**TITLE: Chemistry Reagent Receipt and**

**Verification Process**

**Principle / purpose:** New shipments and lots of chemistry reagents must be verified prior to being put in use. This procedure outlines the receipt and verification process.

**Complexity Level:** Moderate (High – Procalcitonin)

**Safety:**

* The required personal protective equipment for this procedure
  + - Gloves
    - Impermeable lab coats, worn closed
    - Shield
    - Approved protective eyewear
* Gloves and lab coats should be worn at all times during analysis of samples.
* Samples must be opened behind a safety shield.

**PROCEDURE:**

**Reagent Receipt:** All reagents, detergents, and items must be labeled with received dates.

# Receiving Reagents (items specific for an analyte):

# Compare reagents received to packing slip.

# Note any discrepancies in the amount received and notify supervisor or designee.

# Label each item with received date.

* 1. Label lot/shipment with “Do Not Use” or site specific sticker.
  2. Store reagents per manufacturer’s recommendation.

1. **Receiving Auxiliary Reagents/Detergents (items NOT specific for an analyte):**

# Compare items received to package slip.

# Note any discrepancies in the amount received and notify supervisor or designee.

# Label each item with received date.

* 1. If the item packaging contains package insert, record information on Miscellaneous Package Insert Verification Log.

**Reagent Verification:** All new shipments and lots must be verified prior to being put in use. All new lots require quality control (QC) and patient blind duplicate (BDUP) testing. New shipments of the same lot number require quality control (QC). Reagents of the same lot and shipment require quality control (QC).

**Note: If reagent is used for multiple analytes, all analytes must be verified, e.g. ISE reagents.**

1. **New Lots**
   1. Obtain Reagent Verification Log for analyte.
   2. Record Date Received, Lot Number, Expiration Date, and Visual Check on log.
   3. Load reagent per instrument operating procedures.
   4. Calibrate reagent if required.
   5. Perform QC and verify in Remisol. Document on Reagent Verification Log.
   6. Perform BDUP testing. Document on Reagent Verification Log.
   7. Both QC and BDUP must be within acceptable limits before reporting patient data. See **Blind Duplicate Testing** section below.

# Once lot has been verified, apply “Ready to Use” or site specific labels on validated lot numbers.

1. **New Shipment, Same Lot**
   1. Obtain Reagent Verification Log for analyte.
   2. Record Date Received, Lot Number, Expiration Date, and Visual Check on log.
   3. Load reagent per instrument operating procedures.
   4. Calibrate reagent if required.
   5. Perform QC and verify in Remisol. Document on Reagent Verification Log.
   6. Circle **N/A** under BDUP column of Reagent Verification Log.
   7. QC must be within acceptable limits before reporting patient data.

# Once lot has been verified, apply “Ready to Use” or site specific labels on validated lot numbers.

1. **Same Shipment, Same Lot**
   1. Verify Reagent Verification Log has been documented for shipment.
   2. If not logged, record required information on Reagent Verification Log. See instructions for **New Shipment, Same Lot** above.
   3. If logged, load reagent pack per instrument operating procedures.
   4. Calibrate reagent if required.
   5. Perform QC and verify in Remisol. Document on Reagent Verification Log if not previously recorded.
   6. QC must be within acceptable limits before reporting patient data.

**Blind Duplicate Testing:**

The laboratory uses patient blind duplicate testing to confirm there are no changes in matrix interactions between different lot numbers of reagent. Blind duplicates can also be used when troubleshooting QC issues. After calibration of the new lot has been accepted, pull two patient specimens.

\*If possible, one should be low and one should be high for the reagent lot to be verified.

**Selecting BDUP Samples:**

The following are **unacceptable** for patient BDUP testing:

* + - Samples significantly below or above normal range.
    - Samples with results outside of linearity (> or <).
    - Samples stored at inappropriate temperatures.
    - Aged samples.
    - Serum/plasma not removed from red blood cells.
    - Specimens not stored capped
    - Hemolyzed samples

If an acceptable blind duplicate is not available, circle “No Sample Available”.

1. **Programming BDUPs on analyzer for DxC tests**
   1. Under the sample order entry screen, select “Clear”
   2. Enter the sample id number EX:C-LTLI1,C-LTL2
   3. Select “OK” twice.
   4. Select “Control”
   5. Select the correct panel based on the test that is going to be ran. Ex: CK select C-LTL1 and C-LTL2
   6. Select Test
   7. Select "Reagent Cart"
   8. Select both lots of reagent for that analyte.
   9. Save and run the sample in the appropriate bar-coded tube.
2. **Programming BDUPs on analyzer for DxI tests**
   1. Under the sample order entry screen on the DxC, select “Clear”
   2. Enter the sample id number EX:C-LTLIMM1,C-LTLIMM2
   3. Select “OK” twice.
   4. Select “Control”
   5. Select the correct panel based on the test that is going to be ran. Ex: BHCG select C-LTLIMM1 and C-LTLIMM2
   6. Select Test
   7. Remove new lot reagent pack from the DxI
   8. Save and run the sample in the appropriate bar-coded tube.
   9. Once results print remove the old lot reagent pack from the DxI and replace with the new lot reagent pack.
   10. Repeat steps a-f for the new lot reagent pack
3. Once completed the results will print.
4. Record the reagent lot numbers and Compare the results of the two reagent lots.
5. Record both results for each sample on the correct "Reagent Lot Verification Log".
6. If the difference between the two results is clinically insignificant (+/- 10%), the new lot is acceptable.
7. If the value of the reagent lot verification is NOT ACCEPTABLE,
   1. Check the sample volume
   2. Make sure stored/frozen sample is completely thawed and mixed
   3. Pour-up fresh aliquot after adequate mixing.
   4. Re-run the sample.
   5. If samples fails again pull another Blind Duplicate sample and repeat procedure.
   6. Repeat failure on second Blind Duplicate sample may indicate need for re-calibration.
   7. If the second Blind Duplicate sample does not work, after recalibration consult the supervisor or designee.
8. Once acceptable, REMOVE the red DO NOT USE sticker from the new reagent lot.

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| **Medical Director Approval** –  ARMC Cancer Center ARMC Main Lab |  |  |
| **Medical Director Approval –** MedCenter Mebane |  |  |

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**SOP HISTORY PAGE**

**SOP Number:** CHEM-110

**SOP Title:** Chemistry Reagent Receipt and Verification Process

**Written By:**

**Manual in which Hard Copy of this SOP is located:** General Chemistry Procedure Manual

**Distribution:** no other locations

**Supersedes Procedure:**

SOP CHANGE CONTROL

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