QUALITY CONTROL PROGRAM GENERAL LABORATORY

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PURPOSE

To describe the quality control systems in place at FHS Laboratories.

BACKGROUND

The Laboratory Quality Plan involves monitoring the facilities, personnel, test methods and equipment, reagents, materials and supplies, procedure manual, equipment maintenance, calibration and calibration verification, control procedures, remedial actions, and maintenance of quality control records.
Quality control (QC) is a process for assessing the accuracy and reliability of a test system. The goal of Quality Control as part of Laboratory Quality Plan is to assure the reliability of laboratory test data. Quality Control systems are used to predict and control variation in any analytical technique and to insure that results are reliable, accurate, precise, meaningful and timely.

In the clinical laboratory this is accomplished by running specimens with known values (controls) along with patient unknowns to determine if the analytical system is functioning within prescribed boundaries. The Quality Control Policy includes frequent and regular review of data by technologist, MT Coordinator and Manager.
For quantitative tests, the laboratory manager sets the limits. Quality control limits are clearly stated in the QC policy for each department and in the specific Work Instruction. The method used to evaluate quantitative QC data is the Levey-Jennings approach and the applicable Westgard rules.

RELATED DOCUMENTS

Critical Supply Log	J-F-CH0805
Quality Control Westgard Rules Statistics	R-PO-CH0809
Lot to Lot Correlation Log	R-F-CH0814
Failed Patient Run	R-P0-CH0808
Failed Patient Run Verification Form	R-F-AD4368
Quality Plan	R-PO-AD0600
Quality Policy Equipment	R-PO-AD300
Quality Plan Error Prevention	R-PO-AD0545
FDA Medical Device Reporting	R-PO-AD0330

CALIBRATION AND CALIBRATION VERIFICATION

See FDA Medical Device Reporting

QC RECORDS

See Quality Plan

MAINTENANCE /FUNCTION CHECKS

See Quality Policy Equipment

REMEDIAL ACTION/ CORRECTIVE ACTION

See Quality Plan and Error Prevention and Detection Policy

VALIDATION OF METHODS

See Quality Plan
FDA Medical Device Reporting
Quality Policy 3 Equipment
Method Validation Policy

STATISTICAL QUALITY CONTROL

For quantitative assays, performance is monitored through the use of quality control material with matrices similar to patient specimens. Control specimens are included in the run and assayed in the same manner as patient specimens. Control results are recorded in the Laboratory Information System. Run validity is judged by the use of the Westgard multi rule control scheme. The control rules used are assay dependent. The number of control levels used, either two or three, likewise is assay dependent. Materials used are typically unassayed, some are assayed. The actual mean, standard deviation from the mean and coefficient of variation (expressed as a percent of the mean) are calculated for each assay and used to establish internal control ranges.
R-F-AD4368-00
For unassayed and assayed controls, values are compared to peer group or historical statistical data to better evaluate the obtained control values.

See Statistical Quality Control using Westgard Rules Policy

DAILY QUALITY CONTROL

Quality control performance is documented using control materials for each analyte each day that tests are run in the laboratory.

Frequency and control material is listed in the section specific Quality Control Information Chart. Controls are treated the same as patient specimens. No patient test results are reported unless the control results are adequate. Manufacturer's instructions and other general quality control measures for their particular test are adhered to.

TEMPERATURE MONITORING

Equipment temperatures are recorded daily and checked against established range. Corrective action is initiated for temperatures outside established range. If acceptable temperature ranges for refrigerators and/or freezers are exceeded, the contents are sequestered and evaluated for possible adverse effects. When evaluation is complete reagents deemed stable for use are released to inventory.

If controlled temperatures are critical for a particular procedure, temperatures are checked at the beginning and end of the process to assure stability.

When a new refrigerator or freezer is brought into the general lab, the temperature must be monitored daily for 7 days and found to be acceptable before the equipment can be used in the lab.

Blood bank temperature-controlled storage devices are monitored for at least 24 hours upon receipt, then subjected to instrument qualification guidelines specific for that storage device.

REVIEW PROCESS

The Quality Control Policy includes the prompt review of processes to detect significant clerical, analytical errors and unusual laboratory results. These processes are designed to provide timely correction of errors. Quality Improvement Measurements (QIM), Failed Patient Run Forms, Daily Quality Control Outlier Reports, Quality Control Processing Reports, Summary Statistic Reports, Results Review Reports, Error Correction Reports, Maintenance logs, Communication logs, etc. are part of the systematic review of processes.

Quality control requires constant review and communication of any deviation from established processes to include control values. Some of the activities include but are not limited to the below listed processes.

1. The technologist performing the assay reviews values.

2. The technologist uses statistical QC rules to determine if the QC values obtained fall within acceptable limits.

3. Quality Control results are entered into the LIS and reviewed for acceptance criteria following Westgard Rules.

4. Shifts /trends, etc. are evaluated and documented by the technologist.

5. The Medical Technologist Coordinator is notified if corrective action is indicated.

6. The anion gap calculation is used as additional quality control warning.

7. Day to day oversight of QC parameters and corrective action is documented in Cerner using QCI, or when available, the instrument software screens that allows footnoting.

8. Reagent performance is evaluated and documentation is noted in the Critical Supply Log or Lot to Lot Correlation Log or EP Evaluator.

9. Instrument error logs are printed and reviewed daily by technologist and the need to troubleshoot is assessed.

10. The technologist is responsible for informing the MT Coordinator or Manager of repeated QC failures and instrument problems so proper troubleshooting can be instituted, using the Failed Patient Run Policy if necessary.

11. QIM forms are completed for mislabeled specimens, rejected specimens, unacceptable delays and other noted problems to include QC and reagents and equipment.

12. Corrective action to include troubleshooting is included in this process of identifying problems and implementing system solutions. All steps are documented in the proper log or worksheet.

~~13.~~ QC is reviewed more frequently on any instrument that has an analyte under observation due to new reagent, QC ranges or instrument problems. The Manager or MT Coordinator or designee reviews the L-J charts.

14. The Manager or MT Coordinator or designee reviews the monthly QC Charts and Summaries.

RECONSTITUTION OF CONTROLS AND CALIBRATORS

Manufacturer's instructions are followed when preparing control material, reagents and calibrators. The technologist performing the task strictly adheres to material requirements such as volume, stability, temperature, storage conditions, mixing and all other variables that can affect the accuracy of control data. Reconstitution of calibration and control materials used in quantitative assays is performed with a pipette. Plastic transfer pipettes are used only when volume required is approximate, procedures that require patient sample or control material delivered in drops or if test kits come with pipettes, these should be used to perform testing.

Calibrators, controls, reagents and all other materials are inspected prior to use to check for expiration dates and signs of contamination.

To obtain consistent vial-to-vial assay values the control material requires proper storage and handling. Some general guidelines to follow when handling control material are:

- Treat control material same as patient specimen and run in accordance with the instructions accompanying the instrument, kit or reagent being used.
- When indicated allow controls to reach room temperature prior to use, do not leave a room temperature for excessive periods unless this is the indicated storage temperature.
- Swirl controls and reagents gently to attain homogeneity, avoid bubble formation.
- Promptly after use replace stopper and return to storage temperature.
- Do not use past expiration date.
- Controls are not intended to use as standards.
- If there is evidence of microbial contamination or excessive turbidity, discard the vial.

REAGENT VERIFICATION PROCESS

Reagent performance is verified for each shipment and lot number of reagent received before it is put into service. New Reagent lots, when applicable, are tested in parallel with old lots or concurrently to insure the new lot or shipment yields consistent patient results. For quantitative tests, reagent validation is performed by assaying QC material, old PT material and or patient samples.

If calibration material is not utilized for the assay, a Lot to Lot Correlation of the new reagents is done. A minimum of 5 samples are used to determine this correlation.

If calibration material is utilized for the assay, new shipments of the same lot are validated using calibration when necessary and QC alone, as there should be no change in potential matrix effects on shipments of the same lot. If reagent does not meet criteria further, evaluation is required.

For new Protime reagents, the Geometric Mean of the Protime and INR must be validated before being put into use.

FHS laboratories, when applicable, requests data from vendors on previously conducted studies and compares to current data obtained during the reagent verification process.

The reagent performance, whether the reagent passes or fails and the date the reagent is placed into service are documented on the Critical Supply Receipt log.

FHS Laboratory uses only reagents labeled with their identification, the date received, the lot number, an expiration date and recommended storage requirements. Reagents and supplies are not used beyond their expiration dates, except in rare circumstances after validation of the new expiration date, and medical director approval.

For reagents that do not have an expiration date provided by the manufacturer, FHS laboratory managers will assign an expiration date of a year and set a validation frequency to test reagent stability or department specific.

Components of any kits of reagents are not interchanged with other kits with different lot numbers unless specifically allowed by the manufacturer. Lids are always replaced on dry reagents to avoid premature deterioration. Aseptically approved laboratory practices are used when preparing reagents.

MONTHLY QUALITY CONTROL REVIEW

Levey-Jennings Charts and Monthly Summary Reports show the performance trends of standard control parameters and control samples and are monitored by the Manager or MT Coordinator or designee.

When reviewing this data the following points are considered:

a. Appearance of the Levey - Jennings plots:
   - Are the points evenly scattered about the mean?
   - Are the majority of the points within +/- one SD?
   - Are shifts or trends evident?
   - Appropriate footnoting and documentation

b. Review of statistical parameters/ historical statistical review:
   - Do the current month's means and standard deviations approximate the previous month's means and standard deviations?
   - Do the monthly means and standard deviations approximate the given mean and standard deviation?

If test data are acceptable, no further action is required other than document review.

If a test system or analyte has unacceptable data due to imprecision, systematic error, sudden cumulative data shift, or not correlating with peer data the reasons for unacceptability are investigated by the manager or MT Coordinator or designee.

The investigational process includes areas such as calibration history, new lot changes, maintenance and any other variable that can affect the data. The investigation also evaluates the result of the shift on patient result data. Control statistics are updated once the problem is identified and corrective action is initiated.

All quality control ranges are reviewed and updated as needed by the Manager or MT Coordinator or designee.

A Data Summary report of QC Peer group comparison (such as Beckman IQAP Hematology or BioRad Control Data QC Net, etc.) is reviewed if available to verify that values for SDs and CVs are within the peer group values for the instrument and analyte.

The ~~Manager or Designee~~ Manager or MT Coordinator or designee performs monthly review of departmental QC, maintenance records and temperature charts.

ESTABLISHING A NEW QUALITY CONTROL BASE

For quantitative tests, a new control database is established. The Laboratory Director or designee establishes quality control limits. For unassayed controls, all control material of a new lot is run concurrently with the existing lot to obtain a minimum of 20 data sets over 5-10 working days (ideally). Prior to phasing out the old set, data are evaluated to determine if more values are required to complete the evaluation. Calculations include the mean, SD and CV; these values are compared to data obtained from previous lots of control material.

When evaluating assayed control ranges, the data provided by the manufacturer is used as a guideline. FHS Laboratories evaluate collected data and compare to historical statistical data for the analyzer / analyte and determines if adjustments are needed to the manufacturer provide ranges. If the values obtained match the manufacturer provided ranges and no adjustments are indicated this is recorded during the data review process, if adjustments are indicated and new ranges are set, the recovery ranges should fall within the manufacturer provided ranges.

For low frequency methods, controls are run several times each run by different technologists to accumulate sufficient data. In addition to using control material a minimum of 5 patient samples covering the analytical range are included if applicable to detect matrix effect.

The control mean is determined by analyzing the material many times over a sufficient time in the analytical system. These values are graphed to establish that they do conform to a commercially available Gaussian distribution. Values are collected over a time period that will incorporate all of the variances that could affect the precision of the assay. The data is represented on a Levey - Jennings chart, which represents quality control values on the y-axis and time on the x-axis; the chart is set at 2 standard deviations. Prior to setting the QC limits data are reviewed to evaluate medical necessity and precision. Assays are evaluated as to how results are used in the clinical environment. The new mean generated from a new lot is considered a temporary target mean if the number of values collected are less than 20. A temporary target mean requires daily monitoring before a true set of statistics can be established for the control.

QUALITATIVE TESTS

For qualitative tests, the positive control must be clearly positive and the negative control must be negative for the patient's results to be valid. Appropriate positive and negative controls are tested as recommended by the manufacturer and as specified in the quality control chart for the department.

For qualitative tests kits, new lots are checked against old lots before placed in used. Crosschecking includes testing known positive and negative external controls with the old kit and the new kit. For HCG test kits in addition to external controls, a negative and positive patient pool control is also tested with each new lot number or new shipment to detect matrix effect.

ADDITIONAL STUDIES

1. FHS participates in external correlations of major analytes with other PacLab and PAML testing partners. Correlations include Coagulation, Chemistry, Enzymes, Bilirubin and lipids, Hematology, Hemoglobin A1C, Iron/IBC, Ligand, TDM and Urine Chemistry.

2. CAP materials are used as external, ~~or~~ internal, and/or system comparison after evaluation is complete and results submitted fall in the acceptable category.

~~3.~~ Intra-laboratory Test Correlations and/or split patient correlation studies are performed as needed at FHS sites.

4. Internal studies include precision, carry over, instrument comparisons, analyte correlations, calibration and calibration verification

5. If more than one instrument or method is used to test for a given analyte, the instrument/methods are checked against each other at least twice a year for correlation of results. CAP PT materials may be used for comparison after PT results are submitted. Patient samples or PacLab and PAML correlation samples may also be used.

6. Analytical Measurement Ranges (AMR) are validated by using matrix-appropriate materials which include the low, mid, and high range of the AMR. These may include CAP linearity materials, Maine Standards, or other appropriate samples.

REFERENCES

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4. Basic QC Practices, Training in Statistical Quality Control for Health Care Laboratories. James O. Westgard, Westgard QC Inc, 1998.
5. CLIA Final Rules for Quality Systems, James O. Westgard, 2004.
6. A Quality System Model for Health Care; Approved Guideline. NCCLS GP26-A.
7. Evaluation of Matrix Effects; Approved Guideline – Second Edition. CLSI EP14-A2, 2005.

DOCUMENT APPROVAL Purpose of Document / Reason for Change:			
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