**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**

1. Pooled serum patient sample is made up of 20 random patients and 2 bottles of level 2 or 3 of each type of serum controls.
2. Pooled urine patient sample is made up of 20 urine samples and 2 bottles of level 2 urine control
3. The pooled samples are run daily on each instrument.
4. This is done at the beginning of the month the lot number for those specimens will be the month, 1st day , and the year. For example , April is 04/01/18.
5. The sample is run 5 times to establish a mean and standard deviation.
6. The two controls are entered in Meditech just like any other chemistry control and ranges established.
7. The patient control is run daily on each instrument.
8. The printout of reagent lot numbers will be compared to the previous days lot numbers.
9. Any change in lot numbers will be compared with the previous lot number and a variance calculation will be performed. All results will be written in the lot-to-lot verification form.
10. The printout with the lot number compared will be stapled to the lot to lot sheet and filed in the lot to lot book
11. If the results are not, in range, trouble shooting must be performed and the supervisor notified of the problem. Document in a Analyzer corrective action form.

**Quantitative Tests**

For quantitative tests, the new reagent lot is validated by assaying a pooled 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: March 9, 2018

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**Parallel Testing (Lot to Lot) Acceptability Table**

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| --- | --- | --- | --- |
| **Routine Chemistry** |  | **Immunology** |  |
| ALT | Target Value ±20% | B-HCG | Target Value 10%or ±3SD |
| Albumin | Target Value ±10% | BNP | Target Value ±10% or 3 SD |
| ALK Phos | Target Value ±30% | Troponin I | Target Value ±30% or 3SD |
| AST | Target Value ±20% | Myoglobin | Target Value ±30% or 3SD |
| Bilirubin, Total | Target Value ±20% or 0.4 mg/dl | Tacrolimus | Target Value ±12.5% or 0.5 mg/mL |
| Calcium | Target Value ±1.0 mg/dl | Vitamin D 25OH | Target Value 20%or ±3SD |
| Chloride | Target Value ±5% | CKMB | Target Value 10%or ±3SD |
| CK | Target Value ±30% | HIV | Target Value ±20% or 3SD |
| CO2 (TCO2) | Target Value 10%or ±3SD | Hepatitis panel | Target Value ±20% or 3SD |
| Creatinine | Target Value ±15% or 0.3 mg/dl | **Hematology** |  |
| Glucose | Target Value ±10% or 6 mg/dl | RBC | Target ±6% |
| Lipase | Target Value ±30% | HGB | Target ±7% |
| Magnesium (Mg) | Target Value ±25% | HCT | Target ±6% |
| Potassium | Target Value ±0.5 mmol/L | WBC | Target ±15% |
| Sodium | Target Value ±4 mmol/L | PLT | Target ±25% |
| Total Protein | Target Value ±10% | PT | Target ±15% |
| BUN | Target Value ±9% or 2 mg/dl | PTT | Target ±15% |
| Ethanol | Target Value ±25% | **Drugs of Abuse** | Target Value ±20% |
| Ammonia | Target Value ±20% |  |  |
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