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

This Procedure is Applicable to the following Corewell Health sites:
Corewell Health Beaumont Troy Hospital

Applicability Limited to: N/A

Reference #: 33986

Version #: 2

Effective Date: 05/23/2025

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 ensuring 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.

2. Responsibility

Personnel who have completed the competency requirements will perform these 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 weeks of each calendar month
G. Quarterly: Every 3 months ± 2 weeks

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. Biomedical: Facilities department that performs repairs and some maintenance of equipment for Corewell Health

4. Procedure

A. Purpose of QC / PM Review
1. 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.

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 (the form on which the QC/PM data is recorded during normal operations).
2. The Blood Bank Supervisor or Lead Medical Technologist will initial and date the form, along with a notation 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 supervisor or designee.
   c. 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 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 confirm that QC is reviewed in a timely manner.
2. The Supervisor or Lead Medical Technologist has been designated to review the laboratory information system (LIS) Factor Overrides to monitor any inappropriate or change of results that have been entered into the computer as well as the consistent adherence to policy for processing, resulting, allocating and issuing of products.
3. The Supervisor or Lead Medical Technologist, as well as medical technologists that have been trained have been 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 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.
5. 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.
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.

G. Daily QC Review of Routine Reagent QC
1. Daily QC may be reviewed by the Blood Bank Supervisor, Lead Medical Technologist, or Medical Technologist.
2. The routine reagent QC racks are documented at midnight and described in Transfusion Medicine procedure, *Quality Control of Routine Blood Bank Reagents and Quality Control of the Manual Gel System Reagents*.
   a. Daily QC is documented on downtime forms; *Reagent List for Quality Control of Manual Testing, Manual 60 Minute No LISS and Tube DAT QC Log, Manual Blood Bank Reagent QC Log, Manual Gel Screen and Gel DAT QC Log, and Manual Tube ABO/Rh QC Log.*
   b. Antigen typing QC is documented on the antigen typing worksheet.
   c. Determine whether the criteria for satisfactory QC / PM review are met and document as "S" (satisfactory) or "U" (unsatisfactory) on the Transfusion Medicine form, *Review of Daily Reagent QC Racks*.

H. Monthly Review of QC
1. The monthly review of each QC by the Blood Bank Supervisor or Lead Medical Technologist is documented on Transfusion Medicine form, *QC and Preventative Maintenance Checklist*.
2. The Medical Director reviews and documents monthly QC review on the Transfusion Medicine form, *Record of Monthly Quality Control Review*.

I. Monthly Review of PM
1. The monthly review of each PM is documented on Transfusion Medicine form, *QC and Preventative Maintenance Checklist*.
2. The Medical Director reviews and documents the monthly PM review on Transfusion Medicine form, *Record of Monthly Quality Control Review*.

J. Documentation of Unsatisfactory QC/PM
1. For any unsatisfactory QC/PM 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 supervisor or designee.
c. Follow-up and investigation must occur for any outliers, trends, or omissions that were not previously addressed.

5. Revisions

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

6. References

1. AABB, Technical Manual, current edition.
2. CAP, Transfusion Medicine Checklist, current edition.

7. Procedure Development and Approval

Document Owner:

Laura Judd (Operations Specialist)

Writer(s):

Alyssa Malone (Medical Technologist Lead)

Reviewer(s):

Ghada Hawasli (Medical Technologist Lead)

Approver:

Brittnie Berger (Dir Sr, Lab Operations), Elzbieta Wystepek (Dir, Laboratory Services), Kelly Sartor (Mgr, Division Laboratory), Masood Siddiqui (Staff Pathologist), Ryan Johnson (OUWB Clinical Faculty), Sarah Britton (VP, Laboratory Svcs), Teresa Lovins (Supv, Laboratory)

8. Keywords

Not Set