## POLICY

Before using a new lot number of reagent, it must first be checked against the existing lot number to ensure precision and accuracy of results from lot-to-lot.

**IMPLEMENTATION**

1. Place a “**DO NOT USE THIS LOT NUMBER**” sticker on the first box of the new lot when a new lot number of QC, reagent, calibrator is received. The technologist receiving the QC, reagent or calibrator marks the **date received and initials** of the technologist in permanent marker. In addition, the technologist fills out AD02-029 Form A, Laboratory Receiving Log **adhered** to the refrigerator. Supervisor should review and sign the Receiving Reagent log monthly.
2. Check the new lot of reagent by performing the test on all levels of controls used. Accept in Cerner if the controls fall within the specified ±2 SD range.
3. A patient sample is run off the new lot, comparing the results to the previous lot where possible. Comparison results are then acceptable as long as the control results are within the specified +/- 2SD range. Where patient-based comparison specimens are unavailable to validate reagents, proficiency testing materials with peer group established mean values are acceptable for validation of new reagent lots. The Supervisor ensures the results are within “**Lot-to-Lot Verification Acceptability Criteria” (Refer to Attachment A).**
4. Lead/Supervisor reviews and ensures that new calibrator lot number points and expiration dates are entered into the instrument correctly. The technologist records the information on CHQA01-008 Form A2 New Lot Calibration Reagent Log ~~gives the instrument printout sheet of new lot calibration to the Supervisor in addition to the New Lot Calibration check Off Sheet~~ (**CHQA 01-008 Form A2**).The form ~~printout~~ must be completed with  ~~contain~~ the following information: Date reagent calibrated ~~received,~~  reagent name, old and new lot numbers, calibrator lot number, all level of control values are acceptable, patient results with the old lot numbers, and patient results with the new lot numbers and the reason for calibration (i.e. New Lot #, QC issues, Calibration expired on board).
5. Supervisor/ Lead Tech monitors the QC of the new lot for five consecutive days and reviews the QC/Calibration records on the instrument and signs off on CHQA01-008 Form A2. ~~records all information on the Abbott Calibration Log located on the H drive.~~
6. If the controls do not fall within the specified ±2 SD range, check the instrument’s parameters and calibration, where applicable, and perform the test again. If the new lot number consistently gives out‑of‑control results, do not use that lot number. Notify supervisor of any lot number giving out-of-control results. Repeat the above procedure with a different lot number, if available. If the different lot number is also out of range, refer to procedure CHQA01-002, Chemistry Quality Control, for further instructions.
7. Use forms CHQA01-008 Form D3 Lot to Lot for manual Lot to Lot for fFN, hCG, Clinitest.

**REFERENCES**

Procedure for Checking New Lot Numbers of Chemistry Reagents, LAB-G1-30-11, CCMC, General Chemistry Policy Manual, S. Vann, 06/83, Revision 1.

**Approval Signatures:**

|  |  |  |
| --- | --- | --- |
| **Date** | **Printed Name** | **Signature** |
| 2/29/2016 | Jennifer Lore, MFS, MT  Chemistry Supervisor |  |
| 2/29/2016 | Vanessa Rawlings  Laboratory Supervisor, Elkins Park |  |
| 2/29/2016 | Nancy A. Young, M.D., FCAP  Medical Director |  |

**History Review**

|  |  |  |
| --- | --- | --- |
| **Date Reviewed** | **Reviewed By** | **Revisions** |
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**LOT TO LOT VERIFICATION ACCEPTABILITY CRITERIA**

|  |  |  |
| --- | --- | --- |
| **General Chemistry:** |  | **% Difference** |
|  | **Albumin** | **+/- 10%** |
|  | **Alk Phos** | **+/- 30%** |
|  | **ALT** | **+/- 20%** |
|  | **Ammonia** | **+/- 10%** |
|  | **Amylase** | **+/- 30%** |
|  | **AST** | **+/- 20%** |
|  | **Bili Total** | **+/- 20%** |
|  | **Bili Direct** | **+/- 20%** |
|  | **BUN** | **+/- 10%** |
|  | **Calcium** | **+/- 10%** |
|  | **Cholesterol** | **+/- 10%** |
|  | **CO2** | **+/- 10%** |
|  | **CPK** | **+/- 30%** |
|  | **Creatinine** | **+/- 15%** |
|  | **GGT** | **+/- 10%** |
|  | **Glucose** | **+/- 10%** |
|  | **HDL Cholesterol** | **+/- 30%** |
|  | **Iron** | **+/- 20%** |
|  | **Lactic Acid** | **+/- 10%** |
|  | **LDL Cholesterol** | **+/- 30%** |
|  | **LDH** | **+/- 20%** |
|  | **Lipase** | **+/- 30%** |
|  | **Magnesium** | **+/- 25%** |
|  | **Phosphorus** | **+/- 10%** |
|  | **TIBC** | **+/- 20%** |
|  | **Total Protein** | **+/- 10%** |
|  | **Triglyceride** | **+/- 25%** |
|  | **Uric Acid** | **+/- 17%** |
|  | **UCFP** | **+/- 30%** |
| **Toxicology:** |  |  |
|  | **Acetaminophen** | **+/- 20%** |
|  | **Alcohol** | **+/- 25%** |
|  | **Digoxin** | **+/- 20%** |
|  | **Dilantin** | **+/- 25%** |
|  | **Gentamicin** | **+/- 25%** |
|  | **Lithium** | **+/- 20%** |
|  | **Phenobarb** | **+/- 20%** |
|  | **Salicylate** | **+/- 20%** |
|  | **Tegretol** | **+/- 25%** |
|  | **Theo** | **+/- 25%** |
|  | **Tobramicin** | **+/- 25%** |
|  | **Valproic Acid** | **+/- 25%** |
|  | **Vancomycin** | **+/- 20%** |
|  |  | CHQA01-008 Attachment A |

## 

## LOT TO LOT VERIFICATION ACCEPTABILITY CRITERIA

|  |  |  |
| --- | --- | --- |
| **Endocrinology:** |  | **% Difference** |
|  | **AFP** | **+/- 10%** |
|  | **B-12 Serum** | **+/- 10%** |
|  | **hCG** | **+/- 10%** |
|  | **CEA** | **+/- 10%** |
|  | **CKMB** | **+/- 10%** |
|  | **Cortisol** | **+/- 25%** |
|  | **Ferritin** | **+/- 10%** |
|  | **Folic Acid** | **+/- 10%** |
|  | **Free T4** | **+/- 10%** |
|  | **FSH** | **+/- 10%** |
|  | **LH** | **+/- 10%** |
|  | **Prolactin** | **+/- 10%** |
|  | **PSA** | **+/- 10%** |
|  | **Total T3** | **+/- 10%** |
|  | **T3 Uptake** | **+/- 10%** |
|  | **Total T4** | **+/- 20%** |
|  | **Troponin I** | **+/- 10%** |
|  |  |  |

CHQA01-008 Attachment A