BIOGENIX

POLICY PROCEDURE FOR VERIFICATION OF NEW LOTS & SHIPMENTS PRIOR TO USE

	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

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
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4. POLICY STATEMENT

4.1 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.

4.2 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

5.1 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.

5.2 This policy 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 5.3.2.3 of ISO 15189:2012 of Medical Laboratories requirements of quality and competence

6. SCOPE

6.1 The scope of this policy and procedure extends to all reagents used in all steps of performing the test performed at BIOGENIX Laboratory.

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.

8. ACRONYMS

8.1 QC material - Quality Control material

8.2 LTLV - Lot-to-Lot Verification

9. RESPONSIBILITIES

9.1 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.

9.2 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 Verification (LTLV) study could be initiated.

10. PROCEDURE

All the reagents are verified before use for examining patient samples.

10.1. Why we need to verify the reagent Lot

10.1.1. Change in reagent components

10.1.2. Instability of reagent components

10.1.3. Incorrect calibration of the new reagent lot

10.1.4. Damage during transportation or storage

10.2. Qualitative Assays:

10.2.1. When a **new lot received for reagent, Lot –to- Lot Validation** is to be performed using 6 samples (3 negative and 3 positive) or 9 samples (3 negatives, 3 weak reactive and 3 reactive)

10.2.2. For Nucleic Acid Extraction and Real-time fluorescent RT-PCR kits reagents, LTLV should be performed on 5% of the total number of samples on one plate that is around 6 patient samples.

10.2.3. In case of new reagent kit and new shipment but for same lot internal quality control is sufficient.

10.2.4. **Acceptance criteria**: positive sample should come positive and negative sample should come negative.

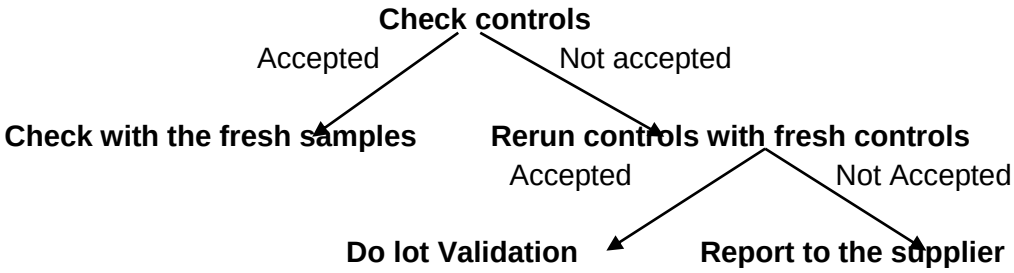
10.2.5. LTLV is performed using all components of one Lot, i.e. without mixing reagent components from different Lots.

10.2.6. Internal quality controls are included with both runs.

10.2.7. Using patient samples, the difference between the two values run on the old and new lot should not be more than 10% of the average of the two derived values.

10.2.8. If the values are more than 10%, a corrective action has to be taken

10.2.9. Corrective actions taken for failed LTLV are performing extensive machine cleaning, third party calibration, communicating with the supplier.



10.3. For Quantitative tests

10.3.1. When a **new lot received for reagent Lot –to- Lot Verification** is to be performed using: 5 samples (Patient samples or PT sample)

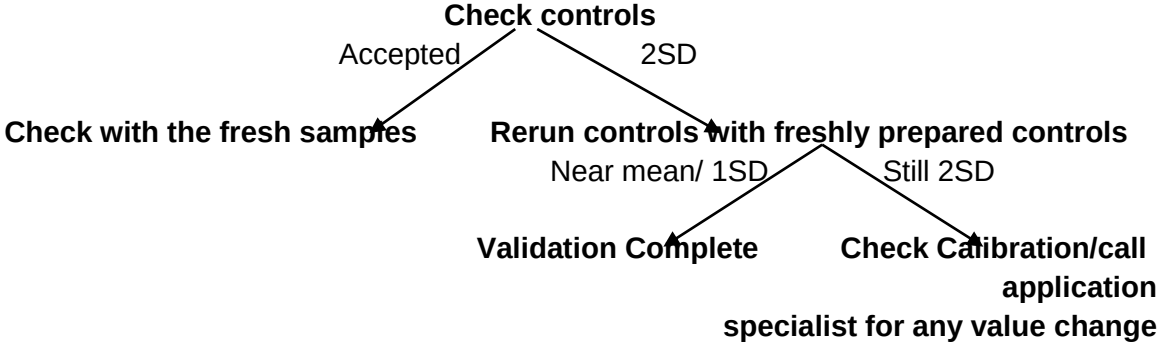
10.3.2. In case of new reagent kit and new shipment but same lot, internal quality control is sufficient.

10.3.3. Results of the patient samples are then entered in verification sheet and calculations are made using following formula:

$$\frac{\textbf{Result from new reagent – Result from old reagent}}{\textbf{Result from old reagent}} \textbf{ X 100}$$

10.3.4. **Acceptance criteria**: Comparing the result with acceptable bias if available and if no, compare with the imprecision values given in the kit insert.

10.3.5. What if acceptance criteria are not met? QC or patients outside the limits?



If still not validated report the reagent to application specialist

10.4. In case reagent is not acceptable a red sticker is put on the reagent and recorded in incident form

10.5. We have an understanding with our suppliers that if reagents are unacceptable after lot verification they will take it back.

10.6. Many reagents have onboard expiry date so it cannot be checked at the time of receiving the reagents.

10.7. The reagents which have green stickers mean that the reagent is verified and ready to use.
10.8. Reagents without sticker means the reagent is not verified till date.

11. CROSS REFERENCE

11.1. ISO 15189 Medical laboratory- Requirements for Quality and Competence.
11.2. CLSI guidelines EP26A and EP12A2
11.3. All common checklist from CAP (07.28.2015)

12. RELEVANT DOCUMENTS & RECORDS

12.1 BG/REC/GEN/018 Lot to lot verification sheet