VERIFICATION AND VALIDATION TOOLKIT

Verification or Validation Process Checklist

To ensure correct diagnosis and treatment, clinical laboratory testing must be accurate and reliable. A key component of the quality assurance process is the verification or validation of new instruments and tests to confirm their ability to perform prior to implementation.

The Verification and Validation Toolkit walks users through this process and provides additional resources, templates and examples for use in the laboratory.

Find the complete toolkit at aphl.org/VV-Toolkit

The toolkit has eight sections:

1. Verification and Validation 101
2. Verification and Validation Process Checklist
3. Obtaining Appropriate Test Samples
4. Qualitative Assays
5. Quantitative Assays
6. Related Processes
7. Safety Considerations and Risk Assessments
8. Cost Analysis and Budget

This section of the toolkit provides a **Process Checklist (page 2)** that walks users through test verification or validation plan development, plan initiation, creation of the testing and summary report and test implementation. The steps below will assist in determining if a verification or validation needs to be performed, and the events or steps that should occur for implementation of a new test method.[1]

This section also includes **Additional Process Resources (page 4)** with editable templates and examples related to the verification/validation process, including an editable version of this checklist.

1 Bankowski MJ, Cankovic M, Dunlap J, Furtado LV, Gong J, Huard T, et al. Molecular Diagnostic Assay Validation. Update to the 2009 AMP Molecular Diagnostic Assay Validation White Paper. 2014. Accessed Oct 1, 2023: www.amp.org/AMP/assets/File/resources/201503032014AssayValidationWhitePaper.pdf?pass=29

Process Checklist

☐ Choose a Verification or Validation Process

Refer to Verification and Validation 101 to determine which approach is appropriate.

☐ Develop a Plan/Proposal

The following is a general outline for a test verification or validation plan or proposal:

I. Introduction and Reason for the Study

- May include the purpose and scope, definitions, literature review, staff roles and responsibilities, and location of laboratory (for laboratories operating under multi-site certificates)
- Verification of FDA-cleared test, modification of FDA-cleared test, or validation of new LDT, etc.
- Statement regarding internal review board (IRB) approval requirement or request needed
- Whether there is an established SOP or associated job aids, or if they need to be created
- How test results will be used (screening, diagnostic, confirmatory or monitoring)

II. Safety Considerations

- Consider the inclusion of the laboratory's safety officer during the planning stages
- Biorisk assessment
- Chemical risk assessment
- Hazardous waste management

III. Methodology for Each Performance Characteristic Evaluated

- Which performance characteristics will be evaluated is dependent on qualitative or quantitative testing (see Qualitative Assays and Quantitative Assays sections)
- Number and type of samples (See Obtaining Appropriate Test Samples)
- Testing procedure
- Whether the test will be run on multiple instruments
- Controls (including calibrators for quantitative testing)
- Whether an Individualized Quality Control Plan (IQCP) is appropriate
- Gold standard comparator
- Environmental and storage conditions
- Limiting factors indicated in FDA EUA or approval, or as defined per manufacturer

IV. Acceptance Criteria

V. Data Analysis and Evaluation Plan

☐ Get Plan Approval from Laboratory Director

Additional individuals may need to pre-approve the plan prior to the laboratory director, such as quality assurance officers or unit supervisors or managers.

☐ Initiate Verification/Validation Plan

- Ensure there are sufficient quantities of reagents, consumables and personnel time prior to executing the verification or validation plan.
- Ongoing evaluation of data obtained during the verification or validation should occur to determine if the planned testing method needs modification. If modifications are identified, it is critical that any changes to the proposed plan be documented, technically justified, reviewed and approved.
    - Are the acceptance criteria being met?
    - Are the samples appropriate?
    - Are there any limitations to collecting the appropriate sample amounts?
    - Are there matrix issues?
    - Are there cross reactivity or interference issues?
    - Will there need to be additional testing performed beyond what was proposed in the plan?

☐ Complete Testing

☐ Create Testing and Summary Report

The following is a general outline for a test verification or validation summary report:

I. Overall Data Summary

- May include overall summary of data and acceptance criteria results
- Statement of any modifications made to the validation plan with rationale

II. Performance Data Results

- Results with supporting traceability to repeat the testing under conditions as close to the original as possible
- Deviations to sample size and acceptance criteria from the plan that were made along with a justification. If deviations were made, a statement of impact or variance should be included.
- Calculations of the performance characteristics
- Explanation of discrepancies
- Instrument-to-instrument comparison (if applicable)
- Limitations

III. Conclusion

- Statement regarding the acceptability of the method, its fitness for use, and any clinical claims that will be made (if applicable).
- Recommendations of changes that need to be made to the test process based on the evaluation.
- If the study showed that the test method was not acceptable or could not be properly performed, documentation of the corrective action steps taken and its approval by the responsible laboratory leadership.

☐ Complete Associated Documents

- Pertinent SOP or SOP edits
- Individualized Quality Control Plan (IQCP), if applicable
- Training documentation and competency assessments
- Related equipment functionality and maintenance documentation
- Any job aids or other documentation necessary to routinely perform testing
- LIMS updates and verification

☐ Get Summary Report Approval from Laboratory Director

Approval of the verification or validation summary report by quality assurance officers, unit supervisors, or managers may be necessary prior to laboratory director approval.

☐ Test Implementation

Once the verification or validation summary report is approved at the appropriate level, the laboratory can move on to implementation activities.

The following considerations should be made, and if applicable be included in the verification or validation plan:

- Adding the procedure to the document control system and to the test menu
- Adding new equipment to the laboratory's maintenance and calibration plan (if not already completed)
- Training staff members
- Updating scope of service documents, as applicable
- Delegation statement if responsibilities are delegated by laboratory director
- Scheduling proficiency testing or comparison studies
- Updating the laboratory quality assurance plan and quality control processes to include continuous monitoring
- Communicating implementation plan to submitters
- Confirming electronic patient test result output with submitters

Additional Process Resources

Templates

- Editable Verification/Validation Process Checklist
- Method Verification/Validation Plan Approval Checklist
- Verification Plan Template
- Validation Plan Template
- Verification Summary Report Template
- Validation Summary Report Template

Examples

- Employee Training Verification Checklist Example
- Guidelines for Verification and Validation of Laboratory Methods (Minnesota)
- Method Validation-Verification Summary Report Example (Fairfax County, VA)
- Method Verification Template Example (Indiana)
- Validation and Verification SOP Example (Texas)
- Validation Plan Example (Washington)
- Validation Summary Report Example (Washington)
- Verification Plan Example (Washington)

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