**Purpose**

To meet regulatory agency requirements which states that there must be a written document for the design and evaluation of the laboratory quality control program. This procedure replaces previous procedures.

**Policy**

Quality control criteria will be established for Clinical Chemistry and Immunology tests. Compliance with regard to these criteria will be assessed by daily review of the quality control documents, taking appropriate action when needed as described in the following specific procedures. Control specimens will be tested in the same manner and by the same personnel as patient/client samples.

**Procedure**

**Qualitative Quality Control**

For qualitative results where the controls are reported as either positive or negative:

1. The controls are verified pools or validated commercial material.
2. If the positive control is reported as "positive" and the negative control is reported as "negative," the system is controlled. REPORT PATIENT RESULTS.
3. If the positive control is reported as "negative" and/or the negative control is reported as "positive," the system is out of control. CONTACT SECTION SUPERVISOR. Investigate problem and correct. Rerun test and controls if applicable. Do not report patient results until problem is corrected.
4. Document corrective action taken.

**Semi-Quantitative Quality Control**

For semi-quantitative results where the controls are reported in non-numeric terms (1+, 2+, small, moderate, titers, etc.):

1. Control ranges will be established with at least 20 determinations of appropriate control material. If 20 determinations cannot be initially achieved, a temporary range will be established until an appropriate number of determinations are made.
2. If the controls fall within the established ranges, the system is in control. REPORT PATIENT RESULTS.
3. If the controls fall outside the established ranges, the system is out of control. CONTACT SECTION SPECIALIST OR SUPERVISOR. Investigate problem and correct. Rerun test and controls if applicable. Do not report patient results until problem is corrected.
4. Document corrective action taken.

**Quantitative Quality Control**

For quantitative tests where the test results are reported in numeric terms, including **multiple automated instruments** utilizing two or three levels of controls:

1. Control ranges will be established with at least 20 determinations of appropriate control material. If 20 determinations cannot be initially achieved, a temporary range will be established until an appropriate number of determinations are made. Calculate the mean (x) and standard deviation (s) from the results for each control material. Establish ranges as x ± 2s. When using the manufacturer's control ranges, the control data sheets (containing the control mean and standard deviation) will be maintained with the test's QC records.
2. If one control observation exceeds the mean ± 2 SD, verify that control is not outdated/expired, has been stored properly, is the correct lot number, and has no signs of contamination before you repeat the test using a new aliquot of the same bottle of control.
3. If the control is suspect or if the repeat result on the same bottle of control exceeds the mean ± 2 SD, open a new/fresh bottle of control and use an aliquot of the new bottle to repeat the test. Discard the old bottle.
4. If the repeat result on a new bottle of control exceeds the mean ± 2 SD, verify that the reagent has been prepared properly, is not outdated/expired, and contains a sufficient number of tests. If the reagent is acceptable, recalibrate the assay if required and repeat the control. If the reagent is suspect, or there are just a few tests left, load new reagent before calibrating and rerun the control.
5. If the repeat result after recalibration, exceeds the mean ± 2 SD, and/or there at 10 or more points on one side of the mean, verify that the lot number of the calibrator being used is the same as that loaded/selected on the analyzer. Recalibrate using the correct calibrator, and repeat the control.
6. When the control values fall within the 2s limits, accept the analytical run and REPORT PATIENT RESULTS.
7. If the controls fall outside the established ranges after all corrective action noted above has been taken, the system is out of control. CONTACT SECTION SPECIALIST OR SUPERVISOR. Investigate problem and correct. Rerun test and controls if applicable. Do not report patient results until problem is corrected.
8. Document corrective action taken.

See Attachment A: *Quality Control Troubleshooting Guideline*

**Reagent/Calibrator Lot Changes**

Shifts in quality control values which occur concurrently with reagent or calibrator lot changes may be detected with the 10x or 12x rule and may be considered acceptable if the following criteria are met:

1. The new mean is within ± 1 SD, (or 10% for enzymes), from the old mean.
2. The CV of a new lot should be comparable to the precision of the previous lot.
3. Document corrective action.

Alternative assayed controls, group statistics from commercial interlab reports from regular control materials, and statements from manufacturer may also be used to provide justification for controls shifts and changes in the mean. This will be documented in the QC charts.

Additionally, patient comparisons may be used to help compare old and new lots of reagents and ensure consistent results. This will be documented with the QC charts.

**Clinical Significance**

The clinical significance of out-of-control analytes will be evaluated by the section supervisor and/or director. If control deviations are not considered clinically significant, patient results may be released with proper documentation as an interim measure until the situation is resolved.

In establishing the given SD for an analyte, clinical significance of patient results may be taken into consideration.

**Review of Quality Control**

All QC will be reviewed daily by the section supervisor or acting supervisor or specialist.

Weekly, QC from automated instruments with QC documentation in the LIS will be printed up for review by the section supervisor or acting supervisor.

The area director or designee will review and sign off the QC monthly.

For automated instruments, the mean, SD, and CV are calculated monthly. This data is also reviewed with respect to the previous months mean and CV. When available, the data is also reviewed against peer group means and CV. Should the imprecisions and accuracy deviate significantly from previous month’s QC, the cause is to be investigated and documented.

**Interlaboratory Surveys**

CAP survey or comparable interlaboratory survey programs will be subscribed to, in order to ensure that all analytical tests are monitored when available. The survey results will be reviewed by the section supervisor and area director. Analytical test values which are not within acceptable ranges must be addressed and investigated. Performance on these surveys will also be taken into consideration when addressing daily quality control.

**References**

1. Fundamentals of Clinical Chemistry, 3rd ed., Tietz, Norbert, p. 246-47, W.B. Saunders Co., 1987.
2. David Plaut, "Fundamentals of Statistical Quality Control Part 1 & 2," given by ASCP Teleconference 3/20/91 & 3/27/91.

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| --- | --- | --- |
| **Prepared By** | **Date Adopted** | **Supersedes Procedure #** |
| Bruce Harris | October 4, 1988 | New |

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| --- | --- | --- | --- | --- |
| **Revision Date** | **Type of Revision** | **Revised by** | **Review/Annual Review Date** | **Reviewed By** |
| 10/04/1988 | New | B. Harris | 10/04/1988 | G. Kost |
| 02/20/1992 | Revised | B. Harris | 02/20/1992 | G. Kost |
|  |  |  | 10/01/1992 | G. Kost |
|  |  |  | 11/15/1993 | E. Abella |
| 09/17/1994 | Revised | K. Omand | 09/29/1994 | G. Kost |
|  |  |  | 01/08/1996 | G. Kost |
|  |  |  | 10/10/1996 | G. Kost |
|  |  |  | 12/02/1997 | G. Kost |
|  |  |  | 10/12/1998 | G. Kost |
|  |  |  | 12/10/1999 | G. Kost |
|  |  |  | 10/27/2000 | G. Kost |
|  |  |  | 12/28/2001 | G. Kost |
|  |  |  | 10/16/2002 | G. Kost |
| 11/10/2002 | Minor Revision | C, Jarvinen | 11/13/2002 | G. Kost |
|  |  |  | 10/20/2003 | G. Kost |
| 10/25/2004 | Minor Revision | C. Jarvinen | 10/25/2004 | S. Deveraj |
|  |  |  | 10/03/2008 | S. Deveraj |
|  |  |  | 09/15/2009 | G. Kost |
|  |  |  | 10/12/2010 | G. Kost |
| 10/19/2016 | Minor Revision. Removed use of 10x and 12x rules. | kdagang | 10/19/2016 | N. Tran |
| 09/21/2017 | Update | kdagang |  |  |
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Attachment A: *Quality Control Troubleshooting Guideline*

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|  | |  | **RUN CONTROLS** | |  | |  | |
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| IN CONTROL. Proceed with testing. | | |  | | Out of control | | | |
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|  | | |  |  | Inspect control for OUTDATE/EXPIRED, proper storage, extended time at room temperature, correct lot number, signs of contamination | | | |
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| One or more issues present | | |  |  | No obvious explanation | | | |
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| Open a NEW bottle of control and RERUN | | |  |  | Rerun, new aliquot from SAME bottle of control | | | |
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|  | |  |  |  | Out of control | | | |
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|  | |  |  |  |  | |  | |
|  | |  |  |  | Open a new bottle of control and RERUN | | | |
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| IN CONTROL. Proceed with testing.  DISCARD OLD BOTTLE OF CONTROL. | | |  |  | Out of control | | | |
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|  |  |  | |  | |
|  | | |  |  | Check reagent for improper preparation, outdate, low number of tests; load new reagent if necessary,  RECALIBRATE AND RERUN CONTROLS | | | |
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| IN CONTROL. Proceed with testing. | | |  | | Out of control | | | |
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|  | | |  |  | Verify correct calibrator lot number loaded/used (especially if there’s been a SHIFT in QC), load new calibrator data if required, RECALIBRATE AND RERUN CONTROLS | | | |
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| In control, Proceed with testing | | |  | | Out of control | | | |
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|  |  | |  |  | Contact Specialist or Supervisor | | | |
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