Current Status: *Active* **PolicyStat ID:** *13426226*

Sutter Health
Sutter Roseville Medical Center

Origination: *8/13/2020*
Effective: *4/17/2023*
Final Approved: *4/17/2023*
Last Revised: *4/17/2023*
Next Review: *4/16/2025*
Owner: *Nadera Dashty: Supervisor, Lab Analytic*
Policy Area: *Lab - Transfusion Service*
References:
Applicability: *Sutter Roseville Medical Center*

Transfusion Services Test and Quality Assurance Review

PURPOSE

The purpose of this procedure is to provide a mechanism for consistent and timely review of work performed in Transfusion Services for accuracy and conformance to technical and computer procedures.

POLICY

- Work will be reviewed by the Transfusion Services Supervisor or the Transfusion Services Technical Specialist on a regular basis, preferably on the following business day.
- Errors will be classified into 4 categories:
  - Level 1- Amended reports, modifications or deviations from SOP that meet criteria as a biological deviation as defined by the FDA.
  - Level 2- Amended reports, modifications or deviations from SOP that meet criteria as a biological deviation as defined by the FDA if a blood product or RhIg had been issued.
  - Level 3- Testing error that did not meet criteria as a biological deviation as defined by the FDA.
  - Level 4- Computer entry or minor clerical errors or omissions.
- Documentation for corrective action will accompany each monthly summary. Level 1 and level 2 errors require formal documentation due to requirement for root cause analysis as part of FDA reporting. Level 1 errors will be followed up with a patient safety report (PSR). Education, notification, and corrective action for level 3 and level 4 errors will be performed at the discretion of the Transfusion Services Supervisor. Corrective action taken for each error or omission is dependent upon the severity of the incident.

PROCEDURE

Printing Reports

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1.</td><td>In Sunquest roll and scroll call up Quality Assurance Report (BBR7) using the chart below:
<table>
<tr><th>Prompt:</th><th>Enter:</th></tr>
<tr><td>Function</td><td>BBR</td></tr>
<tr><td>Printer</td><td>Enter desired printer</td></tr>
<tr><td>Option</td><td>7</td></tr>
<tr><td>Hospital ID</td><td>RV</td></tr>
<tr><td>Accept (A) Modify (M) Reject (R)</td><td>A</td></tr>
<tr><td>Full Report</td><td>F</td></tr>
<tr><td>Start Date</td><td>T-1 or Date (SQ limit is T-7)</td></tr>
<tr><td>End Date</td><td>T-1</td></tr>
</table></td></tr>
<tr><td>2.</td><td>Repeat sequence in step 2 substituting SS at the Hospital ID prompt.</td></tr>
<tr><td>3.</td><td>In Sunquest roll and scroll call up Test Result Review (Reaction Results) Report (BBR22) using the chart below:
<table>
<tr><th>Prompt:</th><th>Enter:</th></tr>
<tr><td>Function</td><td>BBR</td></tr>
<tr><td>Printer</td><td>Enter desired printer</td></tr>
<tr><td>Option</td><td>22</td></tr>
<tr><td>Patient Allocation Testing Date Range</td><td>4</td></tr>
<tr><td>Hospital Number</td><td>Enter to accept default</td></tr>
<tr><td>Hospital ID</td><td>RV</td></tr>
<tr><td>Accept (A) Modify (M) Reject (R)</td><td>A</td></tr>
<tr><td>Start Date</td><td>T-1 or Date (SQ limit is T-7)</td></tr>
<tr><td>End Date</td><td>T-1</td></tr>
<tr><td>Report Reaction Results?</td><td>Y</td></tr>
</table></td></tr>
<tr><td>4.</td><td>Repeat sequence in step 3 substituting SS at the Hospital ID prompt.</td></tr>
<tr><td>5.</td><td>If reports are printed for test and quality assurance review, complete the Date Printed column on the SRMC Test and Quality Assurance Review Sign-Off log for the BBR7 and BBR22 report.</td></tr>
</table>

Reviewing Quality Assurance Report (BBR7)

Step	Action
1.	Review BBR7 (*Quality Assurance Report*) for HID:RV and all tests resulted with a tech code in the 9000 series for HID:SS. • Look for QA flags that should not have been overridden. • Verify that an appropriate reason code was used for the override. • Verify overrides were performed by CLS only. • Verify that reports that have been amended have the appropriate amended comment appended.
2.	Complete the *Date Reviewed* and *Reviewed by* columns on the *SRMC Test and Quality Assurance Review Sign-Off* log for the BBR7 report.
3.	Save 1st page of blank report and all pages that have information printed for RV report and attach to form. • Save documents after monthly review and retain for prescribed time period. • For HID:SS, discard blank pages and those that are not performed by SRMC.

Reviewing Test Result Review (Reaction Results) Report (BBR22)

This report is a print out of the testing grids and interpretation entries made into Sunquest by accession number. All new information entered or changed in a prior report that has been printed will appear in bold type.

Step	Action
1.	Review the RV and SS (tech codes in 9000 series) report looking for the following information (but not limited to): • If antibody screen results have not been entered using the analyzer interface, that grid reactions have been entered and match the antibody screen interpretation. • Correct recheck code/testing has been ordered for patients whose history question has been answered. • Crossmatches have been resulted correctly and that AHG crossmatches have been done if the patient has a history of clinically significant antibodies or the current antibody screen is positive. • Appropriate attribute codes have been entered for patients who require special products (irradiated, CMV negative, Sickle Cell protocol, HLA matched, etc.) and that those products have been provided. • Weak D test has been performed on Rh negative cord blood samples and maternal postnatal samples prior to completing Fetal Bleed workup. • Antibody identification has been entered, if applicable. • Amended results have been properly documented. • That the units ordered (UO) has been updated appropriately for respective order. • Dated problem information (PB) comment has been added to *Blood Administrative Data* (BAD) file for trauma or unidentified patients. • Special antigen or reference laboratory charges have been added. • Identify patients who have been over charged so that appropriate credits can be made.
2.	Errors/omissions are classified in regards to where in the process the error occurred: Specimen Collection, Clerical Errors, Testing, Product Handling, QC/PM/QA Review, Write Overs or Outpatient Infusion Center as well as the category levels defined in the policy section of this procedure.
3.	Collate the information and document corrective action on the *Biological Deviations* spreadsheet for each occurrence.
4.	Review data for trends or possible problems with processes or procedures during the monthly review.
5.	Graph data results and include with the monthly review.

Follow Up Action

Using the chart below, take the appropriate follow up action:

If:	Then:
Level 1, 2, 3, or 4 error	• Repeat testing as needed. • Edit results. • Amend any external reported test results. • Forward to Transfusion Services Supervisor for follow up. • Level 1 errors require FDA report and PSR.
Charges missing	Add appropriate charge codes in Sunquest.
Error that results in over charging patient	Add Sunquest credit/bill code, if available, or leave information in Transfusion Services Supervisor's mailbox.

All revision dates: 4/17/2023, 4/21/2021, 8/13/2020

Attachments

Biological-Product-Deviation-Reporting-Blood-and-Plasma-Establishments_March-2020.pdf
SRMC Test and Quality Assurance Review Sign-Off.pdf

Approval Signatures

Step Description	Approver	Date
Medical Director	Lindsey Westerbeck: Executive, Lab Services	4/17/2023
Laboratory Director	Lindsey Westerbeck: Executive, Lab Services	4/4/2023