Verde Valley Medical Center Northern Arizona Healthcare	LABORATORY DEPARTMENT POLICY AND PROCEDURES	Department: GENERAL Number: 101-Prfi-gu-rev04/2015

QUALITY CONTROL PROCEDURE

POLICY

Each Department in this Laboratory has its own quality control schedule. Please refer to each department's individual procedure for specific data concerning frequency of quality control runs.

POLICY

1. Quality control results in this Laboratory are reviewed on a daily and monthly basis.
2. The technologist performing assays in any Department is responsible for
    a. running all quality control samples the same way patient samples are run
    b. reviewing all quality control results prior to reporting patient results
3. All quality control results must be within ±2 Standard Deviation (S.D.) for results to be reported.
4. Any value exceeding ±2 S.D. must be evaluated and additional action taken prior to release of patient results.
5. All outlying quality control values and any corrective action must be documented.
6. With the receipt of a new lot number of QC material for quantitative tests, whether assayed/unassayed, parallel studies must be done with a minimum of 20 points to establish new mean, SD and CV values.

REVIEW CRITERIA

Daily

1. The technologist performing assays in any Department is responsible for reviewing all quality control results prior to reporting patient results.
    a. All points are present and properly documented.
    b. Control results are within the 2 S.D. limits prior to reporting tests.
    c. All control results that are outside of the 2 S.D. range are brought back into control and the troubleshooting steps are documented on the log.
    d. Determine if any results are >3 S.D. If any results are >3 S.D., evaluate the problem and take corrective action (e.g., service, recalibration, etc.).

Monthly

1. Review is performed by a Lead Tech, Laboratory Director or approved designee.
2. Monthly review includes a study of each L-J chart, identifying shifts, trends, adjustment of QC ranges, documenting findings, and/or corrective action.
3. Any updating of L-J charts is performed by the section Lead Tech.
4. Any updates of means and standard deviations performed by the section Lead Tech are verified with assayed materials and/or a "peer group review" with the quality control manufacturer.
5. All changes to the acceptable range for QC are done by the appropriate section Lead Tech with notification of the adjustment provided to the Laboratory Director, along with the appropriate documentation.
6. The monthly QC report with any changes or significant events noted is given to the Laboratory Director and Medical Director for review.
7. All QC documentation is retained and stored in an appropriate location for 2 years to be available for review by inspectors.

TROUBLESHOOTING

1. If two consecutive results:
    a. Determine the number of results outside of the 2 S.D. range. If two consecutive results are greater than 2 S.D., evaluate data and take corrective action.
    b. A shift of >10 consecutive quality control results on one side of the mean. Required action may include fresh QC, reagent, recalibration, or instrument maintenance.
    c. A trend of >10 consecutive quality control results varying from the mean in one direction. Required action may include fresh QC, reagent, recalibration, or instrument maintenance.
2. Any problems not resolved at the bench level must be brought to the attention of the section Lead Tech. Reporting of test results must be suspended for the assay in question until quality control for that assay is acceptable.
3. Corrective action steps that may be taken include, but are not limited to:
    a. Re-run of control material – do not keep re-running control if repeats are not resolving the problem.
    b. Opening fresh control material;
    c. Running assayed material;
    d. Opening fresh reagent;
    e. Calling section Lead Tech;
    f. Recalibration;
    g. And/or maintenance of instrument.
    h. Calling service
    i. Included in this process is the use of the manufacturer's trouble shooting guidelines as published in the appropriate instrument reference manuals.
4. If corrective action requires calibration of primary reagent or maintenance on analyzer, at least two (2) patient specimens from previous acceptable QC run must be repeated. Repeats must be within acceptable laboratory standards and properly documented as acceptable/unacceptable.
5. The section Lead Tech or designee is responsible for monthly review and for extensive troubleshooting on daily problems unable to be resolved at the bench level. The section Lead Tech or designee is also responsible for gathering data for establishing acceptable means and standard deviations of unassayed material.
6. If problems identified cannot be resolved by standard methods, the section Lead Tech decides which action is necessary. If adjustment of the mean and standard deviation is necessary, the section Lead Tech is responsible for this action.
7. All outlying quality control values and any corrective action must be documented.

REFERENCES

1. Clinical Laboratory Improvement Act of 1988 (CLIA '88) Standards.
2. College of American Pathologists (CAP) General Checklist

Prepared by/Title/Date: Linda Gadway, Lab Director 12/05 **Approved by/Title/Date:** Signature on File in Lab	**Committee Approval/Date:** Policy & Procedure _____	**Dates Reviewed/Revised:** 7/09 10/09 10/13 04/2015

CHEM QC Corrective Action Worksheet
Laboratory Department
Verde Valley Medical Center

Test _____ Instrument _____

Date _____

Reagent Lot _____

Control Material _____ Control Lot _____

1. State the problem :

   _____

   _____

2. Have there been any recent instrument problems?

   _____

   _____

3. Is current calibration acceptable? YES NO

4. Assayed Controls or Calibrators(If available and ran)
   a. Level 1 our mean_____ Manufacturer range/SD _____
   b. Level 2 our mean_____ Manufacturer range/SD _____
   c. Level 3 our mean_____ Manufacturer range/SD _____

5. Patient Correlation (Rerun minimum of 2 patients from a time prior to this problem if applicable)
   a. _____ _____ _____ _____ _____ (previous results)
   b. _____ _____ _____ _____ _____ (current results)

6. Change of Mean and Range
   a. Current Mean _____ Suggested Mean _____
   b. Current Range_____ Suggested Range_____

7. Changed in LIS by _____ Date _____
8. Changed in instrument by _____ Date _____

Reviewed by _____ Date _____