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User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition

This document provides a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both precision and method-comparison studies.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Abstract

Clinical and Laboratory Standards Institute document EP12-A2—*User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition* provides the user with a consistent approach for protocol design and data analysis when evaluating qualitative diagnostic tests. Guidance is provided for both precision and method-comparison studies.

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