Policy Statement	Accrediting agencies and state regulators require Laboratories to maintain a Quality Control process.
Purpose	The Core Laboratory uses standardized, commercial QC materials. These materials are designed to assess the reliability of the testing methods used. The laboratory runs QC according to equipment manufacturer's instructions and/or predetermined method requirements.
Scope	This procedure applies to all testing associates in the Core Laboratory.
Responsibility	All associates are responsible for following this procedure without exception. In addition, the Lead/Charge Technologist is responsible for QC review and ensuring that the proper remedial action is taken.
Related Documents	CORE 6035 Ja QC Statistics Report CORE 6035 Jb Test Specific QC Report

Quality Control Materials

Quality Control Materials vary depending upon the method. Refer to the operating or assay specification documents for the specific control you need for a particular test. Anyone who runs QC materials must handle these materials according to the manufacturer's instructions. Do not deviate from the storage and handling instructions. These instructions are usually found in the package insert. Package inserts for current lot numbers are kept in the sections.

Equipment and Supplies

Equipment and supplies needed are specified in the operating and QC procedures for each test. Additional supplies may be used as needed.

Pre-Analytical

Establishing Ranges

There are three factors by which the Core Laboratory can establish QC ranges:

1. Historical Data: This information is gathered at the beginning of a new lot number. Prior to controls being made available for use, each level is run at least 10 times concurrently with the old lot number. The results are recorded in Meditech and will give a historical mean and standard deviation based on those results. Over time, the historical data is reviewed and adjustments can be made.
2. Target Range/Manufacturer's Range: For a new control or lot number, the manufacturer's range is entered into Meditech or the specified analyzer. This range is valid only until the new range is established. The CAP requires that each lab establish its own ranges. Therefore the manufacturer's range serves as the target range until that time. Once the data from a new control or lot number are analyzed, the target range is established and entered into Meditech. These ranges are evaluated over time.
3. Peer Group Data: Peer group information is used to establish peer group ranges. This information is then used to indicate our position relative to labs that run the same equipment and the same lot numbers. This data is reviewed monthly by a lead technologist and is also used to evaluate QC ranges.

Ranges cannot be established nor adjusted without justification. The purpose of quality control is to assess the precision and accuracy of an assay or analyzer. The QC ranges are used to insure dependability and consistency of the methods used in the lab.

Schedule

The schedule for running QC is dependent on the lab section and the test. Chemistry QC must be run every 24 hours. The exception to this rule is the Basic Metabolic Panel, BMP, which must be run every eight hours. The Free Phenytoin and Osmolality assays have three levels; only two levels are required each day. Two levels of Hematology QC must be completed every 8 hours with all three being run twice a day. ESR QC is run every 24 hours. Coagulation QC must be completed every eight hours; HIT and TT as needed. QC for Centaur QC is completed at the beginning of each dayshift and the beginning of each evening shift. MiniVIDAS QC must be completed everyday that testing is performed. Urinalysis QC must be completed every 24 hours. Rapid tests require liquid Q.C. to be performed weekly with external controls. Electronic controls are performed daily.

QC is required prior to running patient samples, after calibrations, instrument repairs or major maintenance (such as a lamp change, pump service, electrode change, etc), a change in critical reagents or critical instrument components. The QC results will assist you in determining whether you can proceed with patient testing.

Analytical

QC Preparation

- Store all QC material according to manufacturer's instructions, until ready to use. Controls arrive in the laboratory, either frozen or refrigerated. Refrigerated controls can be lyophilized or in liquid form. Prepare for testing according to the package instructions.

    1. Frozen QC:

        a. Controls that arrive frozen must be placed immediately in the designated freezer. Controls must be kept frozen until ready for use.
        b. Once you remove a frozen bottle from the freezer, you must thaw it according to directions. Do not thaw by any method not approved by the manufacturer. Most control material should thaw for a minimum of 24 hours refrigerated or at room temperature unless otherwise instructed.
        c. If an emergency arises, such as spilling a bottle or cross contamination and you need to thaw a bottle quickly, do so but write "quick thaw" and the date on the bottle and take another bottle out of the freezer and put it in the QC refrigerator. That way, the next tech will know that its stability is limited.

    2. Refrigerated QC

a. Both liquid and lyophilized controls are stored in the designated refrigerator per manufacturer's storage requirements.
b. If the control is lyophilized and needs to be reconstituted, follow the instructions in the package insert. A Class A volumetric pipette must be used when reconstituting lyophilized QC for tests in the chemistry departments. De-ionized *reagent grade* water is usually required. You should always use *fresh* de-ionized water. Do not use any other solutions, such as saline, unless indicated. Refrigerate after preparation, per manufacturer's directions.

- Once the control is ready for testing, store in the designated QC refrigerator. Do not take QC material out of the refrigerator until ready to use.

Procedure

- Upon opening a bottle of control for the first time, you must write the date opened, expiration date, and time, when applicable, on the label. Most controls have a limited shelf life once opened. Any QC that you use must be dated.

- Check for the date opened and the opened expiration date on the bottle before you run the control. If the bottle is approaching the expiration date, confirm that additional QC material is available and ready for use.

- Check the lot number and lot expiration of the control before running. If the lot number differs from that indicated on the QC chart or worksheet, notify the Lead Technologist.

- If the lot number is within 30 days of expiration, you should notify a Lead Technologist.

- If the controls are aliquoted into separate tubes, check to insure proper identification and date. They usually have a barcode label and can go directly onto the analyzer.

- All secondary control containers used in the laboratory must be labeled with the solution name, date, time, and/or dilution factor if it is a manual dilution.

- Do not take QC out of the refrigerator until ready to use. Allowing the QC to sit on the counter for an extended period of time will affect its stability. If you take the controls out and do not think you will be able to run them right away, return them to the refrigerator at once.

- If the QC is not in an aliquot tube, add to a sample cup. The sample cup can go directly on the analyzer. Avoid cross contamination and spills.

- Run the controls according to the test operating procedure. Run using the assigned barcode number / identifier. Program that number into the analyzer, if necessary.

Post-Analytical

- QC results must be reviewed after completion to ensure they are within the accepted standard deviations determined by this policy.
- QC results must be reviewed before running patient samples.
- QC results are reviewed monthly for shifts, trends and monitor precision.
- All resultant delays in patient testing must be communicated to the internal nursing areas via the paging system.

All Meditech barcoded QC materials should cross the interface from the analyzer to Meditech automatically. If the assay uses a worksheet, the QC results can be entered into the appropriate field on that worksheet. In some cases, you must enter the result manually into Meditech. When this occurs, you must use the Quality Control Desktop in Meditech. Ensure that the accurate test methodology is used when entering the results manually. Results that do not enter Meditech must be reviewed by the technologist on the analyzer screen or on the instrument print-outs. QC records that cross an interface are retained in Meditech. All manual QC is retained in storage for 2 years, minimally.

Canned Comments

All quality control results that fall outside the established ranges must be documented in Meditech using one of the following canned comments:

- QC: QC failed. Control will be repeated. No patients will be run on this analyzer until resolved.
- QC0: Troubleshooting completed. QC in range.
- QC3: QC repeated. Results out of range. Testing suspended until issues resolved
- QC5: QC was run post instrument service. QC results in range.
- QC6: Assay recalibration successful. QC repeated. QC results are in range.
- QC7: New Control Lot. Establishing new ranges. Manufacturer's QC OK.
- QC8: New Reagent Lot. Establishing new ranges. Manufacturer's QC OK.
- QC9: Inadvertently ran incorrect QC. Will repeat with correct control.

Do not delete out of range control results. All results falling outside established parameters must be followed by one of the above canned comments. You must troubleshoot any out of range QC results that generate a violation. You must document all QC issues in Meditech.

Out of range results can be indicative of a problem with a testing method or analyzer and must be addressed accordingly. You should hold patient's samples from that analyzer or use an alternative method until the issue is resolved. Below are the steps to follow when QC results are out of range and are rejected.

Chemistry Remediation

1. Check the control history.
2. Repeat the control, using the same bottle, but a different sample cup or tube.
3. If > 2 SD again, then open bottle of new control material and run it.
4. If result is ≤ 2SD, the run is OK and patient results may be released.
5. If result is > 2 SD in a Chemistry test, then first check the reagent volumes and expiration dates.
6. If reagent volumes are within appropriate volume limits, recalibrate the instrument.
7. If recalibration is out then notify the Charge Tech and perform user level instrument maintenance.

Sysmex Remediation

1. Check the control history.
2. Repeat the control.
3. If > 2 SD again, then open bottle of new control material and run it.
4. If result is ≤ 2SD, the run is OK and patient results may be released.
5. If result is > 2SD then first check the reagent volumes and expiration dates.
6. If reagent volumes and expiration dates are ok, then notify the Charge Tech and perform user level instrument maintenance.
7. Rerun control once user level instrument maintenance is completed, if control is still out contact the instrument service representative for repair.

BCS System Remediation

1. Check the control history.
2. Confirm that daily maintenance has been performed; if not indicated perform daily maintenance.
3. Repeat the control.
4. If > 2 SD again, reconstitute new control material and run it.
5. If result is ≤ 2SD, the run is OK and patient results may be released.
6. If result is > 2SD then first check the reagent volumes and expiration dates.
7. If reagent volumes and expiration dates are ok, notify the Charge Tech, then perform probe check with an intensive wash five times. Spare sample probes are kept underneath the analyzer.
8. Rerun control once user pipette check is completed, if control is still out contact the instrument service representative for repair.

IRIS Remediation

iChemVELOCITY

1. Confirm QC is in correct rack position, adjust if necessary.
2. Re-pour and re-run all controls.
3. If results are still not acceptable – check strips loaded in instrument for discoloration. If discolored, discard and add new strips and repeat.
4. If results are still not acceptable, notify your Lead/Charge Technologist.

iQ200 Analyzer

1. Look at message code to see why the control failed.

Note: If control failed due to an identification error or QC out of order, resolve this error.

2. Mix QC material well.
3. Pour fresh aliquots and re-run control.
4. If results are not acceptable, notify Lead/Charge Technologist.

Centaur XP Remediation

The Centaur XP has quality control software built into the analyzer. This software reviews each quality control result after completion to ensure that it is acceptable. In the event that quality control falls outside of the defined ranges, the analyzer will alarm to the technologist both visually and audibly.

1. Check the control history.
2. Quality control must be repeated.
3. If QC is still out of range, the test should be calibrated.
4. If calibration is out notify the Charge Tech and technical support.
5. Once the results are within range, a comment must be entered into the quality control system and the result must be manually reviewed.

Note: The Centaur XP quality control results will not be included in the shift review. The technologist must review QC prior to testing patient samples.

miniVIDAS Remediation

1. Check the control history.
2. Repeat the control.
3. If > 2 SD again, then run the standards in duplicate with QC.
4. If result is ≤ 2SD, the instrument is now okay to perform patient testing.
5. If the control is still out of range, contact the instrument technical service line.

Trend / Shift

A trend is an unusual result pattern that can lead to a quality control failure. A trend occurs when five control measurements get progressively higher or progressively lower.

A shift occurs when six or more consecutive points are above or below the mean.

A shift or trend does not cause an automatic stop run. If a trend or shift is suspected it should be brought to the attention of the lead technologist of that particular section for review. When a lead technologist is not available a printed copy of the graph should be left in their mail box for review.

References

1. Terault GA, Steindel SJ. Q-Probe 94-08. Daily quality control exception practices. Chigago, IL: College of American Pathologists, 1994.
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3. Hyltoft Petersen P, Ricos C, Stockl D, Libeer JC, Baadenhuijsen H, Fraser C, Thienpont L. Proposed guidelines for the internal quality control of analytical results in the medical laboratory. Eur J Clin Chem Clin BioChem 1996; 34:983-999.
4. CORE 0000 QP: Core Laboratory Quality Management Plan