LifeCell

QC Lot Comparison Form

LC/DIA/LAB/GEN/SOP-017/FOM-01 | Effective Date: 09/02/2022

Issued by: ABHINAV | Month & Year : FEB 2023 | Location: BIOCHEMISTRY PUNE

			Old Lot					New Lot								
S.No	Date	Reagent Name	Lot No.	Expiry Date	Manufacturer Mean	Manufacturer SD	Obtained Result	Lot No.	Expiry Date	Manufacturer Mean	Obtained Result	Manufacturer SD	SD	Done by	Verified By	Comment
1	13.02.2023	LH	40400	31.10.2023	0.95		0.83	40410	30.9.2024	0.95	0.91			Dynamesh	Sonal	Manufacturer stated mean and SD is comparable, Lot is accepted
2	13.02.2023	LH	40400	31.10.2023	0.95	0.09	0.88	40410	30.9.2024	0.95	0.84	**0.09**	0.015	Dynamesh	Sonal	Manufacturer stated mean and SD is comparable, Lot is accepted
5	13.02.2023	Testosterone	40400	31.10.2023	3.6		3.06	40410	30.9.2024	3.6	3.21			Dynamesh	Sonal	Manufacturer stated mean and SD is comparable, Lot is accepted
6	13.02.2023	Testosterone	40400	31.10.2023	3.6	0.34	3.21	40410	30.9.2024	3.6	3.19	**0.34**	0.01	Dynamesh	Sonal	Manufacturer stated mean and SD is comparable, Lot is accepted

15.02.2023

into service and is reviewed biennially thereafter as part of the procedure manual review by the Laboratory Director or designee. The laboratory director is responsible for establishing the maximum allowable dilution of samples that will yield a credible laboratory result for clinical use.

7.2.5. AMR Verification Materials

7.2.5.1. Verification of the analytical measurement range (AMR) is performed with matrix-appropriate materials, which, at a minimum, include the low, mid and high range of the AMR with appropriate acceptance criteria. The matrix of the sample (ie, the environment in which the sample is suspended or dissolved) may influence the measurement of the analyte. In many cases, the method manufacturer will recommend suitable materials.

7.2.5.2. Other Suitable Materials for AMR Verification:

- Linearity material of appropriate matrix, exp - CAP CVL Survey-based or other suitable linearity verification material.
- Previously tested patient/client specimens, which may be altered byadmixture with other specimens, dilution, spiking in known amounts of ananalyte, or other technique.
- Primary or secondary standards or reference materials with matrix
- characteristics and target values appropriate for the method.
- Patient samples that have reference method assigned target values.
- Control materials, if they adequately span the AMR and have method specific target values.

7.2.6. Lot Verification for QC Material

7.2.6.1. New lot of controls should be run in parallel with old lot of controls for 2 consecutive runs to verify the manufacturer-stated mean & SD.

7.3. Daily QC:

7.3.1. **Handling QC Material**:

7.3.1.1. The laboratory shall ensure that for each test system, control procedures are performed using the number and frequency specified by the manufacturer or established by the laboratory

7.3.1.2. All commercial Quality Control specimens are tested in the same manner and by the same personnel routinely performing the testing on client/patient samples.

7.3.1.3. QC samples are tested before testing the client/patient samples.

7.3.1.4. Quality control samples are prepared and performed as per manufacturer instructions. (review kit inserts prior testing the QC)

7.3.1.5. At time of analysis, QC material are verified for:

7.3.1.5.1. Expiry date.

7.3.1.5.2. Manufacturer's insert.

7.3.1.5.3. Manufacturer's instruction and recommendations

7.3.1.6. Control material testing shall be performed before resuming patient testing when a complete change of reagents is introduced, major preventive maintenance is performed, or any critical part that may influence test performance is replaced and over time, rotated among all operators performing the test.

7.3.1.7. Preparation of Randox IQC Materials:

7.3.1.7.1. Maternal control (Level 1, Level 2, Level 3): open the vial carefully, avoiding any loss of the material.

7.3.1.7.2. Reconstitute with 1ml of distilled water in each vial

7.3.1.7.3. Replace the rubber stopper, close the vial and leave for 30 minutes before use.

7.3.1.7.4. Ensure that all traces of dry materials are dissolved by swirling gently