Beaumont Laboratory
Clinical Pathology
Royal Oak, MI 48073

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Related Documents:

Reagent and Calibration Standards, Lot-to-Lot Comparisons

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Purpose

This form is intended to guide the Chemistry staff in performing reagent lot-to-lot comparisons when new lot numbers of reagent or new shipments of the same lot number of reagent are received.

Policy

Per CAP Checklist item COM.30450 New Reagent Lot Verification, ***"New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service".***

For quantitative and qualitative non-waived testing, new reagent lots and/or shipments must be tested in parallel with old lots before or concurrently with being placed in service to ensure that the calibration with the new lot of reagent maintains consistent results for patient specimens.

For qualitative tests, minimum cross-checking includes retesting at least one known positive and one known negative sample from the old reagent lot against the new reagent lot. A weakly positive sample should also be used in systems where patient results are reported in that fashion.

Patient specimens should be used to compare a new lot against the old lot, when possible, since it is patient specimens that are tested.

Proficiency testing materials with peer group established means and QC materials are acceptable alternatives for validating new reagent lots. However, the laboratory should be aware that PT and QC materials may be affected by matrix interference between different reagent lots. Thus, even if results show no change following a reagent lot change, a calibration inconsistency for patient specimens could exist nonetheless, masked by matrix interference affecting the PT or QC material. It is for this reason – to confirm the absence of matrix interference- that the use of patient samples is recommended.

If QC material is used, the material should have a peer group established mean value based on inter-laboratory comparison that is method specific and includes data from at least 10 different laboratories.

The use of QC material alone is adequate to check a new shipment of a reagent lot currently in use, as there should be no change in potential matrix interactions between QC material and different shipments of the same lot number of reagent.

Specimen Collection and Handling

Pull specimens from current day's run and/or from recent archive for comparison testing between current and new lots of reagent.

Procedure

Tag all new reagent lots/shipments as soon as possible after receipt. Lot tags for ***new lots*** will be differentiated from those for ***new shipments*** with a red "NEW LOT" stamp. Evaluate new lots as they are put into use before patient testing.

We appreciate the advantages of prior testing, but recognize that this is not possible for some analyzers/analytes (e.g. Atlas Reagent Strips, etc.)

<u>New Lot, Quantitative Testing</u>

1. Calibrate the new reagent lot after loading reagent onto respective analyzer/test system.
2. Assay current (unassayed) quality control materials, *in duplicate*, for each new lot.
3. Perform patient comparisons (N=5, that span AMR for analyte).
4. Evaluate QC results (must be within current 2SD QC range) for analyte tested.
5. If QC is unacceptable:
    a. Run assayed QC
    b. Evaluate unassayed QC against peer group established mean
    c. Perform N=5 patient comparisons near range(s) of failed QC level(s).
6. Evaluate patient results *individually* for acceptability.
7. If new lot is required for immediate use but failure(s) occur within sample patients, accept new lot based on QC acceptability alone and consult with Technical Director for further direction.
8. MT2 for technical area can "final approve" new lot provided above QC and N criteria are met. Otherwise, consult with Technical Director for further direction.
9. MT2 will trend new reagent lots using AVG % difference for N patients compared.
10. Tag new lot as "ready for use" and log all QC in LIS or Unity.
11. Lot information is entered in Excel spreadsheet on Sharepoint when New Lot goes into use.

Acceptability Criteria Options for Patient Specimens

1. Within absolute or percent limits of TEA, defined by analyte and analyzer, that are currently applied for our semiannual instrument-to-instrument patient comparisons
2. Within evaluation limits (percent, absolute, SD) by analyte, that are utilized by CAP for proficiency testing

<u>New Shipment, Quantitative Testing</u>

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current (unassayed) quality control materials, for each new shipment.
3. Evaluate QC results (must be within current 2SD QC range) for analyte tested.
4. If QC is unacceptable, run assayed QC, if available, and evaluate unassayed QC against peer group established mean.
5. MT2 for technical area can approve new shipment provided above criteria are met. Otherwise, consult with Technical Director for further direction.
6. Lot information is entered in Excel spreadsheet on Sharepoint when <u>new shipment</u> of current lot goes into use.

New Lot, Qualitative Testing - Instrument or Manual Procedure (e.g. Hepatitis, hCG, HIV)

1. Calibrate the new lot, if required per instrument operating procedure.
2. Document results on New Lot Verification Sheet for respective assay.
3. Assay current (unassayed) quality control materials
4. Evaluate QC results (must be acceptable)
5. Perform patient comparisons, one known positive and one known negative. Must recover same results with new lot.
6. MT2 for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
7. Log all QC in LIS or Unity.
8. New lot information is entered in Excel spreadsheet on Sharepoint when new lot goes into use.

New Shipment, Qualitative Testing - Instrument or Manual Procedure (e.g. Hepatitis, hCG, HIV, etc.).

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current (unassayed) quality control materials.
3. Evaluate QC results (must be acceptable).
4. MT2 for technical area can approve new shipment provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. Log all QC in LIS or Unity.
6. New shipment information is entered in Excel spreadsheet on Sharepoint when new shipment of current lot goes into use.

New Lot, Exception Analytes, Analyzers

For some assays, it is difficult to obtain patient specimens for comparison testing (e.g. blood gas specimen integrity for Radiometers, low specimen census for some DAU/TDM assays in Toxicology). For some instruments, only current lot calibration can be held in the analyzer. For such assays, QC materials alone will be utilized to check new reagent lots.

1. Assay all available current (unassayed) quality control materials. Must be within range.
2. Evaluate QC against peer group established mean value (inter-laboratory comparison) if peer group includes data from at least 10 different labs.
3. Otherwise, evaluate next 5 runs of QC with Technical Director for any QC shifts (preferably complete within 24 hrs).
4. MT2 for technical area can approve new shipment provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. Log all QC in LIS or Unity.
6. Lot information is entered in Excel spreadsheet on Sharepoint when New Lot goes into use.

Procedure for Calibration Standards

1. Follow manufacturer's instructions. Reconstitute calibrator if necessary.

2. Monitor calibrator acceptability for a new lot of calibration standards by evaluation of subsequent QC.

Authorized Reviewers

Section Medical Director or Technical Director

Reagent and Calibration Standards, Lot-to-Lot Comparisons

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/AutoChem/DocControl/CH/LOP/QCQA
Master printed document stored in Automated Chemistry General Policy and Procedure Manual, Core Lab
Number of Controlled Copies posted for educational purposes: 0
Number of circulating Controlled Copies: 2
Location of circulating Controlled Copies:
Automated Chemistry General Policy and Procedure Manual, Stat Lab
Special Testing Department Policy and Procedure Manual

Document History

Signature	Date	Revision #		Related Documents Reviewed/ Updated
Prepared by: V. Peterson, MT(ASCP)SC				
Approved by: Elizabeth Sykes, MD	05/19/2011			
Reviewed by: (Signature)	**Date**	**Revision #**	**Modification**	**Related Documents Reviewed/ Updated**
Mark Kolins, MD	11/17/2011			
Steven M Truscott, PhD	05/30/2013	**r01**	Added calibrator verification; changed from RC.PS.CP.QA.SOP.005	
Steven M. Truscott, PhD	2/10/2015	**r02**	Changed patient samples to span AMR, calibrator verification requirements, removed reference to Roche AVL	
Revised by: Robin Carey-Ballough, MT(ASCP)	12/8/2016	**r03**	Specified criteria for evaluation as TEA for quantitative assays. Qualify assayed QC use to if available.	
Kenneth Simkowski, PhD	12/13/2016			
E Sykes MD	02/02/2018			
Peter Millward, MD	11/19/2018			
Revised by: Robin Carey-Ballough, MT(ASCP)	08/27/2019	**r04**	Updated QC entry to include Unity and lot tag tracking to Sharepoint	
Approved: Qian Sun PhD	10/3/2019			