



TEST METHOD VERIFICATION

What is Verification?

Test method verification is a simplified validation process employed to check or verify a test method's performance characteristics. It typically includes a subset of the parameters evaluated when a complete validation is performed, and asks the question "*Does this new test method perform to its specification in my laboratory?*"

When is it done?

It should be done before a new externally validated test method is employed by the laboratory to report results.

How is it done?

The laboratory should:

- Develop a clear, detailed verification procedure that defines the parameters to be evaluated.
- Define and approve the acceptance criteria (e.g., manufacturer's package insert) to be used in analyzing the results.
- Compare experimental results to the previously established performance characteristics.
- Based on the results, accept or reject the test method.
- Summarize the data collected from the verification study in a final report.

The following is the most common subset of characteristics used in verification studies:

Characteristics Analyzed	Types of Experiments Performed
<ul style="list-style-type: none"> • Accuracy • Precision • Reportable range of test results for the test method • Manufacturer's reference intervals (medical laboratories) 	<ul style="list-style-type: none"> • Comparison of methods to estimate inaccuracy or bias • Replication experiment to estimate imprecision • Linearity type experiment to estimate imprecision and to determine reportable range • Collecting reference values to verify the established reference range

Why is it necessary?

- To provide objective evidence that your laboratory has the ability to achieve acceptable results for a given test method.
- To prove that an externally validated test method is acceptable for its intended use.