BIOGENIX

POLICY PROCEDURE FOR RECEPTION, STORAGE AND ACCEPTANCE TESTING OF REAGENT AND CONSUMABLE

	NAME	DESIGNATION	SIGNATURE	DATE
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2. REVISION HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				

3. REVIEW HISTORY

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1	1.0				

4. POLICY STATEMENT

4.1 The reagent and consumables are received in the store and verified as per this procedure

4.2 New reagent lots and/or shipments must be evaluated in parallel with old lots before or concurrently with being placed in service to ensure that testing with the new lot of reagent maintains consistent results for patient specimens.

4.3 It is strictly prohibited in BIOGENIX Laboratory to mix components of different kits or lot numbers owing to difference in manufacturing conditions, shipping and storage.

5. PURPOSE

The main objective of this procedure is to:

5.1. Simplify approval processes and minimize delay in placing orders;

5.2. Assure on schedule delivery;

5.3. Minimize the risk associated with goods and services.

5.4. Many factors may affect the reproducibility of results in individual patients but one that has challenged laboratories for many years is variation between different manufacturing lots of reagents leading to analytical errors or shifts in patient results.

5.5. This procedure aims to provide protocol for the validation of new reagent lot and shipments prior to being qualified as acceptable for use for daily patient sample testing.

This procedure is as per clause 5.3.2. of ISO 15189:2012 of Medical Laboratories requirements of quality and competence

6. SCOPE

6.1. This procedure covers the activities associated with reception, storage, acceptance testing and Inventory management of reagent and consumables.

6.2. Target Audience: All BIOGENIX Laboratory staff

7. DEFINITIONS

7.1. Lot No.: A Lot number is an identification number assigned to a particular quantity or batch of material or reagents from a single manufacturer. The lot number enables tracing of the constituent parts and gives consumers an identifier that they can use in contacting the

manufacturer and researching the production of reagents received.

7.2. Vendor: One that provides products or services to a business for a fee.

7.3. Supplier: person/company who will supply the concerned item.

8. ACRONYMS

8.1 **QC material** - Quality Control material

8.2 **LTLV -** Lot-to-Lot Validation

9. RESPONSIBILITIES

9.1 BIOGENIX purchase department

9.2 All BIOGENIX Laboratory technologists and team leaders, who perform patient testing using reagents of different lot and shipments are responsible to abide to this policy.

9.3 It is the responsibility of the laboratory store to notify the Quality Department once a new reagent Lot has arrived so the Lot-to-Lot Validation (LTLV) study could be initiated.

10. PROCEDURE

10.1. **Reception and Storage:**

10.1.1. Upon receiving of the reagent/ consumable the staff who is receiving checks:

10.1.1.1. expiry date (if short expiry i.e. less than 3 months either item is returned or supplier is contacted);

10.1.1.2. temperature, packaging;

10.1.1.3. Quantity is matched to the ordered quantity in the LPO;

10.1.2. All the items which are received are entered in stock receiving Sheet

10.1.3. All items received are updated in corresponding Inventory sheet.

10.2. **Acceptance Testing**:

10.2.1. The reagents are verified before use for examining patient samples. Verification is done by doing Quality controls with the reagents, or by comparing results or 6 patient's samples/5% of the total number of samples.

10.2.2. For qualitative tests take 3positive and 3 Negative samples.

10.2.3. For Detail procedure refer to Verification of new lots & shipments prior to use

10.3. **Adverse Incident Reporting:** Any adverse incident in concern with reagents and consumables are recorded in Incident report Form, and immediate action is taken to resolve the issue.

10.4. **Records:** All the reagents and consumables that are received in the lab. are recorded in the stock receiving sheet.

10.4.1. Records for reagents and consumables consist of following:

i. Lot number of reagents
ii. Supplier contact information
iii. Date of receiving, expiry date and date of opening.
iv. Condition when received
v. Manufacturer's instructions
vi. Reagent verification records
vii. Date of opening of control and Calibrators
viii. For the controls and calibrators which are reconstituted in the lab. date of reconstitution and the name of person who reconstituted is recorded.

10.5. No expired item is kept in the laboratory. Expired reagents and consumables are discarded as per the recommendation of manufacturer.

11. CROSS REFERENCE

11.1. ISO 15189 Medical laboratory- Requirements for Quality and Competence.

12. RELEVANT DOCUMENTS & RECORDS

12.1 Stock receiving Sheet

12.2 Lot to lot verification of Qualitative and quantitative test Reagent

12.3 BG/REC/GEN/004 Control and Calibrator Reconstitution Record