that can be requested.
 - .01 BLOOD COMPONENT REQUEST POINTER TO BLOOD PRODUCT FILE (#66)

This is the component requested. Selects only components that can be selected within the division.

| | Field Name Help Prompt | | | |
|--------|--|---|---|--|
| Field# | Description | | Data Type (PM=Pattern Match) | |
| | | PRE-OP REQUEST | SET '1' FOR YES; '0' FOR NO; | |
| | .03 | YES indicates this is a pre-operat REQUEST DATE/TIME | tive request. DATE (PM=Exact date (with month and day) required, time allowed and echo the answer) | |
| | | This is the date/time of the reque | est. | |
| | .04 | NUMBER OF UNITS This is the number of units reques Type a Number between 1 and 50, 0 | NUMBER sted. Decimal Digits. | |
| | .05 | DATE/TIME UNITS WANTED | DATE (PM=Exact date (with month and day) required, time allowed and echo the answer) | |
| | | This is the date/time the units ar | • | |
| | .06 | PREVIOUS TRANSFUSIONS | Field Not in Use | |
| | .07 | PREVIOUS TRANSFUSION REACTION | Field Not in Use | |
| | .08 | ENTERING PERSON | POINTER TO NEW PERSON FILE (#200) | |
| | This is the person entering the request. | | equest. | |
| | .09 | REQUESTING PERSON This is the person making the requ ANSWER MUST BE 2-17 CHARACTERS IN | | |
| | 1 | UNITS SELECTED FOR XMATCH (Subfile Multiple These are units selected for cross SELECTS UNTS WITHOUT DISPOSITION | | |
| | | .01 UNIT SELECTED FOR XMATCH This is the unit selected for | POINTER TO BLOOD INVENTORY FILE (#65) crossmatch. | |
| | | .02 INVERSE SPECIMEN DATE This is 9999999-collection da crossmatch. TYPE A NUMBER BETWEEN 1 AND 9 | - | |

COMPONENT REQUEST REASON FREE TEXT

why the request should still be completed. ANSWER MUST BE 2-80 CHARACTERS IN LENGTH

If request does not meet acceptable criteria enter the reason

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB AUDIT as the

2.1

screen.

Field Name Help Prompt Data Type (PM=Pattern Match) Description Field# APPROVED BY FREE TEXT 2.2 This is the person approving the crossmatch request. ANSWER MUST BE 2-30 CHARACTERS IN LENGTH 2.3 TREATING SPECIALITY POINTER TO FACILITY TREATING SPECIALTY FILE (#45.7) This is the treating specialty of the crossmatch request. .85 TRANSFUSION RECORD (Subfile 63.017) Multiple This is data concerning the patient's transfusion. .01 TRANSFUSION DATE/TIME DATE (PM=Exact date (with month and day) required, time allowed and echo the answer; allows dates up to the current time) This is a reverse chronological order of blood components transfused. .02 COMPONENT POINTER TO BLOOD PRODUCT FILE (#66) This is the component transfused. Selects only blood components that can be transfused. NOTE: User can only elect from entries in the BLOOD PRODUCT file (#66) which have BB as the identifier. COMPONENT ID .03 This is the component identification number. ANSWER MUST BE 2-12 CHARACTERS IN LENGTH .04 ENTERING PERSON POINTER TO NEW PERSON FILE (#200) This is the person entering information on the transfusion. .05 ABO SET 'A' FOR A; 'B' FOR B; 'AB' FOR AB; 'O' FOR O; ABO group of component .06 RH SET 'POS' FOR POSITIVE; 'NEG' FOR NEGATIVE; Rh type of component .07 UNITS POOLED NUMBER This is the number of units pooled. TYPE A WHOLE NUMBER BETWEEN 0 AND 99.

Data Type (PM=Pattern Match) Description Field#

.08 TRANSFUSION REACTION

'1' FOR YES;
'0' FOR NO;

SET

SET

YES indicates a transfusion reaction was associated with this transfusion.

DATA ENTERED VIA OLD RECORDS .09

'1' FOR YES;

FILE (#65.4)

If transfusion data entered in the transfusion record via previous records option then a 'YES' will be entered here. NOTE: Data are not entered by the user.

. 1 VOL(ml) TRANSFUSED NUMBER Enter in milliliters the volume of the unit transfused. Type a Number between 1 and 1000, 0 Decimal Digits.

POINTER TO BLOOD BANK UTILITY .11 TRANSFUSION REACTION TYPE

Indicates type of transfusion reaction

NOTE: User can select from entries in the BLOOD BANK UTILITY file (#65.4) which have TRANSFUSION REACTION as the screen.

- TRANSFUSION COMMENT (Subfile 63.186) 1 Multiple
 - .01 TRANSFUSION COMMENT FREE TEXT These are comments on the transfusion. ANSWER MUST BE 1-80 CHARACTERS IN LENGTH

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB TRANS as the screen.

CROSSMATCH COMMENT (Subfile 63.027) 2 Multiple

> .01 CROSSMATCH COMMENT FREE TEXT These are comments on the crossmatch.

ANSWER MUST BE 1-80 CHARACTERS IN LENGTH

.86 TRANSFUSION REACTION DATE (Subfile 63.0171) DATE Multiple

Transfusion reactions that cannot be assigned to a specific unit are entered here.

.01 TRANSFUSION REACTION DATE DATE (PM=Exact date

(with month and day) required, time allowed and echo the

answer)

Transfusion reactions that cannot be assigned to a specific unit are entered here.

Patient Functions

Field Name Help Prompt Data Type (PM=Pattern Match) Field# Description POINTER TO BLOOD BANK UTILITY TRANSFUSION REACTION TYPE FILE (#65.4) Stores the type of transfusion reaction Selects only transfusion reaction entries NOTE: User can select from entries in the BLOOD BANK UTILITY FILE (#65.4) which have TRANSFUSION REACTION as the screen. PERSON ENTERING REACTION POINTER TO NEW PERSON .03 FILE (#200) Person entering reaction information TRANSFUSION REACTION COMMENT (Subfile 63.172) Multiple Multiple for transfusion reaction comment .01 TRANSFUSION REACTION COMMENT FREE TEXT Answer must be 2-68 characters in length. HOSPITAL ID .09 COMPUTED Computed field to present the hospital ID from the parent file. FREE TEXT .91 ANSWER MUST BE 1-20 CHARACTERS IN LENGTH Patient information .92 LOCATION TYPE 'C' FOR CLINIC; 'M' FOR MODULE; 'W' FOR WARD; 'Z' FOR OTHER LOCATION; 'N' FOR NON-CLINIC STOP; 'F' FOR FILE AREA; 'I' FOR IMAGING; 'OR' FOR OPERATING ROOM; This field is used for Workload Classification. Other location type is the default answer. REPORT ROUTING (LOCATION) . 1 FREE TEXT ANSWER MUST BE 1-19 CHARACTERS IN LENGTH The most current location where a lab procedure was requested. .101 REPORT ROUTING (PROVIDER) POINTER TO NEW PERSON FILE (#200) The most current requesting person who requested a lab procedure. .11 CUMULATIVE REPORT PAGES (Subfile 63.03) POINTER Multiple Current temporary (active) page numbers for the cumulative report.

Field# Description

Data Type (PM=Pattern Match)

.01 CUMULATIVE REPORT PAGES POINTER TO LAB REPORTS FILE (#64.5)

First piece page number for the cumulative report.

- 1 PAGE NUMBER
 TYPE A WHOLE NUMBER BETWEEN 1 AND 9999
 Second piece page number for the cumulative report.
- .2 HLA ANTIGENS PRESENT (Subfile 63.14) POINTER Multiple
 These are HLA antigens associated with this patient.
 SELECTS ONLY HLA ANTIGENS

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have HL as the identifier

- .01 HLA ANTIGEN PRESENT POINTER TO FUNCTION FIELD FILE (#61.3)

 NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have HL as the identifier.
- .02 HLA ANTIGEN PRESENT COMMENT FREE TEXT ANSWER MUST BE 2-80 CHARACTERS IN LENGTH
- .21 HLA ANTIGENS ABSENT (Subfile 63.141) POINTER Multiple
 These are HLA antigens NOT associated with this patient. Selects HLA antigens.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have HL as the identifier.

- .01 HLA ANTIGENS ABSENT

 POINTER TO FUNCTION FIELD
 FILE (#61.3)

 This is the HLA antigen NOT associated with this patient.

 NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have HL as the identifier.
- .02 LA ANTIGEN ABSENT COMMENT FREE TEXT ANSWER MUST BE 2-80 CHARACTERS IN LENGTH

Patient Functions

| | Field Help H | | |
|--------|-----------------|--|--|
| Field# | | | Data Type (PM=Pattern Match) |
| 1 | BLOOD Multi | BANK (Subfile 63.01) | DATE |
| | .01 | DATE/TIME SPECIMEN TAKEN This is the date/time the specimen | DATE (PM=Exact date (with month and day) required, time allowed (including seconds) and echo the answer; allows dates up to the current time) was collected. |
| | | ENTER PAST OR PRESENT DATE/TIME ON | ILY |
| | .03 | DATE REPORT COMPLETED | DATE (PM=Exact date (with month and day) required, time allowed and echo the answer) |
| | | This is the date the report was co | ompleted. |
| | .04 | ENTERING PERSON | Field Not in Use |
| | .05 | SPECIMEN | POINTER TO TOPOGRAPHY FIELD FILE (#61) |
| | | This is the specimen collected. | , , , , , , , , , , , , , , , , , , , |
| | .055 | COLLECTION SAMPLE | Field Not in Use |
| | .06 | ACCESSION NUMBER This is the blood bank accession. ANSWER MUST BE 1-20 CHARACTERS IN | FREE TEXT |
| | .07 | PHYSICIAN | Field Not in Use |
| | .08 | WARD | Field Not in Use |
| | .09 | PHLEBOTOMIST | Field Not in Use |
| | .1 | DATE/TIME RECEIVED | Field Not in Use |
| | .12 | ACCESSION LINK | Field Not in Use |
| | .99 | SPECIMEN COMMENT (Subfile 63.199) Multiple | |
| | | This is a comment on the specimen. ANSWER MUST BE $2-80$ CHARACTERS IN | |
| | | .01 SPECIMEN COMMENT Answer must be 2-68 characters | FREE TEXT s in length. |

| | Field Name Help Prompt | | |
|-------------|---------------------------|--|---|
| Field# | _ | iption | Data Type (PM=Pattern Match) |
| 2 2 0 2 0 1 | 2.1 | * | FREE TEXT iserum ne user can select from entries |
| | 2.2 | DIRECT AHG(5 min incub) | Field Not in Use |
| | 2.3 | DIRECT AHG CC | Field Not in Use |
| | 2.4 | ANTI-IgG Anti-human globulin (not broad spe | FREE TEXT ectrum) |
| | | NOTE: In addition to free text, the in the AGGLUTINATION STRENGTH file | |
| | 2.5 | ANTI-IgG CC | Field Not in Use |
| | 2.6 | ANTI-COMPLEMENT Anti-human globulin (complement synome: In addition to free text, the in the AGGLUTINATION STRENGTH file | ne user can select from entries |
| | 2.7 | ANTI-COMPLEMENT (5 min incub) | Field Not in Use |
| | 2.8 | ANTI-COMPLEMENT CC | Field Not in Use |
| | 2.9 | DIRECT AHG INTERPRETATION | SET 'P' FOR POSITIVE; 'N' FOR NEGATIVE; 'I' FOR INVALID, USE EDTA SPECIMEN; |
| | | Interpretation of the direct AHG | |
| | 2.91 | DIRECT AHG TEST COMMENT Any comment on the direct AHG test ANSWER MUST BE 1-80 CHARACTERS IN | |
| | | NOTE: In addition to free text, the in the LAB DESCRIPTIONS file (#62 the screen. | |
| | 3 | ELUATE ANTIBODY (Subfile 63.012) Multiple Selects only antibodies | POINTER |
| | | NOTE: User can only select from er file (#61.3) which have AB as the | |
| | | .01 ELUATE ANTIBODY | POINTER TO FUNCTION FIELD FILE (#61.3) |
| | | These are eluate antibodies. Selects only Blood group Anti | |
| | | NOTE: User can only select fr FIELD file (#61.3) which have | |

| | Help | Promp | t | |
|--------|------|----------|---------------------------------|-------------------------------|
| Field# | Desc | cription | n | Data Type (PM=Pattern Match) |
| | 4 | SCREE | N CELL METHOD (Subfile 63.014) | Field Not in Use |
| | | .01 | SCREEN CELL METHOD | Field Not in Use |
| | | .02 | TECHNIQUE | Field Not in Use |
| | | 1 | SCREEN CELL (Subfile 63.015) | Field Not in Use |
| | | | .01 SCREEN CELL | Field Not in Use |
| | | | .02 SOURCE | Field Not in Use |
| | | | .03 INTERPRETATION | Field Not in Use |
| | | | .04 IS | Field Not in Use |
| | | | .05 37 C | Field Not in Use |
| | | | .06 AHG | Field Not in Use |
| | | | .07 CONTROL CELL | Field Not in Use |
| | | | .08 ROOM TEMP | Field Not in Use |
| | | | .09 12-18 C | Field Not in Use |
| | | | .1 4 C | Field Not in Use |
| | 6 | ANTIB | ODY SCREEN INTERPRETATION | SET |
| | | | | 'N' FOR NEG; |
| | | | | 'P' FOR POS; |
| | | | tibodies are present in the pa | = |
| | | scree | n interpretation will usually b | be positive. |

6.1 RBC ANTIGEN PRESENT (Subfile 63.011) POINTER Multiple

Antigens present on RBC's of patient are entered here. Selects red blood cell antigens

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier.

.01 RBC ANTIGEN PRESENT POINTER TO FUNCTION FIELD FILE (#61.3)

Antigens present on RBC's of patient are entered here.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier.

- .02 COMMENT FREE TEXT Answer must be 1-80 characters in length.
- 6.2 RBC ANTIGEN ABSENT (Subfile 63.0112) POINTER Multiple

Antigens identified as absent on red blood cells are entered here. Selects red blood cell antigens

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier.

.01 RBC ANTIGEN ABSENT POINTER TO FUNCTION FIELD FILE (#61.3)
Antigens identified as absent on red blood cells are entered here.

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AN as the identifier.

Field# Description Data Type (PM=Pattern Match)

.02 COMMENT

FREE TEXT

Answer must be 1-80 characters in length.

- 6.3 HLA ANTIGEN PRESENT (Subfile 63.013) Field Not in Use
 .01 HLA ANTIGEN PRESENT Field Not in Use
 .02 COMMENT Field Not in Use
 - .02 COMMENT FICTOR NOT IN 03C
- 6.4 HLA ANTIGEN ABSENT (Subfile 63.0114) Field Not in Use
 .01 HLA ANTIGEN ABSENT Field Not in Use
 .02 COMMENT Field Not in Use
- 7 SERUM ANTIBODY (Subfile 63.46) POINTER Multiple
 These are the serum antibodies

These are the serum antibodies.

SELECTS ANTIBODIES

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AB as the identifier.

.01 SERUM ANTIBODY POINTER TO FUNCTION FIELD FILE (#61.3)

NOTE: User can only select from entries in the FUNCTION FIELD file (#61.3) which have AB as the identifier.

- .02 ANTIBODY COMMENT FREE TEXT ANSWER MUST BE 2-30 CHARACTERS IN LENGTH
- 8 ANTIBODY SCREEN COMMENT (Subfile 63.48)
 Multiple
 These are antibody screen comments.
 - .01 ANTIBODY SCREEN COMMENT FREE TEXT ANSWER MUST BE 2-80 CHARACTERS IN LENGTH

NOTE: In addition to free text, the user can select from entries in the LAB DESCRIPTIONS file (#62.5) which have BB TESTING as the screen.

- 9 RBC TYPING METHOD (Subfile 63.018) Field Not in Use
 .01 RBC TYPING METHOD Field Not in Use
 .02 TECHNIQUE Field Not in Use

 1 ANTISERUM (Subfile 63.019) Field Not in Use
 .01 ANTISERUM Field Not in Use
 - .02 LOT #
 .03 INTERPRETATION Field Not in Use Field Not in Use .04 IS Field Not in Use .05 37 C Field Not in Use .06 AHG Field Not in Use .07 CONTROL CELL Field Not in Use .08 ROOM TEMP Field Not in Use .09 12-18 C Field Not in Use .1 4 C Field Not in Use

| | Help Prompt | | |
|--------|------------------------|--|---|
| Field# | Descrip | tion | Data Type (PM=Pattern Match) |
| | 10 | ABO INTERPRETATION This is the patient's ABO interp | SET 'A' FOR A; 'B' FOR B; 'O' FOR O; 'AB' FOR AB; 'ND' FOR NOT DONE; retation. |
| | | - | |
| | 10.2 | ABO TYPING TECH Technologist interpreting ABO ty | POINTER TO NEW PERSON FILE (#200) ping results |
| | 10.3 | ABO TESTING COMMENT This is a comment on the ABO tes ANSWER MUST BE 1-80 CHARACTERS | FREE TEXT ting. |
| | 11 | RH INTERPRETATION | SET 'NEG' FOR NEG; 'POS' FOR POS; 'ND' FOR NOT DONE; |
| | | This is the patient's Rh interpr | |
| | 11.2 | RH TYPING TECH | POINTER TO NEW PERSON FILE (#200) |
| | | Technologist interpreting Rh typ | ing results |
| | 11.3 | RH TESTING COMMENT This is a comment on the Rh test ANSWER MUST BE 1-80 CHARACTERS | FREE TEXT ing. |
| | 129 129.1 129.11 | PT CELLS+ANTI D (sal) PT CELLS+RH CTRL (sal) PT CELLS(sal)+ANTI D(hp IS) PT CELLS(ser)+ANTI D(hp IS) PT CELLS+ANTI D (hp 37) PT CELLS+ANTI D (hp AHG) PT CELLS+ANTI D SLIDE (hp) PT CELLS(sal)+RH CTRL (hp IS) PT CELLS(ser)+RH CTRL (hp IS) PT CELLS+RH CTRL (hp 37) PT CELLS+RH CTRL (hp AHG) PT CELLS+RH CTRL SLIDE (hp) INTERPRETATION OF RH TESTING RH TEST COMMENT PT Cells(sal)+Anti D(mod) IS PT Cells(ser)+Anti D(mod) IS PT Cells+Anti D(mod) 37 | Field Not in Use |

| | Help Prompt | | |
|--------|-------------|--------------------------------|-------------------------------|
| Field# | Descrip | | Data Type (PM=Pattern Match) |
| | 136 | PT Cells+Anti D(mod) AHG | Field Not in Use |
| | 138 | PT Cells(sal)+RH Ctrl(sal) IS | Field Not in Use |
| | 139 E | PT Cells(ser)+RH Ctrl(sal) IS | Field Not in Use |
| | 139.1 | PT Cells+RH Ctrl(sal) 37 | Field Not in Use |
| | 139.11 | PT Cells+RH Ctrl(sal) AHG | Field Not in Use |
| | 141 | PT CELLS(ser)+ANTI A IS | Field Not in Use |
| | 142 | PT CELLS(sal)+ANTI A IS | Field Not in Use |
| | 143 | PT CELLS+ANTI A SLIDE | Field Not in Use |
| | 144 | PT CELLS(ser) + ANTI B IS | Field Not in Use |
| | 145 | PT CELLS(sal)+ANTI B IS | Field Not in Use |
| | 146 | PT CELLS+ANTI B SLIDE | Field Not in Use |
| | 147 | PT CELLS(ser)+ANTI A,B IS | Field Not in Use |
| | 148 | PT CELLS(ser) + ANTI A, B (RT) | Field Not in Use |
| | 149 | PT CELLS(sal)+ANTI A,B (IS) | Field Not in Use |
| | 149.1 | PT CELLS(sal)+ANTI A,B (RT) | Field Not in Use |
| | 149.11 | PT CELLS+ANTI A,B SLIDE | Field Not in Use |
| | 149.12 | PT SERUM+A1 CELLS | Field Not in Use |
| | 149.13 | PT SERUM+B CELLS | Field Not in Use |
| | 151 | INTERPRETATION OF ABO TESTING | Field Not in Use |
| | 152 | ABO TESTING COMMENT | Field Not in Use |
| | 153 | INTERPRETATION ABO GROUP(cell) | Field Not in Use |
| | 154 | INTERPRETATION ABO GROUP(ser) | Field Not in Use |

File continues with other laboratory data for anatomic and clinical pathology.

Software Limitations

| Functionality | Description of Software Limitations |
|---|--|
| Patient- Specimen Receipt & Order Entry | Manual system for patient/recipient armband |
| | identification. |
| | Manual system for recording and tracking the |
| | identification of the phlebotomist. |
| | Partial system for entry of blood component |
| | requests/orders (chart and SF518). |
| | No provision for a cumulative system of records for |
| | blood components requests within the Blood Bank software, (i.e., data is editable and represents only |
| | current information). |
| Patient - Test Result Entry (other than | No provision for test result interpretation based on |
| crossmatching) | actual testing results, (e.g. evaluation of reactions of |
| crossmatching) | antisera). |
| | Manual entry of test result interpretations of all |
| | required testing. |
| Patient - Unit Selection & Pretransfusion | No provision for test result interpretation based on |
| Testing | actual testing results, (e.g. evaluation of reactions of |
| | antisera). |
| | Manual entry of test result interpretations of all |
| | required testing. |
| | Manual documentation of previous history checks. |
| | No automatic updating and evaluation of donor |
| | recruitment/recall information based on actual |
| | donation data. |
| | Partial system for evaluating units selected versus |
| | blood component requests. |
| | No provision for evaluation of requirements for |
| | irradiation of directed donor units, i.e., unit from a |
| | donor who is a blood relative. |
| | No provision for evaluation of requirements for |
| | hemoglobin testing on units used for massive or |
| | exchange transfusions. |
| | No automatic provision for evaluation of specific |
| | component requirements, e.g., CMV negative units. |
| Patient- Transfusion Data Entry | No provision for performance of electronic crossmatch. No provision for electronic primary documentation of |
| 1 attent- Transfusion Data Entry | blood administration data. |
| | blood adillillistration data. |
| | No provision for electronic documentation of autologous |
| | blood collected/transfused as part of preoperative |
| | salvage procedures. |

| Functionality | Description of Software Limitations |
|--|---|
| Patient - Investigation of Adverse Effects | No provision for test result interpretation based on actual testing results, e.g. evaluation of reactions of antisera. |
| | Manual entry of results of testing associated with transfusion reaction investigations. No provision for reporting pathologist's |
| | evaluation/summary of transfusion reaction investigations. |
| Patient - Records | Manual record-keeping system prior to the computerization with site determination regarding entry of "old" data. Manual record-keeping system for actual test results. Partial system for recording blood administration data, i.e., date/time of transfusion and whether patient had a reaction. Manual system of records for blood components requests, i.e., data within the Blood Bank software is editable and represents only current request |
| | information. No provision of record-keeping system for "look back" notifications. |

<u>Intended Uses</u>

| IU# | Functionality | Description of Intended Use |
|-----|-------------------|---|
| P1 | Patient - General | Ability to set up a site parameter to indicate whether the fields for direct antiglobulin testing should be included in the edit template for entering ABO/Rh and antibody screening results. |
| P2 | Patient - General | Ability for the site to define standardized canned comments that are accessible during data entry based on the entry in the Screen field (#5). |
| P3 | Patient - General | Ability for the site to define consultation reports for both serum antibodies and positive direct antiglobulin tests. |
| P4 | Patient - General | Ability for the site to define which antibodies are clinically significant and to designate what corresponding antigen should be lacking in units of red blood cells selected for a patient possessing that antibody. |
| P5 | Patient - General | Ability for the site to define which test results should be displayed when accessioning blood bank specimens/entering blood component requests. |
| P6 | Patient - General | Ability for the site to define types of transfusion reactions for selection in data entry. |
| P7 | Patient - General | Provision of a unique cumulative record for each individual patient based on the data elements detailed above for the blood bank portion of the LAB DATA file (#63). |
| P8 | Patient - General | Maintenance of patient record confidentiality for test results/transfusion histories by providing different levels of security access such that the type of data access can be defined by individual user. |
| P9 | Patient - General | Site specific control to set up the entries in the BLOOD PRODUCT file (#66) for component specific requirements and algorithms to reflect facility operating procedures. See Section IX for a listing of the data elements and the description of their use. |
| P10 | Patient - General | Limited simultaneous access by multiple terminals/ users to the same patient record for purposes of data entry for specified options. |
| P11 | Patient - General | Cumulative patient data/transfusion record, including data on clinically significant antibodies, transfusion reactions and units transfused, updates immediately upon data entry. |
| P12 | Patient - General | Displays patient transfusion record in reverse chronological order for a specified date range (in either detailed or summary format), including any history of previous transfusion reactions and entries in the ANTIBODIES IDENTIFIED field (#.075) or BLOOD BANK COMMENTS field (#.01) of the LAB DATA file (#63). User can also specify the component if so desired. |
| P13 | Patient - General | Limited access to those units currently assigned to the same division as the user. |
| P14 | Patient - General | Accommodation of the use of a bar code reader for entry of the unit ID |
| P15 | Patient - General | Tracking of changes in verified data for specific data elements defined for the LAB DATA file (#63). |
| P16 | Patient - General | Tracing of verified data entered for critical data elements as detailed for the LAB DATA file (#63) when entered via the supervisory edit options requiring a higher level of security |
| P17 | Patient - General | Tracking of the person entering the data into the computer |

| IU# | Functionality | Description of Intended Use |
|-----|---|---|
| P18 | Patient - General | Elimination of the need for duplicate data entry by also updating the unit record immediately upon data entry. |
| P19 | Patient - General | Display of patient demographics, including first and last names, social security number, date of birth, ABO/Rh of record (if one exists), and admitting diagnosis. |
| P20 | Patient - General | Display of an alert message for any patients with a previous antibody history, regardless of division, based on entries in the Antibodies Identified field (#.075). |
| P21 | Patient - General | Display of previous transfusion reactions, regardless of division, for both unit specific and non-unit specific reactions. |
| P22 | Patient - General | Display of an alert message for any patients who have autologous and/or directed units in inventory, regardless of the division, based on a match in the Restricted For field (#8) of the unit. |
| P23 | Patient - General | Limited component selection to those components for which the Can Be Requested field (#.15) in the BLOOD PRODUCT file (#66) =YES and which are assigned to the appropriate division. |
| P24 | Patient - General | Provision of a variety of reports that can be used for supervisory review. Including one which details the patient's ABO/Rh, AB Screen results, DAT results and serum/eluate antibodies, for the current specimen and a specified number of previous specimens, as well as entries in the Antibodies Identified field (#.075) and the Blood Bank Comments field (#.01). |
| P25 | Patient - General | Entry of special instructions in the Blood Bank Comments field (#.01) regarding specific component requirements. |
| P26 | Patient - Old Records | Entry of previous transfusion history, ABO/Rh, clinically significant antibodies, red cell phenotyping and transfusion reactions. |
| P27 | Patient - Old Records | Provision of access to fields for entry of comments/special instructions, which might be relevant for future reference. |
| P28 | Patient - Old Records | No entry of historical unit information, if unit is in the current BLOOD INVENTORY file #65. |
| P29 | Patient - Old Records | Ability to edit information entered from old records prior to computerization, (i.e., cannot access units in the BLOOD INVENTORY file (#65)). (Requires a higher level of security access). |
| P30 | Patient - Specimen Receipt & Order Entry | Ability for the site to define Blood Bank tests in the LABORATORY TEST file (#60) which can be ordered by both Blood Bank personnel and other hospital personnel, e.g., transfusion request, type and screen, etc. |
| P31 | Patient - Specimen Receipt & Order Entry [LREV] | Display of test description information based on entries for the specific test in the LABORATORY TEST file (#60). |
| P32 | Patient - Specimen Receipt & Order Entry [LREV] | Ability to accept orders for Blood Bank tests which are entered through other software packages and to update the status of the order as appropriate. |
| P33 | Patient - Specimen Receipt & Order Entry | Displays a listing of accessions for the patient for a specified accession area, including previous transfusion reaction information and data from the Antibodies Identified field (#.075) and the Blood Bank Comments field (#.01) if data exists. |
| P34 | Patient - Specimen Receipt & Order Entry | Ability for the Blood Bank personnel to enter component requests, for those which can be requested, for a specific patient. |

| IU# | Functionality | Description of Intended Use |
|-----|--|---|
| P35 | Patient - Specimen Receipt & Order Entry | Check to determine whether a previous specimen has been accessioned which was collected within the last 72 hours, regardless of division. |
| P36 | Patient - Specimen Receipt & Order Entry | Evaluation of the age of patient specimens available for the specific accession area and appropriate division to determine whether any meet the requirements based on the entry in the Maximum Specimen Age field (#16) of the BLOOD PRODUCT file (#66) for the specific component. |
| P37 | Patient - Specimen Receipt & Order Entry | Display of the most recent lab values for specified tests to allow auditing of the request based on locally defined parameters. |
| P38 | Patient - Specimen Receipt & Order Entry | Ability for the site to define, by specific surgical procedure in the OPERATIONS (MSBOS) file (#66.5), by specific blood component, the maximum number of units which may be requested without additional justification. |
| P39 | Patient - Specimen Receipt & Order Entry | Evaluation of pre-operative component requests against audit criteria as defined by the facility. |
| P40 | Patient - Specimen Receipt & Order Entry | Ability for the site to define specific audit criteria for pre-op and non pre-op requests, by blood component. |
| P41 | Patient - Specimen Receipt & Order Entry | Evaluation of requests against facility defined audit criteria for the specific component and current lab results, flagging requests which may be potentially inappropriate and allowing for input of additional justification for those requests. |
| P42 | Patient - Specimen Receipt and Order Entry | Capture of appropriate data for evaluation of ordering practices by treating specialty through a variety of different reports. |
| P43 | Patient - Specimen Receipt and Order Entry | No deletion of accession if there is verified data entered for that accession. |
| P44 | Patient - Test Result Entry (other than crossmatching) | Creation of the patient's historical ABO/Rh record based on the first entry of ABO/Rh results for the patient. |
| P45 | Patient - Test Result Entry (other than crossmatching) | Requirement for the use of a separate option to edit the patient's historical ABO/Rh record. (Requires a higher level of security access). |

| IU# | Functionality | Description of Intended Use |
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| P46 | Patient - Test Result Entry (other than crossmatching) | Comparison of current ABO/Rh interpretations to patient history and display of a warning message if a discrepancy exists. |
| P47 | Patient - Test Result Entry (other than crossmatching) | Display of a warning message on those patients who have no previous history to be used for comparison with current results. |
| P48 | Patient - Test Result Entry (other than crossmatching) | Automatic display of patient medications (both inpatient and outpatient, oral and IV) for patients upon entry of a positive direct antiglobulin test. |
| P49 | Patient - Test Result Entry (other than crossmatching) | Ability to view patient's medications, i.e. both inpatient and outpatient oral and IV. |
| P50 | Patient - Test Result Entry (other than crossmatching) | Tracking of data entry errors for ABO/Rh when comparisons with previous history fail to match even if data is corrected since such errors might adversely affect the patient if not caught. |
| P51 | Patient - Test Result Entry (other than crossmatching) | If changes are made in verified data for ABO/Rh testing, antibody screening or direct antiglobulin testing, automatic generation of a comment "reported incorrectly as" to indicate the original data. This comment is then included on the Blood Bank Test Report. |
| P52 | Patient - Test Result Entry (other than crossmatching) | Ability to generate a cumulative Blood Bank Test Report which includes the patient demographics (name, SSN, DOB and historical ABO/Rh), antibodies identified, the test results of individual specimens (ABO, Rh, Direct AHG, Antibody Screen, Serum Antibody and Eluate Antibody), and if requested, the current component requests. |
| P53 | Patient - Test Result Entry (other than crossmatching) | Creation of a print queue upon entry of test results and provides the ability to either print the Blood Bank Test Report in batches for all patients in the queue or to delete the queue. |
| P54 | Patient - Test Result Entry (other than crossmatching) | Custom consultation reports for patients with irregular antibodies and/or positive direct antiglobulin tests based on data entered for specific specimen and site specific file set-ups. |
| P55 | Patient- Unit Selection & Pretransfusion Testing | No selection of units which are expired through the usual option, requiring a different option and a level of security access to enter compatibility information and assign an expired unit to a patient. |
| P56 | Patient- Unit Selection & Pretransfusion Testing | Ability to assign units or enter crossmatch results if the age of the specimen exceeds the maximum requirements for the specific component requires a higher level of security access and a different option than that used routinely. |
| P57 | Patient- Unit Selection & Pretransfusion Testing | Predefined algorithm and parameters defined for the specific component, to prevent selection of units that are not ABO/Rh compatible. |
| P58 | Patient- Unit Selection & Pretransfusion Testing | Ability to assign a unit which is not ABO/Rh compatible according to the component specific parameters, requiring a higher level of security access and a different option than that used routinely. |

| IU# | Functionality | Description of Intended Use |
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| P59 | Patient- Unit Selection & Pretransfusion Testing | User controlled choice as to whether selection of units should be limited to those not currently assigned to another patient. |
| P60 | Patient- Unit Selection & Pretransfusion Testing | Display of any entries in the LAB DATA file (#63), Blood Bank Comments field (#.01) including those which might detail specific component needs. |
| P61 | Patient- Unit Selection & Pretransfusion Testing | Display of a warning message if the current volume is less than the average volume for the component if it is a pediatric component. |
| P62 | Patient- Unit Selection & Pretransfusion Testing | Display of a message indicating the number of days left before expiration of unit. |
| P63 | Patient- Unit Selection & Pretransfusion Testing | Prevents access to units which have not been appropriately 'selected' unless data is entered via a different option with a higher level of security and an automatic audit trail. |
| P64 | Patient- Unit Selection & Pretransfusion Testing | Algorithm to evaluate confirmatory testing and display of a warning message if required testing has not been completed. |
| P65 | Patient- Unit Selection & Pretransfusion Testing | No change in the unit status to make the unit available for subsequent issue if the unit recheck results do not match the unit login information. |
| P66 | Patient- Unit Selection & Pretransfusion Testing | No ability to delete the patient's historical record of ABO/Rh. |
| P67 | Patient- Unit Selection & Pretransfusion Testing | Comparison of the unit ABO/Rh to the patient history and prevents unit selection if there is no patient ABO/Rh on record. |
| P68 | Patient- Unit Selection & Pretransfusion Testing | Entry of crossmatch interpretation prevented if no ABO/Rh results have been entered on the current specimen. |

| IU# | Functionality | Description of Intended Use |
|-----|--|--|
| P69 | Patient- Unit Selection & Pretransfusion Testing | Display of a warning message if no results are entered for the antibody screening on the current specimen. |
| P70 | Patient Unit Selection & Pretransfusion Testing | Generation of a label containing patient identification and unit information to be attached to the tie tag for the unit in order to minimize opportunities for transcription errors. |
| P71 | Patient- Unit Selection & Pretransfusion Testing | Algorithm to evaluate unit phenotyping of allogeneic (homologous and directed) units, against clinically significant patient antibody in order to prevent selection of the unit for the patient if the corresponding antigen is present in the unit. |
| P72 | Patient- Unit Selection & Pretransfusion Testing | Evaluation of unit phenotyping of allogeneic (homologous) units against clinically significant patient antibody and display of a warning message if the corresponding Ag is not entered in the RBC Antigen Absent field (#.05). |
| P73 | Patient- Unit Selection & Pretransfusion Testing | Determination as to whether crossmatch result is required for the specific component. |
| P74 | Patient- Unit Selection & Pretransfusion Testing | Status change to 'assigned' for subsequent issue is prevented if the crossmatch result is anything other than' C' or 'IG'. |
| P75 | Patient- Unit Selection & Pretransfusion Testing | Status change to allow issue of the unit is prevented unless the initials entered match those of the user <u>and</u> the user also holds the appropriate security key. |
| P76 | Patient- Unit Selection & Pretransfusion Testing | Release of units back to available inventory if the result entered for the crossmatch is not 'C' or 'IG' |
| P77 | Patient- Unit Selection & Pretransfusion Testing | No ability to select units not associated with the appropriate division (even autologous) |
| P78 | Patient- Unit Selection & Pretransfusion Testing | Selection of autologous unit for a different patient than the patient designated is prevented. |
| P79 | Patient- Unit Selection & Pretransfusion Testing [LRBLQPR] | Automatic display of the current information on component requests and units assigned/available for issue. |
| P80 | Patient - Transfusion Data Entry | Calculation of the number of units in a pool and entry of the data in the Pooled/Divided Units field for the pooled product which was created if a pooled product is transfused. |

| IU# | Functionality | Description of Intended Use |
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| P81 | Patient - Transfusion Data Entry | Entry of unit specific transfusion reaction data, (i.e., type of reaction and appropriate comments). |
| P82 | Patient - Transfusion Data Entry | Entry of future transfusion dates prohibited. |
| P83 | Patient - Transfusion Data Entry | Capture of appropriate data for evaluation of transfusion practices by treating specialty through a variety of different reports. |
| P84 | Patient - Investigation of Adverse Effects | Entry of transfusion reaction data which is unrelated to a specific unit. |
| P85 | Patient - Investigation of Adverse Effects | Report of transfusion data, sorted by patient, including both reactions associated with a specific unit and those not associated with specific units. |
| P86 | Patient - Investigation of Adverse Effects | Report for use in identifying potential cases of transfusion transmitted disease, based on search of those patients transfused within the previous six month period for specific patient test results using facility specified tests and facility defined values. |
| P87 | Patient - Management/ Quality Improvement | Report of crossmatch transfusion ratios, sorted by treating specialty, in either summary or detailed format to allow a review of ordering patterns. |
| P88 | Patient - Management/ Quality Improvement | Report of patient's crossmatched for a specified date range, sorted by date/time crossmatched, to allow a review of ordering patterns. Report includes specimen info, unit ID, XM result, outcome of XM (released or transfused) and statistics on the # of patients crossmatched, # of specimens crossmatched, # of units transfused, the C:T ratio and the # of crossmatches for each result (C, IG, etc.). |
| P89 | Patient - Management/ Quality Improvement | Report of autologous unit dispositions, sorted by whether the unit was transfused or not, including the patient information, treating specialty if unit was transfused, component, unit ID and the number of days in inventory, to allow evaluation of utilization patterns. |
| P90 | Patient - Management/ Quality Improvement | Mechanism to identify units with a prolonged infusion time, based on component specific local parameters for maximum infusion time. |
| P91 | Patient - Management/ Quality Improvement | Administrative data report which detail data requested on the annual AABB questionnaire, sorted into inventory and donor groupings. |
| P92 | Patient - Management/ Quality Improvement | Report of potentially inappropriate transfusions based on the auditing done during specimen log-in /order entry, sorted by location to which the unit was issued for transfusion. |
| P93 | Patient - Management/ Quality Improvement | Patient report for use in outcome assessments, integrating transfusion episodes and clinical lab results for site selected tests. User can request the report for specific patients and date ranges or specify that reports should be printed for all patients transfused within a specified date range. |

| IU# | Functionality | Description of Intended Use |
|------|--|---|
| P94 | Patient - Management/Quality Improvement | Hard copy listing of patients who have been transfused for a specified treating specialty, for a specified date range. |
| P95 | Patient - Management/Quality Improvement | Report of all units transfused within a specified date range, sorted in alphabetical order by patient, and in chronological order for the specified disposition dates. Report includes patient name and SSN, unit ID, component, # in pool if appropriate, volume, inspection information, issue location, transfusion date/time and transfusion reaction information. |
| P96 | Patient - Management/Quality Improvement | Report of all units transfused within a specified treating specialty, a specified component and a specified date range, sorted by treating specialty, then by component, then alphabetically by patient. Report includes patient transfused, transfusion date/time, primary care physician, cost, unit ID and statistics for each treating specialty on # patients given RBC components, # patients given non-RBC components and cost. |
| P97 | Patient - Records | Permanent on-line storage of Blood Bank data, i.e. data is not included in algorithm used for archiving patient test results. |
| P98 | Patient - Records | Hard copy listing of patients who have clinically significant antibodies. |
| P99 | Patient - Records | Hard copy listing of patients who have Blood Bank data for reference during computer downtimes. Report includes the patients historical ABO/Rh, any clinically significant antibodies or special instructions, and if requested, results of the most recent ABO/Rh and Antibody Screen. User can specify the range of patients and whether all patients with BB data should be included or if listing should be limited to those with antibodies or comments. |
| P100 | Patient - Statistics | Capture of workload information and feeds data to non-BB laboratory files which is subsequently used for a variety of local and national reports, including the CAP Laboratory Management Index Program and DSS. |