1. PURPOSE

1.1. To ensure validity of test results through Internal Quality Control in Biochemistry Laboratory

2. SCOPE

2.1. This procedure is applicable to all the testing activities of the Biochemistry - Laboratory

3. REFERENCES

3.1. ISO 15189 Standard

4. RESPONSIBILITY

4.1. Quality Manager

4.2. Laboratory Director

5. PROCEDURE

5.1. Internal QC checks

5.1.1. Two levels of QC are run at least once on the day the test is performed

5.1.2. The daily QC values are documented and LJ charts (Levey-Jennings chart) are plotted on a daily basis

5.1.3. The laboratory derives its own mean and standard deviation (SD) using a minimum of 20 data points to plot an LJ chart.

5.1.4. The laboratory has defined its criteria for accepting or rejecting the run and be able to justify the application. The criteria are detailed in further sections of the document

5.1.5. The laboratory analyzes QC outliers, their causes and take immediate corrective action

5.1.6. The laboratory analyzes the 'out-of-control situation' by applying the following steps

- **5.1.6.1.** Search for recent events that could have caused changes
- **5.1.6.2.** Examine environmental conditions
- **5.1.6.3.** Follow manufacturer's troubleshooting guide
- **5.1.6.4.** Refer to instructions of manufacturers of equipment, reagents or QC / calibrator

5.1.7. The laboratory calculates the monthly mean, SD and % CV and documents the same in a register

5.1.8. The laboratory maintains control charts to demonstrate the stability of the analytical measuring systems.

5.2. Criteria for accepting or rejecting New LOT

5.2.1. New LOT of reagents will be checked against reference material before being used for patient testing

5.2.2. For acceptable performance, all control values fall within +/- 2SD

5.2.3. If one control value falls within +/- 2SD and the other within 2-3SD, the new LOT of reagents will be accepted if none of the previous 15 control values were out of 2SD in the same direction.

5.2.4. Unacceptable performance is indicated when one control value is greater than 3SD or one control value falls between 2-3 SD on 2 consecutive runs

5.2.5. If control results are unacceptable, perform the following corrective action steps:

5.2.5.1. Rerun the control one time

5.2.5.2. Controls are still unacceptable, begin troubleshooting and recalibration

5.2.5.3. If controls are still unacceptable, call the Instrument - Technical team for directions

5.3. Criteria for rejection or acceptance of a procedure "run"

5.3.1. The instrument has acceptable performance and the "run" is accepted if:

5.3.1.1. All control values fall within +/- 2 SD of the established mean

5.3.1.2. One control value fall within +/- 2 SD and the other within 2-3 SD. (However, at this level none of the previous 15 control values should be between 2-3 SD in the same direction; notify the technical leader)

5.3.2. The instrument has unacceptable performance and the "run" is rejected if

5.3.2.1. One control value is greater than 3 SD

5.3.2.2. Both control values are greater than 2 SD

5.3.2.3. One control value is between 2-3 SD on two consecutive "runs"

5.3.3. If the "run" is rejected

5.3.3.1. Hold the patient results if they have not already been reported

5.3.3.2. Re-assay the rejected test using an aliquot of fresh quality control material

5.3.3.3. If QC is acceptable, proceed with patient analysis (patients reported prior to Q.C. rejection do not need to be re-assayed)

5.3.4. If QC fails, check the following

5.3.4.1. Instrument or procedure for problems, re-calibrate if necessary

5.3.4.2. Reagents for correct preparation, contamination, or other problems

5.3.4.3. QC material preparation, outdate, storage or contamination

5.3.4.4. Accept the repeat run if

5.3.4.4.1. The controls meet the above defined acceptance criteria

5.3.4.4.2. The Technical In-charge/Quality Manager leader approves the results from the "run"

5.3.4.5. If the values on the fresh controls are still unacceptable in the repeat "run", consult with the Technical Incharges and go over the procedures to identify the sources of error.

5.3.4.6. After the assay system quality failure has been resolved (if it is not due to problems with the QC material) all patient samples tested prior to the assay failure but after the last successful QC test must be re-tested and, if necessary, corrected reports issued

5.3.4.7. Observe plots on successive runs of controls on Levy-Jennings charts and consult with the Technical In-charge/Quality Manager for possible sources of error in procedures if

5.3.4.7.1. Twelve successive control values are consistently above or below the mean value, even if all the values are within acceptable limits

5.3.4.7.2. Twelve successive control values show a consistent trend upward or downward, even in all the values are within acceptable limits.

5.3.4.8. A monthly review of all Quality Control data is conducted by the Quality Manager and Laboratory Director leader

5.3.4.9. Unrecognized problems and potential problems are discussed and recommended actions are instituted towards correcting problems or trend, including any clinically significant increases in imprecision.

6. RECORDS

6.1. The following records are maintained by the agencies, in the format mentioned, for the period defined

S. No	Records	Retention Period
1	Records of Internal QC checks – Machine Records	1 Year
2	Mean, SD & CV Calculation register	1 Year
3	QC Failure – CAPA Register	1 Year
4	Monthly - LJ Charts Register	1 Year
5	QC Consumption & Stock Condition Register	1 Year
6	QC Stock – Receipt Register	1 Year
7	Calibrators – Stock Consumption & Condition Register	1 Year

8	Calibrators – Stock Receipt Register	1 Year
9	QC Storage Area – Temperature & Humidity Check Register	1 Year
S. No	**Record**	**Retention Period**
10	Calibrators Storage Area – Temperature & Humidity Check Register	1 Year
11	Employee Training Records – QC & Calibrators usage	1 Year
12	Equipment Calibration Register	1 Year
13	Instrument Calibration Register	1 Year