Policy Statement	The laboratory must have a process to assess equipment and supplies and their performance characteristics to ensure that reliable, reproducible and accurate conditions are met for the intended application.
Purpose	To ensure that all laboratory products perform as expected for the intended use.
Scope	This policy applies to all sections of the Clinical Laboratory
Responsibility	It is the responsibility of the Lead Technologist to write the validation protocol and perform the validation. It is the responsibility of the Medical Director to approve and sign the validation protocol and the finalized documentation.
Related Documents	LADM 5002 Fa Validation Plan Template LADM 5002 Fb Validation Summary Template LADM 5002 Fc Internal Installation Checklist

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Validation Requirements

The laboratory performs a validation/verification to assess function as intended under optimal conditions. A validation is performed when the instrument, equipment or assay standard published methods are modified in any way. Some examples would include, but are not limited to, changes in sample type, collection container or intended patient population. Any non-FDA approved/cleared testing or Laboratory-Developed Test requires a validation. A validation may cause a change in testing complexity. All parameters should be reviewed. In all other cases, a verification of the previously established performance specifications performed by the manufacturer is required. Examples of items that need to be validated or verified include:

- New equipment
- New assay/methodology
- New select pre-analytical supplies/reagents/equipment
- After intermittent testing (A test that has been taken out of production with patient and proficiency testing suspended. Examples include national reagent backorders and instrument malfunction without immediate replacement. The length of suspended time which requires a validation/verification should be determined by the Medical Director.)

There are no specific standards for validation/verification. The following guidelines should be used in conjunction with Medical Director input and approval.

	Verification	Validation
Reportable Range	3 points near low end, midpoint, and high end	3 points near low end, midpoint, and high end
Analytical Measuring Range (AMR)	3 points near low end, midpoint, and high end	3 points near low end, midpoint, and high end
Reference Range	20 samples	40-60 samples; 120 or more is ideal
Accuracy	20-40 samples across AMR	At least 40 samples across AMR; could be > 100
Precision	2-3 samples at clinical decision points run daily for 5 days	Run study for 20 days

*See definitions section for details.

Re-verification is required when changes are made that could impact the equipment or process characteristics. Re-verification should be considered when there are notable changes in quality detected by quality assurance activities or when changes in raw material suppliers may result in subtle, potentially adverse differences in characteristics of the raw material. Re-verification is required for the movement of equipment.

Equipment/Pre-Analytical Supplies/Reagents

Installation Qualification (IQ) Process

Most often, the manufacturer, BioMed or Facilities Management will perform the installation qualification of an instrument or equipment. This is completed in a manner that meets the predetermined environmental and manufacturer requirements defined in a plan or checklist. The installation will be completed to ensure it is done properly and ready for the next pre-implementation qualification. When the IQ is done the laboratory needs to verify that the plan corresponds to the operator's manual setup instructions. The IQ must be performed before using the instrument or equipment in the live environment. In the event that the equipment does not come with a predetermined installation plan or checklist utilize the generic internal form (LADM 5002 Fc).

Operational Qualification (OQ) Process

The laboratory must confirm that the equipment is operational for its intended use and location. OQ includes activities as power-up, initial calibration and verification of functionality. The manufacturer, BioMed or Facilities Management will perform the OQ with the laboratory's assistance. The laboratory needs to retain a copy of the results obtained from performing the OQ and approve the results before proceeding in the validation process. OQ and IQ can be performed simultaneously.

Performance Qualification (PQ) Process

The laboratory must develop a plan to ensure that the instrument or equipment performs as intended in the environment. The PQ confirms that the equipment produces acceptable results under normal operating conditions and functions in a way that meets regulatory requirements and is consistent with the manufacturer's claims. The PQ plan must be approved by the Medical Director prior to beginning the process. The plan must include the functional conditions and test cases (as appropriate) for evaluation of the full range of intended use. The laboratory must set criteria for the acceptance of performance, record the results of executing the plan and assess the results for acceptability. The instrument or equipment is not ready for use until the criteria are met and the plan is completed. The PQ must be completed by the laboratory, not the manufacturer, BioMed or Facilities Management.

Equipment Use

The laboratory must train associates to use instruments and equipment. Associates must read all associated policies and procedures prior to use. Training must be documented on the appropriate training event or vendor provided form.

Assay/Methodology Change

The laboratory must develop a PQ plan to ensure that the assay performs as intended in the environment on the specified instrument. The PQ confirms that the assay produces acceptable results under normal operating conditions and functions in a way that meets regulatory requirements and is consistent with the manufacturer's claims. The PQ plan must be approved by the Medical Director prior to beginning the process. The plan must include the intended sample type and number of samples to be tested. The laboratory must set criteria for the acceptance of performance, record the results of executing the plan and assess the results for acceptability. The assay is not ready for use until the criteria are met and the plan is completed. The PQ must be completed by the laboratory, not the manufacturer, BioMed or Facilities Management.

Intermittent Testing

When a test is put back into production, the following requirements must be met:

1. Proficiency or alternative assessment performed within 30 days prior to restarting patient testing
2. Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing
3. Competency assessed for technologists within 12 months prior to restarting patient testing

The laboratory must develop a PQ plan to ensure that the assay has maintained performance standards during the time it was out of production. The PQ plan must be approved by the Medical Director prior to beginning the process. The plan must include the intended sample type and number of samples to be tested. The laboratory must set criteria for the acceptance of performance, record the results of executing the plan and assess the results for acceptability. The laboratory must establish a training/competency schedule to ensure that all associates are competent to perform testing. The assay is not ready for use until the criteria are met, the majority of associates are trained and the plan is completed. The PQ must be completed by the laboratory, not the manufacturer, BioMed or Facilities Management.

Documentation

At the completion of the validation process, the following documents should be retained.

- Completed and Signed Validation Plan
- Completed and Signed Validation Summary
- Copy of Procedure and all associated documents
- Training documentation (in associate technical binders)
- Testing data
- Copy of calculations, interpretations, and comments

- Copy of results reports (internal inquiry, external inquiry, and EMR)
- Documentation of interface validation
- Copy of communication sent to Director Chairs and other clients

Definitions

- Accuracy – the closeness of argeement between the result of a particular measurement and the true value of the measurand/analyte
- Alert Value - a test result that in and of itself may indicate a potentially dangerous or life-threatening situation of imminent nature.
- Analytical Measuring Range (AMR) – the range of analyte values that a method can directly measure in a specimen without dilution, concentration, or other pretreatment not part of the usual assay process
- Delta Check - A comparison of consecutive values for a given test in a patient's laboratory record used to detect abrupt changes
- Precision – the degree to which repeated measurements under unchanged conditions show the same result
- Sensitivity – the ability of clinical test to accurately detect the analyte or identity of interest at a particular concentration or under particular circumstances, relates to the test's ability to identify positive results
- Specificity – the ability of a clinical test to operate free from interference by variables other than the analyte or identity of interest, relates to the test's ability to identify negative results
- Reference Range – the range of test values expected for a designated population of individuals
- Reportable Range – the span of test result values over which the laboratory can establish or verify the accuracy of the instrument or test system measurement response

Validation/Verification Plan

Title:

Date

Assessment of:

○ Verification ○ Validation (Validation requires supporting documentation for the revision of manufacturer's criteria)

Is construction or reorganization required? ○ Yes ○ No

Brief Description:

Responsibilities: (Indicate individual names or group titles)

Review of IQ

Train Associates

Review of OQ

Write Validation Summary

Perform PQ

Perform Interface Validation

Update Procedures/Policies/Training Documents

Reference Method:

Specimen Type:

Proposed Number of Samples:

Performance Criteria:

Validation Plan Written By:

Signature & Date

Validation Plan Approved By Medical Director:

Signature & Date

Validation/Verification Summary

Title:

Summary of Findings:

Were any changes made to the Validation Plan? ◯ Yes ◯ No Date of Completion:

If yes, explain:

For Equipment or Pre-Analytical Supplies: All fields must be filled in for this section. Attach all supporting documentation.

Serial Number BioMed Number PO Number

List Policies Revised and/or Created:

Was training complete? ◯ Yes ◯ No Was a Downtime Procedure created? ◯ Yes ◯ No ◯ N/A

Was the Interface Validation completed? ◯ Yes ◯ No ◯ N/A

For Assays: All fields must be filled in for this section. Attach all supporting documentation.

List of Policies Revised and/or Created:

Was training complete? ◯ Yes ◯ No Online Test Search Updated? ◯ Yes ◯ No Was the Saint Updated? ◯ Yes ◯ No

Was CAP Notified? ◯ Yes ◯ No Date of Notification: PT to be Used:

Created in Meditech Test and Live? ◯ Yes ◯ No Print Screen Shot from Meditech for: ◯ Internal ◯ External ◯ EMR

Reportable Range: Precision: Specificity:

Reference Range: Accuracy: Sensitivity

Assays cont'd:

Alert Value: | Delta Checks: | CPT/Charge Code:

QC Schedule: | Autoverification Rule:

Interfering Substance(s):

Cross Reactivity:

Interpretation: | Canned Comment:

For Intermittent Testing: All fields must be filled in for this section. Attach all supporting documentation.

Has the procedure been reviewed in the last 12 months? ◯ Yes ◯ No Last Review Date:

Was the verification completed within 30 days prior to restarting testing? ◯ Yes ◯ No Projected Start Date:

Was proficiency testing performed within 30 days prior to restarting testing? ◯ Yes ◯ No PT Testing Date:

Was training complete? ◯ Yes ◯ No

Notifications: (Indicate dates of notification.)

Lab Administrative Director: | Quality Coordinator:

Outreach Manager: | Director Chairs: ◯ N/A

Supervisor of Support Services: | Nursing/Clients: ◯ N/A

Approvals: (Signatures are required)

Validation Completed by: | Signature & Date

Validation Approved by Medical Director: | Signature & Date

Print Form

Installation Checklist

Lab Contact:

Department:

Equipment:

Vendor:

Model Number:

Serial Number:

Purchase Order Number:

Service Order Number:

Delivery Date:

Installer Name:

Installation Date:

Task	Initials or N/A		
1. Supervised the instrument unpacking/uncrating and transportation to the lab by the shipping company.		Date:	
2. Checked for shipping damage. Contacted vendor if any damage is noted.		Date:	
3. Compared accessories shipped with the product to the items listed on the packing list. Contacted vendor if any items were missing.		Date:	
4. Ensured that all necessary supplies/reagents arrived to complete installation. Contacted vendor if any items were missing.		Date:	
5. Reviewed electrical requirements prior to installation. Ensured that the appropriate electrical outlet was available and operational.		Date:	
6. Instrument and related software, if applicable, installed in accordance with the appropriate installation instructions provided by the manufacturer.		Date:	
8. Completed or scheduled any connectivity verification for applicable devices.		Date:	
7. Retained any documentation of performance checks required by the installation protocol with the instrument.		Date:	

Comments/ Corrective Action(s)

Installer Signature:

Date: