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Reagent Lot-to-Lot Verification

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document 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 reagents are received.

II. POLICY:

A. Per College of American Pathologists' (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"***.

B. 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.

C. 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.

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

E. Proficiency testing materials with peer group established means and Quality Control (QC) materials are acceptable alternatives for validating new reagent lots. However, the laboratory should be aware that Proficiency Testing (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.

F. 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. If this criteria is not met, patient specimens must be ued to perform a reagent lot-to-lot verification.

G. 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 reagents.

H. The Canton Laboratory uses peer group data for reagent verification to meet the CAP standard.

III. 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.

IV. PROCEDURE:

A. Tag all new reagent lots/shipments as soon as possible after receipt. Evaluate new lots as they are put into use before testing patients.

B. **New Lot, Quantitative Testing**

1. Calibrate the new reagent lot after loading reagent onto respective analyzer/test system.
2. Assay current quality control (QC) materials for each new lot.
3. Select three to five patients who have test results previously reported from the current analyte lot. Perform patient comparisons on the newly calibrated analyte lot and the current analyte lot and record data on a Lot-to-Lot Worksheet.
4. If there is no current lot of reagent available, use the reported patient results.
5. Evaluate QC results for analyte tested. QC results must be within current range.
6. If QC is unacceptable do not begin testing patients with the new lot until approved by MT Lead, Supervisor, or Technical Director. To troubleshoot:
    a. Recalibrate assay.
    b. Run assayed QC if available. The Lot-to-Lot is acceptable for running patients if the assayed QC is within range.
    c. Perform 3-5 additional patients in a range near the failed QC.
    d. If available, load new reagent lot on another instrument, calibrate, QC materials and lot-to-lot patient specimens and compare results from other instrument as a troubleshooting process. This would be used if patient results matched but QC results did not.
    e. Consult Lead Medical Technologist (MT) if QC results are still not in

control.

7. Evaluate patient results *individually* for acceptability using Total Error Allowable (TEA) defined by analyte.
8. If patient results do not agree within the TEa, do not begin using the new lot until approved by MT Lead, Supervisor, or Technical Director. To troubleshoot:
    a. Pull additional patients.
    b. Recalibrate assay and repeat QC and patients.
    c. Consult Lead MT, Supervisor, or Technical Director if results still do not match.
    d. Call reagent vendor to begin investigation of a bad lot of reagent or calibrator.
9. 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, Lab Manager, Supervisor, or Lead MT for further direction.
10. For new lots that meet the acceptabiity criteria, the MT performing the Lot-to-Lot can begin testing patients. The Supervisor, Lead MT, or Technical Director will final approve the new lot and file it accordingly.
11. All QC is documented electronically.
12. Lot information is tracked in the laboratory.

C. **New Shipment, Quantitative Testing**

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current QC materials, for each new shipment.
3. Evaluate QC results for analyte tested. QC results must be within current range.
4. If QC is unacceptable, run assayed QC, if available, and perform the procedure used for new lots of reagents.
5. Supervisor or MT Lead can approve new shipment provided the above criteria are met. Otherwise, consult with Technical Director for further direction.
6. All QC is documented electronically.
7. Lot information is tracked within the laboratory.

D. **New Lot, Qualitative Testing - Instrument or Manual Procedure**

1. Calibrate the new lot, if required per instrument operating procedure.
2. Document results on a Lot-to-Lot Worksheet for respective assay.
3. Assay current QC materials.
4. Evaluate QC results for analyte tested. QC results must be within current range.
5. Perform patient comparisons, one known positive and one known negative. Must recover the same qualitative results with new lot.
6. Record the QC and patient results, including the numeric results, if available, on a

Lot-to-Lot worksheet.

7. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
8. All QC is documented electronically.
9. Lot information is tracked within the laboratory.

E. **New Shipment, Qualitative Testing - Instrument or Manual Procedure**

1. Calibrate the new shipment, if required per instrument operating procedure.
2. Assay current quality control materials.
3. Evaluate QC results for analyte tested. QC results must be within current range.
4. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. All QC is documented electronically.
6. Lot information is tracked within the laboratory.

F. **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 Drugs of Abuse/ Therapeutic Drug Monitoring assays). 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 quality control materials. QC results must be within current 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. If less than 10 labs are within the peer group, evaluate the next 5 runs of QC for any QC shifts (preferably complete within 24 hrs).
4. Supervisor or MT Lead for technical area can approve new lot provided above criteria are met. Otherwise, consult with Technical Director for further direction.
5. All QC is documented electronically.
6. Lot information is tracked within the laboratory.

Attachments

Abbott Architect Reagent Verification Lot Number Comparison- Canton Laboratory.pdf

HIV Lot to Lot Worksheet.pdf

Lot to Lot Qualitative Worksheet.pdf

Lot to Lot Worksheet .pdf

Qualitative_Reagent_Lot-to_Lot_Dearborn.pdf

Reagent Lot Number Comparison .pdf

Reagent Lot to Lot and Patient Reproducibility .pdf

Reagent Lot_to_Lot .pdf

Reagent_Lot-to_Lot_Dearborn.pdf

Total Allowable Error (TEA) Reference Guide .pdf

Approval Signatures

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