

# Known Defects and Anomalies

## Introduction

The Known Defects and Anomalies (KDAs) table consists of system actions that do not meet performance expectations established in VBECS design documents. Some defects and anomalies require user workarounds such as being directed to view information in one report that was expected in another report. Defects and anomalies do not require a workaround if the software performs acceptably.

## Risk Assessment and Impact to Patient Care Assessment

A team of subject matter experts assess a defect or anomaly for potential harm and the impact to patient care using their knowledge of blood banking. Using the table in Figure 1, Risk Assessment Table, the Level of Concern is determined. A Level of Concern of Major cannot be mitigated with a workaround to an Acceptable level or identified as a KDA. The Level of Concern of “Minor” indicates that there is no expectation of injury to the patient, operator, or bystander as a result of software failure, including the possible application of a mitigating workaround.

All defects and anomalies must have an associated Risk rating of “Acceptable” and a Level of Concern of “Minor”. The Likelihood of Occurrence categories are Frequent, Probable, Occasional, Remote, or Improbable, as indicated by the business process.

**Important Note:** All system errors/shutdowns occur where the user is normally prohibited from proceeding to process the unit or patient in VBECS; train users to STOP and evaluate the correctness of continuing the action manually is strongly recommended.

Figure 1: Risk Assessment Table:

|                          |            | Levels of Concern |             |             |
|--------------------------|------------|-------------------|-------------|-------------|
|                          |            | Minor             | Moderate    | Major       |
| Likelihood of Occurrence | Frequent   | Acceptable        | Intolerable | Intolerable |
|                          | Probable   | Acceptable        | Intolerable | Intolerable |
|                          | Occasional | Acceptable        | Intolerable | Intolerable |
|                          | Remote     | Acceptable        | ALARP       | Intolerable |
|                          | Improbable | Acceptable        | Acceptable  | ALARP       |

## Related Manuals and Materials

- VistA Blood Establishment Computer Software (VBECS) Technical Manual-Security Guide
- VistA Blood Establishment Computer Software (VBECS) User Guide (The KDAs are referenced as Appendix E but are maintained with a separate revision table).

## Printing Requirements

This document is formatted to print on legal (8.5 x 14 inch) paper.

\*CR (Code Request Tracking System Number), DR (Document Request Tracking System Number), HD, INC, I, or R (Enterprise Complaint System Ticket Number), CQ (CPRS ClearQuest Tracking System Number), Defect or Task or CA SDM ticket.

**How the Known Defects and Anomalies is Organized**

- The table is organized by the option where the issue occurs in VBECS.
- Description of the Issue, Risk Assessment, and Affected Security Role columns provide pertinent information about the defect or anomaly.
- Recommended Workarounds are provided with the Additional Comments column providing more detail as needed.
- Throughout VBECS is the only section where the item may occur in various places in the application not in just one option.

**Terms**

See the VBECS User Guide Glossary for definitions of other terms and acronyms used in this table.

**Security**

Six security roles are available in VBECS. Security Levels and User Roles from most to least restrictive are: Blood Bank Technologist (most restrictive), Enhanced Technologist, Lead Technologist, Traditional Supervisor, Enhanced Supervisor, Administrator/Supervisor (least restrictive). In order to simplify this analysis three categories may be used to clarify the AFFECTED USER category: Administrator (Administrative Supervisor and Enhanced Supervisor); Supervisor (Traditional Supervisor and Lead Technologist, and above); All Users (Enhanced Technologist and Technologist, and above). Additional users are a System Administrator (Windows Network Administrator) and a VBECS Administrator (Server Administrator) which are restricted, usually to a primary and a backup person.

| Option Where the Issue Occurs | Description  | Recommended Workaround   | Level of Concern | Likelihood of Occurrence | Risk        | Impact to Patient Care | Security Role Mitigations (Affected User) | Additional Comments   | Tracking System Number* | New Tracking System Numbers* |
|-------------------------------|--|--|------------------|--------------------------|-------------|------------------------|---|---|-------------------------|------------------------------|
| Through-out VBECS             | VBECS maps an institution as an orderable location if the VistA institution file is more than 5 digits in length. Examples are rehab, nursing home or hospice units.                                     | Set VistA location to 5 digits if this location will be used to map orders to VBECS in the VBECS Administrator.          | Minor            | Remote                   | Accept-able | Low                    | All users                                 | VBECS can only accept a VistA location 5 digits in length. Sites are advised to limit locations that order blood to 5 digits in length. | CR 3,229<br>HD 625192   | 210159<br>I5868220FY15       |
| Through-out VBECS             | VBECS will display a system error message and will not function if the administrator sets a future date in VBECS settings.   | VBECS Administrators must set the date on the server to a current or past date. Verification of settings is recommended. | Minor            | Improbable               | Accept-able | Low                    | All users                                 | This is identified immediately by the first user logged into the system in Test and in Production.                                      | CR 2,153                | 209085                       |
| Through-out VBECS             | Outgoing completion messages from VBECS will stay in a status of sending when services are stopped when a message is sending or when an unexpected exception is received from the receiving application. | The messages cannot be resent by a user.   | Minor            | Occasional               | Accept-able | Low                    | All users                                 | None Contact the National Help Desk if you encounter this problem. The VBECS team will make the correction.                             | CR 2,715                | 209647                       |

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|-------------------------------|--|--|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Through-out VBECS             | <p>A patient name will be truncated in these screens when one of the name fields (Last, First, or Middle) exceed 22 characters:</p> <p>Blood Unit Details tab<br/>Patient Specimen Selector control<br/>Patient Order Selector control<br/>Patient Order Selector for Report control</p> <p>VBECS will only display the first 25 characters of the name.</p> | None available.  | Minor            | Remote                   | Acceptable | Low                    | All users                                 | The full name is displayed elsewhere on the screens identified or it is provided as read only information and is not used to make decisions for the selected patient.   | CR 2,658                | 209590                       |
| Through-out VBECS             | If the user enters a full last name and clicks the ellipsis to search for a patient when entering a unit in Incoming Shipment, VBECS retrieves patients that match the entered name along with others that match the first four letters of the searched name.  | None required as our feedback from the field sites and other user groups is that the user is trained to enter the full SSN for a patient and not use a pick list to select a patient for any option in VistA or VBECS.   | Minor            | Probable                 | Acceptable | Low                    | All users                                 | The returned search results are displayed with the best matches at the top of the list. User may have a longer patient list presented to find the required patient.   | CR 1,635<br>INC 782209  | 208567<br>I7741648FY16       |
| Through-out VBECS             | When a 10-character last name is entered in the Patient Select Tool, VBECS looks for a specimen UID.   | Feedback from the field sites and other user groups is that the user is trained to enter the full SSN for a patient and not use a pick list to select a patient for any option in VistA or VBECS. Search by the initial of the last name and last four digits of the patient ID (SSN), or the full patient ID. | Minor            | Remote                   | Acceptable | Low                    | All users                                 | Using standard patient search criteria avoids this potential confusion.   | CR 2,004                | 208936                       |
| Through-out VBECS             | VBECS records the standard patient name format: the first initial included in the data after the second comma, e.g., last name, first name, middle initial. This conflicts with the VistA standard patient name presentation.  | None required as the patient is correctly identified and name is readable, simply formatted differently from VistA's presentation.   | Minor            | Frequent                 | Acceptable | None                   | All users                                 | The patient names are not considered a unique identifier. The ID number (DFN, ICN) is used to identify the patient record. The legacy system may record data in the middle-initial field that is not included in the VBECS display of the patient name. | CR 1,903                | 208835<br>I6114955FY16       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|--|--|
| Through-out VBECS             | When only a few non-specific characters are entered in the patient search field, no matches are found and the option times out without displaying a message to the user. | Enter the full last name, or the full patient ID, last name, last name initial, and last four digits of the patient ID (SSN), or the full patient ID. User will enter standard patient search criteria. | Minor            | Occasional               | Acceptable | None                   | All users                                 | This is not a valid search entry. As this does not result in a patient display, the user must reenter the correct search information.   | CR 1,901<br>CR 2,927   | 208833<br>209859   |
| Through-out VBECS             | A system error occurs if a user enters non-standard (symbols or punctuation) information into the patient, unit, or product code fields and uses the search.             | Do not enter non-standard information into the patient, unit, or product code fields.   | Minor            | Occasional               | Acceptable | Low                    | All Users                                 | None  | CR 2,768<br>CR 2,774   | 209700<br>209706<br>I7609296FY16   |
| Through-out VBECS             | When multiple windows are overlaid in the VBECS application, they may appear incompletely drawn.   | Minimize and maximize the VBECS application or remote desktop connection window to refresh the screen.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The user can easily identify that the data screen is incomplete and cannot use or continue until refreshed.   | CR 1,771   | 208703   |
| Through-out VBECS             | Clearing a checkbox using the mouse delete function, after the OK button is enabled, does not disable the OK button and allows the blank field(s) to be saved.           | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,328   | 210258   |
| Through-out VBECS             | Column headers not repeating on subsequent pages when the section information extends over multiple pages.   | None required.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | Data is presented in full.<br>Division Equipment Report<br>Inappropriate Transfusion Request Report<br>Medication Profile<br>Order History Report<br>Patient History Report<br>Transfusion Complications Report<br>Transfusion Reaction Report (TRW)<br>Unit History Report | CR 3,474<br>CR 3,478<br>CR 3,540<br>CR 3,542<br>CR 3,544<br>CR 3,545<br>CR 3,546<br>CR 3,547<br>CR 3,539 | 210404<br>210408<br>210470<br>210472<br>210474<br>210475<br>210476<br>210477<br>210469 |
| Through-out VBECS             | Some error messages in VBECS read "contact your system administrator" which should read something like this, contact National Service Desk for VBECS Server support.     | File a ticket for service with NSD and include the shutdown message text.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Copy to Clipboard and paste the message into a document to attach to the NSD ticket.  | CR 3,587   | 210517   |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Through-out VBECS             | A report requested to print in the future prints per Central Time (CT), not local time zone when not CT. (See list of affected reports in Additional Comments)   | None.   | Minor            | Frequent                 | Acceptable | None                   | All users                                 | Patient History<br>C:T Ratio<br>Prolonged Transfusion<br>Transfusion Reaction Count<br>Administrative Data<br>Testing Worklist<br>Blood Availability<br>Division Transfusion<br>Cost Accounting<br>Issued Returned<br>Audit Trail<br>Finalize Print TRW<br>Division Workload<br>Exception<br>Order History<br>Transfusion Requirements<br>Transfusion Complications<br>Transfusion Effectiveness<br>Inappropriate Transfusion Request | CR 3,588<br>INC 1303428 | 210518<br>I5879201FY15       |
| Through-out VBECS             | Pick a big report (20+ pages). While the report is "loading" click the Print button. The report will print, but the VBECS session is frozen and the printer will not print future documents.<br><br>(Additional Comments contains a list of affected reports.) | Allow the report's print preview to load completely, then click the Print button. | Minor            | Occasional               | Acceptable | None                   | All users                                 | Blood Unit History<br>Division Workload<br>Equipment Inventory<br>Inappropriate Transfusion Request<br>Issued Returned Units<br>Medication Profile<br>Order History<br>Outgoing Shipment Invoice<br>Patient History<br>Prolonged Transfusion Time<br>Reagent Inventory<br>Supply Inventory<br>Transfusion Complications<br>Transfusion Reaction Count<br>Transfusion Reaction Workup  | CR 3,586                | 210516<br>I6133364FY16       |

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|---------------------------------------|---|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>ABO/Rh Confirmation</b>            | Confirming more than three units in a batch results in workload multiplication. Increasing the batch confirmed in two unit increments increases the workload count again. (e.g., 3-4 units will have a double workload; 4-6 units have a triple workload, and so on). | None available.   | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | None  | CR 2,830<br>HD 400511   | 209762<br>I5881287FY15       |
| <b>ABO/Rh Confirmation</b>            | A repeat ABO/Rh Confirmation on a unit that is currently assigned to a patient in VBECS does not remove patient assignment from a unit when the unit is quarantined.  | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The unit cannot be issued from VBECS while it is quarantined.   | CR 2,849                | 209781                       |
| <b>ABO/Rh Confirmation</b>            | If units are selected and users change the search criteria, the selected units stay selected even if they do not match the current search criteria.   | Deselect units that will not be tested in this option. Units not completely tested are not available for patient selection. | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS presents selected units for review prior to performing testing and entering results.  | CR 1,578                | 208510                       |
| <b>ABO/Rh Confirmation</b>            | VBECS displays “Abo/Rh” instead of “ABO/Rh” in the ABO/Rh mismatch message.   | None required. Format is understandable to users.   | Minor            | Frequent                 | Acceptable | None                   | All users                                 | None  | CR 1,723                | 208655                       |
| <b>ABO/Rh Confirmation</b>            | Patient assignment is not released automatically when a unit is quarantined due to discrepant ABO/Rh retype testing.  | None required. The unit is quarantined and cannot be selected for a different patient or issued for this patient.           | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS prevents issuance of a unit with discrepant testing. Quarantined units are clearly marked in VBECS and cannot be issued.  | DR 2,982                | 213499                       |
| <b>Accept Orders: Accept an Order</b> | A VBECS system error occurs when a user tries to print out an order and the patient location was not included in the order information from CPRS.   | Cancel the order without a location. Request a new order using the CPRS GUI version.  | Minor            | Remote                   | Acceptable | Low                    | All users                                 | The CPRS GUI version requires a patient location for the order to be submitted. The CPRS roll and scroll version allows an order to be placed without a patient location. Using the CPRS order dialog roll and scroll version is not recommended. | CR 3,199<br>HD 540813   | 210129<br>I6118732FY16       |

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|---|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Accept Orders:<br/>Accept an Order</b> | The VBECS order dialog “Requirements” field that displays the CPRS Modifier is limited to 29 characters.   | Limit selectable modifiers in CPRS to 29 characters.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Requirements displayed are CPRS order Modifier entered as part of a blood component order such as Irradiated or Leukoreduced.   | DR 3,962<br>HD 445850   | 214479<br>I6266982FY16       |
| <b>Accept Orders:<br/>Accept an Order</b> | Orders that are accessioned in the Laboratory package with a date/time collected of T@U are not accepted by VBECS.   | Enter a time and collection date for specimen collection in the Laboratory package to allow VBECS to process the specimen.<br>OR<br>Do not use T@U to accession VBECS orders in the Laboratory package. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,063                | 209993                       |
| <b>Accept Orders:<br/>Accept an Order</b> | VBECS only displays the first 20 characters of the ordering location when the user clicks on the Ordering Details button to see the Ordering Division field. | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Ordering locations in Vista can be shortened or changed if the uniqueness of a location cannot be determined with the first 20 characters.  | CR 2,919                | 209851                       |
| <b>Accept Orders:<br/>Accept an Order</b> | The display restricted or assigned units button in Accept Orders was disabled for performance.   | The Blood Availability Report displays units assigned and restricted for all patients.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None  | CR 2,903                | 209835                       |
| <b>Accept Orders:<br/>Accept an Order</b> | On the Accept Orders screen, clicking the Received and Wanted column headers does not sort on the date and time of the Pending Order List.                   | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | All order information is viewable. This is the column sort function, which may or may not be used. As sites have stated that, they select an order by entering the specimen UID or patient information this is a rarely used search criteria. | CR 2,098                | 209030                       |

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|---------------------------------------|--|--|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| <b>Accept Orders: Accept an Order</b> | The emergency order check box is not enabled unless there is a CPRS order and a patient specimen accessioned in VistA. | Accession the component order in VistA without the specimen to use the emergency order function in VBECS. The VistA order can then be changed when the specimen is received. | Minor            | Occasional               | Acceptable | Low                    | All users  | Alternately, process the emergency issue of units manually, per local policy, until the specimen is received and accessioned. Processing an emergency blood component issue is an uncommon occurrence. Generally, a specimen is collected and may be available at the time though testing may be incomplete at the time of issue depending on the patient population of a facility. | CR 1,604                | 208536                       |
| <b>Accept Orders: Accept an Order</b> | The Evaluate MSBOS button is disabled for TAS pre-op orders. TAS only orders cannot be marked as inappropriate.        | None available.  | Minor            | Occasional               | Acceptable | None                   | All users  | When a surgical procedure has no TAS or component recommendation, VBECS allows the order but does not mark the request for report review. The provider has ordered a TAS when there is no pre-op recommendation.  | CR 1,944                | 208876                       |
| <b>Accept Orders: Accept an Order</b> | A specimen may not be marked unacceptable when Maintain Specimen is accessed during the acceptance of an order.        | None required. The specimen may be marked unacceptable without relation to the order by using the Maintain Specimen option.  | Minor            | Occasional               | Acceptable | Low                    | All users attempting to associate an unacceptable specimen with a VBECS order. | Directly access Maintain Specimen to mark a specimen unacceptable without cancelling the order. This arose from a misunderstanding of the system functionality. The specimen can be marked unacceptable and the order can be cancelled in each one's appropriate option.  | DR 2,851                | 213368                       |

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|-----------------------------------|---|---|------------------|--------------------------|------------|------------------------|---|---|------------------------------------|------------------------------|
| Accept Orders: Pending Order List | VBECS requires more than 15 seconds to print a Pending Order List report.   | None required.  | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | The amount of time required to generate the report is proportional to the number samples processed by the blood bank.                       | CR 2,622                           | 209554                       |
| Accept Orders: Pending Order List | An expired order warning message appears incorrectly based on the date the component order was received (first appears on the Accept Orders Pending Order List) by VBECS, not the date the order was processed and accepted in VBECS (accepted and moved to the Component Order Pending Task List). | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,275<br>HD 790160<br>HD 795836 | 210205<br>I6118883FY16       |
| Administrative Data Report        | The number of transfused units on the Administrative Data Report does not match with the total number of units transfused on other VBECS reports.   | The total of transfused units includes units based on completion date and time so units may not be included in specific date range reports. The report also includes units that were inactivated. | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | If the transfusion of the blood unit was invalidated and then the unit was transfused again, it will count as 2 transfusions on the report. | CR 2,838<br>CR 3,079               | 209770<br>210009             |
| Administrative Data Report        | The Administrative Data Report does not contain all of the plasma product types in the final count of units received via Incoming Shipment.   | Manual calculations must be used to derive the missing data from the number of units received.  | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | The FP24 and apheresis plasma products are not counted as FFP received.   | DR 3,539<br>HD 338438              | 214056<br>I6119054FY16       |
| Administrative Data Report        | The total number of red cell units transfused units on the Administrative Data Report does not match the total transfused on the C:T Ratio Report.  | Manual calculations must be used to compare the total number of units transfused by using this report and the division C:T Ratio Report.  | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | None  | DR 3,539<br>HD 338438              | 214056<br>I6119054FY16       |

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|-----------------------------------|--|--|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| <b>Administrative Data Report</b> | The number of units outdated will not change regardless of the date range requested. It ignores the date ranges selected and retrieves the total number of units outdated since production installation. | In the Blood Availability Report, select a Custom Report to view the expired units in a given date range. Select all component classes and all unit statuses. Indicate the inclusive date range for a month by selecting the date for "Expires Before" as the calendar date of the day after the selected range should end (end date) and the "Expires After" as the calendar date of the day before your range should start (start date). | Minor            | Frequent                 | Acceptable | Low                    | All users  | See <i>FAQ Outdate Units Report for a Selected Date Range</i> for a detailed example.  | CR 3,258<br>HD 590459   | 210188<br>I6123587FY16       |
| <b>Antibodies</b>                 | The Antigen Negative Compatibility Percentage field allows the entry of a decimal that causes the reversal of the entry (e.g., user entry of "1.5" becomes "51") and may be saved.                       | Enter whole numbers; do not enter decimals. Check the accuracy of the entry before saving.   | Minor            | Occasional               | Acceptable | Low                    | Administrator  | This data is managed by security role and is for information only.   | CR 1,842                | 208774                       |
| <b>Antibodies</b>                 | Anti-A,B is not selectable as a patient antibody.  | Users can enter the Anti-A,B antibody in the patient's Special Instructions.   | Minor            | Remote                   | Acceptable | Low                    | Administrator  | This antibody is historical from VistA and is not utilized for selection of blood components for transfusion.  | CR 1,872                | 208804                       |
| <b>Audit Trail Report</b>         | When the user inactivates a unit's ABO/Rh confirmation test results or inactivates a unit record and enters the required comment, VBECS does not print the comment on the Audit Trail Report.            | Immediately print the Audit Trail Report for this activity and manually complete the comment; save it for review.  | Minor            | Frequent                 | Acceptable | Low                    | Supervisor   | The inactivation is recorded and maintained. The unsaved comment does not impact patient testing or transfusion records and is an infrequent occurrence.       | CR 1,824<br>CR 2,353    | 208756<br>209285             |
| <b>Audit Trail Report</b>         | Changes made to a unit's log-in CMV or Sickie Cell status are not displayed on the report.   | The initial and updated information in the Unit History Report   | Minor            | Frequent                 | Acceptable | None                   | Supervisor when blood unit CMV or Sickie cell changes have been processed. | The change history is correctly maintained with each unit record. It is standard VBECS behavior to display this type of data change on the Audit Trail Report. | CR 2,318                | 209250                       |

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|-------------------------------|--|--|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| <b>Audit Trail Report</b>     | VBECS displays only the ISBT 128 five-digit product code in the sub-header sections of the report.   | None required. This is the product code without the donation type and divisions which are not required for accurate interpretation of this report entry. | Minor            | Frequent                 | Acceptable | None                   | Supervisor when a blood unit changes have been processed.              | The full eight-digit product code is available in the Unit History Report. Format is understandable to users.   | CR 1,824                | 208756                       |
| <b>Audit Trail Report</b>     | Changes to a blood unit's disease marker testing do not appear in the report.  | None required.   | Minor            | Frequent                 | Acceptable | None                   | Supervisor when a blood unit's disease marker status has been changed. | Changes to the biohazardous marker are displayed in the Edit Unit Information section, testing details are available in the Unit History Report. It is standard VBECS behavior to display this type of data change on the Audit Trail Report. | CR 1,907                | 208839                       |
| <b>Audit Trail Report</b>     | The report displays changes to the database during MSBOS configuration even though a value was not actually changed by the user. This is due to fields in the database changing from null to NO.   | None required.   | Minor            | Occasional               | Acceptable | None                   | Supervisor reviewing the Audit Trail after initial configuration.      | This is the day one data update of the database with the standardized default data on the MSBOS. Additional local configuration of the MSBOS is also displayed.   | DR 1,312                | 211829                       |
| <b>Audit Trail Report</b>     | The report does not differentiate reagent types by case size when indicated by a letter only when both have Minimum Reagent Levels have been defined on the same day, e.g. K, k or C, c.   | Update the minimum levels on different days and print the report on each day.  | Minor            | Occasional               | Acceptable | None                   | Supervisor   | None  | CR 2,730                | 209662                       |
| <b>Audit Trail Report</b>     | The Audit Trail Report does not display the Date/Time data was originally saved or the user comment entered for the change. Audit Trail Report entries for Units does not display Unit ABO/Rh at log-in, Expiration date/time, Date/Time received, or the user comment entered for the change. | Immediately print the Audit Trail Report for this activity and manually complete the comment and other pertinent details; save it for review.            | Minor            | Frequent                 | Acceptable | Low                    | Supervisor reviewing the Audit Trail.                                  | See the Unit History report for the missing data saved in other options.  | CR 2,334                | 209266                       |

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|----------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Audit Trail Report</b>        | The change that was done prior to the most recent change to data will not display on Audit Trail report for its date range.  | The previous change is displayed when the date range selected includes the date of the most recent change.                                | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | Expand the date range selected to view the change.  | CR 3,385                | 210315                       |
| <b>Blood Availability Report</b> | The Blood Availability Report does not include units that went to a final status on the day the user requests the report start and stop on (e.g., start 1/30/11 and end 1/30/11).  | Expand the date range of the report to include the units in a final status.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,132                | 210062                       |
| <b>Blood Availability Report</b> | Running the Blood Availability Report for units with no disposition (Available Expired) first and then the Daily Inventory (All Units) Report will result in an error on the Daily Inventory (All Units) Report and no values displayed. | Do not run the Blood Availability Report for units with no disposition (Available Expired) before the Daily Inventory (All Units) Report. | Minor            | Occasional               | Acceptable | None                   | All Users                                 | None  | CR 3,234                | 210164                       |
| <b>Blood Availability Report</b> | Custom Report may not display all of the selected criteria in the Report Criteria Section displayed at the end of the report when many are selected. The page number may also be absent.   | None required as this problem occurs only when an extensive list of criteria are selected.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | When selecting many criteria for a custom report, keep a manual list as you create the report.  | CR 3,443                | 210373                       |
| <b>Blood Products</b>            | VBECS allows a user to activate a blood product code for a shipper without an associated HCPCS code or text.   | Add the HCPCS code after the blood product code is activated.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The user can proceed to activate a unit without the code. This may be preferred functionality when the code is unknown so all blood products can be entered without delay for patient availability. | CR 1,217                | 208150                       |
| <b>Canned Comments</b>           | System error occurs when an attempt is made to use Maintain Comments if the user who configures a division in VBECS Administrator is not added to the division as a VBECS user.  | The user that configured the division must be added to the users list in VBECS.   | Minor            | Occasional               | Acceptable | Low                    | Administrator                             | None  | CR 2,241                | 209173                       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|--|--|-----------------------------------|----------------------------------|
| Canned Comments               | Inactivation of all the canned comments for a category will prevent a user from completing any process that uses these canned comments.  | Do not delete all of the canned comments.   | Minor            | Occasional               | Acceptable | Low                    | Administrator  | Comments can be recreated by user with appropriate security.   | CR 2,243                          | 209175                           |
| Configure Division            | Custom Timezone does not work.   | Use standard timezone options.  | Minor            | Occassional              | Acceptable | Low                    | Administrator  | None.  | CR 3,566                          | 210496                           |
| Configure Daily QC            | In a VBECS configured for multidivision use the lot numbers for testing reagents will not pre-fill day to day when sites are using the same reagent rack designations.                                   | The sites comprising a multidivision can agree to assign different reagent rack names to prevent overlap. This will allow the reagent lot number to pre-fill with the values from the previous day. | Minor            | Occasional               | Acceptable | None                   | All users performing Daily Reagent QC testing in a multidivision configuration of VBECS.                             | None   | CR 2,690<br>HD 335126             | 209622<br>338438                 |
| Configure Daily QC            | Reverse ABO cell testing results are not displayed on the Testing Worklist Report. Various reagent lot numbers are not displayed including QC kit, Reverse ABO cells, PEG, LISS, or Anti-Human Globulin. | Manually record daily reagent QC testing and reagent lot numbers to remain compliant with regulatory requirements.  | Minor            | Frequent                 | Acceptable | Low                    | All users performing Daily Reagent QC testing.<br><br>Supervisor who configures and reviews QC output for compliance | The incompletely displayed QC lot numbers and results force the blood bank to establish a policy to record results to maintain a complete record for accreditation and regulatory compliance which has been put in place by the sites. | CR 2,385<br>CR 2,436<br>HD 249548 | 209317<br>209368<br>I6132187FY16 |
| Configure Daily QC            | VBECS does not permit configuring daily QC to use either Anti-A or Anti-B test with an O Cell  | None required.  | Minor            | Occasional               | Acceptable | Low                    | Administrator  | Negative control s are available for both antisera. Explanation for system behavior with no user impact.   | DR 2,206                          | 212723                           |
| Cost Accounting Report        | A Reflex ABID test that was entered in error displays on the Cost Accounting Report.   | None available.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report; Supervisor is responsible for its review   | The corrected and entered-in-error entries are included. Extra cost is identifiable on report.   | CR 1,994                          | 208926                           |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Cost Accounting Report</b> | If a user places a unit on the outgoing shipment invoice, cancels the invoice, and then places the same unit on another outgoing shipment invoice, VBECS displays a return credit twice on the report.                            | Deselect a unit prior to canceling the invoice to avoid the credit appearing twice on the Cost Accounting Report.  | Minor            | Occasional               | Acceptable | None                   | All users can print the report; Supervisor is responsible for its review  | Extra credit is identifiable on report.   | CR 1,905                | 208837                       |
| <b>Cost Accounting Report</b> | A unit with an edited return credit in final status will not revert to the original return credit amount when the unit's final status is removed.   | Select Edit Financial Data and correct the return credit amount.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report; Supervisor is responsible for its review  | Extra cost is identifiable on report.   | CR 1,871                | 208803                       |
| <b>Cost Accounting Report</b> | The tally of discarded units, waste or credit, may include quarantined units and may not accurately reflect the unit discard as waste vs. credit. When the default credit amount is selected, it appears as \$0.00 on the report. | Units listed on the report were quarantined or discarded for the selected date range. Verify the unit and quarantine status of a unit by checking its Unit History Report. | Minor            | Occasional               | Acceptable | None                   | All users can print the report; Supervisor is responsible for its review. | Extra credit is identifiable on report.   | CR 2,448                | 209380                       |
| <b>Cost Accounting Report</b> | When the patient has a middle name, the middle name is not displayed.   | Users are instructed to correct the names on printed copies of reports to be saved.  | Minor            | Frequent                 | Acceptable | Low                    | All users   | None  | CR 3,383                | 210313                       |
| <b>CPRS</b>                   | Orders that expire in VBECS are updated in CPRS but the laboratory order component is not marked as expired.  | None required.   | Minor            | Frequent                 | Acceptable | Low                    | All users   | None  | CR 3,184<br>HD 532136   | 210114<br>I6132702FY16       |
| <b>CPRS</b>                   | Testing comments appear in duplicate on the CPRS Blood Bank Report.   | None required.   | Minor            | Frequent                 | Acceptable | None                   | All users   | The testing comments are saved by specimen and by test in VBECS. Both sets of comments are sent to CPRS resulting in the duplication. | CR 3,143<br>HD 461287   | 210073<br>I6132891FY16       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| CPRS                          | CPRS: Orders are not completed in CPRS and Lab when multiple order completion message identifiers are requested within 1/100 <sup>th</sup> of a second of each other.                                      | Discontinue the order in CPRS and cancel the order in Lab.  | Minor            | Remote                   | Acceptable | Low                    | All users                                 | The completed test results display as expected in CPRS. The likelihood of occurrence of this is rare and should not interfere with normal business practices. This would be very infrequent as multiple users would need to complete orders on the same patient simultaneously. | CR 2,397                | 209329                       |
| CPRS                          | CPRS Order details do not include the identity of the VBECS user who rejected the order.   | The user that rejected the order can be retrieved from the Order History Report for the patient in question.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | None  | CR 2,776<br>HD 381217   | 209708<br>I6133067FY16       |
| CPRS                          | The CPRS Blood Bank report for Diagnostic tests displays the date/time the test was completed which is inconsistent with other lab test reports that display the collection date/time.                     | None available.   | Minor            | Frequent                 | Acceptable | None                   | All users                                 | Pending a CPRS update of the VBECS Blood Bank report (HD 404587).   | CR 3,263<br>HD 404587   | 210193<br>I6133363FY16       |
| CPRS                          | Vista Legacy Transfusion Reactions appear on the CPRS Blood Bank Report VBECS records section with a timezone corrected time and without an implicated blood unit identification number (when applicable). | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Complete Transfusion reaction information is displayed in the Legacy portion of the report.   | CR 3,314<br>HD 766109   | 210244<br>I6133632FY16       |
| CPRS                          | VBECS sends user entered (Details) comments for the TRW to CPRS but Canned Comments selected for the TRW (Dropdown) are not.   | Do not use TRW Canned Comments. Enter the desired comment text into the Details (free text) comments section. | Minor            | Frequent                 | Acceptable | Low                    | Supervisor                                | This problem exists in all prior versions of VBECS.   | CR 3,402<br>INC 949581  | 210332<br>I6133806FY16       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|--------------------------------------|------------------------------|
| CPRS                          | The VBECS background job to expire unfilled component orders 10 days after acceptance also updates "Filled" component orders to "Expired". In CPRS the VBECS order details change from "c" (completed) to "e" (expired). The associated Lab order remains "c". | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,239<br>DR 4,458                 | 210169<br>214974             |
| CPRS                          | VBECS-OERR messages recording incorrect Date Time Of Message in Message Log table.   | None required. The time associated with the order available to the user is correct in both CPRS and VBECS.                | Minor            | Frequent                 | Acceptable | None                   | None                                      | Added as a reference for Product Support as this may be noted during investigation of the Message LOG for other problems with a CPRS order. This problem exists in all prior versions of VBECS. | CR 3,456                             | 210386                       |
| CPRS                          | MSBOS information is not displayed in the Order Dialog when used in an Associated Institution.   | None.   | Minor            | Occasional               | Acceptable | Low                    | CPRS users at Associated Institutions.    | None.   | CR 3,590<br>INC 768397<br>HD 0774043 | 210520<br>I6134391FY16       |
| C:T Ratio Report              | When a unit is crossmatched more than once to a patient, the C:T Ratio Report will count the transfusion of that unit twice.   | Disregard the second transfusion instance and recalculate the C:T ratio .   | Minor            | Occasional               | Acceptable | Low                    | All users reviewing the report            | This happens when the unit was crossmatched and released for a patient, then crossmatched with a new specimen to that same patient and transfused.  | CR 2,748<br>HD 421286                | 209680<br>I6134538FY16       |
| C:T Ratio Report              | The report will show a C:T Ratio of zero (0) any time units are crossmatch and none are transfused on a patient.   | Any C:T ratio of zero (0) indicates that the user must take the total number of units crossmatched as the true C:T ratio. | Minor            | Frequent                 | Acceptable | Low                    | All users reviewing the report            | None  | CR 2,780                             | 209712                       |
| Discard or Quarantine         | A VBECS system error occurs when a user tries to discard a unit that was brought in through Incoming Shipment with an inactive shipper.  | Activate the shipper and then discard the unit as desired.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | VBECS does not allow a user to save a unit without an active shipper unless the VistALink connection is lost while the user is trying to process a unit that does not have a shipper defined.   | CR 3,048<br>HD 489651                | 209978<br>I7736458FY16       |

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|---|---|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Discard or Quarantine</b>                  | Cannot designate a Discard/Quarantine Tech ID though the exception report contains both "Test By" and "Override By" columns.          | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | Discard/Quarantine option does not accommodate the entry of a second user for retrospective entry.  | CR 2,076                | 209008                       |
| <b>Discard or Quarantine</b>                  | Units in an Issued status can be discarded which creates a data lock on the blood unit.   | Do not Discard a unit in an Issued status.  | Minor            | Improbable               | Acceptable | None                   | All users                                 | None  | N/A                     | 268926<br>17048459FY16       |
| <b>Division Transfusion Report</b>            | The report will only print the Division Transfusion Report by physician for the first 50 physician's in the VBECS database.           | Do not run the Division Transfusion Report by all physicians. Selected physician report can be run but should be limited to no more than 50 physicians at a time. | Minor            | Occasional               | Acceptable | None                   | All users                                 | The report search in VBECS is limited to 2000 characters. Requesting a report that exceeds this limit will result in an incomplete report.                    | CR 3,170                | 210100                       |
| <b>Division Transfusion Report</b>            | The column headers for the section are not displayed on the subsequent page when the section displays to more than one page.          | None required.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | None  | CR 3,441                | 210371                       |
| <b>Division Workload Report</b>               | The Division Workload Report will not print as "Preliminary" when the report contains the current day in the range of data requested. | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Users are cautioned to pay attention to the date range of this report. Workload is an administrative report that is not required the day the data is created. | CR 2,148                | 209080                       |
| <b>Division Workload Report</b>               | The column headers for the section are not displayed on the subsequent page when the section displays to more than one page.          | None required.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | None  | CR 3,441                | 210371                       |
| <b>Document ABO Incompatible Transfusions</b> | When transfusion interruption is indicated, the OK button enables allowing the user to save prior to changing the transfused amount.  | Record the amount transfused before saving the transfusion event.   | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | None  | CR 3,062                | 209992                       |

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|---|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Document ABO Incompatible Transfusions</b> | When a unit ID is scanned or typed and the user enters a volume transfused, there is a system error.  | Click the search button and select the unit to be transfused.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | None   | CR 3,259<br>HD766120    | 210189<br>I6134688FY16       |
| <b>Edit Financial Data</b>                    | When a unit is “transferred,” VBECS does not enable the Return Credit field in the Edit Unit Financial Data window.   | Process the unit through Remove Final Status, adjust the return credit amount, and reprocess the outgoing shipment information.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Return credit is set up as a default value so this would only be used for a rare return outside of the vendor contract amount. | CR 1,777                | 208709                       |
| <b>Edit Unit Information</b>                  | When Inactivating a unit the incorrect list of canned comments is presented. The list of comments shown corresponds to the canned comment category "Unit Status Removal" instead of "Unit Inactivation".  | Enter comments selectable during “unit inactivation” in the Canned Comment Category of “Unit Status Removal”.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | Canned comments are site configurable to include desired comments. “Other” and a free text comment is also available.          | CR 2,270                | 209202                       |
| <b>Edit Unit Information</b>                  | When two ABO/Rh confirmation tests are present and both require invalidation, VBECS does not allow both tests to be invalidated in the same transaction.  | Perform one invalidation action at a time. Invalidate one test, leave the option, and go back to invalidate the second test.   | Minor            | Remote                   | Acceptable | None                   | All users                                 | This may be the desired functionality.   | CR 1,906                | 208838                       |
| <b>Edit Unit Information</b>                  | Inactivating the parts of a split units will result in negative workload equal to the number of splits created applied to the total number of units logged in.  | None available.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | Infrequent user action that only affects laboratory workload reports.  | CR 2,224                | 209156                       |
| <b>Edit Unit Information</b>                  | The "Biohazardous?" checkbox can be cleared for Donation Type: For Autologous Use Only, Biohazardous, but the donation type of the unit is not editable. If the unit is re-edited, the checkbox displays as re-checked and disabled. The Unit History Report indicates this field is cleared. | When an autologous unit is considered biohazardous because the testing results are incomplete and expected, select the donation type “For Autologous Use Only” and select incomplete disease marker testing which sets the biohazardous indicator. The biohazardous indicator and disease status are editable when testing results are received. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Select the donation type “For Autologous Use Only, Biohazardous” only when the unit testing is not pending                     | CR 2,262                | 209194                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| <b>Edit Unit Information</b>  | On the Antigen Typing Tab, the weak D results in the Selected Tests Details displays only one of the two rows of the tested grid.                         | None Required  | Minor            | Occasional               | Acceptable | Low                    | All users                                      | Weak D test results are displayed on the Testing Worklist Report. This problem exists in all prior versions of VBECS.  | CR 3,497                | 210427                       |
| <b>Enter Daily QC Results</b> | The secondary reagent is Check Cells (CC) for the Daily QC test CC. Changing the AHG, PS lot number does not enable the testing grid cell.                | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                      | None   | CR 3,188                | 210118                       |
| <b>Enter Daily QC Results</b> | Reagents that are not associated with test results when the QC is partially saved are marked as satisfactory on the Testing Worklist Report.              | Complete all QC testing in one instance saving once.<br><br>Do not perform partially completed QC testing.                                   | Minor            | Occasional               | Acceptable | Low                    | All users                                      | If the user partially saves rack QC results and finishes it later, the results that were originally left blank and are now completed display as unsatisfactory on the Testing Worklist Report even though the reagent appears as satisfactory in Enter Daily Reagent QC. | CR 3,074<br>INC 483694  | 210004<br>I7736282FY16       |
| <b>Enter Daily QC Results</b> | Changing the tested with lot number (ex. LISS) does not enable the Enter Daily Reagent QC test grid.  | Change the lot number of the primary reagent as well as the secondary reagent to allow testing of both.                                      | Minor            | Occasional               | Acceptable | Low                    | All users performing Daily Reagent QC testing. | Refer to FAQ: Retesting QC for a listing of primary and secondary reagents.  | CR 3,176                | 210106                       |
| <b>Enter Daily QC Results</b> | The user cannot save a partially filled worksheet due to inactivity timeout.  | The user must maintain activity on their screen/session to prevent the activity timeout, and then the lock on the worksheet will not expire. | Minor            | Occasional               | Acceptable | None                   | All users                                      | Unsaved data must be reentered if the locally configured timeout is exceeded.  | CR 2,131                | 209063                       |
| <b>Enter Daily QC Results</b> | Rack Daily QC cannot be saved if one of the QC'd racks was partially QC'd.  | Perform QC for only one rack at a time or for multiple racks to segregate non-QC'd racks from partially completed racks.                     | Minor            | Occasional               | Acceptable | None                   | All users                                      | This is a rare issue since normal workflow is to complete all QC testing together or to have each user perform own QC.   | CR 2,145                | 209077                       |
| <b>Enter Daily QC Results</b> | If a partially tested rack is designated as not tested for a given day, VBECS displays the reagent rack on both the Partially Tested and Not Tested tabs. | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                      | None   | CR 1,761<br>CR 1,918    | 208693<br>208850             |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Enter Daily QC Results        | Twenty-four-hour expiration messages are displayed more frequently than required.  | Acknowledge the expired reagent-warning message and continue.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Explanation of VBECS behavior. User requirements need further definition.  | CR 1,768                | 208700                       |
| Enter Daily QC Results        | When a user clicks No on the decision box to not use a reagent/antiserum that is within 24 hours of expiration (23:59 on the expiration date), VBECS moves the cursor to the next reagent lot number field and <i>does not</i> remove the lot number of the previous cell. | Change the lot number of the reagent or continue using it until the actual expiration date and time.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | Explanation of VBECS behavior. User requirements need further definition.  | CR 1,861                | 208793                       |
| Enter Daily QC Results        | VBECS antiglobulin testing grids for QC have a title of IAT. The same grid for patient testing is titled AHG.  | None required.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | IAT and AHG are synonyms for the antiglobulin testing and is not a patient safety concern.   | DR 1,230                | 211747                       |
| Enter Daily QC Results        | PS AHG always appears on the lot number page though it may not be used.  | Enter the Lot number of the specific AHG used for antibody screen QC. Note in the procedure that the lot number is accurate for the reagent used in QC and testing. | Minor            | Occasional               | Acceptable | Low                    | All users in full service divisions.      | Explanation of VBECS behavior.   | DR 2,679                | 213196                       |
| Enter Daily QC Results        | When performing Daily QC with an expired reagent, the user gets no override warning for the expired reagent. No Exception report is captured.  | VBECS displays that the Reagent is Expired by marking it with a red E. Do not select and use expired reagents.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | When expired reagent must be selected, immediately print the Daily Reagent QC Testing Worklist report and add a manual override comment regarding the expired reagent testing details. | CR 3,268<br>HD 780500   | 210198<br>I6191630FY16       |
| Enter Daily QC Results        | A rack can be set as partially tested and marked as "Qc'ed Offline" at the same time.  | None required. Uncheck the QC'ed Offline check box, as appropriate, complete the QC or invalidate the partially completed rack QC and mark as tested offline.       | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The Rack will be listed as "Tested = No", selecting it will prompt for the "Rack QC not performed" override as the partially tested rack setting is enforced.                          | CR 3,367                | 210297                       |

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| Option Where the Issue Occurs | Description   | Recommended Workaround   | Level of Concern | Likelihood of Occurrence | Risk       | Impact to Patient Care | Security Role Mitigations (Affected User) | Additional Comments  | Tracking System Number* | New Tracking System Numbers* |
|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Enter Daily QC Results        | <p>When entering results on a partially tested QC rack, the exception "Decrease in reagent reactivity of 2 or more" does not occur.</p> <p>Previous QC results for Screening Cells and ABO Reverse Typing reagents are not being recognized properly to identify significant changes in reactivity (≥2+). The system does not display an override associated with "Decrease in Reagent Reactivity".</p> | The tech checks the previous day's Testing Worklist Report to view the reagent's reactivity and assess it to avoid reagent reactivity problems. Supervisor review of daily testing and quality control reactivity is recommended in within 24 hrs. | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | Compare the results from the previous date's QC manually. This problem exists in all prior versions of VBECS.  | CR 3,368<br>CR 3,429    | 210298<br>210359             |
| Equipment                     | Edited fields already filled in during creation of a new Maintenance type entry are not saved.  | Enter data once in each field, save. Re-open the Maintenance type and edit, save.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | This problem exists in all prior versions of VBECS.  | CR 3,401                | 210331                       |
| Exception Report              | Thawed plasma product types are displayed as fresh frozen plasma on the Exception Report.   | Users can view the Unit History Report for the correct product type name.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | The Unit History Report and CPRS both show the product code name which is accurately represented.              | DR 4,008<br>HD 460025   | 214525<br>I7704787FY16       |
| Exception Report              | An Exception Report entry is not created when a unit is resultated as weak D positive or weak D inconclusive and is properly quarantined.   | None required as the unit is quarantined appropriately and is not available for patient selection.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | DR 3,832                | 214349                       |
| Exception Report              | Duplicated exception entries (instead of only one) will appear on the Exception Report when a unit is issued that did not meet the antigen negative requirements of the patient at issue.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The number of duplications that appear correlate to the number of the patient's antigen negative requirements. | CR 2,924                | 209856                       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Exception Report              | “Visual Inspection Information” and the selected processing “User Information” are not included in Exception Report entry.   | See the Unit History report, Issue/Return section for the “Visual Inspection Information” as an entry detail for Transaction Type: Unit unsatisfactory upon return from issue.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | DR 2,479                | 212996                       |
| Exception Report              | The exception type “Previously recorded results invalidated” displays an incorrect time for the "Date/time results invalidated."   | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The time displayed in the "Date/time results invalidated" field is the time the results were entered.  | CR 2,686                | 209618                       |
| Exception Report              | The “Expired reagent QC’d” exception type section does not include the rack identification or the phase.   | The lot numbers and testing phases associated with the DAT testing are included in the Testing Worklist Report in the Miscellaneous testing and QC sections, respectively, of the report. The rack identifier and/or phase may be manually added to the Exception Report prior to or during the review. | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 1,626<br>CR 1,636    | 208558<br>208568             |
| Exception Report              | Not all exception types use the date and time of the save as the date and time of the exception.   | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,055                | 208987                       |
| Exception Report              | The previously recorded Results Inactivated exception type is not generated when a crossmatch is inactivated by Invalidate Test Results or by using the red X in the grid. | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The Testing Worklist Report contains the details of the invalidated testing and is recommended for daily supervisory review with the Exception Report. Infrequent event that is performed by a user with higher security role if the blood product was issued. | CR 2,035                | 208967                       |
| Exception Report              | The User ID is displayed in the Tested By column (instead of User Name) for exception type: Expired Task Processed.  | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,106                | 209038                       |

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|-------------------------------|--|------------------------|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Exception Report              | Modification exceptions do not display full (eight-digit) product codes for ISBT 128 labeled units. The sixth, seventh, and eighth digits are not included.  | None available.        | Minor            | Occasional               | Acceptable | None                   | All users                                 | Obtain the full ISBT 128 product code from the Unit History Report, as necessary. Format is understandable to users.   | CR 1,995                | 208927                       |
| Exception Report              | If patient ABO/Rh results are not entered in the order of performance (current testing is entered before the retrospective data entry), the Exception Report entries for an ABO/Rh interpretation discrepancy are displayed based on the time the data are entered (the OK button is clicked). | None available.        | Minor            | Occasional               | Acceptable | None                   | All users                                 | The correct blood type system rules are applied. The report columns state Current/Previous, the individual exceptions include the date/time of entry allows the sequencing of testing.   | CR 2,048                | 208980                       |
| Exception Report              | Exception Report and Blood Unit History Report display the testing status code from the database in the "Testing Status" section for autologous units.   | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | The values displayed in "Testing Status" translate to:<br>1 - NEG - Unit fully tested and negative for all disease markers.<br>2 - POS - Unit tested and positive for one or more disease markers, Biohazard.<br>3 - NFT - Unit not fully tested for one or more disease markers, Biohazard. | CR 2,118                | 209050                       |
| Exception Report              | The user ID of the issuing user appears on the report instead of the user name.  | None available.        | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,201                | 209133                       |
| Exception Report              | VBECS Exception Report does not display a patient's first name for Unacceptable/Expired Specimen Used exceptions.  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | Patient ID and specimen UID are presented in full with patient last name allowing further investigation of the exception as required.  | CR 2,309                | 209241                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Exception Report              | The Exception Report section “Antigen Testing Phase Change” does not display test interpretations.  | None required.   | Minor            | Occasional               | Acceptable | None                   | Supervisor responsible for report review  | The Testing Worklist Report is identified as one of the reports requiring supervisor review. The supervisor reviews the test results as part of their investigation. | CR 2,642                | 209574                       |
| Exception Report              | VBECS displays ISBT unit ID and product short name, but not the product code.   | None available.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | See the Unit History report for the missing data saved in other options.   | DR 2,323                | 212840                       |
| Exception Report              | The exception type <i>QC decrease reagent reactivity</i> $\geq 2$ displays the incorrect result for Screening Cells, e.g., result for SC 1 displays for SC 2 and so on.                         | None required.   | Minor            | Occasional               | Acceptable | None                   | Supervisor                                | None   | CR 3,429                | 210359                       |
| Exception Report              | The column headers for the <i>Exception type: Expired Unit Received</i> section are not displayed on the second page when the exception entry displays over more than one page.                 | None available.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | None   | CR 3,439                | 210369                       |
| Exception Report              | When invalidating results from Unit Antigen Typing the Exception Report does not show all invalidated values.   | View the invalidated tests on the Testing Worklist Report and the Unit History Report. | Minor            | Remote                   | Acceptable | None                   | All users                                 | Originally CR 2,022. INC000001305639   | CR 3,591                | 210521<br>I5935904FY16       |
| Finalize/Print TRW            | Barcode scanning of a specimen UID displays a tilde (~) in front of UID in the pre and post transfusion specimen fields.  | Do not use the barcode scanner to enter a transfusion reaction specimen ID.            | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None   | CR 3,200                | 210130                       |
| Finalize/Print TRW            | A system error occurs when a user enters previously recorded testing interpretations for a transfusion reaction and then unchecks the testing box, checks that box again and clicks OK to save. | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Once testing is entered, there should not be a need to uncheck the testing box and recheck in normal practice.   | CR 2,804<br>HD 381573   | 209736<br>I6253943FY16       |

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|--|--|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Finalize/ Print TRW</b>               | Changes to previously selected canned comments associated with an implicated blood unit are not saved when a user changes them in a Transfusion Reaction Workup. | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None   | CR 2,867                | 209799                       |
| <b>Finalize/ Print TRW</b>               | A system error occurs when a user attempts to finalize a TRW with a canned comment and >350 characters of additional text in the comment field.                  | Limit finalize TRW comments to <350 characters to allow save.  | Minor            | Occasional               | Acceptable | Low                    | Lead Technologist and above               | The comment is saved when the system error is generated but VBECS will not be able to print the TRW.   | CR 2,852<br>HD 474282   | 209784<br>I7712858FY16       |
| <b>Finalize/ Print TRW</b>               | A system error occurs if a user has a TRW open and then attempts to open a second instance of the same TRW.  | Restart VBECS session and open one TRW to result and finalize.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None   | CR 2,815                | 209747                       |
| <b>Finalize/ Print TRW</b>               | VBECS only displays 350 characters entered into the Transfusion Reaction Details field on the Finalized Transfusion Reaction Report. Yeah                        | The details text is available to ~1000 characters on the Transfusion Reaction Count Report (Detailed).   | Minor            | Occasional               | Acceptable | None                   | Supervisor                                | Report is printed for medical director signature and charting. Printed report can be updated manually if required or by using a VistA consult.                                       | CR 2,230                | 209162                       |
| <b>Finalize/ Print TRW</b>               | A finalized Transfusion Reaction Workup cannot be corrected once it has been finalized.  | Request a correction of a finalized Transfusion Reaction Report in the VBECS database. Contact the National Help Desk if you encounter this problem. | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                | Users are cautioned to double check the workup before finalizing. Report is printed for medical director signature and charting. Printed report can be updated manually if required. | DR 1,633<br>HD 499216   | 212150<br>I6254326FY16       |
| <b>Free Directed Unit For Cross-over</b> | VBECS displays the logged on user performing the Free Directed Units for Crossover process even if he selects a different user name in the Removed By field.     | Do not use Free Directed Units for Crossover during downtime.  | Minor            | Occasional               | Acceptable | Low                    | Enhanced Tech                             | When processed in downtime, the selected user is recorded on the downtime form.  | CR 1,853                | 208785                       |

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|--|---|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Free Directed Unit For Cross-over</b> | A duplicate unit record may be created when an ISBT 128 unit is entered with a donation type of “D” and changed to a donation type of “V” during Free Directed Unit option and the unit was also entered during Incoming Shipment with the donation type “V”. | When a unit is received from the blood supplier with a donation type of “V” and the unit is to be restricted to a patient as a directed donation, the product code must be manually entered with a “D” to allow the restriction in a Full Service Blood Bank. A Transfusion Only facility type will not encounter this problem as the option Free Directed Unit is not enabled. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | If the user tried to bring the unit into inventory using both methods, the incorrect unit can be invalidated to prevent the duplicate record. The unit label would reflect the correct unit status per local policy. | CR 2,261                | 209193                       |
| <b>Incoming Shipment</b>                 | ISBT expiration date barcodes from the Department of Defense are not scannable due to different embedded prefix characters to indicate date only versus date and time.  | Manually type in the expiration date and time of the blood unit per the eye-readable expiration date information.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | This is generally associated with blood units that have a standard 2359 expiration time and the unit may be optionally configured to include time or not.  | DR 3,610<br>HD 360751   | 214127<br>I6303125FY16       |
| <b>Incoming Shipment</b>                 | VBECS will not accept entry of ISBT units when the first letter of the donor identification number is "ABDIUO".   | Units with these letters cannot be brought into VBECS and must be sent back to your supplier.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The letter generally indicates the unit’s country of origin or a non-collection facility. The U.S. blood collection facilities all use “W”.  | CR 3,061                | 209991                       |
| <b>Incoming Shipment</b>                 | VBECS allows a user to change the time in the Date Received field to a future time.   | VBECS defaults to the current date and time when the incoming shipment screen is opened. Instruct user to not change the time in the Date Received field to a future time.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The invoice date/time is used to determine an entered unit’s appropriate maximum storage time.   | CR 2,933                | 209865                       |
| <b>Incoming Shipment</b>                 | VBECS does not allow the entry of a 10 digit FDA number in Incoming Shipment when the user is prompted to activate the facility.  | Close the Incoming Shipment window and open Tool, Local Facilities to create a new supplier with a 10 digit FDA number.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The entry of a 10 digit FDA number is permitted but must be entered through the Local Facilities option and not directly through Incoming Shipment.  | CR 3,131<br>HD 515950   | 210061<br>I6310248FY16       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Incoming Shipment             | When a unit is received for the second time from a blood supplier, a user can remove the ABO/Rh of the unit and VBECS permits saving without a blood type making the unit unavailable.   | Do not remove the blood type when entering the unit back into inventory and review the data entered into VBECS against the unit labels before saving. | Minor            | Occasional               | Acceptable | Low                    | All Users                                 | If a unit is saved without a blood type, inactivate the unit and re-enter it in Incoming Shipment.<br>If a unit is saved without a blood type, it cannot be properly confirmed nor selected. | CR 3,191<br>HD 538535   | 210121<br>I6310642FY16       |
| Incoming Shipment             | When a user enters a valid date in the Expiration Date field and tabs out of the field, the save button is enabled. If the user returns to the expiration date, clicks the Delete or Backspace key to delete it, and tabs out of the field, the button remains enabled and the previously entered date and time are saved. | Inactivate and reenter the unit to correct the entry.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | User is allowed to correct the date before save which would be the usual reason for revisiting the field. The date is presented for review before the user finally accepts.                  | CR 1,605                | 208537                       |
| Incoming Shipment             | The Unit History Report will not show a unit that has been in inventory as CMV negative, shipped out, and then received again through Incoming Shipment as CMV negative.   | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | VBECS still holds the CMV negative indicator and treats the unit as CMV negative. User is expected to reenter the CMV test during unit receipt.  | CR 1,932                | 208864                       |
| Incoming Shipment             | The Unit History report displays results of Antigen Typing on a unit when the additional daily QC rows (POS and NEG) are processed the testing row is displayed three times.   | Select the one labeled for the Antisera as the result, or look at the Testing Worklist Report.  | Minor            | Frequent                 | Acceptable | None                   | All users                                 | QC results are also displayed but easily distinguishable from unit testing.  | CR 2,181                | 209113                       |
| Incoming Shipment             | When entering a Codabar labeled blood unit, the FDA registration number does not fully format until the unit id and product code fields are completed.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | All of the unit information is fully and correctly displayed when the unit information is entered in full, prior to saving.  | CR 3,257<br>HD 765659   | 210187<br>I6310385FY16       |

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|--------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Incoming Shipment</b>       | After clicking the Find button; in the Select Invoice dialog, if the user selects a valid shipper, than selects the blank white row (at the top of the combo box) and then re-selects a valid shipper, the system displays a system error.   | Do not select the blank row in the shipper list box. If the blank row is selected, click it, close the window and start a new search.                                   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None  | CR 3,270                | 210200                       |
| <b>Invalidate Test Results</b> | When a user is prompted to save a comment when invalidating a <b>test</b> result, they can select a comment and then hit the space bar before saving. Tapping the space bar removes the comment and still allows the user to save the blank comment.<br><br>The lack of proper comment text associated with the invalidated test then prevents direct access to the SI and TR option for this patient. | Review the comment before saving to confirm the comment is correct.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,240<br>HD 720879   | 210170<br>I6310462FY16       |
| <b>Invalidate Test Results</b> | A VBECS system error occurs when a user attempts to invalidate two crossmatch results and the blood unit was assigned, crossmatched, released, reassigned, and crossmatched again on the same specimen.  | Invalidate the first crossmatch save and exit the invalidate Patient Results option. Reenter the Invalidate Patient Results option to invalidate the second crossmatch. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Requires security role to complete and would be performed administratively.                     | CR 1,925                | 208857                       |
| <b>Invalidate Test Results</b> | When an antigen typing is invalidated; VBECS selects the Pending Task List check box. If the user does not clear the box, the test is automatically put back on the Pending Task List.   | Cancel the test on the Pending Task List, as necessary.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The user would be prompted to return to option by the test reappearance.                        | CR 1,596                | 208528                       |
| <b>Invalidate Test Results</b> | VBECS does not display the implicated unit product code for a transfusion reaction workup in the Invalidate Patient Test Results option.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The option displays the product short name, which is materially equivalent to the product code. | CR 2,026                | 208958                       |

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|--------------------------------|--|---|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| <b>Invalidate Test Results</b> | “The patient has history of justified ABO/Rh change” warning message contains an extra space.  | None required.  | Minor            | Remote                   | Acceptable | None                   | All users  | None  | CR 1,597                | 208529                       |
| <b>Invalidate Test Results</b> | A system error occurs when attempting to invalidate a crossmatch test after the unit has been marked unsatisfactory for issue in Issue Unit.   | If the unit is unsatisfactory for issue because the crossmatch test is incorrect, do not mark the unit unsatisfactory, release the unit from assignment and invalidate crossmatch test.                                     | Minor            | Occasional               | Acceptable | None                   | All users  | The steps follow user expectations but the error message should inform the user to use another process. This is an administrative process with security role. | CR 3,190                | 210120                       |
| <b>Invalidate Test Results</b> | The expected confirmation message does not display to the user informing them that the test was added back to the Pending Task List.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users  | None The inactivated test is added to the Pending Task List as indicated by the user.   | CR 2,579                | 209511                       |
| <b>Issue Blood Components</b>  | The area to mark a unit unsatisfactory for issue extends beyond the checkbox. A user that clicks in that area, but not the checkbox, could inadvertently mark a unit unsatisfactory for issue. | A VBECS Confirmation message window appears to verify the user wants to remove patient association and quarantine the unit. The user must click No if they mistakenly indicated the unit was unsatisfactory for issue.      | Minor            | Occasional               | Acceptable | Low                    | All users  | None  | CR 3,208<br>HD 590527   | 210138<br>I6310709FY16       |
| <b>Issue Blood Components</b>  | A system error occurs when a user attempts to issue a unit assigned or crossmatched to a patient with an expired specimen.   | Go to Orders, Maintain Specimen, change the specimen expiration date so it is not expired and issue the unit. This may require a temporary change of the Maximum Specimen Expiration Date in the Configure Division option. | Minor            | Occasional               | Acceptable | Low                    | All users except Supervisor who is allowed to proceed with override. | The steps follow user expectations but the error message should inform the user to use another process. This is an administrative process with security role. | CR 2,092                | 209024                       |
| <b>Issue Blood Components</b>  | When the user clicks Cancel, VBECS closes without displaying a confirmation message that data are lost.  | If canceled in error, recreate the data.  | Minor            | Occasional               | Acceptable | Low                    | All users  | The steps follow user expectations to reduce the number of user responses.  | CR 1,598                | 208530                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| Issue Blood Components        | Plasma can be issued frozen without thawing when associated with the order type is "OTHER."   | "OTHER" products require special consideration by local policy.  | Minor            | Occasional               | Acceptable | Low                    | All users  | Most Plasma product codes are processed in an FFP order not in the OTHER orderable. "OTHER" products are handled with local policies as described in the User Guide section.  | CR 2,254                | 209186                       |
| Issue Blood Components        | Due to an unjustified discrepant ABO, the assigned O negative units appear on the Emergency Issue tab, not the assigned tab, without an information message to explain why. | None required.   | Minor            | Occasional               | Acceptable | None                   | None   | The unit may be issued. The unit may meet crossmatch requirements but VBECS still invokes Emergency Issues rules since other testing criteria have not been met.  | CR 1,794                | 208726                       |
| Issue Blood Components        | VBECS may display an inactivated unit in the unit search screen without any indication of its inactivated record status.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users when inactivated unit records are available in the division. | The best practice for issue is to scan the unit information. The unit relocation cannot proceed if an inactivated unit is selected off the list. Users are directed by User Guide and local policy to use the unit for selection. | CR 1,877                | 208809                       |
| Issue Blood Components        | When VBECS opens the Issue Blood Components window the focus (cursor) is not in the unit ID field.  | A user must first click in the Unit ID field to bring the focus to that field before scanning or entering a unit number. | Minor            | Frequent                 | Acceptable | None                   | All users  | No errors are expected to result.   | CR 2,129                | 209061                       |
| Issue Blood Components        | When VBECS warns that a unit is assigned to another patient; the user is prompted to process an override and enter a comment to proceed.                                    | Complete the override to proceed.  | Minor            | Occasional               | Acceptable | Low                    | All users  | The entered comment is not recorded or displayed on the Exception Report.   | CR 1,798                | 208730                       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Issue Blood Components        | The message displayed reads "Original and repeat ABO/Rh interpretation do not match." The 2nd sentence in the designed message "You must resolve the discrepancy before units can be issued." is not displayed.  | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | VBECS will not allow the user to proceed with selecting a unit until the discrepancy is resolved thus mitigating the hazard.  | CR 2,203                | 209135                       |
| Issue Blood Components        | The workload recorded for Issue Units is doubled on the VBECS Workload Report.   | None required as the Vista workload reported is accurate and correct. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Workload validation clarification.  | CR 2,242                | 209174                       |
| Issue Blood Components        | Surgical initiative status is sent as assigned not compatible or issued.   | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The unit is available for bedside verification to the surgical initiative only after the unit has been physically issued from the blood bank regardless of the unit status in VBECS. Unit is correctly handled between VBECS and Surgery so only units that are issued by VBECS are transfused. | CR 2,333                | 209265                       |
| Issue Blood Components        | Blood is issued to the Vista Hospital location associated with the VBECS division, not a Vista hospital location associated with a mapped associated Vista Institution hospital location in VBECS Administrator. | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Optionally, use the remote storage location to add details of exactly where the products for transfusion were delivered to at the remote site. Clarification of design to allow more details as to transfusion locations.   | DR 2,881                | 213398                       |
| Issued/Returned Units Report  | The report returns more information than is requested. The Issued/Returned Report will include the transactions from the day prior to the start date requested by the user.                                      | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The report provides an additional day of information.   | CR 2,736                | 209668<br>I5535833FY15       |

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| Issued/ Returned Units Report | The date and time of unit return is not included on this report if it is different from the time the returned unit is selected (retrospective entry) at the time of data entry. The report does not include issue and return comments, as expected.     | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The report does not include the selected date/ time or processing date/ time fields. This information is displayed on the Unit History Report in the Issue Information section. Comment fields are not available at the time of issue or return, so none are available for the report. | CR 2,044                | 208976                       |
| Issued/ Returned Units Report | If a unit is entered into Incoming Shipment as one product code and then issued, and after issue modified to a new product code, the Issued/Returned Units Report will not show the original product code. Only the new modified product code displays. | A user can determine the original product by viewing the Unit History Report.         | Minor            | Occasional               | Acceptable | Low                    | All users                                 | This is performed by a user with proper security role.   | CR 2,185                | 209117                       |
| Issued/ Returned Units Report | If a unit is assigned to a patient, released from assignment, and then re-assigned to the patient, duplicate issue records will display on the Issued/Returned Units Report.  | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The report displays the correct issue information with a time and date stamp. A user can easily determine the last issue event.  | CR 2,596<br>HD 443058   | 209528<br>I6310770FY16       |
| Issued/ Returned Units Report | The Issue/Returned Report does not display the processing user and time of entry when results are entered retrospectively.  | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Retrospective data entry has supporting downtime documentation to capture the user information.  | DR 2,072                | 212589                       |
| Justify ABO/Rh Change         | When a database conversion blood type is one of the two blood type results involved in a justification, the database conversion blood type does not display on the Audit Trail Report entry of the justification.                                       | None required.  | Minor            | Occasional               | Acceptable | Low                    | Administrator                             | The information is available on the Patient Record Report. Details are readily available to the reviewer.  | CR 1,913                | 208845                       |
| Justify ABO/Rh Change         | When initially displayed, the VBECS patient name field in the Justify ABO/Rh Change option may not display the expanded field.  | Maximize the window to display the expanded (full name) field for long patient names. | Minor            | Occasional               | Acceptable | Low                    | Administrator                             | Details are readily available to the user.   | CR 1,914                | 208846                       |

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| <b>Log Into VBECS and Vista</b> | A cancelled Vista Logon - Authorization window at initial sign-on reopens automatically several times before staying closed.  | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 1,837                | 208769                       |
| <b>Log Into VBECS and Vista</b> | System error occurs when a user tries to log in and their role has been inactivated in that division instead of presenting the message "Your role within the division <Name> was inactivated. Please contact your system administrator."            | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The user is not able to access the division.  | CR 2,361                | 209293                       |
| <b>Maintain Minimum Levels</b>  | The minimum stock level for the reagents field allows the entry of a decimal that causes the reversal of the entry (e.g., user entry of "1.5" becomes "51") and may be saved.   | Enter whole numbers; do not enter decimals. Check the accuracy of the entry before saving.   | Minor            | Occasional               | Acceptable | Low                    | Administrator                             | There is no location to allow decimal entries but may occur through misuse of the option. Entries are not tied to patient testing and are used for reagent maintenance. | CR 1,686                | 208618                       |
| <b>Maintain Minimum Levels</b>  | Multiple shipments of the same lot number of a reagent type can cause a discrepancy in the total number available displayed on the Reagent Inventory Report and what is in inventory.   | Refer to the most recent entry of a reagent for the number of vials available when the shipment was received.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS can only display the data entered and does not manage inventory.  | CR 2,599<br>HD 301562   | 209531<br>I7608732FY1 6      |
| <b>Maintain Minimum Levels</b>  | Update reagents shows different information for a lot number than the Reagent Inventory report. The Reagent Inventory report displays each individual entry but the update reagent lot number view displays only the last entry for the lot number. | Enter with * at the beginning and end of the lot number. User may also re-enter lot number if changing the invoice number. See the Reagent Inventory Report. | Minor            | Occasional               | Acceptable | Low                    | Administrator                             | The report displays all changes in full.  | CR 2,209                | 209141                       |

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|----------------------------------|---|--|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| Maintain Minimum Levels          | In a multidivisional environment, the reagent report for a division will print one line item for each division that has set minimum levels for that reagent type. For example, if you have minimum levels for Reagent A, and two other divisions have minimum levels for Reagent A, that reagent information will print three times on your report. | There is no crossover of data, and no safety issue. If minimum levels are not set in a division, then it will not factor into the display. In a single-division environment, there is no such problem. | Minor            | Occasional               | Acceptable | None                   | Administrator  | The report accurately displays the inventory at each division.  | CR 2,233                | 209165                       |
| Maintain Specimen                | When extending a specimen expiration date, the override message that the patient has been transfused in the past 3 months appears even though the patient was transfused more than 3 months prior to the specimen expiration date.  | None required. Complete the override as requested to proceed per local policy and procedure.   | Minor            | Occasional               | Acceptable | Low                    | All Users when extending a specimen expiration date. | None  | CR 2,802<br>HD 394421   | 209734<br>I7611644FY16       |
| Maintain Specimen                | For a component order that does not require a specimen, VBECS calculates the order's expiration date and time to the "minute" from the collection time, not the appropriate day with an expiration time of 23:59.   | Request a new component order, as needed.  | Minor            | Occasional               | Acceptable | Low                    | All users  | VBECs expires the order at the time of day 10 days after the order was accepted. The order is simply expired hours earlier on the 10 <sup>th</sup> day. | CR 1,930                | 208862                       |
| Maintain Specimen                | When a specimen expiration is more than 72 hours in the future and a blood product is issued, the specimen expiration is recalculated to 72 hours from the time of issue.   | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users  | The expiration date is recalculated at blood product issue to expire hours earlier on the 3 <sup>rd</sup> day when it would normally expire.            | CR 2,485<br>HD 382525   | 209417<br>I7609484FY16       |
| Modify Units (not Pool or Split) | When an inappropriate product type is selected for THAW, the user is allowed to proceed but cannot fully complete the modification as there is no target product.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users  | Re-enter the unit with the proper modification method. Code should have prevented the selection of the unit in this modification.                       | CR 2,286                | 209218                       |

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|-------------------------------|--|--|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| Modify Units: Pool Units      | User cannot add units to a pooled unit created in VBECS with a Sterile Connecting Device (SCD).  | Recreate the pool.   | Minor            | Occasional               | Acceptable | Low                    | All users  | 1. Release the patient assignment , if any.<br>2. Inactivate the pooled unit (Blood Unit, Edit Unit Information).<br>3. Remove the final status of each original unit in the pool (Supervisor, Remove Final Status).<br>4. Create the new pool including all selected units.   | CR 2,875                | 209807                       |
| Modify Units: Pool Units      | VBECS permits a biohazardous unit to be added to a pool and does not automatically designate the pool as biohazardous. By system design, a biohazardous unit is not automatically marked quarantined to allow processing of a unit that has to be given regardless of this biohazardous state. | The user has the option to make the unit quarantined and biohazardous. This includes AUTOLOGOUS. | Minor            | Occasional               | Acceptable | Low                    | All users receiving biohazardous blood unit. (extremely rare).       | Unit Short Name displays “QUAR” and the long name includes it as well. Blood centers do not ship biohazardous products unless there is a documented medical necessity. When a biohazardous unit must be added to inventory the blood bank has specific storage and handling policies to segregate this unit from the main blood inventory. | DR 1,984                | 212501                       |
| Modify Units: Pool Units      | During the Pool Unit function the assigned to patient information is not displayed even though the assigned to patient has been selected for the pooled unit.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users in a division where pooling modification has been enabled. | Before the pool is saved and proceeding to label verification, VBECS requires confirmation of the patient assignment. This occurs after the patient has been selected by the user during pool modification.  | CR 3,344                | 210274                       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| Modify Units: Split a Unit    | A system error occurs when a user attempts to Split, Discard, or Quarantine a unit and the unit has multiple antigen typing records of the same antigen (e.g., from Incoming Shipment and from testing).                             | In order to perform the process, Split, Discard, or Quarantine, the user must remove the typing record that occurred in Incoming Shipment or Edit Unit Information by editing the unit, and then perform the split, discard, or quarantine process. | Minor            | Occasional               | Acceptable | Low                    | All users  | This is associated with a unit record and not a patient.   | CR 2,096                | 209028                       |
| Modify Units: Split a Unit    | When red cell products are ABO/Rh confirmed and then split, the confirmation is not inherited by the target units. The split units are not available for selection until a confirmation test is entered for each unit.               | Selected for the patient prior to split modification, the split units are issuable to that patient without workaround.  | Minor            | Occasional               | Acceptable | Low                    | All users<br>When split modification is enabled at the facility. | User must enter ABO/Rh confirmation test results on the split units to select them. Unit is available for issue if selected for the patient prior to modification.   | CR 2,295                | 209227                       |
| Modify Units: Split a Unit    | When red cell products are antigen typed and subsequently divided, the antigen typing information is not inherited by the target units. When selected in Select Units, the message that the units are not antigen negative displays. | Prepare the original unit for all antigen negative requirements prior to selection and modification. The split units are issuable without override. Ensure that the split units are properly labeled and that the BTRF is correctly printed.        | Minor            | Occasional               | Acceptable | Low                    | All users<br>When split modification is enabled at the facility. | User must enter the antigen typing information on each of the split units before selecting them. Normal business process has the split as the last step prior to issue to maximize the time available for transfusion, unless a sterile connecting device is used. | CR 2,354                | 209286                       |

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|-----------------------------------|---|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Modify Units: Split a Unit</b> | When red cell products are divided the CMV negative and SC negative status are not inherited by the target units.                                   | VBECS alerts the user to the missing requirement. The user may proceed, completing the required override documentation. | Minor            | Occasional               | Acceptable | Low                    | All users when a unit with CMV and SC negative units are split. When Split modification is enabled at the facility. | The user should ensure that the unit is labeled CMV negative per local policy by viewing the Incoming Shipment section of the unit's Unit History Report. The unit record cannot be changed without removing the assignment which then leads to CR 2295 and CR 2,354 (Split units in available status, but unavailable for selection. Split units do not have antigen negative status.). VBECS notifies the user of the lack of computer documentation and allows continued processing for patient use. | CR 2,363                | 209295                       |
| <b>Modify Units: Split a Unit</b> | An incorrectly formatted date may be entered in the expiration date field; the user is not warned; VBECS saves its calculated expiration date/time. | Enter a date/time in the correct format, mm/dd/yyyy hh:mm.  | Minor            | Occasional               | Acceptable | Low                    | All users when they opt to change the system calculated expiration date of a modified product.                      | The user may refer to the unit history report for the saved expiration date/time. There is no reason to change the calculated date/time in modification.  | CR 2,494                | 209426                       |
| <b>Modify Units: Split a Unit</b> | When a unit is split and the label verification fails the target, multiple exceptions display on the Exception Report, usually 3 per target.        | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users   | None  | CR 3,405                | 210335                       |
| <b>Order History Report</b>       | The Order History Report only displays the first 20 characters of an ordering location.   | None available.   | Minor            | Occasional               | Acceptable | Low                    | All users   | Ordering locations in Vista can be shortened or changed if the uniqueness of a location cannot be determined with the first 20 characters.  | CR 2,914                | 209846                       |

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| <b>Order History Report</b>   | A VBECS error loop occurs when a user attempts to print the Order History Report and selects an end date before the start date.  | Select a date range for the report that has an end date after the start date of the report.                          | Minor            | Occasional               | Acceptable | Low                    | All users   | Close VBECS and restart session if the error loop occurs as a result of the problem described in the description.   | CR 2,989<br>HD 465511   | 209921<br>I7712348FY16       |
| <b>Order History Report</b>   | Canceled orders are not designated on the Order History Report (summary report).   | The Single Order History Report (detailed) includes the canceled order information.                                  | Minor            | Occasional               | Acceptable | Low                    | Supervisors (When compiling local statistics)                               | Enhancement request to the summary report format. When the order is also cancelled in Vista, which would be the norm, there is a lab report that can be referenced.   | CR 1,945                | 208877                       |
| <b>Order History Report</b>   | The Single Order History Report details the events of each order, rather than all orders, placed for the specimen.   | Create an inclusive report for all tests performed on a specimen by viewing or printing each order's history report. | Minor            | Occasional               | Acceptable | Low                    | Supervisors (When compiling local statistics)                               | Enhancement request to the single order history repeat to organize by specimen rather than ordered test or component.   | CR 1,956                | 208888                       |
| <b>Order History Report</b>   | Single Order History Report contains duplicated workload information for TAS and DAT orders.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users   | Correct information is duplicated.  | CR 2,159                | 209091                       |
| <b>Order History Report</b>   | Specimen History section of the Order History Report displays historic specimen acceptability incorrectly, in that an acceptable specimen is displayed as unacceptable and vice versa. | None required as the current specimen status is correct.   | Minor            | Occasional               | Acceptable | Low                    | All users when a specimen has multiple updates regarding its acceptability. | View the record of specimen changes in the Patient History Report, Patient Specimen section where all activities are audited. The current specimen status is correct. The historic information is reversed. | CR 2,337                | 209269                       |
| <b>Order Reflex Tests</b>     | VBECS does not allow a user to reflex to a weak D test from an ABO/Rh test.  | A user can order an ABID then the weak D test and cancel the ABID to tie the weak D test to the ABO/Rh test.         | Minor            | Occasional               | Acceptable | Low                    | All users   | None  | DR 3,643                | 214160                       |
| <b>Order Reflex Tests</b>     | The Orderable Reflex test for DAT displays as a "DAT" instead of a "Repeat DAT."   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users   | By definition Reflex tests are secondary tests only orderable within VBECS.   | CR 1,158                | 208091                       |

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|-------------------------------|---|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>Order Reflex Tests</b>     | VBECS displays the Xg(a) blood group antigen incorrectly as” XgA.”  | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | Format is understandable to users.  | CR 1,881                | 208813                       |
| <b>Outgoing Shipment</b>      | The outgoing shipping invoice is missing required information regarding a blood unit’s CMV Negative status, biohazardous, and autologous unit testing status. When assigned or restricted, the patient first name and ID are not printed on the outgoing shipment document to maintain patient privacy. | Handwrite pertinent information on the VBECS invoice, when used to ship blood products. | Minor            | Occasional               | Acceptable | None                   | All Users                                 | None  | CR 2,734                | 209666                       |
| <b>Outgoing Shipment</b>      | The Expiration Date column in the list of units included in the shipment includes only the expiration date.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The unit expiration time is displayed correctly on the mock unit label during invoice creation. This does not impede ship out process.    | CR 1,980                | 208912                       |
| <b>Outgoing Shipment</b>      | When the return credit field is opened; VBECS enables the OK button although no change is made.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS evaluates that no changes were made and no changes are saved to the database. OK button is enabled early which is an inconsistency. | CR 1,981                | 208913                       |
| <b>Outgoing Shipment</b>      | The first name of the patient associated with a restricted unit on an Outgoing Shipment Invoice does not display or print.  | None available.   | Minor            | Occasional               | Acceptable | None                   | All users.                                | None This problem exists in all prior versions of VBECS.  | CR 3,536                | 210466                       |
| <b>Patient History Report</b> | An expired order override exception report entry does not appear on the Patient History Report when the Exception Report is requested.  | Users can view the expired specimen override information on the Exception Report.       | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,204                | 210134                       |
| <b>Patient History Report</b> | A VBECS automatic update of the Decision Support System (DSS) appears as an update to the transfusion record on the Patient History and Unit History Reports.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None  | CR 3,007<br>HD 479169   | 209939<br>I7735618FY16       |

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| Patient History Report        | A target blood unit volume may display as zero during batch processing to irradiate or thaw units. If it does, the target unit volume displays as zero on the Unit History Report. | Perform single unit modifications when irradiating or thawing units. Alternately, edit the target's volume in Edit Unit Information.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS volume is a default and does not indicate a transfused volume. This is displayed only within VBECS and is updatable.                                  | CR 1,999                | 208931                       |
| Patient History Report        | The 2nd digit of the minutes under the Date Processed column of the Demographics section is difficult to read when a 30 character patient name is displayed.                       | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None  | CR 2,610                | 209542                       |
| Patient History Report        | When units are restricted for a patient in Incoming Shipments, the restricted units do not display on the Patient History Report.  | Create a custom look up using the Blood Availability report searching for restricted units with minimal criteria selected, or as applicable to view restricted units in inventory. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Restricted units must be assigned to the patient to display on this report. VBECS forces the user to select this unit with a corresponding component order. | DR 1,643                | 212160                       |
| Patient History Report        | The VBECS domain user name (exp. VHATESTVBECSCLUSTER) will appear in the Processed By Field as having added patients to the database on the Patient History Report.                | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | This is accurate but inconsistent as the user's name is usually displayed.  | DR 2,580                | 213097                       |
| Patient History Report        | The Patient History Report displays the NT logon of the user in the Processed By space for database conversion data.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The user is identifiable. This is accurate but inconsistent as name is usually displayed.   | CR 1,908                | 208840                       |
| Patient History Report        | "The" is misspelled in the "A patient must be selected for the report" tool tip.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Typographical error.  | CR 1,703                | 208635                       |

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| Option Where the Issue Occurs | Description  | Recommended Workaround  | Level of Concern | Likelihood of Occurrence | Risk       | Impact to Patient Care | Security Role Mitigations (Affected User)   | Additional Comments  | Tracking System Number* | New Tracking System Numbers* |
|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Patient History Report        | The Exception Type: Expired Task Processed does not display in the Patient History Report.   | None required.  | Minor            | Frequent                 | Acceptable | Low                    | All users when using the Patient History is used to look up a processed exception rather than the Exception Report. | The Exception Report is recommended for daily supervisor review and save.  | CR 2,133                | 209065                       |
| Patient History Report        | The exception for antigen typing testing phase changes does not appear on the Patient History Report.  | Users are directed to review the Exception Report for this information. | Minor            | Frequent                 | Acceptable | Low                    | All users   | The Exception report is identified as one of the reports requiring supervisory review. The impact to the antigen typing result is investigated and addressed at that time not as a result from an entry on the unit or history report. | CR 2,684                | 209616                       |
| Patient History Report        | The report displays the (sub) section header not the heading (sub) section on following pages when a (sub) section prints over multiple pages. | None required.  | Minor            | Occasional               | Acceptable | None                   | All users   | The header is displayed on the first page where the subsection begins.   | CR 2,225                | 209157                       |
| Patient History Report        | Post-transfusion information is printed twice on the Patient History Report "Transfusions" section.  | None required.  | Minor            | Frequent                 | Acceptable | None                   | All users   | Correct information is duplicated.   | CR 2,227                | 209159                       |
| Patient History Report        | Patient History Report: Antigen Positive/Untested Unit issued exception is listed twice.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users   | Correct information is duplicated.   | CR 2,408                | 209340                       |
| Patient History Report        | The section headers are not displayed on the second page when the section displays over more than one page.                                    | None required.  | Minor            | Occasional               | Acceptable | None                   | All users   | None   | CR 3,440                | 210370                       |

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|------------------------------------|--|---|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| <b>Patient History Report</b>      | Patient History Report does not display VistA-converted Special Instructions (SI) and Transfusion Requirements (TR).                                 | None available.   | Minor            | Occasional               | Acceptable | None                   | All users  | This problem exists in all prior versions of VBECS. Patient VistA converted TR are rule based and enforced by VBECS. VistA-converted SI are not rule based but are presented with the VistA-converted TR in all Patient Search windows. | CR 3,548                | 210478                       |
| <b>Patient History Report</b>      | Presumed transfused units in the transfusion section are sorted by Unit ID number rather than by the chronology of testing as it was in VBECS 1.6.1. | None available.   | Minor            | Frequent                 | Acceptable | None                   | All users  | None  | CR 3,551                | 210481                       |
| <b>Patient Information Toolbar</b> | VBECS does not display transfusion reactions that are not finalized.   | Check the PTL for non-finalized transfusion reaction workups.   | Minor            | Occasional               | Acceptable | Low                    | All users when a TRW is pending completion and this option is used to look up the information.   | This test is incomplete without the finalization and is not ready for evaluation using this option.   | CR 1,658                | 208590                       |
| <b>Patient Information Toolbar</b> | The Recent Orders option does not display pending orders (not accepted) or completed transfusion reaction workups.                                   | Access transfusion reaction workup information from the patient's Transfusion Reaction History Report or the Finalize/Print TRW option. | Minor            | Frequent                 | Acceptable | Low                    | All users when a TRW is completed and this option is used to look up the information rather than the appropriate use of reports that contain completed test results. | This may result in a repeat order of the TRW, which would be cancelled when received and the patient history checked during processing.   | CR 1,927                | 208859                       |
| <b>Patient Information Toolbar</b> | Recent Orders is showing Order Status values like "Not Started" and "Filled", which are actually Task Statuses.                                      | None available.   | Minor            | Occasional               | Acceptable | None                   | All Users  | The Order History Report is showing Order Status values like "Pending" and "Canceled", which are valid Order Statuses.  | DR 4,458                | 214974                       |

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|-------------------------------|--|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Patient Merge                 | VBECS displays duplicate merge events to user for merge.   | Users can process one of the merge events manually and clear both merge alerts.  | Minor            | Occasional               | Acceptable | Very Low               | All users                                 | The Master Veteran Index team is working on a patch to discontinue sending a duplicate message.  | CR 3,099<br>MVI CR 232  | 210029                       |
| Patient Merge                 | A merge alert displays but has no discernable differences between the patient information in VBECS.  | None available.  | Minor            | Occasional               | Acceptable | Very Low               | All users                                 | If the “merge from” matches the” merge to”, Contact the National Help Desk for Tier 3 support.<br>A merge of DFN to another DFN is not rare, but the patient information associated to those DFN values being identical is uncommon.<br>VBECS does not display a change in the DFN identifier when two records are merged. It is possible that a site would merge two identical patient records with only the DFN being different. | CR 3,060                | 209990                       |
| Patient Testing               | A user is permitted to select two partially completed tests with different test phases (e.g., AHG only and All Phases) along with a not started test. The testing phase for the not started test will present as AHG only even though results for all phases are required by VBECS. Entering only AHG test results for the specimen that was not started and saving will result in a partially completed test that cannot be completed or invalidated. | Select partially completed orders that have been previously saved with the same grid test pattern. Optionally, a not started test may be selected with these but must be tested with the same grid pattern to avoid the problem. | Minor            | Occasional               | Acceptable | Very Low               | All users                                 | Contact the National Help Desk if you encounter this problem. Specimens that cannot be completed or invalidated require the attention of Tier 3 support.   | CR 3,118                | 210048                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Patient Testing               | VBECS does not clear the test interpretation cell when the user clicks the red X in a Transfusion Only division and is in any of the testing grids in Patient Testing.                            | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users at TO facilities.               | Invalidation is accepted only in Invalidate Patient Testing. The intent of the red x is to clear the grid for re entry of reaction results. The user may clear the interpretation cell and re enter the interpretation. VBECS will perform row validation between the entered reaction results and the interpretation enforcing various system rules. | CR 1,644<br>CR 1,645    | 208576<br>208577             |
| Patient Testing               | A VBECS system error occurs when a user tries to save a result of “H” (hemolysis) in the Patient Antigen Typing testing grids.  | Users are instructed not to enter “H” in the Patient Antigen Typing test grids. Any attempt to save a result of “H” will cause a system error and clear the testing grid of that result when the user re-enters VBECS. | Minor            | Occasional               | Acceptable | None                   | All users                                 | The key for acceptable entries in the testing grid does not include “H” but it is permitted to enter until saving.  | CR 2,685                | 209617                       |
| Patient Testing               | The pattern IS-N 37-X AHG-P CC-N is considered valid for antibody screen testing.   | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | This is technically acceptable for a prewarmed crossmatch or sites using PeG enhancement. This is allowed with the processing of an override for Nonstandard test methods.  | DR 2,140                | 212657                       |
| Patient Testing               | A system error may result when the user tries to enter unacceptable characters or tab where not allowed.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Difficult to reproduce requiring significant manipulation to trigger. Do not tab around needlessly while in the patient testing grids.  | CR 2,367                | 209299                       |
| Patient Testing               | A user is allowed to enter more than 50 characters in the Off-Site Location field when entering antibody ID results without a message from VBECS that only the first 50 characters will be saved. | Do not exceed 50 characters for the name of the off-site testing location.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 2,626                | 209558                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Patient Testing               | When a site is defined as “full service” and daily QC was not performed the Exception Report exception type: “QC not performed on rack used for testing” entry is not saved when the associated patient has a middle initial(MI). | Standard practice is not to override the QC not performed warning message. Verify the QC was performed daily by reviewing the Testing Worklist Report. | Minor            | Occasional               | Acceptable | Low                    | All users when Daily QC was not performed and the patient with an MI is tested. | The user is warned that QC has not been performed in all instances. This exception is accurately collected and displayed for unit testing and patients without a middle initial. The user is warned at each testing episode when QC has not been performed and the override is collected in all but a rare situation. There is some flexibility in the 24 hour clock regarding QC testing. | CR 2,402                | 209334                       |
| Patient Testing               | Comments entered in the DAT POS and NEG control cell rows are not displayed on any report in VBECS or CPRS.   | Enter comments only in the patient test row.   | Minor            | Occasional               | Acceptable | Low                    | All users   | Display should not have multiple comment rows. Comments related to the patient testing are entered in the patient row. This is a training issue. Comments related to the patient test should only be entered in the patient test comment cell.   | CR 2,421                | 209353                       |
| Patient Testing               | Users cannot order a reflex weak D test for an ABO/Rh test as ordered from CPRS.  | Order a reflex antibody ID (ABID) and the weak D test at the same time. Then cancel the ABID.  | Minor            | Occasional               | Acceptable | Low                    | All users   | None   | DR 3,643                | 214160                       |
| Patient Testing               | VBECS is unable to compare <i>expired and incomplete</i> tests, including ABO/Rh when saving specimen results for the same patient.   | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users   | Complete all specimen tests prior to specimen expiration.  | CR 3,288                | 210218                       |

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|---|---|--|------------------|--------------------------|------------|------------------------|--|---|-------------------------------------|----------------------------------|
| <b>Patient Testing</b>                        | The "Unit ER issued, testing problem" exception override appears for any issued or transfused unit when testing problems are encountered in a specimen associated with the unit's order group. The specimen may or may not be the specimen associated with the RBC pre-transfusion testing. | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users ONLY when processing testing associated with an issued unit order. | The message may occur when a user does not expect it as related to the specimen association of the RBC order and may lead to an unnecessary investigation. Ultimately, the patient benefits as the situation is investigated to ensure compatible blood was transfused.<br>See <i>FAQ KDA CR 3,488 Testing Problem Associated with an Issued Unit</i> | CR 3,488<br>DR 5,080<br>INC 1050805 | 210418<br>215596<br>I7744603FY16 |
| <b>Patient Testing: Pending Task List</b>     | When a user enters random alphanumeric characters (nonsense); VBECS may or may not return a list of patients.   | Enter viable search criteria: full name or first initial of last name and last four digits of the patient ID.                            | Minor            | Occasional               | Acceptable | None                   | All users  | Test sites state that they also use the full SSN for patient identification.  | CR 1,891                            | 208823                           |
| <b>Patient Testing: Pending Task List</b>     | A system error occurs when the search option "Results Corrected" is used.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users  | There are other fields available for use that will present the orders associated for a single patient.<br><br>Field sites report that they require entry of the patient full SSN or specimen UID to select an order for processing.   | CR 2,490<br>HD 264904               | 209422<br>I7740017FY16           |
| <b>Patient Testing: Record Patient ABO/Rh</b> | Test entries are not cleared when canceling out of the Invalid Results message.   | Correct the testing entries or click the red X to return to the PTL and retest.  | Minor            | Occasional               | Acceptable | Low                    | All users  | None  | CR 2,042                            | 208974                           |
| <b>Patient Testing: Record Patient ABO/Rh</b> | In a Transfusion Only ABO/RH testing grid, free text comments cannot be saved.  | Create the comment in Canned Comments, Patient Testing context, select it. Inactivate the Canned Comment, if it is not to be used again. | Minor            | Occasional               | Acceptable | Low                    | All users  | None  | CR 3,290                            | 213807                           |

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|---------------------------------------|---|------------------------|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Patient Testing: Record a Cross-match | When the user attempts to save a negative or not tested check cell result, VBECS displays the “Invalid result. Check cells must have a positive result. Repeat test,” not “Interpretation does not match your results. Please correct” message. | None required.         | Minor            | Occasional               | Acceptable | Low                    | All users   | The message displayed to the user is misleading; VBECS requires entry correction to proceed. The user must enter a valid result.  | CR 1,862                | 208794                       |
| Patient Testing: Record a Cross-match | A currently crossmatched unit is selected for a different patient. The unit status displays as “Crossmatched.”  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users when the local practice is to crossmatch a single blood unit for multiple patients. | VBECS displays the unit status in a hierarchy when a crossmatch is present on any patient or unit and the unit is available for selection, assignment, or crossmatch to another patient.  | CR 1,601                | 208533                       |
| Patient Testing: Record a Cross-match | When returning to partially completed crossmatch tests or testing additional units, the originally selected crossmatch grid configuration is applied.   | None required.         | Minor            | Occasional               | Acceptable | None                   | Any user that has saved incomplete test results and returns to enter the remaining results.   | The test is partially completed with a test pattern setting and must be completed in that format. This is a training issue.   | CR 1,972                | 208904                       |
| Patient Testing: Record a Cross-match | A user can bypass the entry of test results in the IS field when performing a crossmatch.   | None required.         | Minor            | Occasional               | Acceptable | None                   | All users   | VBECS saves the entered results but does not allow the entry of a crossmatch interpretation while the testing fields are incomplete, as required to accommodate saving partially completed tests. The user may enter their results in any order but may not save the entry until completed. | CR 1,620                | 208552                       |

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|--|--|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Patient Testing: Record a Cross-match              | The following pattern cannot be saved. No interpretation entry is allowed. A tool tip message appears: Invalid Result. <i>Check cells must have a positive result. Repeat Test.</i>      | None available.  | Minor            | Occasional               | Acceptable | Low                    | All users.  | None This problem exists in all prior versions of VBECS.   | DR 4,586<br>INC 814517  | 215102                       |
|  | IS   | 37   | AHG              |                          |            |                        |   |  |                         |                              |
|  | Positive   | Negative (0) or Not Tested (X)   | Positive         |                          |            |                        |   |  |                         |                              |
| Patient Testing: Record a Direct Antiglobulin Test | DAT grid does not properly calculate the QC status of the PS AHG reagent when multiple lot numbers are used on the same day.   | View the QC data for the day for the lot number in question from the Testing Worklist Report and re-enter the results for the test grid (or repeat the testing). | Minor            | Occasional               | Acceptable | Low                    | All users when multiple lots of the same reagent type are in use on that day. | The user may repeat the reagent QC results or look them up and reenter them. The requirement stated that the reagent should not require repeat on the same day. Some sites require retesting of the reagent at each use.                                     | CR 2,179<br>HD 850459   | 209111<br>I7742872FY16       |
| Patient Testing: Record a Direct Antiglobulin Test | The Anti-Human Globulin reagent lot number entered is not saved when QC is recorded with the patient test. The Patient Testing Worklist Report displays the positive control lot number. | Record the reagent lot number for the Anti-Human Globulin in the test comment field.   | Minor            | Occasional               | Acceptable | Low                    | All users   | When the primary AHG reagent is tested with daily QC, there is no issue. This is an issue with subsequent AHG testing associated with an antibody identification where the user must manually add the reagent lot number in addition to the displayed entry. | CR 2,020<br>HD 925191   | 208952<br>I7743500FY16       |
| Patient Testing: Record a Direct Antiglobulin Test | VBECS displays “IgG” instead of “Anti-IgG” in the Tested With column of the Patient Testing Worklist Report.   | None required.   | Minor            | Frequent                 | Acceptable | None                   | All users   | Reagent name is clear as this is the only reagent with this name.  | CR 1,638                | 208570                       |

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|--|---|---|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Patient Testing: Record a Patient Antibody Screen</b>           | VBECS displays a system error message when the user clicks a tab for antigen testing, does not enter any test results, and clicks Cancel and Yes to close the window. | Do not cancel out of testing without entering test results.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The user has indicated to exit this option. The user must log into VBECS to continue.  | CR 1,797                | 208729                       |
| <b>Patient Testing: Record a Patient Antibody Screen</b>           | The Patient Antibody Screen with a Positive Interpretation may be saved as a completed test with blank reaction results.  | None Available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Invalidate the Antibody Test and enter all test results. This problem exists in all prior versions of VBECS.   | CR 3,500<br>INC 1078801 | 210430<br>I7744748FY16       |
| <b>Patient Testing: Record a Transfusion Reaction Workup (TRW)</b> | When a second implicated unit is selected prior to the completion of the first unit, VBECS does not record the associated data entry for the second unit.             | Add the first unit completely, and then add subsequent units. | Minor            | Occasional               | Acceptable | Low                    | All users                                 | Details affected are the Bag Returned information, hemolysis, Checks OK, and Comments. This does not occur when the user selects units for entry from left to right. The user may invalidate the TRW testing prior to finalization and enter the data. | CR 2,053                | 208985                       |
| <b>Patient Testing: Record a Transfusion Reaction Workup (TRW)</b> | A system error occurs when a user attempts to access a transfusion reaction workup that is already in progress and locked by another user.                            | None available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Simultaneous data entry on the same order is not allowed to avoid data corruption. They must log into VBECS to continue with other orders.   | CR 2,215                | 209147                       |
| <b>Patient Testing: Record a Transfusion Reaction Workup (TRW)</b> | Date Reaction Noted and Date Reaction Investigated is updated and reset to the current division date/time each time the TRW is opened for editing.                    | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | The Date Reaction Noted is recorded correctly and displayed as first entered on the Patient History Report. This is a display issue only as the original Date Reaction Noted is correctly recorded in the database and on the report.                  | CR 2,218                | 209150                       |

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|---|--|--|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Patient Testing Worklist and Testing Worklist Reports | The Rack QC Testing Worklist Report section of the Testing Worklist Report only displays the testing tech and not the identity of the logged in tech that entered the results. | Maintain the original testing records for the QC that was performed offline with the testing tech information. Do not change the testing tech name when entering results in VBECS so that the logged in tech that enters the results is included on the Testing Worklist report. | Minor            | Occasional               | Acceptable | Low                    | Supervisor responsible for report review  | Local policy dictates the storage of downtime records. Storage of the original work in addition to the computer entry is customary.   | DR 3,556                | 214073                       |
| Patient Testing Worklist and Testing Worklist Reports | Crossmatch tests that were invalidated and retested are not marked on the testing report.  | The sequence of test performance by date and time on the report identifies the most recent result.   | Minor            | Occasional               | Acceptable | None                   | Supervisor responsible for report review  | This is a training issue. The tests are displayed in the order of testing.  | CR 2,034                | 208966                       |
| Patient Testing Worklist and Testing Worklist Reports | The generation of testing reports may be prolonged.  | The report can be scheduled to print.  | Minor            | Occasional               | Acceptable | None                   | Supervisor responsible for report review  | This report is printed for review. This is dependent on the amount of data being retrieved.   | CR 1,867                | 208799                       |
| Patient Testing Worklist and Testing Worklist Reports | Rack IDs are not consistently displayed in the Patient Testing Worklist Report.  | None available.  | Minor            | Frequent                 | Acceptable | None                   | Supervisor responsible for report review  | 1) The one letter rack IDs are supposed to appear in the first line of the testing entry. In many cases, it is appearing in seemingly random line number positions, sometimes appearing multiple times in one testing entry.<br><br>2) When an XM test is invalidated, the Rack ID is not displayed. The missing rack IDs are an artifact when the same rack is used for the series of tests. | CR 2,063                | 208995                       |

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|---|--|------------------------|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Patient Testing Worklist and Testing Worklist Reports | The weak D report format includes line items for IS and RT although these phases are disabled in the testing grid and may never have entered results.  | None required.         | Minor            | Occasional               | Acceptable | Low                    | Supervisor responsible for report review  | The report displays these phases with no results when none have been entered.   | CR 2,040                | 208972                       |
| Patient Testing Worklist and Testing Worklist Reports | The Patient Testing Worklist Report displays "Inc" for test interpretations that have different meaning. In the Interpretation column for crossmatch tests, "Inc" means incompatible; for other diagnostic tests, "Inc" means "inconclusive" interpretation. | None available.        | Minor            | Frequent                 | Acceptable | None                   | Supervisor responsible for report review  | Crossmatch test does not include an "inconclusive" interpretation. Other diagnostic tests do not have an "incompatible" interpretation. The definition is associated with the particular test and is not confusing to the blood bank staff. | CR 2,032                | 208964                       |
| Patient Testing Worklist and Testing Worklist Reports | VBECS displays an extra comma after the last specimen UID when a patient has multiple associated specimen UIDs.  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | Extra comma does not interfere with the displayed data.   | CR 1,579                | 208511                       |
| Patient Testing Worklist and Testing Worklist Reports | Testing Worklist Report: Unit and Patient Testing Details window reflects the reagent rack's testing status on the current date not on previous dates (retrospective data entry) and may require an override to proceed.                                     | None Available.        | Minor            | Occasional               | Acceptable | None                   | Supervisor responsible for report review  | Verify that QC was performed on the selected date(s) using the Testing Worklist Report. This is a report pulled for review and part of that review is to review that QC was properly performed on each date selected for the report.        | CR 2,384                | 209316                       |

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|---|--|---|------------------|--------------------------|------------|------------------------|---|--|---|----------------------------------|
| Patient Testing Worklist and Testing Worklist Reports | Testing Worklist Report does not provide a comprehensive list of reagent lot numbers entered for daily reagent rack QC.  | Continue to record all reagent lot numbers on a rack with existing process (hard copy or spreadsheet). Retain with Testing Worklist review records. | Minor            | Frequent                 | Acceptable | Low                    | All users                                 | The user must record some lot numbers manually as they are not displayed on the report. Field sites have opted to continue current manual recording of all lot numbers to minimize confusion.  | CR 2,385  | 209317                           |
| Patient Updates                                       | VBECS performance will slow when a patient has ten or more active ordered components because it must calculate the active orders for each patient checked.   | None Available.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | It is unlikely that this will occur unless the patient has multiple duplicate orders for the same blood component.   | CR 2,177  | 209109                           |
| Patient Updates                                       | The last update date time is updated on all Patient Updates displayed each time a new update is viewed.  | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None   | CR 2,711  | 209643                           |
| Patient Updates                                       | Patient updates display in VBECS for active patients when the data change is unrelated to VBECS data.  | None Available.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The changing demographics do not affect VBECS or the patient identity so the update will not reflect any changes. However, the patient update event is still logged and appears on the Patient History Report and the Transfusion Requirements Report. | CR 2,580<br>CR 3,249<br>HD 418676<br>INC 777862 | 209512<br>210179<br>I7614992FY16 |
| Patient Updates                                       | When a Vista patient update removes a patient's middle name VBECS displays the Patient Name and the Previous name in the Patient Name column. The Previous Name column displays the previous name correctly. | Close and re-open the Patient Update window. The subsequent display of the patient information is correct.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | This is a display issue only. The VBECS database, reports and any future transactions have the correct information.  | CR 2,709  | 209641                           |

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| Option Where the Issue Occurs  | Description  | Recommended Workaround  | Level of Concern | Likelihood of Occurrence | Risk       | Impact to Patient Care | Security Role Mitigations (Affected User)      | Additional Comments   | Tracking System Number*             | New Tracking System Numbers*     |
|--------------------------------|--|---|------------------|--------------------------|------------|------------------------|--|---|-------------------------------------|----------------------------------|
| Post – Transfusion Information | The Presumed Transfused indicator does not clear when post-transfusion information is updated.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                      | The transfusion end date is maintained properly in the database; the Presumed Transfused indicator is retained. The updated transfusion data are displayed in the Unit History Report. This may actually be a benefit as the record is clearly marked and indicates that the update occurred over 48 hours after administration and may require investigation as to why the information was not earlier made available. | CR 1,936                            | 208868                           |
| Post – Transfusion Information | The OK button is enabled on the Post Transfusion Information window when a Traditional Supervisor or above selects a unit that was marked transfused.        | None required.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor                                     | The OK button should only be enabled after a change has been made to saved information.   | CR 2,550                            | 209482                           |
| Post – Transfusion Information | No warning displays for missing workload process when entering post-transfusion information.   | None required.  | Minor            | Occasional               | Acceptable | Low                    | Supervisor responsible for workload reporting. | Associate workload process with Enter Post-transfusion Data. The application does behave correctly when a workload process is defined.  | CR 2,263                            | 209195                           |
| Post – Transfusion Information | A system error occurs when entering post-transfusion information if the tabs are selected out-of-order.  | Enter the tabs in order presented to avoid causing VBECS error. | Minor            | Occasional               | Acceptable | Low                    | All users                                      | If a VBECS error occurs no data is saved and the information must be re-entered.  | CR 2,208,<br>CR 2,879,<br>HD 426258 | 209140<br>209811<br>I7615610FY16 |
| Post – Transfusion Information | The calendar control cannot be used to enter transfusion start or end date. Selecting the calendar presents an error repeatedly until a system error occurs. | Use the keyboard to enter a transfusion start or end date.      | Minor            | Occasional               | Acceptable | Low                    | All users                                      | None  | CR 3,266<br>HD 784117               | 210196<br>I7742192FY16           |

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|---|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Print Unit Caution Tag &amp; Transfusion Record Form</b> | A VBECS system error occurs when a user enters a crossmatch for a patient and attempts to print caution tags or a blood transfusion record form while another user is performing testing on the same patient. | Reprint the caution tags from the Print Unit Caution Tags & Transfusion Record Form option.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None   | CR 2,922                | 209854                       |
| <b>Print Unit Caution Tag &amp; Transfusion Record Form</b> | VBECS displays a message that the caution tag(s) were successfully printed, but the printer has failed and printing was not successful.   | Physically verify that the requested tag is printed. The "Success" message is a message that the print has queued to the print queue, and does not verify that the printing has actually occurred. | Minor            | Occasional               | Acceptable | None                   | All users                                 | If the tag didn't print, the user would reprint the tag. The tag usually has printed successfully without incident.  | CR 2,059                | 208991                       |
| <b>Print Unit Caution Tag &amp; Transfusion Record Form</b> | A VBECS system error occurs when a Caution Tag is requested and the printer is not correctly configured.  | Configure the printer as detailed in the VBECS Technical Manual and SecurityGuide with subsequent testing prior to use.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | This will be discovered during local validation and corrected prior to production installation.  | CR 1,660                | 208592                       |
| <b>Print Unit Caution Tag &amp; Transfusion Record Form</b> | VBECS can only print ten blank caution tags per request. A user request for more than ten blank caution tags will result in only ten tags printed.  | Perform several requests for ten blank caution tags to fulfill the quota if more than ten caution tags are required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,624                | 209556                       |
| <b>Print Unit Caution Tag &amp; Transfusion Record Form</b> | The printed Caution Tag displays "Not Applicable" in the crossmatch field when a unit does not require a crossmatch. The Blood Transfusion Record Form (BTRF) displays "Not Required" in the same situation.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The messages are materially equivalent. If the user feels that this is unacceptable they would manually change the text on one of the documents to match letter for letter with the other. | CR 2,007                | 208939                       |

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|--|---|------------------------|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| Print Unit Caution Tag & Transfusion Record Form | When an antigen negative requirement was entered in Special Instructions and Transfusion Requirements, the message and tool tip includes the antigen negative requirement in a sentence structured for an antibody history insertion. | None required.         | Minor            | Occasional               | Acceptable | None                   | All users  | The statement is grammatically incorrect but conveys that the unit is untested or positive for the required antigen to a Blood Bank user.   | CR 1,814                | 208746                       |
| Print Unit Caution Tag & Transfusion Record Form | VBECS cannot print a BTRF documenting retrospective crossmatch compatibility.   | None required.         | Minor            | Occasional               | Acceptable | None                   | Supervisor reviewing retrospective data entry related to emergency issue of blood products | The information is available in the various reports associated with testing documentation. The user may want to write up a document “for the records” based on paper record driven policy for documentation for retrospective test entry related to the issuance of blood products with incomplete pretransfusion testing. This form is not required as one has already been written and used to document the blood product administration. | DR 1,956                | 212473                       |
| Print Unit Caution Tag & Transfusion Record Form | When blank Caution Tags are printed in preparation for down time and the print job is canceled, the number printed is not correct in the message.   | None available.        | Minor            | Occasional               | Acceptable | None                   | All users  | The user may count the number of tags printed to determine how many blank tags should be printed.   | CR 2,003                | 208935                       |

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|--|---|------------------------|------------------|--------------------------|------------|------------------------|--|---|-------------------------|------------------------------|
| Print Unit Caution Tag & Transfusion Record Form | On the BTRF, the Technologist Initials are those of the original assigning tech not the current tech. This happens when the unit has been selected, crossmatched, released from assignment by the first tech. The unit is selected and crossmatched again by a different tech. Both names appear on the Caution Tag (Assigning Tech/Crossmatch Tech). | None available.        | Minor            | Occasional               | Acceptable | None                   | All users  | None  | CR 3,265<br>HD 777028   | 210195<br>I7741504FY16       |
| Print Unit Caution Tag & Transfusion Record Form | Unexpected, and incorrect, tooltip presents in Print Back Up Forms  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users  | None  | CR 3,361                | 210291                       |
| Print Unit Caution Tag & Transfusion Record Form | When the compatibility interpretation "Incompatible: Given with Medical Director Approval" is selected, the time of the crossmatch prints outside the grid and partially displaying the minute digit.   | None required.         | Minor            | Occasional               | Acceptable | None                   | All users  | None  | CR 3,445                | 210375                       |
| Prolonged Transfusion Time Report                | Units issued to a remote storage location will appear on the report when the transfusion start time is greater than 30 minutes after issue time.  | None available.        | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review | Units issued to a remote storage location should not appear to have a prolonged issue time as this setting indicates that the unit is issued to a monitored location maintained at the proper temperature for the product type. | CR 2,803                | 209735                       |

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|--|--|---|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| <b>Prolonged Transfusion Time Report</b> | When the user clicks OK after selecting the printer, the print preview view of the Prolonged Transfusion Report closes.  | None available.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review | The user has requested the hard copy and no longer requires this view. This is not consistent with other reports in the application.   | CR 2,231                | 209163                       |
| <b>Prolonged Transfusion Time Report</b> | The delayed start time presented is the total time from issue to start time; the prolonged transfusion presented is the time from issue to the transfusion end time. | None available.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review | The times are not inaccurate but are not in the preferred format where a delayed start would calculate only 30 minutes after issue to the start for its calculation (example, 34 minutes, not 4 minutes). The prolonged transfusion would be from the start to end time that exceeds the maximum transfusion time (MTT) set for the component class, for example, 500 minutes, not 30 minutes when maximum MTT is 470. This is a report for a transfusion committee. The data is accurate, but does not present as the VBECS business rule is written. | CR 2,499                | 209431                       |
| <b>Reagents</b>                          | Checking all of the reagents types to view on the Reagent Inventory Report will only display reagents with at least one vial in inventory.                           | Select specific reagents individually to view and print.<br>Print and save a copy of the report prior to zeroing out any expired product lot numbers. | Minor            | Occasional               | Acceptable | Low                    | All users  | Reagents that have zero vials remaining will not display.  | CR 3,133<br>HD 514507   | 210063                       |
| <b>Reagents</b>                          | Comments entered for unsatisfactory reagents do not appear on any VBECS reports.   | The comments are saved in VBECS but are not viewable. No workaround is available.   | Minor            | Frequent                 | Acceptable | Low                    | All users  | If the comments must be verified or viewed, the user can file a request for this information with the National Help Desk.  | DR 4,346<br>HD 541145   | 214862                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|--|---|-----------------------------------|----------------------------------|
| Reagents                      | Once tripped, the message warning of low reagent inventory continues to alert the user in Update Reagents even when the inventory is above the minimum.                           | Set the "Minimum Stock Vial Level" in Maintain Reagent Minimum Inventory to zero to disable the warning message.   | Minor            | Occasional               | Acceptable | None                   | All users  | This is an annoyance that is corrected by resetting the configured number to zero for the specific reagent lot number.                | CR 1,505                          | 208438                           |
| Reagents                      | When reagents are received, updated and marked unsatisfactory in the same transaction; comments and details entered are concatenated and are not displayed on the Reagent report. | Document the reason a reagent was unsatisfactory upon receipt on the manufacturer's invoices for future reference. | Minor            | Occasional               | Acceptable | Low                    | All users can print the report, but a Supervisor would be responsible for review | None  | CR 1,875                          | 208807                           |
| Reagents                      | VBECS does not maintain a reagent lot number's history when the quantity of an expired reagent is set to zero.  | Do not set the reagent lot number quantity to zero when the record is to be maintained.                            | Minor            | Occasional               | Acceptable | Low                    | All users can print the report, but a Supervisor would be responsible for review | This is an expired reagent and would not be used routinely. The lot number continues to be available for use should that be the case. | CR 1,958<br>CR 1,931<br>HD 359714 | 208890<br>208863<br>I7609159FY16 |
| Reagents                      | A system error occurs when sorting reagents by invoice if the invoice contains any non-numeric characters   | Do not enter non-numeric characters for the invoice number.  | Minor            | Occasional               | Acceptable | None                   | All Users  | None  | CR 2,528                          | 209460                           |
| Reagents                      | A warning icon appears when the user selects "No" to the entry confirmation message.  | Click the Clear button to continue.  | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review | The user must click clear to close the window. This is a nuisance in a non-patient care option in the application.                    | CR 1,952                          | 208884                           |
| Reagents                      | The Vials Received per Lot Number field in Log In Reagents allows the entry of a decimal that causes the reversal of the entry (e.g., user entry of 1.5 becomes 51).              | Enter whole numbers; do not enter decimals. Check the accuracy of the entry before saving.                         | Minor            | Occasional               | Acceptable | None                   | All users can print the report but a Supervisor would be responsible for review  | This is a nuisance in a non-patient care option in the application.   | CR 2,067                          | 208999                           |

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|-------------------------------|---|--|------------------|--------------------------|------------|--|--|---|-------------------------|------------------------------|
| Reagents                      | When the inclusive dates entered for Expiration Date Before/After include the current date, reagents that expire on the current date may not be included.   | None required.                                     | Minor            | Occasional               | Acceptable | None   | All users can print the report but a Supervisor would be responsible for review  | The reagent is not expired on the date the report is requested. The reagent is available.   | CR 1,966                | 208898                       |
| Reagents                      | Anti Pk, Anti-PP1, Anti-I, and Anti-I(int) are available as reagent types with no corresponding active test.  | None required.                                     | Minor            | Occasional               | Acceptable | None   | All users can print the report, but a Supervisor would be responsible for review | There are no associated test for these antigens in VBECS.   | CR 1,882                | 208814                       |
| Reagents                      | The time defaults to the time when the user enters the Reagent, Update Inventory window, not the time when a lot number is selected.  | None required.                                     | Minor            | Occasional               | Acceptable | None   | All users can print the report, but a Supervisor would be responsible for review | As the report is generated after the user enters the option, this would not be a significant time difference that would impact the information in the report.   | CR 2,068                | 209000                       |
| Reagents                      | In a multi-divisional environment, the reagent report for a division will print one line item for each division that has set minimum levels for that reagent type. For example, if you have minimum levels for Reagent A, and 2 other divisions on your VBECS have minimum levels for Reagent A, your division's reagent information will print three times on your report. | None required.                                     | Minor            | Occasional               | Acceptable | None in a single division.<br><br>Low in a consolidated division | All users can print the report, but a Supervisor would be responsible for review | There is no crossover of data and no safety issue. If minimum levels are not set in a division, then it will not factor into the display. In a single-division environment, there is no problem. Correct information is duplicated. This occurs only in consolidated divisions. | CR 2,233                | 209165                       |
| Reagents                      | A system error occurs when attempting to save an edit without a reason for change when the reason for change was entered and removed.   | Do not remove the reason for change before saving. | Minor            | Occasional               | Acceptable | None   | All users  | None  | CR 3,390                | 210320                       |
| Reagents                      | When updating inventory, set a Reagent then blank out the Number of Vials field. The OK button remains enabled.   | None required.                                     | Minor            | Occasional               | Acceptable | None   | All users  | None  | CR 3,393                | 210323                       |

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|---------------------------------------|--|------------------------|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Release Units From Patient Assignment | The scanner icon is currently displayed but is not working.  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | This is an inconvenience. The user may opt to release units using the patient route rather than the unit driven route.  | CR 2,200                | 209132                       |
| Release Units From Patient Assignment | In the Release Units menu option, a system error occurs if the user selects a comment, then deletes it by pressing the space bar and clicks the OK button to save.                           | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | The release of units requires a comment to save.  | CR 2,769                | 209701                       |
| Release Units From Patient Assignment | In the Release Units menu, if someone issues one of the units appearing on your list, prior to your save, the unit is locked in Issued status and cannot transition to 'Presumed Transfused. | None available.        | Minor            | Improbable               | Acceptable | None                   | All users                                 | Do not hold the Release Units option for long periods of time.  | N/A                     | 259491<br>R6690123FY16       |
| Return Issued Units To Blood Bank     | When all assigned units are released, the component order status is returned to "Not Started" on the Pending Task List.  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users                                 | The order remains available for use and expires normally based on division settings. This is viewed as a training issue. The order status is calculated based on the units currently associated with the order. | CR 2,051                | 208983                       |
| Return Issued Units To Blood Bank     | VBECS may display an inactivated unit in the unit search screen without any indication of its inactivated record status.   | None required.         | Minor            | Occasional               | Acceptable | Low                    | All users                                 | All unit information is correct.  | CR 1,877                | 208809                       |

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|-----------------------------------|--|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Return Issued Units To Blood Bank | Visual Inspection Information is not included in Exception Report.   | View the Unit History Report for the visual inspection associated with an exception recorded for a blood unit relocation.          | Minor            | Occasional               | Acceptable | None                   | All users   | The display of the visual inspection response is included in the unit's Unit History report which may be opened during the investigation of the exception by the supervisor.   | CR 2,119                | 209051                       |
| Return Issued Units To Blood Bank | The selected unit marked unsatisfactory for return is removed from the Select Units to Return list view, but the information in the Selected Unit pane for the unsatisfactory unit remains unchanged.                      | None required.   | Minor            | Occasional               | Acceptable | None                   | All users   | The display changes when another unit is selected and updates the view.  | CR 2,089                | 209021                       |
| Select Units                      | A system error occurs when a user enters a unit product code and presses "Enter" rather than "Tab" key.  | When a user is entering unit ID and product code via the keyboard, press the "Tab" key or use the mouse to move to the next field. | Minor            | Occasional               | Acceptable | Low                    | All users   | Recommended business practice is to use the hand held barcode scanner, not type in the barcoded information.<br><br>The error occurs because the user presses "Enter" which clicks OK without submitting the unit information causing the crash. | CR 3,227                | 210157                       |
| Select Units                      | A system error occurs when a user selects a unit and then filters the available units search screen for a product different than the unit selected and uncheck the unit selected.  | Uncheck all selected units before filtering available units.   | Minor            | Occasional               | Acceptable | Very Low               | All users   | The steps to get to the system error are convoluted in normal practice and may never be encountered.   | CR 2,821                | 209753                       |
| Select Units                      | In a multidivisional database, restricted units residing in another division will be displayed but are not selectable. The tool tip (mouse over) message wording incorrectly states, "Unit is <b>not</b> in division ###." | Read this message without the word NOT in the sentence. The division shown is the division where the unit is physically located.   | Minor            | Occasional               | Acceptable | None                   | All users in consolidated VistA with multiple VBECS Divisions | The unit is not selectable as it is physically in a different location. This occurs only in consolidated divisions which are limited in number and with restricted units which are not a high volume product.                                    | CR 2,107                | 209039                       |

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|-------------------------------|---|------------------------|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| Select Units                  | Applicable only when Split Modification is enabled. VBECS displays ISBT unit ID and product short name, but not the product code.   | None available.        | Minor            | Occasional               | Acceptable | Very Low               | All users in divisions where split unit modification is enabled.   | The user scans/enters the product information and does not use the pick list. A split ISBT unit's uniqueness is determined by the seventh and eighth digit of the product code; therefore, VBECS cannot identify the difference.   | DR 1,729<br>HD 1054260  | 212246<br>I7743149FY16       |
| Select Units                  | The message used to state that the patient has a history of Anti-K and the unit is positive for the antigen K, references the antigen type as anti-K and the antibody as K as well as all other antibody/antigen pairs. | None required.         | Minor            | Occasional               | Acceptable | None                   | All users when the patient has an identified irregular antibody and selected an untested or positive unit for the patient. | The terms are flipped but the content of the message is clear to a blood bank user.  | CR 2,093                | 209025                       |
| Select Units                  | Autologous, directed, or designated or dedicated blood units located in one division of a multidivisional database do not display in another division if the status is assigned or crossmatched.                        | None required.         | Minor            | Occasional               | Acceptable | Low                    | Limited to all users in consolidated Vista with multiple VBECS Divisions   | Release the unit from assignment; the patient is no longer in the facility. Transfer any autologous or directed and assigned units with the patient. This assumes that the patient has been moved and physically in the other site while the restricted unit is actively selected for the patient. This requires a current specimen and its testing. This is a very unusual circumstance as autologous and directed units are generally associated with elective surgical procedures where a patient transfer is not common. | CR 2,050                | 208982                       |

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|-------------------------------|---|------------------------|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Select Units                  | <p>When there is a patient blood typing discrepancy and the unit does not meet requirements for selection, VBECS displays a warning with text that is not worded exactly as specified.</p> <p>System message displayed “VBECS-Not selectable unit [unit number]. This order must be emergency issued. This unit doesn't qualify for emergency issue and may not be selected.”</p> | None required.         | Minor            | Occasional               | Acceptable | None                   | All users when an ABO discrepancy is found during the course of testing a selected patient. | VBECS is working correctly and enforcing the emergency issue compatibility rules and issuing universally compatible unit(s). ABO discrepancy is an uncommon occurrence in a transfusion service regardless of the root cause. The patient ABO/Rh discrepancy information is available in the Patient History or Exception Report. The message should read: “This patient had a previous ABO/Rh discrepancy and entry of a justified blood type with the following comment: <insert type of discrepancy from record>. Perform ABO/Rh on the current specimen to continue using normal rules and policies or follow emergency issue rules and policy as related to patient ABO/Rh retrieval and blood compatibility.” | CR 1,548                | 208480                       |
| Select Units                  | The Unit Expiration field is blank prior to the unit selection confirmation.  | None required.         | Minor            | Occasional               | Acceptable | None                   | All users   | The unit expiration displays when a unit is selected. The expiration date is always displayed on the mock face label. The information is accurately displayed on the screen, just not in this specific field.   | CR 1,899                | 208831                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Select Units                  | When a user selects an antigen positive unit for a patient with an antigen negative requirement; VBECS displays the product name instead of product type in the warning message.                                | None required.   | Minor            | Remote                   | Acceptable | None                   | All users                                 | The long product name contains more information than the product type for the unit.   | CR 2,010                | 208942                       |
| Select Units                  | When the patient's blood type is unknown or inconclusive and the user uses the unit search option, VBECS displays available cryoprecipitate units for selection without grouping the units by blood type.       | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Available units are displayed correctly. Click the ABO/RH column header of the available unit list to reorganize the unit list by blood type, as desired. | CR 1,727                | 208659                       |
| Select Units                  | When associating a specimen with a patient in the "Select Unit for a Patient" window; the "Expires" field within the "Associate with Specimen" panel, displays the time in AM/PM format.                        | VBECS normally displays date/time fields in the "military" time format. Workaround is to look in Maintain Specimen and check the expiration time military time format. | Minor            | Occasional               | Acceptable | None                   | All users                                 | This is an inconsistent presentation which does not impede the user.  | CR 2,120                | 209052                       |
| Select Units                  | VBECS displays a Codabar product code with an appended donation type code in the display and in the tree view of Select Units for Patients.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Codabar product codes do not require the appending of the donation type. This appended donation type information is correct for the unit.                 | CR 2,030<br>HD 479485   | 208962<br>I7736134FY16       |
| Select Units                  | The message displayed reads "Original and repeat ABO/Rh interpretation do not match." The 2nd sentence in the designed message "You must resolve the discrepancy before units can be issued." is not displayed. | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | VBECS will not allow the user to proceed with specimen processing until the discrepancy is resolved.  | CR 2,203                | 209135                       |
| Select Units                  | The Lab Order number does not display when the clipboard icon tool is selected.   | User can view the Lab Order number using the Pending Order List or the Order History Report.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The lab order is available on those screens where it is needed. This is an additional display of the information that is not essential to the user.       | CR 2,190                | 209122                       |

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| Select Units                  | When a Rh positive unit is selected for a Rh neg patient with anti-D, the Enhanced Technologist does not receive the warning that unit is antigen positive. | None available. The warning message for selection of an Rh positive unit for an Rh negative patient does appear.            | Minor            | Occasional               | Acceptable | None                   | Technologists when selecting Rh positive blood products for an Rh negative patient.            | A Lead Technologist is required to issue this unit to the patient and an exception is collected. Issue Unit is handling this situation correctly as designed.   | CR 2,406<br>DR 3,020    | 209338<br>213537             |
| Select Units                  | A system error occurs when attempting to associate a specimen in Select Unit with an order when no unit is selected.  | Ensure that a unit is selected when associating a specimen UID with units processed without a specimen for emergency issue. | Minor            | Occasional               | Acceptable | None                   | All users, retrospective data entry when specimen has not been associated during Accept Order. | Alternately, associate the specimen UID in Accept Order when possible. The user is attempting to associate the specimen to nothing. A unit must be selected. This is in place to allow users to associate a specimen with blood products for retrospective testing after the unit has been processed in emergency circumstances.  | CR 2,411                | 209343                       |
| Select Units                  | A system error occurs when the user clicks very quickly on the multiple messages in select unit regarding eXM eligibility and printing tags/forms.          | View, read, and respond to the presented messages.  | Minor            | Occasional               | Acceptable | None                   | All users who are clicking faster than the messages can be read and responded to.              | This has been identified is a training issue and possible enhancement to consolidate redundant messages for the selected units. The user is “counting” and clicking ahead of VBECS message presentation. The original information is saved, but VBECS crashes due to the database constraint violation. The user is clicking faster than the messages can be read and responded to. | CR 2,501<br>HD 354125   | 209433<br>I7608931FY16       |
| Select Units                  | The system is allowing an optional crossmatch for blood units in the OTHER component class that are not usually crossmatched.                               | None required.  | Minor            | Occasional               | Acceptable | None                   | All users  | None  | CR 3,269<br>DR 4,553    | 210199<br>215069             |

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| Select Units                                    | The message "Unit not eligible for eXM. ABO/Rh confirmation was not performed." displays when selecting non-RBC containing blood units, for example Fresh Frozen Plasma.  | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users   | None   | CR 3,273<br>HD 801629   | 210203<br>I7742363FY16       |
| Select Units                                    | A system error occurs when selecting a unit and a duplicate Component Requirement is set in a division.   | Inactivate the duplicate Component Requirement so that only one is active in the division. | Minor            | Occasional               | Acceptable | Low                    | All users   | None   | CR 3,350<br>HD 862780   | 210280<br>I7746768FY16       |
| Select Units                                    | When the components are not from the same component class donation RBC or WB, and a less restrictive donation type from PT_1.06 is selected, no overrides appear (no warnings or alerts that Autologous or Directed are available). | Select all Restricted units manually when known.   | Minor            | Occasional               | Acceptable | Low                    | All users   | Pick-lists will display Restricted for patient name in VBECS 2.2.0.  | N/A                     | 219714<br>R5607515FY15       |
| Special Instructions & Transfusion Requirements | When opening the Special Instructions and Transfusion Requirements (SI and TR) option, there is no audible alert for patients with existing entries.  | None required.   | Minor            | Frequent                 | Acceptable | None                   | All users   | The user is in the option proper, this was a misunderstanding of the requirement for an audible alert associated with the existence of SI and TR.  | DR 2,152                | 212669                       |
| Supplies: Log in Supplies                       | VBECS does not allow a user to select an expired supply item with an override during modification.  | Do not use an expired supply item.   | Minor            | Occasional               | Acceptable | None                   | All users, when selecting an expired supply item to associate with a unit modification. | Standard of practice is to use only in-date supplies. This would be an unusual situation. The lot number can be entered with a different expiration date as a work around if in-date supplies must be used. Supplementary documentation related to the use of an expired supply are required, including a local risk assessment. | CR 1,807                | 208739                       |

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| <b>Supplies: Log in Supplies</b>                        | Log-In Supplies Inventory list view does not sort when column headers are clicked.  | None required.  | Minor            | Occasional               | Acceptable | None                   | All users when attempting to sort the list using the column headers.              | None  | CR 2,100                | 209032                       |
| <b>Supplies: Log in Supplies</b>                        | A supply can be added and saved without Lot Number.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users   | None  | CR 3,324                | 210254                       |
| <b>Testing Worklist Report: Rack QC Testing section</b> | Rack QC section is sorted by the rack name rather than by the chronology of testing as it was in VBECS 1.6.1.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users   | None  | CR 3,533                | 210463                       |
| <b>Transfusion Complications Report</b>                 | VBECS cannot be queried for data in a date range occurring prior to VBECS installation.   | The user must include a Vista report request for dates prior to VBECS installation. | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review. | The existing Vista report is used for data retrieval prior to the production use of VBECS. Vista blood bank reports remain available for retrieval. | CR 2,255                | 209187                       |
| <b>Transfusion Complications Report</b>                 | Transfusion Complications Report does not work with the report scheduler.   | Users must run the report when needed.  | Minor            | Remote                   | Acceptable | None                   | All Users   | None  | CR 3,334                | 210264                       |
| <b>Transfusion Effectiveness Report</b>                 | Lab Test Name displays the Vista short name for the test.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review. | The user should be familiar with this test name. If they are not, they would query Vista.   | CR 2,135                | 209067                       |
| <b>Transfusion Effectiveness Report</b>                 | When requesting the Transfusion Effectiveness Report when no data is found the message "No information is available, per entered search criteria" displays. | None required.  | Minor            | Occasional               | Acceptable | None                   | All users can print the report, but a Supervisor would be responsible for review. | This is consistent with design.   | DR 2,539                | 213056                       |

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|--|--|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| <b>Transfusion Reaction Count Report</b> | The report only displays text entered in the “details” field of the Finalize TRW screen. The canned comments entered are suppressed on the report.   | Enter all comments in the “details” field for them to print on the report.   | Minor            | Occasional               | Acceptable | Low                    | All users can print the report, but a Supervisor would be responsible for review. | None   | CR 2,860<br>HD 415291   | 209792<br>I7615012FY16       |
| <b>Transfusion Reaction Count Report</b> | Transfusion Reaction Count Rpt: Transfusion Information section: Patient. The patient prints twice in the Transfusion Information section on the report. Once with the correct treating specialty, (e.g., HEMATOLOGY/ONCOLOGY) and once with a blank treating specialty. | None required.   | Minor            | Occasional               | Acceptable | None                   | All users   | Correct information is duplicated.   | CR 2,282                | 209214<br>I7614739FY16       |
| <b>Transfusion Reaction Count Report</b> | Ordered and pending transfusion reaction workups are not included in the report.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report but a Supervisor would be responsible for review.  | These are incomplete tests. Only finalized TRW are included in the report.   | CR 1,974                | 208906                       |
| <b>Transfusion Reaction Count Report</b> | Date Range uses the date the Transfusion Reaction Work Up (TRW) was entered, rather than the Date Reaction Noted as set in Patient Testing: Enter Transfusion Reaction Workup.   | The search terms for the Transfusion Reaction Count Report use the last date the TRW was updated, and the "Date Reported" is found in the details of the report.               | Minor            | Occasional               | Acceptable | Low                    | All users can print the report, but a Supervisor would be responsible for review. | The TRW may or may not be included in the count if it was updated after the date reported and that is used for the report selection.   | CR 2,220                | 209152                       |
| <b>Transfusion Requirements Report</b>   | The partial report displays patient blood types and Transfusion Requirements. The cumulative report does not display ABO/Rh when there is no other requirement.  | To create a report with all patients' blood types and Transfusion Requirements, print a partial report with the date range from VBECS implementation through the current date. | Minor            | Occasional               | Acceptable | Low                    | All users can print the report but a Supervisor would be responsible for review.  | The user must request the report using the workaround. If a cumulative report format is selected only patients with transfusion requirements and antibodies are displayed, not all patients on file. | CR 1,971                | 208903                       |

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|--|--|---|------------------|--------------------------|------------|------------------------|--|--|-------------------------|------------------------------|
| <b>Transfusion Requirements Report</b> | A report printed with an end date of today does not print "Preliminary" in the header.   | Check the subsequent pages of the report and write "PRELIMINARY" on the front page of the report prior to filing.   | Minor            | Occasional               | Acceptable | None                   | All users can print the report but a Supervisor would be responsible for review. | The information included in the report is accurate to the time printed. There is a possibility of a gap of information should the user not overlap the print requests. Generally, this report is printed for the day prior or time period that does not include the current day. | CR 1,969<br>DR 2,584    | 208901<br>213101             |
| <b>Transfusion Requirements Report</b> | The Transfusion Requirements report prints all divisions; no option to print selected divisions.                                       | None required.  | Minor            | Occasional               | Acceptable | None                   | All users can print the report but a Supervisor would be responsible for review. | The patient files are available at this level to all divisions in the consolidated database. This is a disconnect between the written rule and the desired information handling.   | DR 2,605                | 213122                       |
| <b>Transfusion Requirements Report</b> | The Transfusion Requirements report will not print if the user selects the date Vista records were loaded into the VBECS database.     | Access the Vista Blood Bank Reports option and use Patient Antibody Report (short list) to retrieve the list of transfusion requirements for the patients that were imported during conversion.                       | Minor            | Occasional               | Acceptable | None                   | All users can print the report but a Supervisor would be responsible for review. | Aside from antigen negative requirements, other transfusion requirements are not set in VBECS during the database conversion.  | CR 2,762                | 209694                       |
| <b>Transfusion Requirements Report</b> | Patient information may carry over to the subsequent page due to the nature of the report. Column headers may not repeat on all pages. | Footer has been added to the report stating the following: "Important transfusion related information for a patient may appear on more than one page. Always check the next page for additional patient information." | Minor            | Occasional               | Acceptable | None                   | All users  | Data is presented in full.   | CR 3,543                | 210473                       |
| <b>Transfusion Requirements Report</b> | The Partial format of the report does not allow scheduling to print in the future.   | Print the report immediately.   | Minor            | Frequent                 | Acceptable | None                   | All users  | None.  | CR 3,589<br>INC 1303428 | 210519<br>I5887317FY15       |

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|-------------------------------|--|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| Transmit Workload Data        | User will get the "No workload code defined. Workload credit cannot be applied to this transaction." warning message (if appropriate) when you cancel an order.  | None required.  | Minor            | Occasional               | Acceptable | None                   | None                                      | Setup requires that workload codes be assigned. Canceling an order has no specific workload associated with it. This does not impact billable tests.      | CR 2,236                | 209168                       |
| Unit Antigen Typing           | When a user is completing antigen typing results for a unit and the control results were previously saved, a user can navigate to the QC comments field but is not allowed to save new comments.   | None required.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None  | CR 2,888                | 209820                       |
| Unit Antigen Typing           | VBECS inserts the negative control vial number in the positive control result field if the user uses the down arrow key.   | Navigate using the mouse to prevent this problem in the antigen typing test grid.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | CR 3,014                | 209946                       |
| Unit Antigen Typing           | If the database connection is lost in the milliseconds between testing result save and testing worklist update, the worklist may not be updated as Completed. If the worklist has been Completed but not updated, attempting to access it from the worklist listing will cause a VBECS system error, and the user will need to restart VBECS, and should not invalidate this worklist from the Unit Antigen typing function. | When invalidating a worklist, it is suggested that the user access the worklist to confirm that it is actually Incomplete before invalidating it. | Minor            | Remote                   | Acceptable | Very Low               | All users                                 | Rare occurrence. Invalidations should be made in the Edit Unit Information function.  | CR 2,109                | 209041                       |
| Unit Antigen Typing           | A system error occurs when a user enters reagent lot numbers, uses the Backspace key to erase one of multiple entries, and clicks OK.  | Reenter the reagent lot numbers.  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | The user must log back into VBECS. This has been identified as a training issue. When the user highlights and retypes the lot number this does not occur. | CR 1,572                | 208504                       |

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| Unit Antigen Typing           | VBECS does not display testing comments entered for the control cells when partially completed testing is recalled.  | Testing comments are properly displayed in the Testing Worklist Report.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 1,744                | 208676                       |
| Unit Antigen Typing           | When a user applies a sort order when selecting units for antigen typing that order is not inherited by the testing grid.  | Organize physical tests materials according to the order of units presented on the testing grid.                             | Minor            | Occasional               | Acceptable | None                   | All users                                 | The units sort order is based on the last update date/time which is not displayed to the user. | CR 2,646                | 209578                       |
| Unit Antigen Typing           | Selecting a large number of units (~38) for antigen typing takes a long time for VBECS to process (~3 minutes). During that time the screen appears distorted.   | None required. However, selecting fewer units for a batch avoids this problem.   | Minor            | Remote                   | Acceptable | Low                    | All users                                 | The order of units does change from the selection order and requires verification.             | CR 2,645                | 209577                       |
| Unit History Report           | When a user retroactively updates a unit status through the Discard or Quarantine option, the Unit History Report displays the updated information, but does not display the date the change was made. | None available.  | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | DR 2,020                | 212537                       |
| Unit History Report           | The Antigen Testing Phase Change Exception does not appear on the Unit History Report.   | The Antigen Testing Phase Change Exception appears on the Exception Report which should be reviewed daily by the supervisor. | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,643                | 209575                       |
| Unit History Report           | The Unit History report Costs column displays the incorrect cost if units are pooled.  | See the Cost Accounting Report for cost of Splits/Divides and Pools.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | None   | CR 2,158                | 209090                       |
| Unit History Report           | When a unit is added, the Unit History Report for a pooled unit displays duplicate targets for that unit.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Although duplicated, the correct modification information is included in the report.           | CR 1,880                | 208812                       |

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|-------------------------------|---|---|------------------|--------------------------|------------|----------------------------------|---|---|-------------------------|------------------------------|
| Unit History Report           | The Unit History report does not indicate the CMV status correctly if a unit was re-entered into VBECS without a CMV negative status. This only occurs if the unit was originally entered with the CMV negative status.       | None required.  | Minor            | Remote                   | Acceptable | Very Low risk / Very Low impact. | All users when re-entering a CMV negative unit. | VBECS correctly retrieves the unit's original information and considers the unit CMV negative for selection and issue. If the unit CMV testing status changed and is no longer considered negative at the time of reentry, clear the CMV negative special testing check box in Edit Unit Information. | CR 1,932                | 208864                       |
| Unit History Report           | VBECS displays the five-digit blood product code in the Report Criteria section of the report.  | None required.  | Minor            | Occasional               | Acceptable | None                             | All users                                       | The full product code is displayed properly in the header of the report.  | CR 1,989                | 208921                       |
| Unit History Report           | VBECS displays the user ID rather than the user name in the Transfusion Information Processed By column.  | None required.  | Minor            | Occasional               | Acceptable | None                             | All users                                       | The user is identifiable though this is not the usual presentation.   | CR 1,943                | 208875                       |
| Unit History Report           | The exception details captured for Antigen Testing Phase Change do not appear on the Unit History Report.   | View the Exception Details on the Exception Report for this information for the date the exception was generated. | Minor            | Occasional               | Acceptable | Low                              | All users                                       | The Exception report is identified as one of the reports requiring supervisory review. The impact to the antigen typing result is investigated and addressed at that time not as a result from an entry on the Unit History Report.   | CR 2,689                | 209621                       |
| Unit History Report           | Unit History Report section of the report has the word "antigen" spelled incorrectly.   | None required.  | Minor            | Frequent                 | Acceptable | None                             | All users                                       | There is a typographical error.   | CR 2,114                | 209046                       |
| Unit History Report           | In the Unit History Report, Patient Association section, the Crossmatched to Patient Name and Assigned to Patient Name may not have a space between the first and middle name depending on the length of the patient's names. | None required.  | Minor            | Occasional               | Acceptable | None                             | All users                                       | There is a typographical error.   | CR 2,116                | 209048                       |

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|-------------------------------|---|--|------------------|--------------------------|------------|------------------------|---|--|-------------------------|------------------------------|
| Unit History Report           | When there are inactivated blood units in the VBECS system, an additional redundant Select Units window appears when attempting to create a Unit History Report.  | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | The second window must be closed to proceed.   | CR 2,084                | 209016                       |
| Unit History Report           | Antigen typing interpretations from Incoming Shipment, Edit Unit Information, or testing are presented as the antigen status only on pick lists throughout VBECS.   | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Unit testing information is found on the Unit History Report and the Testing Worklist Report. This relates to pick lists not the blood availability report which would be used to search for type specific units. Assigning units to match patient requirements is not impacted. | DR 1,640                | 212157                       |
| Unit History Report           | The Unit History Report does not display when a unit has been Returned to Shipper or Shipped to Another Facility.   | The Cost Accounting Report contains this information.                                    | Minor            | Occasional               | Acceptable | None                   | All users                                 | This is a secondary report for this information.   | DR 1,641                | 212158                       |
| Unit History Report           | Unit History Report: Transfusion Information section: Patient. The patient prints twice in the Transfusion Information section. Once with the correct treating specialty, (e.g., HEMATOLOGY/ONCOLOGY) and once with a blank treating specialty. | None required.   | Minor            | Occasional               | Acceptable | None                   | All users                                 | Correct information is duplicated.   | CR 2,281                | 209213<br>I7614739FY16       |
| Unit History Report           | Pooled ISBT units of differing ABO/Rh types appear on the Unit History Report as “Mx” rather than “Pooled” designation for the ABO/Rh.  | None required.   | Minor            | Occasional               | Acceptable | Low                    | All users                                 | This is a display only; there is no system-generated blood product label. The nomenclature is described in user documentation.   | CR 1,628                | 208560                       |
| Update Reagent Inventory      | The list of selectable comments in Reason for Change field is not associated with a canned comment category.  | Select a comment or OTHER and enter a free text comment to enter additional information. | Minor            | Occasional               | Acceptable | None                   | None                                      | These appear to be part of the Reagent and Supply comment category but are not part of that list.  | CR 2,752<br>HD 510102   | 209684<br>I7736743FY16       |

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|-------------------------------|---|---|------------------|--------------------------|------------|------------------------|---|---|-------------------------|------------------------------|
| <b>VBECS Administrator</b>    | Active Directory name changes cannot be imported into VBECS.  | Please file a ticket with the National Service Desk requesting a User Name Update.                                  | Minor            | Occasional               | Acceptable | Low                    | All users                                 | None  | DR 3,808<br>HD 415139   | 214325<br>I6126648FY16       |
| <b>VBECS Administrator</b>    | When the user attempts to exit the VBECS Administrator by clicking the X button on the window, it will not close.   | Click on File then Exit to close the application.   | Minor            | Occasional               | Acceptable | None                   | System Administrator                      | None  | CR 2,862                | 209794                       |
| <b>VBECS Administrator</b>    | Facility Name Field does not allow a full view of the registration number and full name of the selected facility.   | None required.  | Minor            | Occasional               | Acceptable | None                   | System Administrator                      | The user can read the FDA registration number which is the unique identifier for the facility. The FDA registration number is not editable where the Name may be edited. The FDA registration number is the unique identifier for a facility. | CR 2,340                | 209272                       |
| <b>VBECS Administrator</b>    | System Administrator can save the Patient Update and Patient Merge tabs for the VBECS Interface without entering a value in the Facility ID field. Failure to enter a facility ID will prevent patient updates and merge alerts from being processed.   | Enter the facility ID in the Facility ID field on the Patient Update and Patient Merge tabs of VBECS Administrator. | Minor            | Occasional               | Acceptable | Low                    | System Administrator                      | VBECS System Administrator is instructed to enter the facility ID in the Facility ID field in the VBECS Technical Manual-Security Guide when VBECS is configured for use.   | CR 2,573                | 209505                       |
| <b>VBECS Administrator</b>    | A user can configure a Vista Institution as a division and an associated institution. Orders placed at that CBOC to be rejected at acknowledgment. The user is alerted to the error in configuration by this message: "Unable to find valid Associated Institutions information. Please check configuration." | None required.  | Minor            | Occasional               | Acceptable | None                   | System Administrator                      | This is corrected during configuration verification during validation testing.  | CR 2,376                | 209308                       |

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| Option Where the Issue Occurs                  | Description   | Recommended Workaround  | Level of Concern | Likelihood of Occurrence | Risk       | Impact to Patient Care | Security Role Mitigations (Affected User)                        | Additional Comments   | Tracking System Number*  | New Tracking System Numbers* |
|--|---|---|------------------|--------------------------|------------|------------------------|--|---|--|------------------------------|
| <b>VBECS Administrator</b>                     | When the Lock Time Out Activity is changed using the spin control, the value saved is decreased by one (1).   | Adjust the Lock Time Out value by typing in the desired value or using the spin control and setting it up one number prior to save. Verify the value is saved as desired. | Minor            | Occasional               | Acceptable | Low                    | Administrator  | None  | CR 3,470   | 210400                       |
| <b>VBECS Administrator</b>                     | VBECS Administrator does not allow for user's name changes.   | None Available.   | Minor            | Probable                 | Acceptable | None                   | Users who have a NT Name change                                  | Contact the National Help Desk if you encounter this problem. This problem exists in all prior versions of VBECS. | CR 3,537   | 210467                       |
| <b>Vista Lab</b>                               | Rejecting an unaccepted order in VBECS, does not follow through and cancel the laboratory order automatically as no user DUZ is passed to Vista Lab.  | Cancel the order in Vista Lab when cancelling an unaccepted VBECS order and there is an unaccessioned Lab order.  | Minor            | Occasional               | Acceptable | Low                    | All users  | See updated <i>FAQ: VBECS Order Cancellation</i>  | CR 3,484<br>VBECS INC 1010931<br>CPRS INC 1037299<br>Lab INC 1037305 | 210414<br>I7744342FY16       |
| <b>Workload Codes (Division Configuration)</b> | Invalidating split units will result in negative workload equal to the number of splits created applied to the total number of units logged in.   | None available.   | Minor            | Occasional               | Acceptable | None                   | All users<br>When split modification is enabled at the facility. | This occurs when split units are incorrectly processed in VBECS.  | CR 2,224   | 209156                       |
| <b>Workload Codes (Division Configuration)</b> | Workload totals for VBECS processes may not match the Vista workload report totals. Repeat orders are known only to VBECS so if workload is generated as a result of a repeat order test the VBECS workload report will include that workload in its totals but the Vista workload report will not. | None required.  | Minor            | Occasional               | Acceptable | Low                    | All users  | Compare the workload code number totals that are equivalent.  | CR 2,240   | 209172                       |
| <b>Workload Codes (Division Configuration)</b> | LMIP/NLT associated CPT codes are not changed by checking or unchecking the boxes.  | Adjust the LMIP/NLT code to CPT code associations in Vista Lab.   | Minor            | Occasional               | Acceptable | None                   | Administrator  | This has been identified as a training issue.   | CR 2,438   | 209370                       |

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Revision History

| Date                                       | Revision | Description   | Author   |
|--|----------|---|----------|
| 11/23/15<br>(continued<br>on next<br>page) | 19.0     | <p><u>Updated for the release of VBECS 2.1.0.</u><br/>Formatted table for addition of a revised section for Risk and Impact to Patient Care Assessments.<br/>Assigned Level of Concern, Likelihood of Occurrence and Risk to each line item. (DR 5,184)<br/>Patient Care levels abbreviated: No identified impact and its variations are now “None”. Low Impact is now “Low”.<br/>Revision History: Removed the Revision History details of KDA versions through version 18.0.<br/>Introduction – first paragraph, last sentence was removed. Also the second paragraph was removed.<br/>The Risk Assessment and Impact to Patient Care Assessment - section was added.<br/>The table structure was updated with 4 additional columns.</p> <p><u>Revised:</u><br/>Important Note: edited “would normally be” to “is normally” prohibited. - Because the - Risk Assessment and Impact to Patient Care Assessment section is new you do not enter this change.<br/>Footer: added I and R, “National Help Desk” changed to “Enterprise Complaint System”<br/>CR 2,849: Description of the Problem: A repeat ABO/Rh Confirmation on a unit that is currently assigned to a patient in VBECS does not remove patient assignment from a unit when the unit is quarantined.<br/>DR 3,808: Revised the Recommended Workaround.<br/>CR 3,048: Recommended workaround now reads: “Activate the shipper and then discard the unit as desired.” Removed earlier recommended workaround.<br/>CR 2,385: Patient Testing Worklist and Testing Worklist Reports: Impact to Patient Care changed to Low from Moderate.<br/>CR 3,368 and CR 3,429 Combined in Enter Daily QC Results.<br/>DR 1,729: Description of the Problem: Added “Applicable only when Split Modification is enabled.” Moved information from description to the Additional Information column.<br/>DR 1,633: removed HD 332336, replaced with HD 499216.</p> <p><u>Removed:</u><br/>Enter Daily QC Results: CR 1,911 (HD 367084), CR 2,437 (HD 269544)<br/>Print Unit Caution Tag &amp; Transfusion Record Form: CR 2,086.<br/>ABO/Rh Confirmation CR 2,396, CR 2,813 (HD 399413)<br/>Patient Testing: Pending Task List CR 3,356, CR 2,812 (HD 395766)<br/>Select Units CR 3,523 (INC 1083461)<br/>Select Units: DR 1,703. Removed as the ICCBBA Product Types are mapped to appropriate orderable and are available for use.<br/>Issue Blood Components CR 3,550<br/>Cost Accounting Report DR 3,792, HD 399931</p> <p><u>Added:</u><br/>New Defect numbers for tracking. Both sets of numbers are listed in this version, old and new.<br/>Configure Division: CR 3,566, Defect 210496<br/>CPRS: CR 3,590, Defect 210520 and INC 768397 HD 0774043.<br/>Exception Report: CR 3,591, Defect 210521<br/>Throughout VBECS: CR 3,586, Defect 210516, and R5219698FY15.<br/>Throughout VBECS: CR 3,588, Defect 210518, and INC 1303428.</p> | BBM Team |

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| Date   | Revision                        | Description  | Author                          |                                  |
|--|---------------------------------|--|---------------------------------|----------------------------------|
| 11/23/15<br>(continued from previous page)         | 19.0                            | Throughout VBECS: CR 3,587, Defect 210517.<br>Transfusion Requirements Report: CR 3,589 INC 1303428, Defect 210519   | BBM Team                        |                                  |
| 3/11/16  | 20.0                            | <u>Updated for the release of VBECS 2.1.0.</u><br><u>Updated the footer for Defect s and Tasks.</u>  |                                 |                                  |
|  |                                 | <u>Added:</u><br>Discard or Quarantine:Defect 268926, 17048459FY16<br>Release Units From Patient Assignment: Defect 259491, R6690123FY16<br>Select Units: Defect 219714, R5607515FY15. |                                 |                                  |
|  |                                 | Replacement CA SDM ticket number for Remedy HD and INC numbers that are no longer active. Both sets of numbers are listed in this version, old and new.                                |                                 |                                  |
|  |                                 | 208567/ INC 782209 ,I7741648FY16   | 209531/ HD 301562, I7608732FY16 | 210004/ INC 483694, I7736282FY16 |
|  |                                 | 208890, 208863, I7609159FY16   | 209622/ I6131999FY16            | 210195, I7741504FY16             |
|  |                                 | 208952/HD 925191, I7743500FY16   | 209668/ I5535833FY15            | 210196, I7742192FY16             |
|  |                                 | 208962/ I7736134FY16   | 209684/ HD 510102, I7736743FY16 | 210203, I7742363FY16             |
|  |                                 | 209111/ HD 850849, I7742872FY16  | 209700/ I7609296FY16            | 210280, I7746768FY16             |
|  |                                 | 209140, 209811, I7615610FY16   | 209734/ HD 394421, I7611644FY16 | 210414, I7744342FY16             |
|  |                                 | 209213, I7614739FY16   | 209784/ HD 474282, I7712858FY16 | 210418 ,215596, I7744603FY16     |
|  |                                 | 209214, I7614739FY16   | 209792, I7615012FY16            | 210430, I7744748FY16             |
|  |                                 | 209417/ HD 382525, I7609484FY16  | 209921/ I7712348FY16            | 210516, I6133364FY16             |
|  |                                 | 209422, I7740017FY16   | 209939/ I7735618FY16            | 214525/ HD 460025, I7704787FY16  |
|  |                                 | 209433, I7608931FY16   | 209939/ I7735618FY16            | 212246/HD 1054260, I7743149FY16  |
| 209512, 210179/HD 418676, INC 777862, I7614992FY16 | 209978/ HD 489651, I7736458FY16 |  |                                 |                                  |
| 3/31/16  | 21.0                            | Revision History for Version 19.0, CR 2,385: Changed “None” to “Low”.  | BBM Team                        |                                  |

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