Beaumont Laboratory
Clinical Pathology
Royal Oak

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Related Documents:

PERFORMANCE GUIDELINES FOR ANALYTICAL METHODS

RC.CH.LOP.QCQA.PY.002.r08

Purpose

The purpose of this document is to provide the Chemistry and Special Testing staff with guidelines for the performance of all analytical methods.

Standard Preparation

Standards (calibrators) and controls prepared in-house should mimic the matrix of the fluid to be analyzed. All chemicals used as primary standards must be of high quality and tested for purity before use unless accompanied by appropriate documentation. Only clinical laboratory reagent water (CLRW) should be used for standards and controls requiring water. Wet chemicals should be weighed in a container that minimizes evaporation. All additions should be made with Class A volumetric pipets and flasks. Proper analytical technique requires measures to ensure quantitative transfer of standard materials.

In-house standards and controls must be segregated by lot and each lot verified for accuracy before placed into service. Each lot should be identified by date of preparation, date placed in service and expiration date. Expiration dates of in-house standards and controls may be re-assigned by Chemistry faculty only after appropriate evaluation studies are reviewed and signed to verify continuing assay performance.

Calibration

Calibration should be performed according to a manufacturer or laboratory's stated requirements for frequency and accuracy. All calibration data should be reviewed by an MT for acceptability and retained for future reference according to laboratory retention policy. After calibration, QC material should be tested and reviewed for acceptability by a medical technologist or supervisor, as appropriate for the assay. QC shifts observed with new lots of calibrator should be noted by laboratory supervisors and discussed with a clinical chemist or pathologist. On automated platforms, calibrations are checked against manufacturer-defined criteria for precision and accuracy (e.g. prior calibration). When calibration fails to meet these criteria, patient testing is not permitted by the automated systems. For lab-developed tests, assigned values for new lots of calibration material should be determined according to the approved procedure for each test.

Recalibration

Each method must be recalibrated as needed to ensure consistent performance.

Recalibration is required:

1. At manufacturer stated intervals
2. When indicated by quality control
3. After a reagent lot change
4. After failed calibration verification
5. At least every six months

Calibration Verification

Calibration verification is the process of confirming the validity of a current calibration. It assumes that verification is a satisfactory substitute for recalibration when a calibration relationship is assumed over an extended period of time. In the absence of recalibration, calibration verification must be performed:

1. At complete changes of reagent
2. When indicated by quality control
3. As recommended by the manufacturer
4. At least 6 months after the last calibration

Calibration verification cannot be satisfied by the use of unassayed control materials. Verification materials must be of an appropriate matrix and have assayed values with manufacturer or laboratory assigned tolerance limits. Recovered results must fall within these limits. In the absence of assayed materials, verification materials may be:

1. Linearity material of an appropriate matrix supplied by a professional or commercial source
2. Proficiency testing material
3. Previously tested patient samples
4. Previously tested patient samples altered by addition or dilution of the analyte
5. Primary or secondary reference materials
6. Calibrators at less than the number required for calibration

Quality Control

See RC.CH.LOP.QCQA.PY.007 “QC Procedures and Policies for Automated Chemistry”
See RC.CH.LOP.QCQA.PY.008 “Method Quality Control” for Special Testing

Reagent Labeling

Reagents (including calibrators and controls) purchased from manufacturers or prepared in-house must be labeled as appropriate with the following information:

- Name of reagent
- Quantity/concentration and matrix
- Storage requirements
- Date opened / prepared
- Initials of individual who opened / prepared the reagent
- Expiration date
- Open expiration date, if opening a container changes the original expiration date
- Hazard designation, if known

Automated systems help control inventory and may maintain reagent information in electronic form. Additional labeling (e.g., date received) should meet department or workstation requirements.

Liquid chemical reagents that do not have a manufacturer-provided expiration date will be assigned ten (10) year expiration; dry/solid chemical reagents without a provided expiration date will be labeled with twenty-five (25) year expiration.

Reagent Use

Reagents must be verified for acceptability when first put into use according to RC.CH.LOP.QCQA.PY.010 "Reagent Lot-to-Lot Comparisons" (Chemistry) or RC.ST.GE.105 "Special Testing Reagent Lot to Lot Comparison General Procedure" (Special Testing). Components from different lot numbers should not be mixed unless specifically permitted. External controls, i.e. non-electronic controls, must be run with each new lot number/shipment of reagent/cartridges. Controls included with a test kit are external controls.

Reagents must be stored according to manufacturer recommendations, or for laboratory-developed tests, according to requirements outlined in method evaluation and laboratory procedures. The laboratory must not use reagents, including calibrators and controls, after manufacturer-assigned expiration dates. In exceptional circumstances where interruption or delay in testing would affect patient safety, laboratory directors must evaluate assay performance and provide written approval for use of expired reagents.

Pipette Accuracy and Precision

Pipettes used for quantitative dispensing are checked at least annually for accuracy and precision. Fixed and adjustable volume pipettes are checked by a photometric method (e.g., the Artel system or equivalent; see Pipette Procedure Manual). The accuracy of pipettes integrated into automated analyzers is checked each day of patient testing using quality controls, with approved QC ranges determining acceptability. Precision of integrated pipettor systems is checked when QC statistics are evaluated at least monthly. Manufacturer instructions should be followed for monitoring and maintaining pipettor accuracy and precision. Within-run and between-run precision studies may be performed as needed for troubleshooting purposes.

Carryover

Carryover is evaluated initially at the time of validation of a test system, as defined in RC.CH.LOP.QCQA.PY.004 “Protocol for New Test Introduction”. For these studies, the laboratory should use the EP Evaluator Carryover module, which requires statistical comparisons of several low samples run separately and after high samples in a defined sequence.

Additionally, carryover must be evaluated after major maintenance or repair of a pipette/auto-sampler assembly to evaluate any change in extent of carryover defined at validation. For this purpose, or for routine troubleshooting, carryover may be evaluated by testing a low concentration sample (1), followed by a high concentration sample, followed by the same low concentration sample (2) to determine a % Interaction:

$$\% \text{ Interaction} = \frac{[\text{Low Result (2)} - \text{Low Result (1)}]}{\text{High Result}} \times 100$$

This calculates the percent of a leading sample that is transferred into the sample following it (carryover). Acceptable values may vary according to the imprecision of the method and range of possible values for the analyte and should be judged by a clinical chemist or pathologist. It may also be evaluated by testing a blank sample after a positive sample such as a standard. Using this approach, it is calculated as follows:

$$\% \text{ Interaction} = \frac{\text{Blank Result} \times 100}{\text{Standard Result}}$$

Analytical Measurement Range

The analytical measurement range (AMR) is established by the range of linearity of the method. It is the range of values that a method can directly measure on a specimen without dilution or concentration. The AMR is established at the time of assay validation and verified at least every six months to be within established tolerances for each assay.

AMR verification requires the use of assayed or acceptable materials at the mid-range, and at or reasonably near the lower and upper limits of the AMR. As long as they satisfy these requirements, materials specified for calibration or calibration verification meet the criteria for AMR verification.

When delegated by the appropriate technical or medical director, completed AMR verification studies may be approved by assistant supervisors or supervisors in Automated Chemistry or Special Testing when established acceptability criteria are met (e.g., EP Evaluator criteria based on established total allowable error as defined in RC.CH.LOP.QCQA.RG.010). Exceptions require review by a technical director.

Maximum Dilution

During method validation, maximum dilution for each analyte is defined by the laboratory based on what is clinically relevant and analytically valid. The appropriate diluent(s) for each analyte, as well as volumes of sample and diluent are validated at that time. Both automated and manual dilutions must be performed according to these parameters.

Result Verification

All patient results must be verified for acceptability prior to reporting, whether they are entered manually into the computer or uploaded automatically from an interfaced analyzer. If auto-verification is in effect, results that satisfy established rules may be released without review by the operator. In the absence of auto-verification, results must by reviewed by the person performing the test. Results which are entered manually into the computer must be reviewed by another individual.

References

CAP Inspection and Accreditation, Automated and Special Chemistry checklists.

Authorized Reviewers

Section Medical or Technical Director

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Document Control

Location of Master: Master electronic file stored on the Clinical Pathology server under S:/Automated Chemistry/Document Control Library/NEW/LOP/QCQA/Master
Master printed document stored in Automated Chemistry Policy and Procedures Manual in core lab.
Number of Controlled Copies posted for educational purposes:
Number of circulating Controlled Copies: 2
Location of circulating Controlled Copies:
Automated Chemistry Policy and Procedures Manual, STAT Lab
Special Testing Policy and Procedures Manual

Document History

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Steven M. Truscott, PhD	02/11/2015		
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Steven Truscott, PhD	1/12/2018	r07	Clarification of calibration section
Elizabeth Sykes, MD	02/02/2018		
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Ashley Hurand, MLS(ASCP)cm	10/31/2019	r08	Removed “After Major Maintenance” from Recalibration and Calibration Verification and added a procedure for reference in QC section.
Qian Sun, PhD	11/6/2019		

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