HACKETTSTOWN REGIONAL MEDICAL CENTER
LABORATORY POLICY MANUAL
QUALITY CONTROL
LABORATORY DEPARTMENT ACCEPTABILITY GUIDELINES

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PRINCIPLE: Sound quality control systems are essential to providing excellent pathology and clinical laboratory services. Consequently, the laboratory's quality control systems need to be designed to ensure the medical reliability of laboratory data. The goal of the quality control function is to achieve quality in laboratory testing and produce the best possible test results and outcomes.

PROCEDURE: As follows.

1. Acceptable control values are defined as +/-2 SD of the analyte/method mean except where the control is an absolute such as negative or positive.

2. If a control value is within the established range, patient results for the analyte/method may be reported.

3. When a control value is outside the established range, patient results should not be reported and corrective action should be initiated by the technologist.

4. Quality control materials are run in the same manner as patient specimens.

5. Hematology QC will print automatically and placed in Daily QC binder after review.

6. Coagulation controls must be printed manually on evening or night shift (after running QC) and placed in Daily QC binder after review.

7. Urinalysis and Chemistry QC prints automatically and will be filed with the daily work.

8. All serology QC results will be logged on the appropriate testing sheet

Note: Record all quality control runs on the log sheet or in the computer system.

ESTABLISHING A RANGE

1. For unassayed controls, each method/analyte will be analyzed a minimum of 25 times over a 30 day period, including previously tested Quality Control material.

2. The method analyte mean will be established by using ; $\overline{x} = \Sigma N/N_1$

   $\overline{X}$ = Mean of analyte results
   N = Sum of analyte results
   N_1 = Total number of results

3. The range will be established by using; $SD\overline{x}$ * %CV
   SD = Standard Deviation

   $\overline{X}$ = Mean
   % CV = Cumulative coefficient of variation for the method
   Range is equal to ; $\overline{x}$ +/-2SD

4. For assayed controls, parallel lots should be run a minimum of five times and results compared. The observed mean and standard deviation should fall within the range published by the manufacturer.

CORRECTIVE ACTION

1. Rerun the analyte/method using the same quality control material. If the control value is within the established range, patient results may be reported. If the control value is outside the established range, proceed to step 2.

2. Rerun the analyte/method using a fresh aliquot or a freshly reconstituted/opened bottle of the quality control material. If the control value is within the established range, patient results may be reported. If the control value is outside the established range, proceed to step 3.

3. Check the reagents for discoloration or bacterial contamination. Replace if necessary. Rerun the quality control material. If the control value is outside the established range, proceed to step 4.

4. Calibrate the analyte/method (if applicable). Rerun the quality control material. If the control value is within the established range, patient results may be reported. If the control value is outside the established range, proceed to step 5.

5. Observe the instrument function; are any syringes moving erratically? Are air bubbles present in the pump lines? Is there sufficient reagent, etc.? Correct any instrumentation problems and perform any delinquent maintenance. Rerun the quality control material. If the control value is within the established range, patient results may be reported. If the control value is outside the established range, proceed to step 6.

6. Contact the manufacturer/instrument hot-line. Perform any check, maintenance or suggestions they may ask. Rerun the quality control material. If the control value is within the established range, proceed to step 7.

7. Notify the supervisor.

Note: Document all steps taken on the corrective action logs or in the appropriate computer system.

REVIEW

1. The technologist performing the quality control will be responsible for its review and corrective action on a daily basis. QC will print daily and after documented review, be placed in Daily QC binders or folders in the department. Documentation will be by initial and date.

2. The director or designee (Laboratory Manager, Supervisor, Respiratory Lead tech) will review weekly. Indications of shifts, trends and biases will be noted after review (and printing) of Levy-Jennings charts and QC results. Review of proper corrective action will be noted.

3. The Laboratory Supervisor or designee will submit the raw data to the respective Quality Assurance Programs for statistical comparison. This will be done after review on a monthly basis.

4. The Laboratory Manager or Supervisor will review the QAP data each month comparing in-lab current, in-lab cumulative and group cumulative data. CVs and SDIs will be monitored and compared to previous months. Any outliers > 2 will be investigated. The Laboratory Director will review QAP reports monthly.

REFERENCES

CLSI, Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved guideline – Third Edition 2006.