1. PURPOSE

1.1. To ensure effective installation, maintenance and operation of the laboratory equipments

2. SCOPE

2.1. This procedure is applicable to all equipment of the laboratory

3. REFERENCES

3.1. Equipment Manuals
3.2. Quality Manual

4. RESPONSIBILITY

4.1. Quality Manager
4.2. Equipment Maintenance In-charge

5. PROCEDURE

5.1. Equipment Maintenance

5.1.1. Equipment is maintained as per instructions of the equipment manuals with necessary calibration and preventive maintenance process as per requirements
5.1.2. The Lab In-charge monitors the schedule of the calibration of equipments and preventive maintenance scheduling of the equipments
5.1.3. Annual Maintenance services is obtained such that the equipments are serviced as per pre-defined timelines
5.1.4. The preventive maintenance and regular servicing are carried out by authorized personnel of the equipment manufacturers
5.1.5. The Equipment service personnel details are maintained in the authorized services personnel file
5.1.6. Equipment maintenance records are maintained as per requirements and defined schedule
5.1.7. List of suitable suppliers for calibration services and maintenance services is maintained by Quality Manager
5.1.8. The basis for inclusion in the list is also recorded in the list of acceptable suppliers for calibration/ maintenance services
5.1.9. The list is updated at least once a year based on the experience and additional suppliers identified. Vendor evaluation is done annually by scoring system.
5.1.10. Some of the considerations for inclusion in the List of acceptable suppliers for calibration/ maintenance services are
5.1.10.1. NABL accreditation for calibration
5.1.10.2. Ability to provide traceability to National/ International measurement standards
5.1.10.3. Equipment manufacturer or their authorized representative

5.2. Equipment Adverse Event Reporting Mechanism

5.2.1. Adverse incidents are events which effect the safety of patients or service users, or equipment operators, or other service personnel

5.2.2. Staff are trained and take responsibility to report adverse incidents involving patient, employee, public health, as instructed in equipment manufacturer guide

5.2.3. Staff are encouraged to report all adverse incidents so that they can be handled positively, e.g., defective equipment put right, training reviewed, instructions for use improved or maintenance increased

5.2.4. All adverse events are documented and relevant corrective actions are documented

5.2.5. After repair or major maintenance of any equipment, the company application specialist runs and checks the satisfactory performance of internal quality controls and calibration and finally runs the patient samples – after prior validation

5.2.6. Service report is documented that the equipment is ready for running the patient samples satisfactorily

5.2.7. The section In-charge and Authorized Signatory will review the patient results and clinically correlate and release the results.

6. RECORDS

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

S. No	Record	Responsibility	Retention Period
1.	Equipment Maintenance Records	Lab Incharge	1 Year
2	Incident and CAPA reports	Quality Manager	1 Year
3	AMC and CMC form	Lab Incharge	1 Year
4	Equipment Calibration Form	Lab Incharge	1 Year
5	Equipment Preventive Maintenance Form	Lab Incharge	1 Year