**Intended Use**

To validate new reagent lots and/or new shipments before or concurrent with use for patient testing.

**Summary**

New reagent lots and/or new shipments are checked against old reagent lots with suitable reference material before or concurrently with use for patient testing. Since it is patient specimens that are tested, good clinical laboratory science includes patient-based comparisons when possible. QC material is an acceptable alternative for validating calibration following reagent lot changes if patient testing is not available. As quality control material may be affected by matrix interference between different reagents lots, the periodic used of patient samples to confirm the absence of matrix interference may be helpful. For quantitative tests, reagent validation is most reliably performed by assaying the same patient specimens with both the old and new lots to ensure consistent results, however QC is acceptable. For qualitative tests, minimum cross-checking includes retesting at least one known positive and negative patient sample (when available) from the old reagent lot against the new reagent lot, ensuring that the same results are obtained with the new lot. 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 log number of reagent.

**Procedure**

**Quantitative Tests**

For quantitative tests, the new reagent lot is validated by assaying a patient sample, proficiency sample or QC material previously run on the old lot of reagent. Documentation is maintained in parallel logs (Lot to Lot). The new lot must recover values defined in the Lot to Lot Acceptability Table to be considered acceptable. Some tests (like direct bilirubin) may require good judgment on what is a clinically significant difference. Failure to recover the values defined in the acceptability table will require troubleshooting and resolution prior to running patient samples.

**Qualitative Tests**

For qualitative tests, the new reagent lot it is checked for consistency by retesting at least one known positive and one known negative patient sample (when available), proficiency sample or QC material from the old reagent lot against the new reagent lot. The same results (reactive/ non-reactive, positive/negative, etc) should be obtained from the old reagent lot and the new reagent lot in order to be considered acceptable. If evaluated on quantitative bases the new lot must recover values defined in the Lot to Lot Acceptability Table to be considered acceptable. Failure to recover the values defined in the acceptability table will require troubleshooting and resolution prior to running patient samples. Assays that do not recover successfully will be addressed immediately prior to running patient samples.

**Precautions and Warnings**

Exercise the normal precautions required for handling all laboratory specimens.

**Effective Date**

Effective date for this procedure: January 15, 2018

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