9-Internal Quality Controls

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ANNUAL REVIEW:

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SUPERSEDES: Procedure titled _____

1. Purpose:

To define the daily internal Quality Control procedures to be followed for monitoring performance of analytes, be alerted to problems that may affect results and ensure that the quality of reported results meet the analytical standards.

2. Policy:

2.1 All non-waived tests conducted in the laboratory are subjected to daily internal Quality Control procedures and appropriate corrective actions. Where testing is done periodically i.e. weekly etc. each batch of analysis is subjected to internal Quality Control procedures. All results are evaluated regularly daily by testing

personal, weekly by Supervisor and monthly by technical consultant/Clinical Consultant/Lab director.

2.2 The control material preferably preferably have the matrix as the test specimens e.g. lyophilized (used of liquid control material is preferred) controls for plasma or serum, urine controls for urines. Calibrations are not to be used as control materials.

2.3 Where possible, the concentration of the analyte should be in the normal and abnormal ranges, corresponding to concentrations that are critical in the medical interpretation of the test results.

2.4 QC material used is usually from the manufacturer of the instrument. Preferably material from a third party with instrument and method specific values (Assayed Control).

2.5 As applicable choose controls with long expiry dates, with convenient vial volumes and long-term stability.

2.6 For assayed controls, before put into service, verify the mean by running each level 3-5 times on the same day, preferably on different consecutives days, then compare it with the manufacturer provided mean. The achieved results should be within the range provided. If near the manufacturer mean, then used it and keep close observation for few days for possible mean adjustment within the first week, or at the end of the month if the Z score between -1 and 1. 20 days observe points will give better stable mean and even better if more than 2 months. In case peer mean from several laboratories' participant is obtainable. This can give a much better stable mean that includes different reagent and calibrater lot, environment and personal.

2.7 For non-assayed controls, 20 results are needed over different 20 days, the mean achieved will be used.

2.8 Patient results are not to be reported unless all daily quality controls are run, as scheduled, reviewed, and approved by the medical technologist in the particular section.

2.9 Technologists working alone on weekends or public holidays are responsible for evaluating and approving the quality controls results. They can seek the help of the Supervisor if needed.

2.10 All batched tests are run with all levels of quality controls for the specific analyte (2 or 3 levels) at the time of analysis.

3. Definitions/Abbreviations:

3.1 Q.C: Quality Control
3.2 S.D.: Standard Deviation
3.3 C.V.: Coefficient of Variation
3.4 IQC: Internal Quality Control
3.5 NACB: National Academy of Clinical Biochemistry
3.6 Clynisys: Laboratory information system
3.7 WLSH: Wisconsin State Laboratory Hygiene
3.8 NYS: Wadsworth Center of the New York State Department of Health
3.9 CAP: College of American Pathologists
3.10 AAB: American Association of Bioanalysts
3.11 RCPA: The Royal College of Pathologists of Australasia and Australasian Clinical Biochemists Association Assurance Program

3.12 CFX: Canadian Fixed Limits from the College of Physicians and Surgeons of Saskatchewan

3.13 BV:2004 update of the Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) Table of Desirable Based on Biological Variation

3.14 BCQM: BeyondCare Quality Monitor

4. Scope:

This applies to all tests (quantitative & qualitative) performed in Clinical Chemistry and all personnel carrying out these tests.

5. Procedure:

5.1 Quality Specification

5.1.1 All QC material and reagents are stored and reconstituted, if required, according to the manufacturer's recommendations.

5.1.2 Quality specifications are set by the Laboratory Director/ Clinical Consultant/Technical Consultant/Supervisor. These specifications represent current acceptable practice. For example, the guidelines of the National Association of Clinical Biochemistry (NACB), the US National Cholesterol Education Program ATP report, biological variation data [½ intra-individual variation], CLIA or CAP [1/2 to 1/3 of Total Error allowable] will be used and not to exceed CLIA acceptable performance at certain concentration. Other source can be used; published data of others like WLSH, NYS, BV, AAB, RCPA and CFX. This information can be retrieved from Data Innovations web site: http/www.datainnovations.com.

5.1.3 Another approach is to use the TEA to set the range; TAE = Bias (difference between laboratory mean and the true value) + 2 x CV, and this use to set the range

5.1.4 If no source found then the CV is built not to exceed QC kit insert data provided

5.1.5 The Hematology Sysmex BCQM*h* program provides a calibration verification system that may detect issues earlier than with traditional quality control methods. Because the XN-L CHECK™, XN CHECK™ and XN CHECK BF™ controls are cleared by the U.S. Food and Drug Administration (FDA) for use as control and calibration verification materials, calibration status is confirmed every time the controls are analyzed. These control materials are traceable to the same international conventional reference measurement procedures as XN CAL™ hematology calibrators.

5.1.6 Hematology Sysmex use historical achieved mean, the range to be apply is +/- 3SD

5.1.7 Hematology when comparing to accumulated peer, the acceptable CV not to exceed 1.5 group CV

5.2 Quality Control Preparation

5.2.1 All QC material and reagents are stored and reconstituted, if required, according to the manufacturer's recommendation

5.2.2At any given time the same lot number of any control material or reagent shall be used as long as it is available in the department and is within the assigned shelf life.

5.2.3All analyses are carried out strictly according to the method instructions provided by the manufacturer. There is to be no deviation whatsoever from these instructions.

5.2.4All QC materials are treated in the same manner as routine patient samples and they shall not receive any special treatment/attention when performed. QC can be auto-verified or verified by the technologist(s) performing the tests.

5.3 Control Charts

5.3.1The most common method of comparing the values observed for control materials with their known values is through the use of Levy-Jennings control charts. Control charts are graphic displays in which the observed values are plotted versus the time when the observations are made. It is preferred that the control limits calculated from the mean, standard deviation and %CV are established in-house. Only the Supervisor and/or designee are authorized to reassign control means.

5.3.2All controls are plotted either manually or electronically.

5.3.3Depending on the analytical platform used, the control values are uploaded electronically or entered manually. Control values that are within the set limits are allowed for auto-verified. For controls that are not auto-verified, the technologist(s) verify these manually after taking all steps to correct errors.

5.3.4Corrective action comments are entered, when required, on the hard copy chart or in the Cerner system.

5.4 Control Rules

WESTGARD Multirules charts are most commonly used. The procedure requires a chart having lines for control limits, drawn at the mean ± 1s, 2s and 3s, and it can be adapted to existing Levey-Jennings charts by the addition of one or two sets of control limits.

The following control rules are used as guidelines:

1 2s This is a “warning” rule. If one control measurement exceeds the mean by ± 2s, the technologist must consider the performance of other controls in the run (“within-run”) and in previous runs (“across run”) before accepting the run and reporting the results.
If using historical achieved mean, accept results withim +/- 3 SD

1 3s The run is considered out of control when one control value exceeds the mean by ±3s. This rule is applied within the run only. It mainly detects random error, but violation may also indicate the beginning of a large systematic error.

2 2s This rule detects systematic error. It should be applied within across runs. This rule is violated within the run when two consecutive control values (or 2 of 3 control values when 3 levels are being run) exceed the “same” (mean +2s) or (mean -2s) limit. The rule is

violated across runs when the previous values for a particular control level exceed the "same" (mean +2s) or (mean -2s) limit.

R 4s This is a "range" rule that detects random error. It is applied within the run only. This rule is violated when the difference in standard deviation between two control values (or 2 of 3 control values when 3 levels are being run) exceeds 4s.

4 1s This rule detects systematic bias and is applied both within and across control materials. It is violated within the control material when the last four values of the same control level exceed the "same" (mean +1s) or (mean -1s) limit. This rule may not require rejection of the run. Rather, it can be an indicator of the need to perform instrument maintenance of calibration. The mean value may also need to be assigned. This is only done after the approval of the Section Supervisor, Clinical Scientist or Consultant.

10x 10 Consecutive control observations falling on one side of the mean (above or below, with no other requirement on size of the deviation) – is a rule that is sensitive or systematic error. This rule may not require rejection but should be used to investigate calibration and or bias requiring correction. The mean value may also need to be reassigned. This is only done after the approval of the Section Supervisor, Clinical Scientist or Consultant.

Hematology Sysmex use historical achieved mean, the range to be apply is +/- 3SD as it use BCQM traceable calibrator

5.5 Frequency of Running QC

- This is dependent on the specific test and platform on which the test is run.
- For tests that are performed daily, run all three/two levels minimum of once every day testing performed.
- For tests that are batched, run all three/two levels with the batch run.
- Run all three/two control levels following major maintenance, troubleshooting with corrective action or calibration.
- Run all three/two QC levels after observing certain shift or drift with QC or patient results after the appropriate troubleshooting following loading of new reagent(s) or calibration of the assay.

The QC should be run as per most stringent requirement (manufacturer recommendations, CLIA, accreditor, CLIA sets minimum number – at least 2 levels (normal/abnormal) each day tests are run – unless otherwise specified in regulations

- ▪ Quantitative tests - 2 levels (normal & abnormal)
- ▪ Qualitative tests – pos & neg controls
- ▪ Titered test – negative and a titered result

5.6 Control Plot and Correction Actions

5.6.1All controls are plotted and when out of control limits the corrective action must be recorded, either on the chart (manual plotting is done) or typed into the LIS. Effective troubleshooting should identify the root cause of QC being out of control. Pay attention to instrument function, reagents and calibrations. After the corrective action has been taken a random selection of patients sample from the previous run are to re-run along with QC materials. If there is no significant difference between the previous and rerun patient samples there is no requirement to amend patient results.

5.6.2The out of control results are not considered in the statistical calculations.

5.6.3Errors could be:

- Random error: error that can be + or -, but the direction or magnitude cannot be predicted
  - Bubble in sample, poor technique, short sampling
  - If repeat – result would be fine
    - Systematic Error (Bias)- error that occurs in a regular pattern, values consistently running above or below the mean, predictable

  • New lot # QC material
  • Clot aspirated into system
  • Change in reagents
  • Change in major part

  With proper justification, mean can be adjusted
- Systematic error; Drift, Gradual change of quality control results moving upward or downward systematically on more than 4 points, could be for the following reasons:

  • QC material deteriorating
  • Deterioration of reagents
  • Gradual buildup of protein on aspirator tip
  • Light source fading

With systematic, repeating QC WILL NOT correct, but proper maintenance, replacing part, calibration, new reagent etc.

5.7 QC Review justifiable reason to adjust mean

5.7.1The designated technologist carrying out the tests is responsible for running all three/two QC levels and reviewing the QC results daily. Any problem must be reported to the section Supervisor-Technical Consultant, appropriate corrective action(s) taken and documented.

5.7.2The QC Summary, derived from LIS, is printed monthly and reviewed and signed by a senior member of the department or designee (SupervisorTC/CC/LD). This includes monitoring imprecision statistics (CVs, etc.) and significant shifts in the mean values.

5.7.3Corrective actions are to be documented, e.g. reassigning of mean based on the achieved CVs and PT bias being acceptable.

5.7.4All QC results are filed in the appropriate and relevant folders.

9. References:

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6. Data Innovations Website: http//www.datainnovations.com