PROCEDURE
Corewell Health East - Chemistry Quality Control - Troy

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

Applicability Limited to: N/A

Reference #: 34357

Version #: 2

Effective Date: 10/23/2025

Functional Area: Clinical Operations, Laboratory

Lab Department Area: Lab - Chemistry

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1. Purpose and Objective

A. The Chemistry laboratory adheres to the Quality Control (QC)/Quality Improvement (QI) program known as Process Improvement (PI) that is outlined in the General Laboratory Policy and Procedure Manual.

B. Presently the most acceptable means of maintaining quality control of chemical analysis in the laboratory is by monitoring specific assay reproducibility with use of commercially prepared control sera, both assayed and unassayed type having a wide range of results. By observing the results of these controls, a decision can be made using guidelines described later in this procedure whether to accept or reject the results of patient analyses.

C. The frequency of running quality control materials varies for each analyzer. Refer to that particular analyzer's procedure manual for specific information regarding which controls are presently being used and how often they are run. Control specimens are tested in the same manner and by the same personnel as patient samples.

D. Each time controls are run their performance must be reviewed prior to releasing patient results.

2. Responsibility

Personnel who have completed the competency requirements will perform these tasks.

3. Definitions

A. **Random Error**: An error whose cause cannot be determined. It can be caused by instability of reagents, instability of measurement conditions such as fluctuations in temperature or voltage of an instrument or wave-length, variability of timing, pipetting or individual technique.

B. **Systematic Error**: A consistent error arising from determinable cause that will affect all measurements in the same direction. Possible causes are incorrect operation of an instrument, instrument calibration, reagent blanks, standards, incorrect dilution or errors by the analyst.

C. **Trend**: A gradual change of control values in one direction, usually greater than ten. It can be due to deterioration of reagents or standards, a dirty measuring cell or other problems.

D. **Shift**: A sudden change of control values in one direction. It can indicate a complete change in one of the reagents or standards.

E. **SD**: Standard Deviation

F. **A1-2s**: Run accepted control is 2-3 SD, other control is <2SD, Last run, control is <2SD.

G. **R 1-3S**: Run rejected. Control is + 3SD.
H. **R 1-2S**: Run rejected. Control > 2SD (Used where there is no provided 2-3SD range).
I. **R 2-2S-0**: Run rejected. Control 2-3 SD other control is 2-3 SD.
J. **R 2-2S-L**: Run rejected. Control 2-3SD. Last run of the same control level is 2-3 SD.

4. Procedure

A. Monthly Quality Control Monitoring
   1. Chemistry and Immunoassay QC analyzers are managed by the Bio-Rad Unity program. Technologists review the QC performance in the program each time they are tested.
   2. Radiometer ABL analyzers are monitored individually by reviewing the computer screen on each analyzer for errors or, by viewing the QC logs on each instrument.
   3. Rejected controls, exceptions and corrective actions need to be documented for each issue.
   4. Quality control results are submitted monthly to the appropriate company for peer group comparison and performance review.
   5. Each month summary reports are provided by Radiometer and Bio-Rad. These reports are reviewed on a monthly basis by the laboratory Medical Director or designee and reviewed by the Chemistry Supervisor or Lead Technologist.
   6. Significant changes in the reports are investigated and documented.

B. Setting Control Ranges

   Primary control material, also known as unassayed or assayed control materials should be tested by repeat analysis to determine a mean and standard deviation for each quantitative method supported by the control. These materials may or may not have a manufacturers' stated range provided with the material.
   1. Unassayed Controls are evaluated on each analyzer over at least 10 analytical runs up to a maximum of 20 runs.
   2. Assayed Controls at minimum need to be validated by running a new lot within an acceptable run of the current lot of control materials
   3. After validation, new lots of assayed and unassayed controls will be assigned a mean and standard deviation(sd) appropriate for our facility.

C. Quality Control Acceptance Criteria
   1. One control out:
      a. > 3SD- Reject run.
      b. >2SD and no + 2-3 SD range is posted- Reject run.
   2. 2 levels of controls + 2-3 SD and a range is posted:
      a. Check the other control in the run- > + 2SD reject the run.
      b. If the other control is <2SD then check the previous result for the control. If >+ 2 SD reject the run.
      c. If the previous value was <2SD, accept the run.
   3. 3 or more levels of controls :
      a. Any one control value is >3SD, reject run.
      b. Any two control values are + 2-3 SD, reject run.
      c. If any one value is +2-3 SD check the result from the previous time that level was tested. If the last value was also 2-3 SD, reject run.

D. Rejected QC runs
   1. Check all expiration dates for reagents and QC materials. Replace if necessary.
   2. Review QC charts to determine if there has been a shift/trend. QC may shift with the introduction of new lot numbers and, a new mean may need to be established. Consult supervisor, Lead Medical Technologist or designee to investigate.
   3. Repeat failed QC with fresh QC vial
   4. Do not process patients on the affected analyzer until QC issue is resolved.
   5. Open new reagent if volume is low or pack has been on the analyzer for an extended period.
   6. Recalibrate reagent, use a different calibrator, check instrument operating parameters, call the instrument hotline and notify supervisor or supervisor designate of the issue. A different

lot of calibrator, reagent or QC may be borrowed from another hospital in the system to assist with troubleshooting, if necessary.

7. When QC is acceptable, the instrument may be used for testing the affected analyte.
8. Samples tested during the rejected run may need result correction.
    a. Attempt to identify when failure started.
    b. Look back to last valid QC results for the parameters in question. Check for reagent additions, calibrations etc. that may have affected QC results.
    c. Repeat patients:
        1) If the batch of patients is small, rerun the affected patients. Example: fetal fibronectin or Osmometer.
        2) If the batch is small, repeat the 5-10 patients prior to the failed QC. Example Architect instruments, tests with low daily volume.
        3) Search Stored Results on the affected Architect instrument by analyte and repeat the most recent patients on the list.
        4) Proceed backwards in groups of 5-10 until you find the group where the original results match the repeated patient results.
        5) If the batch is large where hundreds of patients have been processed, repeat the recent patients and evaluate results.
            a) If results match the previous results, then patient results will not need correction.
            b) If the patient results do not match previous result, Chart review in the Laboratory Information System (LIS). Samples with significantly different results (ie. changed from normal to abnormal or vice versa, large delta check) along with those with no previous value must be retested.
            c) Use Instrument Manager (IM) the stored results screen on the affected instrument to locate patients and rerun the affected tests. The repeated result will appear in IM with a new date and time of testing. Results can be re-sent from IM to the LIS, if necessary.
9. Correct significantly different results as required in the LIS:
    a. Notify appropriate personnel of the corrected reports.
    b. Notify the Medical Director of Chemistry whenever multiple results must be corrected.
    c. Document the problem, patient comparisons and the resolution of the issue.

E. Documenting QC results exceeding + or - 2 SD.
1. Osmometer:
    a. Circle control result.
    b. Document whether the run was accepted or rejected and the QC rule used.
    c. Add action taken to bring the QC into control.
2. Architect Instruments:
    a. When control is > 2SD but, less than 3SD check the previous results in IM or instrument QC logs. If the previous result was also >2 SD, then reject run.
    b. Omitted QC values require an explanation of what action was taken-Wrong QC level run, re-calibration, QC-rerun OK, new reagent etc.
    c. In the Architect, document when a QC data point is "Excluded". (QC/CAL- Levey Jennings) what action was taken to resolve the issue.

F. Adjusting QC ranges:
There are certain circumstances when an assay's QC has shifted and a range change is warranted. A thorough investigation should determine the cause of the shift and whether service is needed for the analyzer. Document what is discovered and any corrective action that has occurred.
1. Prior to adjusting ranges check:
    a. Lot numbers of reagents (is it a new lot?).
    b. Lot numbers of calibrators (is it a new lot?).
    c. Other assays with QC issues on the same analyzer.
    d. Maintenance and service reports.
2. If no explanation is found after checking the above:

a. Call the analyzer hotline.
b. Call Bio-Rad technical support (800-854-6737).

G. Validation of New Reagent Lots:
1. Calibrate new lot on analyzer.
2. Run Quality Control.
3. Run patient correlation following the Reagent Lot-to-Lot Patient Comparisons Procedure

5. Revisions

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

6. References

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7. Procedure Development and Approval

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8. Keywords

Not Set