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Review of Quality Control - Dearborn Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

The purpose of this document is to provide policies relating to the review of quality control (QC) in the Blood Bank.

II. DEFINITIONS:

A. Daily: On a given calendar date
B. Monthly: Within the first weeks of each calendar month.
C. Quarterly: Every 3 months ± 2 weeks; typically in the calendar months January, April, July and October.
D. Bi-Annually: Every 6 months ± 1 month.
E. Yearly: Every 12 months ± 1 month.
F. Beaumont Health Biomedical: Performs repairs and some maintenance of equipment for Beaumont Hospital.

III. POLICIES:

A. Frequency of Quality Control Review

1. The frequency at which QC is reviewed is defined within individual procedures. In general, the following are reviewed: reactivity of reagents and their controls, instrument function checks, and temperature records. QC data must be reviewed and assessed at least once monthly; however, several QC tasks are reviewed at more frequent intervals as defined in the individual procedures.

B. Documentation of QC Review

1. QC review is documented on the applicable form (the form on which the QC data is recorded during normal operations). The Transfusion Services Department Supervisor or Lead Medical Technologist will initial and date the form, along with a notation that the QC has been reviewed.
2. The QC of routine reagents may also be documented in the Blood Bank computer using various reagent QC racks; the review of these QC racks is documented as described in the *Blood Bank CDM - Reviewing and Releasing QC Results in SoftBank.*

C. Purpose of QC Review

1. Whether QC review is documented on a form or in the computer, the documentation of QC review signifies that the Supervisor or Lead Medical Technologist has verified the following:
    a. The form or computer record has been documented completely.
    b. All documented data is within the acceptable range, as defined in the corresponding procedure.
    c. All data has been documented in accordance with the applicable procedure.
    d. If any data is not within the acceptable range, a variance report has been submitted.
    e. Corrective action is initiated, when indicated.
    f. Reagents, supplies, and blood components are used within their expiration date.

D. Personnel Responsible to Review Quality Control

1. The Blood Bank Medical Director has designated the Supervisor or Lead Medical Technologist (MT) to review quality control. While it is preferable that an individual does not review one's own QC, it is acceptable for either supervisor/lead MT to review one's own QC due to the limited number of scheduling factors, limited number of Lead MTs and to ensure that QC is reviewed in a timely manner.
2. The Supervisor or Lead Medical Technologist has been designated to review laboratory information system (LIS) Exception report to monitor any inappropriate or change of results that have been entered into the computer as was as ensuring consistency of policy adherence for processing, resulting, allocating and issuing of products.
3. The Supervisor or Lead Medical Technologist has been designated to review all antibody panels' worksheets for correct interpretation of results, certainty that all significant antibodies are ruled out appropriately, and to make sure all appropriate antigen typing has been performed.
4. The Supervisor or Lead Medical Technologist has been designated to review all downtime patient, unit or component testing worksheets to ensure that the results have been entered correctly into the computer with no clerical errors.

E. Periodic Review by the Blood Bank Medical Director

1. The Blood Bank Medical Director may periodically review QC or audit QC related tasks for a variety of reasons including the implementation of new instrumentation, methodologies, or procedures; information obtained from variance reports; process improvement initiatives; concerns raised at staff meetings or daily huddles; changes in regulatory requirements, etc.

F. Variance Reporting

1. A variance is any event detected that may be an error, accident, complaint, unplanned deviation, or incident that is documented for review, evaluation, investigation, and correction. A variance report is used to document these issues and the corresponding corrective action. For example, a variance report must be documented when components are prepared that do not meet the QC requirements, or any QC data is outside of the acceptable level as defined in the corresponding procedure or policy. Refer to Transfusion Medicine Policy, *Variance Reporting* for additional information.

IV. REFERENCES:

1. CAP Transfusion Medicine Checklist, Current Edition.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	1/19/2022
Policy and Forms Steering Committe (if needed)	Kelly Sartor: Supv, Laboratory	1/18/2022
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	1/18/2022
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	Kelly Sartor: Supv, Laboratory	1/8/2022
	Kelly Sartor: Supv, Laboratory	1/8/2022

Applicability

Dearborn