PROCEDURE
Corewell Health East - Review of Quality Control and Preventative Maintenance - Blood Bank

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Grosse Pointe Hospital, Corewell Health Beaumont Troy Hospital, Corewell Health Dearborn Hospital, Corewell Health Farmington Hills Hospital, Corewell Health Taylor Hospital, Corewell Health Trenton Hospital, Corewell Health Wayne Hospital, Corewell Health William Beaumont University Hospital (Royal Oak)

Applicability Limited to: N/A

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Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Blood Bank

1. Principle

This document provides policies relating to the review of quality control (QC) and preventative maintenance (PM) in the Blood Bank. The review of QC and PM data must be recorded and include follow-up for outliers, trends, or omissions that were not previously addressed.

A. Laboratory quality control is all the measures put in place to eliminate the risk of non-conforming outcomes. It involves systems that safeguard the accuracy, reliability, and timeliness of lab results by early detection of results or measurement errors and the procedures to rectify them.
B. Maintaining accurate and frequent checks of laboratory sample testing through quality control is vital to ensure that patient testing is done right and that it produces accurate results. The integrity of quality control samples is important to both management of overall quality as well as to meeting requirements of proficiency testing.
C. By utilizing quality control practices, a laboratory self-regulates its testing and verifies that the results produced are accurate and precise.
D. 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.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks; usually the Manager, Supervisor, or Lead Medical Technologist, or in some cases Medical Technologists who have been authorized to perform certain review tasks.

3. Definitions

A. QC: Quality Control
B. PM: Preventative Maintenance
C. Precision: Degree of agreement among repeated measurements of the same characteristic on the same sample.
D. Accuracy: How close results are to what is expected from a test

E. Daily: On a given calendar date
F. Monthly: Within the first 2 weeks of each calendar month.
G. Quarterly: Every 3 months ± 2 weeks; typically, in the calendar months January, April, July and October.
H. Bi-Annually: Every 6 months ± 1 month.
I. Yearly: Every 12 months ± 1 month.
J. Designee: Any Blood Bank technical director, or transfusion medicine fellow.
K. CAP: College of American Pathologists
L. Corewell Health Biomedical: Performs repairs and some maintenance of equipment for Corewell Hospital.

4. Procedure

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

B. Frequency of Quality Control Review:
   1. The frequency at which QC/PM 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/PM data must be reviewed and assessed at least once monthly; however, several QC/PM tasks are reviewed at more frequent intervals as defined in the individual procedures.
   2. Of all quality assurance processes, management review is the most important in terms of driving improvements and efficiency to deliver benefits to the Blood Bank beyond compliance.

C. Criteria for Satisfactory QC / PM Review:
   1. QC/PM review is considered satisfactory if the following criteria are met:
      a. The form or computer record has been documented completely and correctly, following the required frequency as indicated in the procedures.
      b. All documented data is within the acceptable range and in accordance with the applicable procedure.
      c. Reagents, supplies, and blood components are used within their expiration date.
      d. There are no outliers, trends, or omissions that were not previously addressed.

D. Documentation of Quality Control and Maintenance Review:
   1. QC and maintenance review is documented on the applicable form(s). This may include the form on which the QC/PM data is recorded during normal operations, and any additional form(s) that pertains to each individual Blood Bank (see Attachments).
   2. The Blood Bank Manager, Supervisor, or Lead Medical Technologist will initial and date the form, indicating that the QC/PM has been reviewed.
   3. If the QC/PM review is unsatisfactory, perform the following:
      a. Document a brief note on the applicable form, indicating why the QC/PM is unsatisfactory.
      b. Document a variance report and submit it to the Manager, Supervisor, or Lead Technologist.
      c. A follow up and investigation must occur for any outliers, trends, or omissions that were not previously addressed.

E. Personnel Responsible to Review Quality Control:

1. The Blood Bank Medical Director has designated the Manager, 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 Manager, Supervisor, or Lead MT to review one's own QC due to the limited number of scheduling factors, limited number of Lead MTs and/or to confirm that QC is reviewed in a timely manner.
2. The Manager, Supervisor, or Lead Medical Technologist has been designated to review the laboratory information system (LIS) Factor Overrides to monitor the consistent adherence to policy for processing, resulting, allocating, and issuing of products.
3. The Manager, Supervisor, or Lead Medical Technologist, as well as medical technologists that have been authorized, are designated to review all antibody panels' worksheets for correct interpretation of results, certainty that all significant antibodies are ruled out appropriately, and to confirm that all appropriate antigen typing has been performed.
4. The Manager, Supervisor, and Lead Medical Technologist, as well as medical technologists that have been authorized, are 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.
5. The Blood Bank Medical Director may periodically review QC/PM or audit QC/PM related tasks for a variety of reasons including:
   a. The implementation of new instrumentation, methodologies, or procedures.
   b. Information obtained from variance reports.
   c. Process improvement initiatives.
   d. Concerns raised at daily rounds, staff meetings, or daily huddles.
   e. Changes in regulatory requirements.
6. Any QC task that is performed by a Laboratory Assistant, or any other employee who is not a Medical Technologist, must be reviewed by the following day. For example, a Laboratory Assistant may document plasma bath cleanings on the Daily Temperature and Quality Control Record; this data is reviewed the following day by a Medical Technologist.
7. See attachments for documentation forms used by each blood Bank

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.
2. A variance report is used to document these issues and the corresponding corrective action.
   a. 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.
   b. Refer to Transfusion Medicine Policy, Corewell Health East - Variance Reporting - Blood Bank - All Beaumont Hospitals for additional information.

5. Revisions

Corewell Health reserves the right to alter, amend, modify, or eliminate this document at any time without prior written notice.

6. Procedures Superseded and Replaced: This procedure supersedes and replaces the following procedures as of the effective date of this procedure: [33986 Corewell Health East – Review of Blood Bank Quality Control and Preventative Maintenance – Troy, 33808 Corewell Health East – Review of Quality Control – Blood Bank – Dearborn, 33920 Corewell Health East – Review of Quality Control – Blood Bank – Royal Oak**]**

7. References

A. AABB, Technical Manual, current edition.
B. CAP, Transfusion Medicine Checklist, current edition.

8. Procedure Development and Approval

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9. Keywords
Not Set