HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Laboratory System for Equipment Validation		
Applies To:	All laboratory staff		
Preparation Date:	January 01, 2025	**Index No:**	LB-DPP-008
Approval Date:	January 15, 2025	**Version :**	2
Effective Date:	February 15, 2025	**Replacement No.:**	LB-DPP-008 (1)
Review Date:	February 15, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 To ensure equipment verification and validation procedures are performed.

2. DEFINITONS:

2.1 Equipment validation: before release of equipment for use the supplier must provide a validation report in which the supplier shows evidence of compliance of the equipment with the required specifications.

2.2 Installation qualification (IQ): the documented collection of activities necessary to establish that an instrument is delivered as designed and specified, properly installed in the selected environment, and that this environment is suitable for the instrument.

2.3 Operational qualification (OQ): the documented collection of activities necessary to demonstrate that an instrument will function according to its operational specification in the selected environment. Emphasis should be placed on "in the selected environment".

3. POLICY:

3.1 Evaluation of the performance of new equipment shall be performed on-site to ensure proper functioning and provision of accurate and precise results when operated according to recommended procedures.

3.2 Critical laboratory equipment's are not used before validation.

4. PROCEDURE:

4.1 **New equipment is generally installed at the laboratory by the supplier.** Before release of equipment for use, the supplier must provide a validation report in which the supplier shows evidence of compliance of the equipment with the required specifications.

4.2 **The laboratory must determine validity of data produced by the piece of equipment**. Among other things, it must define the possible systematic and random error size (i.e. measurement uncertainty). For this, the laboratory must try to use a reference. This can be an already existing piece of equipment of which validity has already been determined and recorded.

4.3 **Installation Qualification:**

4.3.1 Demonstrates that the process or equipment meets all specifications, installed correctly, and all required components and documentation needed for continued operation are installed and in place.

4.3.2 Installation qualification (IQ) is the documented collection of activities necessary to establish that an instrument is delivered as designed and specified, properly installed in the selected environment, and hat this environment is suitable for the instrument.

4.3.3 Responsibility for IQ lies with the user but activities should be supported and can be carried out by the vendor. For example, before the instrument arrives, the vendor should provide the user with environmental specifications so that the use can prepare the installation site specifications.

4.3.4 Tasks performed for IQ includes:

4.3.4.1 Prepare the laboratory facility according to vendor environmental specifications.

4.3.4.2 Control and record environmental conditions, if critical. For example, temperature and humidity.

4.3.4.3 Compare equipment received with the purchase order (including accessories and spare parts).

4.3.4.4 Check equipment for any damage.

4.3.4.5 Verify that the instrument conforms to physical and construction requirements as specified by the user.

4.3.4.6 Check documentation for completeness (operating manuals, maintenance instructions, standard operating procedures for testing, safety and validation certificates).

4.3.4.7 Install hardware (instrument, fittings and tubing for fluid connections, columns in HPLC and GC, power cables, data flow and instrument control cables).

4.3.4.8 Switch on the instruments and ensure that all modules power up and perform an electronic self-test.

4.3.4.9. List equipment manuals and SOP's.

4.3.4.10 Record firmware revisions.

4.3.4.11 Prepare an installation report.

4.3.4.12 Enter instrument data into an inventory data base.

4.3.4.13 Prepare, review and sign formal IQ documentation. All instruments should be entered into IQ protocol and/or into database. The IQ documents should be updated whenever there is a change made to any entry. Examples of changes are a firmware revision and the location of the instrument within a building or site.

4.4 **Testing for Installation Qualification:**

4.4.1 Installation should verify that the instrument hardware and software are properly installed. It does not verify that the instrument conforms to the functional and performance specifications. For individual modules, testing is limited to perform and document the instruments self-diagnostics when it is switched on.

4.4.2 For systems comprised of multiple modules, correct connection between the modules should be verified. For a modular and analytical system, this can be easily achieved by running a test sample and comparing the output with reference plot.

4.5 **Operational Qualification (OP):**

4.5.1 This validation provides evidence that the instrument operates as expected and confirms that the installation was successful. Done by the field representative and lab technicians. This includes:

4.5.1.1 Training of instruments operation;

4.5.1.2 Testing of controls, calibrators and a few patient samples.

4.6 **Detailed functional validation study with predefined acceptance criteria:**

4.5.1 This validation provides evidence that the instrument operates as expected and confirms that the installation was successful. Done by the field representative and lab technicians. This includes:

4.6.1 Prior to testing patient specimens, it is important to evaluate the performance of new equipment to ensure it is working correctly with respect to accuracy and precision, carryover, correlation and re-verification.

4.6.2 The instrument is monitored over a period of time to check if it consistently delivers result within the required parameters.

4.6.3 When machine is moved, all validation should within the acceptance criteria.

4.6.4 Clinical laboratory equipment are not used before completing the validation studies:

4.6.4.1 Clinical equipment should never be used for patient testing until it has been verified through the examination of quality control samples and all validation processes reviewed, assessed and approved by the appropriate medical lab director.

4.6.4.2 When determining the reportable range, calibrators and samples should reflect the full range.

5. MATERIALS AND EQUIPMENT:

N/A

6. RESPONSIBILITIES:

6.1 Laboratory Director
6.2 Chief Medical Technologist
6.3 Laboratory Quality Assurance Officer

7. APPENDICES:

7.1 Equipment validation form

8. REFERENCES:

8.1 Equipment and its Qualification, Rutendo Kuwana, WHO, Geneva, February 2009.
8.2 Laboratory Equipment Qualification and system validation, Dr. Ludwig Huber.
8.3 Laboratory equipment validation and importance of a manufacturer, Sean Murphy, Biopharm International, Mar. 01, 2005.

9. APPROVALS:

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APPENDIX: 7.1 Equipment validation form

Kingdom of Saudi Arabia
Hafar Al Batin Health Cluster
Maternity and Children Hospital

المملكة العربية السعودية
التجمع الصحي بحفر الباطن
مستشفى الولادة والأطفال

EQUIPMENT VALIDATION FORM

INSTALLATION	REMARKS
▪ Everything is available as purchased	
▪ Environment is clean	
▪ Space is capable of supporting system	
▪ Power is available	
▪ Exhaust/ Air is clean	
▪ Software is properly installed & system properly configured	
▪ Data transmission wire correct connection	
▪ Transmitting signal connection	
▪ Fixed station installation	
▪ Screw removals	
▪ Emergency stop button function	
OPERATIONAL	**REMARKS**
• After major changes	
• After repairs	
▪ New machine	
▪ Access control (user)	
▪ Capability	
- Accuracy by Calibration and Control	
- Operator Training	
- Few Patient Samples	
PERFORMANCE	**REMARKS**
▪ System work as intended day in day out	

Serial No.: .....
Model and Company: .....

Checked and Inspected by: .....
Approved by: .....
Date: .....