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| Quality Control in Chemistry |
| **Purpose** | This procedure provides instructions for QUALITY CONTROL IN CHEMISTRY. Quality control is used to monitor analytic processes, detect analytic errors during analysis, and prevent the reporting of incorrect patient values. Stable control material is selected and compared against their expected value. |
| **Policy Statements** | * This procedure is intended for all personnel responsible for reporting patient results.
* Per CAP Chemistry Checklist CHM.14800:

Control specimens are tested in the same manner and by the same personnel as patient/client samples. To that extent, everyone operating the test system is responsible for addressing QC needs and reporting QC results in Sunquest.* Each instrument and/or test system has QC performed at required frequencies either daily or day of use, as described later in this document.
* Controls must be run prior to resuming patient testing when changes occur that may impact patient results.
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| **Materials** | **Reagents, Supplies, Equipment** |
|  | 1. Reagents and Systems needing Quality Control
2. Control Material appropriate for analyte or system to be tested.
3. Sunquest Computer System QC program
4. Current quality control products and their names are stored in the file

CH 2.07a1 Quality Control in Chemistry – Current Product List |
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| **Definitions** | TE: Total Error represents the combination of systematic (bias) and random (precision) error. TE= %bias + 2CV.CV: Coefficient of Variation is the relative standard deviation, or the std dev expressed as a % of the mean. CV=100(SD/x).Levy Jennings Control Chart: A commonly used chart used to plot individual control measurements. Limit lines are drawn at ±2SD and ±3SD. Time is displayed on the x-axis.Mean: The average of a given set of values, designated by an x with a bar over it.SD: Standard deviation is a statistic that describes the spread of a set of measurements around the mean value. SD= [n∑xi2 – (∑xi)2]/[n(n-1)] where xi is an individual measurement, and n is the number of measurements.Westgard rules: A control procedure that uses a series of control rules to test the control measurements.**12s** is the warning rule applied to a data point that is outside the 2SD limit from the mean.**13s** is the control rule indicating a data point is outside of 3SD’s from the mean and applies to the current data point.**22s**applies to the current and previous data point, and indicates the 2 most recent values are outside 2 SD, either within the same material or across materials.**R4s**evaluates the previous 4 data points and is applied when one control is +2 SD and another is – 2 SD, an indicator of imprecision in the method. It may be used within the same control or across controls.**41s**  is the rule that applies to the current control value and 3 previous, and indicates all are on the same side of the mean and outside 1 SD. It can be used within the same control or across controls, and indicates a trend. |
|  | **10x** is a rule applied to the last 10 data points within or across controls, and indicates all points are on the same side of the mean. |
| **Procedures:** |  |
| New Quality Control | **Step** | Action | **Related Document** |
| 1 | New Quality Control material must be analyzed repetitively along with established controls prior to being placed in use. |  |
| **If** | **Then** |
| Unassayed control | Test in daily runs to accumulate at least 20 data points for each test. |
| Assayed control | Test in daily runs to accumulate a minimum of 5, preferred 10 data points for each test. |
|  | 2 | Enter data points into Sunquest QC program using the previously defined QC name followed by ,0. (i.e. a new lot of X1 control would be entered as X1,0 to apply to the new file established.) |  |
|  | 3 | Determine the means and SD’s for each test using Sunquest function QC, Summary data. |  |
|  | 4 | Apply the calculated mean and historic 2SD to establish an acceptable range on unassayed controls. |  |
|  | 5 | Apply the insert ranges to assayed controls once the manufacturer’s range is verified. |  |
|  | 6 | Use peer data when available to verify ranges. |  |
| Daily Quality Control |  |  |  |
| **Step** | Action | **Related Document** |
| 1 | Analyze a minimum of 2 levels of Quality Control material at least once every 24 hours that patient testing is performed. |  |
|  | 2 | Run quality control materials the same way you would a patient. Most instruments have a quality control file that maintains results for statistical purposes, as well as alerting the operator to unacceptable results. Refer to each instrument’s operating procedure for programming quality control. |  |
|  | 3 | Follow the manufacturer’s instructions included with each box of quality control material. The product insert contains instructions for storage, stability, reconstitution, mixing, handling, and intended use. |  |
|  | 4 | Enter Quality control results into the laboratory computer system (Sunquest) where they are evaluated by user defined Westgard rules.1. In MEM, enter the name of the worksheet. Modify the method to the defined method code, and enter the Sunquest control name using C-(name).
2. In OEM, enter the device mnemonic, and carriage return to the designated cup number.
3. Results are displayed with a standard deviation. Accept results that pass all rules.
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|  | 4 | 1. QC data that fail one or more rules will have a Levy Jennings chart pop up, and will prompt for an action comment.
2. Add the most appropriate action comment from the list below, deciding whether the point is to be included or excluded from statistics. Use a comment that will exclude the data if the result is obviously erroneous, such as 0.1 when the expected value is 20.0.
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|  | 5 | Results of both levels must fall within the expected range before patient results can be reported. Do not report patient results until all QC has passed OR Technical Specialist approval has been granted. |  |
|  | 6 | A data point is valid to use in statistical calculations if it is used to release patient results, or validates assay performance. |  |
|  | 7 | Selective editing of QC results skews data, creates a smaller SD, and increases false run rejection. |  |
| Interpreting QC Results |  |  |  |
| **Step** | Action | **Related Document** |
| 1 | **If** | **Then** |  |
| All levels of QC are within 2 SD of the mean. | Patient results are okay to report. End here.  |
| QC Failed | Requires further investigation before reporting patient results. Continue with Step 2. |
|  | 2QC result greater than13s ?22s ?R4s ?41s ?10x ?Out of control, investigate problem12S ?In control, OK to reportNoNoNoNoNoYesYesYesYesYesYes | Use Westgard’s rules according to the schematic below to determine whether a failed point is acceptable. Using a Gaussian distribution, QC data distributed around a mean will be within 2 SD’s 95% of the time. Therefore, 5% of the time it is statistically sound to accept a data point outside 2SD. |  |

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|  | 3 | **If** | **Then** |  |
| QC is in 12s  | Run is accepted, patients are reported. |
| QC is out 12s, and no other rules are violated in the previous 20 points. | Run is accepted, patients are reported. |
| QC is out 12s, and the 22s, 13s, or R4s are violated | Patient results are not reported. Investigate and resolve QC problem. Reanalyze patients as necessary. |
| QC is out 12s, and 41s or 10x | Patients are reported.Investigate potential problems. |
|  | 4 | Investigate the method when QC fails. The first action should **not** be to rerun QC.1. Identify the type of error involved using a Levy Jennings chart.
2. Random error indicates poor precision. Rule failures might be 12s, 13s, and 4Rs.
3. Systematic error is in one direction from the mean, and usually follows a system change. Typical rule failures would be 22s, 41s, and 10x.
4. View the chart, looking for shifts, trends, imprecision, and taking note of dates.
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|  | 5 | Relate the error to possible causes:1. Systematic errors are caused by:
* New reagent lots
* Temperature variation
* Recent calibration (wrong values, reconstituted incorrectly)
* Reagent deterioration
* Overdue instrument maintenance
* Calibration due
* Lamp deterioration
1. Random error is caused by:
* Instrument malfunction
* Pipetting errors
* Air bubbles or short samples
* Plugged tubing
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|  | 6 | Relate common factors. If more than one test on a system is affected, determine what those tests have in common.1. Enzymes: temperature
2. All tests using the same calibrator
3. Same reagent shipping date
4. Same lamp filter or pipettor
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|  | 7 | Check recent changes in the method:1. New reagent lot
2. Recent calibration
3. Documented instrument problems
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|  | 8 | Check the manufacturer’s manual for troubleshooting tips. |  |
|  | 9 | Notify the supervisor if all QC troubleshooting fails, and patient results are not reportable. |  |
|  | 10 | Verify the solution and document the remedy.1. Once the problem is resolved, rerun QC to verify the solution.
2. Assess whether patient results were affected and reanalyze any affected samples since the last successful QC.
3. Document corrective action on the instrument log. For ABL825, ABL90 and Architect i1000, record corrective actions electronically in the instrument.
* For ABLs: Navigate to Quality Control Log, Select the data point by highlighting the row, select Result, select Messages, select Note, then type the corrective actions.
* For Architect, navigate to the maintenance screen. Select any completed maintenance item for the day of corrective action by clicking on the colored hash mark box. In the comments section, type the corrective action.
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| **Sunquest QC Failure Codes** |

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| **Code** | **Meaning** | **Include/ Exclude data** | **Use/ Action** |
| CCAL | Result consistent with recalibration | Included | Recent calibration, QC shift |
| CERR | Computer entry error | Excluded |  |
| DLOG | Range in computer/instrument differ | Included |  |
| IN | Control in 2 SD | Included | 41s or 10x rule failures |
| INSR | Instrument recalibrated | Excluded | Method to be recalibrated |
| LOTC | New lot no. Control /mean not established | Included |  |
| LOTR | New lot reagents started | Included | QC shift due to lot variation |
| MN2S | Mean recalc’d/result prev in 2 SD | Included | Requires supervisor OK |
| O2I3 | This control out 2 SD but in 3 SD, other controls in 2 SD (3 controls) or previous 20 values in 2 SD (2 controls) | Included | Check previous 20 entries in Sunquest or the instrument QC file for previous failures. |
| RNRG | Repeated new reagents | Excluded | Old or expired reagent |
| RNV | Repeated new vial of control | Excluded |  |
| RNVR | Repeated/new vial control with new reagents | Excluded | 2 actions for one repeat |
| RSVC | Repeated/same vial of control | Excluded |  |
| RTRB | Repeated/maint/troubleshooting | Excluded | Maintenance to be done |
| SD2S | Redefined SD/previous result in 2 SD | Included | Requires supervisor OK |
| SH | Short sampled | Excluded |  |
| SUP | Supervisor reviewed/not included in calc | Excluded | Requires supervisor OK |
| VENM | Vendor maintenance: see instrument log | Included | Following mfr. Maintenance |
| WRSN | Westgard rule failure noted, supervisor notified | Included | Requires Technical Specialist Approval |

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| **Procedure Notes** | Refer to the each material’s package insert for open vial stability and expiration dates. |
| **QC Number and Frequency** |

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| **Instrument** | **Quality Control Material** | **Frequency** |
| Advanced Instruments Osmo1 | Advanced Instruments Protinol (serum) and Renol (urine) | All levels, matrix specific, once per calendar day of patient testing |
| Agilent 240Z | BioRad Lead controls | 3 levels each day of use |
| DiaSorin Liaison | Infectious Disease controls, various | 2 levels each day of patient testing |
| HemoCue Low | Eurotrol Low Hemoglobin | 2 levels each day of use |
| Labconco Sweat Chloride | Quantimetrix sweat controls | 2 levels each run |
| Phadia ImmunoCAP 250 | Allergies | Low Medium High  | Each day of use |
| Celiac | Elia Controls | Each day of use |
| Radiometer ABL 825 | AutoCheck 1, 2, and 3 | 1 level automatically every 8 hours  |
| Radiometer ABL90 | Levels 1, 2 and 3 internal QC | 1 level automatically every 8 hours |
| Siemens Dimension RXL MAX | BioRad Controls for serum/plasma | 2 levels, fluid specific, once every 24 hours of testing except Na+, K+, Cl-, every 8 hours |
| Siemens Dimension Vista | BioRad Controls in Vista Vials for serum/plasma, CSF, urineSiemens DAT +/- controls (ABUS) | 2 levels, fluid specific, once every 24 hours of testing |
| Siemens DPC Immulite | Biorad Immunoassay PlusSiemens ACTH controls | 2 levels each assay, each day of use |
| IDS iSYS | BioRad QC for hGH, IDS QC for IGFBP-3 and IGF-1 | 3 levels each shift of patient testing |

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| **References** | 1. Bishop, Michael, et. al. Clinical Chemistry: Principles, Procedures and Correlations, 5th Edition, 2005.
2. CAP All Common Checklist, version 08.21.2017
3. Dufour, D. Robert, Professional Practice in Clinical Chemistry: A Companion Text, 1999
4. Westgard, James O, Basic QC Practices, 2nd Edition, 2002
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
| 1 | L. Lichty | August 2002 | Initial Version |
| 2 | L. Lichty | June 25, 2005 |  |
| 3 | L. Lichty | August 9, 2007 |  |
|  | 4 | L. Lichty | January 10, 2009 |  |  |  |
| 5 | D. Helfinstine/ L. Lichty | April 1, 2011 | New Format, renumbered from CH 0.21, added Liaison and Kryptor controls |
| 6 | D. Helfinstine/ Lichty | November 10, 2014 | Removed RXL, Ketones, BN Prospec. Added Dimension Vista, new Phadia QC. Policy statements CAP CHM.14800 |
|  | 7 | Kelsi Brown/Erin Bartos | April 21, 2017 | Removed Abbott TDX and pH meter, no longer in use. Biennial Review |
|  | 8 | Erin Bartos | September 5, 2018 | Added line regarding running QC prior to resuming patient results if any changes have occurred that may affect the test. Removed Kryptor, added IDS iSYS, ABL90, and Abbott Architect i1000. Other minor clerical changes. Changed minimum unassayed control comparison values to 20. WRSN requires Technical Specialist approval. Added instructions on how to enter corrective actions into the Architect and ABL software. |
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