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Reagent and Calibration Standards, Lot-to-Lot Comparisons - Royal Oak

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.

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.

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. 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.

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

C. **New Lot, Quantitative Testing**

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).
4. Evaluate QC results (must be within current 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. The Lead for technical area can "final approve" new lot provided above QC and patient criteria are met. Otherwise, consult with Technical Director for further direction.
9. Lead will trend new reagent lots using AVG % difference for patients compared.
10. Log all QC in Unity.
11. Lot information is entered in Excel spreadsheet on Sharepoint when New Lot goes into use.

D. **Acceptability Criteria Options for Patient Specimens**

1. Within absolute or percent limits of Total Error Allowable (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.

E. **New Shipment, Quantitative Testing**

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 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. Lead 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 **new shipment** of current lot goes into use.

F. **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. Lead 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 Unity.
8. **New lot information is entered** in Excel spreadsheet on Sharepoint when **new lot** goes into use.

G. **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. Lead 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 Unity.
6. **New shipment information is entered** in Excel spreadsheet on Sharepoint when **new shipment** of current lot goes into use.

H. **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 (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. Lead 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 Unity.
6. Lot information is entered in Excel spreadsheet on Sharepoint when New Lot goes into use.

I. **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.

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
Medical Director	Ann Marie Blenc: System Med Dir, Hematopath	11/8/2021
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory	11/8/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	11/8/2021
Lab Chemistry Best Practice Committee	Elizabeth Sykes: System Med Dir, Chemistry	11/7/2021
Lab Chemistry Best Practice Committee	Qian Sun: Tech Dir, Clin Chemistry, Path	11/5/2021
	Colette Kessler: Mgr Laboratory	11/5/2021

Applicability

Royal Oak