



CLIA Requirements for Validating a New Analyzer

Establish Performance Specifications

- Verify accuracy, precision, reportable range, and reference intervals.
- Confirm analytical sensitivity and specificity if applicable.

Conduct Calibration & Calibration Verification

- Perform calibration per manufacturer guidelines and verify calibration meets required performance standards.

Perform Accuracy Testing

- Compare results with a previously validated method or reference instrument.
- Use patient samples, proficiency testing materials, or certified reference materials.

Assess Precision & Reproducibility

- Run repeated tests on control materials to ensure consistent results.
- Perform within-run and between-run precision assessments.

Determine Analytical Measurement Range (AMR)

- Verify the range over which the instrument produces accurate and linear results.
- Use multiple known concentrations to assess linearity.

Establish Reference Intervals (if needed)

- Verify manufacturer-provided reference ranges for patient populations.
- Conduct studies if no established reference ranges exist.

Conduct Method Comparison Studies

- Compare the new analyzer's results with those from an existing validated method.
- Use patient samples tested on both systems.

Evaluate Carryover & Interference Studies

- Assess if high-concentration samples affect subsequent low-concentration results.
- Test for common interferences (e.g., hemolysis, lipemia, icterus).

Perform Proficiency Testing (if applicable)

- Enroll in external proficiency testing programs.
- Compare results with peer group or regulatory standards.

Document Validation Process & Obtain Approval

- Maintain detailed records of all validation studies.
- Ensure validation results meet regulatory and laboratory-specific criteria.
- Obtain final approval from the laboratory director before use.