BIOGENIX

POLICY PROCEDUR LABORATORY EQUIPMENT CALIBRATION AND METROLOGICAL TRACEABILITY

	NAME	DESIGNATION	SIGNATURE	DATE
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1. TABLE OF CONTENT

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
1	1.0				

4. POLICY STATEMENT

The policy is implemented as per the following procedure.

5. PURPOSE

The Purpose of this procedure which is in accordance with ISO 15189: 2012 clinical laboratories Requirements of Quality and competence clause 5.3.1.4. is to:

a. Define the traceability of measurements and related terminology,

b. Provide practical tips on implementing calibration and test measures.

6. SCOPE

a. All analyzers & equipment of Life dx Laboratory.

b. Target Audience:

i. BIOGENIX Biomedical engineers

ii. BIOGENIX Laboratory staff

iii. Supplier

7. DEFINITIONS

a. Metrological traceability: Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty.

b. Calibration: It is the process that establishes, under specified conditions, the relationship between values indicated by the analytical instrument and the corresponding known values of an analyte.

c. Calibrator: A standard or reference material or substance used to standardize or calibrate an instrument or laboratory procedure.

8. ACRONYMS

N.A.

9. RESPONSIBILITIES

a. BIOGENIX Management

b. BIOGENIX Biomedical Engineers

c. BIOGENIX Laboratory Staff.

10. PROCEDURE

a. Manufacturers usually calibrates its equipment on the basis of operating standards whose values can be traced back to national standards, and therefore the reference values of the International System of Units SI, through the use of reference standards. The values can be traced in several steps and the measurement uncertainty is known for them.

b. Traceability certificate is readily available for the calibrators used in the lab. which are provided by the manufacturer.

c. Not all items of equipment used, need to be calibrated. Only those items of equipment that are used to measure and having a significant effect on the accuracy or validity of the results need to be calibrated. The Technical Manager makes an analysis and prepares a list of equipment to be calibrated.

d. On regular basis the equipment e.g. Pipettes, Centrifuge, Temperature monitoring devices, etc are calibrated by external company, which is accredited under ISO standards according to known schedule

e. Calibration Requirements:

S.No.	Equipment	Calibration Interval
1.	Autoclave	Once a Year (external Calibration)
2.	Balances	Once a Year (external Calibration)
3.	Biological Safety Cabinets	Once a Year
4.	Centrifuges	Once a Year
5.	Pipettes	Every Six months
6.	Temperature Controlled equipment: Data Loggers, incubators and refrigerators, etc.	Once a Year

f. The analyzers are verified for calibration by doing performance check at the time of PPM by the service engineer.

g. The service engineers prepare the maintenance reports for all equipment and all records are kept in equipment maintenance file.
h. Reports are consisting of the name of instruments, serial no. with which the concerned equipment is calibrated and readings.

11. CROSS REFERENCE

a. ISO 15189 :2012 Medical laboratories – Requirements for Quality and Competence
b. CLSI guidelines QMS 13A.

12. RELEVANT DOCUMENTS & RECORDS

a. BG/REC/GEN/035 Calibration certificate summary monitoring list