STANDARD OPERATING PROCEDURE TEMPLATE · ANALYTIC: QC, CALIBRATION, VERIFICATION AND EQUIPMENT

# Method Validation for Laboratory-Developed and Modified Tests

Governing requirement: 42 CFR 493.1253(b)(2)

**Applies to:** ☐ Waived ☐ Moderate complexity ☑ High complexity

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| **Laboratory name** | | **CLIA number** | |
| **Document number** | | **Version** | |
| **Effective date** | | **Next review due** | |
| **Author** | | **Department / section** | |
| **Approved by (laboratory director)** | | **Director signature** | |
| **Approval date** | | **Supersedes document** | |

**Important:** Template only. Before use, this document must be reviewed, adapted to your laboratory's instruments, test systems and the manufacturer's instructions, and approved, signed and dated by the laboratory director. Check current federal, state and accreditation requirements. Not legal advice. Sound Lab Consultants is not affiliated with or endorsed by CMS, CDC, FDA, OSHA, CAP, COLA, The Joint Commission, CLSI or any manufacturer.

## 1. Purpose

To establish performance specifications for laboratory-developed tests and modified FDA-cleared tests before patient testing.

## 2. Scope

High complexity laboratory-developed tests and any modification of an FDA-cleared/approved test.

## 3. Responsibility

- Testing personnel: perform the procedure, record results and stop patient testing when criteria are not met.
- Technical consultant / technical supervisor: sets acceptance criteria, reviews records and approves corrective action.
- Supervisor: ensures schedules are met and records are reviewed on time.
- Laboratory director: approves the procedure and any change to criteria.

## 4. Definitions

**Analytical sensitivity (LoD):** Lowest amount reliably detected.

**Analytical specificity:** Ability to measure only the target, including interferences and cross-reactivity.

## 5. Materials, equipment and records

- Reference materials, characterized specimens
- Interference panel

## 6. Procedure

**1.** Write a validation plan with study designs and acceptance criteria, approved by the director.

**2.** Establish accuracy against a reference method or characterized samples **[Number of samples]**.

| Number of samples | |
|---|---|

3. Establish precision (repeatability and reproducibility) across runs, days, operators and lots.
4. Establish analytical sensitivity (limit of detection) **[LoD study design]**.

| LoD study design | |
|---|---|

5. Establish analytical specificity, including interfering substances and cross-reactive organisms or analytes.
6. Establish the reportable range.
7. Establish reference intervals or cutoffs.
8. Establish any other characteristic required for test performance.
9. Establish calibration and control procedures based on the data.
10. Write the validation report; director signs approval before use.

## 7. Quality control

• Follow the laboratory's QC policy and the manufacturer's instructions; record QC before reporting patient results.

• Stop patient testing and take corrective action when QC or acceptance criteria are not met.

## 8. Interpretation, reporting and documentation

• Keep validation records for the life of the test, at least 2 years.

## 9. Limitations and cautions

• State rules (for example New York) and FDA policy may impose more requirements.

• This is a generic template. Adapt it to your instruments, test systems, manufacturer instructions, state law and accreditation standards before use.

## 10. References


• eCFR, 42 CFR Part 493 Laboratory Requirements (CLIA)
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-493

• CMS, State Operations Manual Appendix C: Survey procedures and interpretive guidelines for laboratories
https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_c_lab.pdf

• CLSI guidelines relevant to this procedure (referenced by name only; obtain current editions from CLSI)

• eCFR, 42 CFR 493.1253 https://www.ecfr.gov/current/title-42/section-493.1253


## 11. Lab-specific notes

| Notes and local requirements | |
|---|---|

## 12. Revision history

| Version | Date | Description of change | Author | Approved by |
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## 13. Annual review log

Procedures and changes must be approved, signed and dated by the current laboratory director before use (42 CFR 493.1251(d)).

| Review date | Reviewed by | Signature | Changes needed (Y/N) | Comments |
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