CHEM.QC.REGCHEM.1.0 REGIONAL CHEMISTRY LABORATORY QUALITY CONTROL

PRINCIPLE

Monitoring and documentation of most quality control is done by the lab through evaluation of data which has been entered into the Misys computer system. The data is reviewed regularly to assure that the highest quality of testing is performed.

DOCUMENT OWNER

Manager, Chemistry & Special Chemistry

RELATED DOCUMENTS

CHEM.QC.REGCHEM.1.1	Misys QC Modifier Codes
CHEM.QC.REGCHEM.1.2	LJC Review Worksheet
CHEM.QC.REGCHEM.1.3	Control Troubleshooting Worksheet
CHEM.QC. REGCHEM.1.4	Mean Changes Worksheet
CHEM.QC. REGCHEM.1.5	Review of Monthly Peer Group Data Worksheet
CHEM.QC. REGCHEM.1.6	Monthly QC Review
CHEM.QC. REGCHEM.1.7	QA Reminder Worksheet
CHEM.QC. REGCHEM.1.8	Sunquest QC Programs
CHEM.QC. REGCHEM.1.9	Checking Patients after Unacceptable Quality Control Worksheet
QA.TEST.5.5	Allowable Error Specifications

PROCEDURE

A. Daily

All quality control material is tested in the same manner and by the same personnel as patient samples. Quality Control must be acceptable before patient results are reported.

1. Control Systems (2 OR 3 controls/run)
   a. Accept the controls if:
      All Control(s) read within 2 SD of the mean value. Enter the values in Misys.
2. Reject the controls if:
   a. One or more control value is greater than 2SD. Enter the value into Misys with appropriate comment (See CHEM.QC.REGCHEM.1.1).
   b. One or more controls are greater than 3 SD of the mean. Enter the value in Misys with appropriate comment (See CHEM.QC.REGCHEM.1.1).
3. If a Run is Rejected:
   a. Hold all patient results.
   b. Re-run control (once)

1) If control is now acceptable, accept control and patients. Enter control into Misys with the appropriate comment (See CHEM.QC.REGCHEM.1.1).
2) If control is still not acceptable proceed to "c" below.

c. Reconstitute/Open fresh control and repeat control testing (once).
1) If control is now acceptable, accept control and patients. Enter into Misys with the appropriate comment (See CHEM.QC.REGCHEM.1.1).
2) If control is still not acceptable, proceed to "d" below.

d. Check controls and reagents. Ensure that correct lot number is in use, that control and reagents have not expired.
1) If lot number of controls not correct, obtain correct lot number, and re-run controls (once). See section A. above for acceptability. Enter results into Misys with the appropriate comment (See CHEM.QC.REGCHEM.1.1).
2) If there is no correct lot number of controls available, alert Manager, or Lead Technologist.
3) If lot number of reagent is expired, replace, recalibrate as needed, and repeat patients and controls as needed (See section 5 below). See section A. above for acceptability. Enter the results into Misys. Include the comment: LOTR (for new LOT of reagent).
4) If reagent is empty, replace, recalibrate as necessary and re-run controls (once) see section A. above for acceptability. Enter values into Misys and include comment: RNRG. Repeat patients as needed (See section 5 below)
5) If both controls and reagents are okay, proceed to section 5 below.

4. Recalibrate/ re-blank and re-run the controls (once).
a. If controls are now acceptable, repeat patients as needed (see section 5 below). Enter values into Misys and comment: with appropriate comment (See CHEM.QC.REGCHEM.1.1).
b. If control(s) are still unacceptable, troubleshoot in conjunction with Manager, or Lead Technologist.
c. See section 5 below.

NOTE: This is the recommended sequence of running controls if controls are not acceptable. If the problem is known (bad vial, bad collect, etc.), skip to the appropriate step.

5. Further troubleshooting of control problems
a. If the above troubleshooting techniques do not solve the problem, alert Manager or Lead Technologist. Further troubleshooting ideas are listed below.

DO NOT ACCEPT CONTROLS OR REPORT PATIENT RESULTS UNLESS CONTROLS ARE ACCEPTABLE.

b. Enter **ALL** controls into Misys, and comment what was done to correct problem. Free text if necessary, use canned comments when appropriate (See CHEM.QC.REGCHEM.1.1 for available canned comments).

1) Run an alternate control when possible. Examples: run calibrators as patients; use old CAP samples of known values. This will help determine if the problem is the control or the instrument. Check with Manager or Lead Technologist before accepting patients based on this information-usually, other information listed below will be used to make decision.

NOTE: Don't run calibrators back as patient right after calibrating with them. This information isn't useful. If available, use a different lot of calibrators, or run calibrators BEFORE calibrating to see if Cal curve is holding.

2) Check the control insert or peer means to see if the range is okay (the mean may not be exactly what is listed in the insert, but our mean must be within the range listed in the package insert or QA report).

3) Check patients against other instruments when possible to see if they have a clinically significant difference.

4) Perform any maintenance, cleaning or repair that is needed

5) Call the instrument hotline and troubleshoot as instructed.

6. Problem Is Resolved - After problem is resolved, and controls are acceptable, select 3 - 5 patients from previous run and re-test. Vary time testing was performed and level of result. Compare patient's previous results (since last acceptable QC) with the new results.

a. If no clinically significant (normal is still normal, high is still high, low is still low), and previous results are within Total Acceptable Error (QA.TEST.5.5) for the analyte, accept previous run.

b. If the difference **IS** considered clinically significant or greater than total error, re-test all patients from previous run and correct results in Misys and QLS as necessary. Any exceptions must be approved by Lead Technologist or Manager.

c. If more than 5 patients require correction, give to Lead Tech, Supervisor or Manager for final decision.

d. Fill out form for checking patient results (CHEM.QC.REGCHEM.1.9).

A RUN/BATCH is defined as the interval within which the accuracy and precision of a testing system is expected to be stable. We will define this interval as the period between acceptable control runs.

B. Weekly

1. The Quality Controls will be reviewed weekly as possible by Lead Technologist (no longer than biweekly). Any exception must be approved by Medical Director or designee.
2. View QC use Function LJ or QC in Misys.
3. Reviewing QC.

   Examine all Quality Controls, and check for the following.

   a. Shifts - 10 or more points on one side of the mean.
   b. Trends- 10 or more successive points that show a gradual increase or decrease. When using duplicate analyzers a shift may be acceptable if comparison between analyzers is acceptable.
   c. Controls that are unacceptable as defined in Daily QC section- look for acceptable comments and actions taken.
   d. Controls were run at appropriate intervals (see QC Testing Intervals).
   e. % CV'S are not excessive- check previous three months % CV for reference.
   f. Use QA Reminder Sheets to alert Techs of errors.
   g. Record review on LJC Review sheet" (See CHEM.QC.REGCHEM.1.2).
   h. Follow up on any problems on Troubleshooting Sheet (See CHEM.QC.REGCHEM.1.3).

      NOTE: Shifts do not necessarily result in action taken or mean changes if shift is not clinically significant or is a result of control insert ranges being in place.

4. Changing QC Data

   There will be times when adjusting the means for a control is the appropriate action to take. To ensure that this is the appropriate action, use the following criteria.

   a. Check insert mean and range when using an assayed control.
   b. Check peer group values when available. This is a good way to see how our instruments are comparing to others. Our value should be with 2SD of peer group mean if nothing has changed since the time the peer group values were calculated.
   c. Check when the current lot number of reagent was put into use. Could the problem be tracked to the new lot of reagent?
   d. Check when the last calibration was performed - Could the problem be that a calibration is needed, or that there was a problem with the last calibration?
   e. Check that correct lot numbers and standard values/set points are in the instrument. Make sure they match the calibrator standards being used.
   f. Make sure we are using the correct lot number of reagent.
   g. Make sure we are using the correct lot number of controls.

h. Is there any maintenance due, or was any major maintenance recently performed?
i. Have there been any other changes to the chemistry affected? (New method in use, etc.)
j. Call the manufacturer to see if other labs are also experiencing shifts.
k. You can check instrument performance by running a standard/calibrator as a patient to see if the value of the standard is recovered. Don't run calibrators back as patient right after calibrating with them. This information isn't useful. If available, use a different lot of calibrators, or run calibrators BEFORE calibrating to see if Cal curve is holding. You can also use any other controls that have an assayed value that are available to you, or old CAP specimens.
l. Correct any of the above problems, and document what was done on the Troubleshooting sheet (See CHEM.QC.REGCHEM.1.3).
m. Check previous three months means to see if this is a long standing shift.
n. Average 3 months of standard deviations to define "usual standard deviation" (USD) – (this may not always be used if all of above is met).
    1) If the difference between expected mean, and actual mean is less than one-half the USD, mean can be adjusted.
    2) If the difference is not medically significant, but is operationally significant (greater than one-half USD), further investigation is required (see sections a-n above), if all above is okay, mean can be adjusted.

5. If all of the above criteria are acceptable, and instrument function, control, standards, and reagents are acceptable, then a mean change is warranted. To successfully change a mean, perform the following:
    a. Use the function QCX to make changes in Misys (see CHEM.QC.REGCHEM.1.8).
    b. Make changes in appropriate instrument if required. (See instrument manual for procedure).
    c. Record all changes made on Troubleshooting sheet (CHEM.QC.REGCHEM.1.3).
    d. Record old and new means on mean change sheet (CHEM.QC.REGCHEM.1.4).
    e. Keep Mean Change sheets as documentation of changes. This is the only way we can keep track of old mean values, as Misys adjusts LJC historically to the date new lot number was put into use.
    f. All documentation will be saved for permanent records.

C. Monthly
1. The monthly LJC's will be printed by the Lead Technologist.
    a. Review for completeness.
    b. Keep all weekly LJC Reviews for the month with the monthly report.
    c. Keep copies of CHEM.QC.REGCHEM.1.3 and CHEM.QC.REGCHEM.1.9 as well as any notes pertaining to QC with the monthly report.

d. The monthly report will be approved and signed by the department Supervisor and Lead Technologist. (CHEM.QC.REGCHEM.1.6).
e. All reports will be stored for inspection agencies.

2. The monthly Quality Assurance reports will be sent in by appropriate date by the Lead Technologist. Refer to individual company instruction manuals for specific instructions on how to submit data.
3. The current Quality Assurance reports will be reviewed by Lead Technologist.
   a. Compare the average precision values of other labs in our peer group to our precision values (SDI and CVI).
   b. Compare our mean values to other labs in our peer group. (Target < 2SDI or < 2CUI).
   c. Document problems and corrective actions on QA report sheet.
   d. The monthly report will be approved and signed by the department Manger and Medical Director, AND Lead Technologist (See CHEM.QC.REGCHEM.1.5).
   e. All reports will be stored for inspection agencies.
4. Maintenance Review will be done monthly by Lead Technologist.
   a. Reviews to include:
      1) Check that all maintenance was done and maintenance sheet was checked off for daily, weekly, and monthly, and periodic maintenance.
      2) Write a QA reminder (See CHEM.QC.REGCHEM.1.7) for anything that was not done, or not recorded on maintenance sheet.
   b. Technologist and Lab Assistants missing maintenance, or missing signing off on maintenance sheet will return signed maintenance reminder to Lead Technologist with any explanation.
   c. Lead Technologist will give all QA reminders to manager for individual files.

REFERENCES

CAP proficiencies (See CAP Review procedure).