

Standard Operating Procedure Guidance

A well-documented SOP serves as evidence of the laboratory's licensure and its adherence to established testing standards. The SOP must be consistent with the test report and vice versa.

CLSI (Clinical and Laboratory Standards Institute) SOP (Standard Operating Procedure) template generally follows a structured format with key sections to ensure clarity and consistency. While CLSI doesn't offer a single, downloadable template, it provides guidance on document structure and content. The specific content and organization of your SOP template will depend on the particular procedure it covers.

Elements of an SOP may include, but are not limited to:

1. Title and SOP Number

- Unique and descriptive title of the lab test.
- SOP identification number (for version control and referencing).

2. Purpose

- Clearly state the objective of the SOP — what the lab test is intended to determine or measure and its clinical usefulness.

3. Scope

- Define the boundaries of the SOP: where, when, and to whom it applies.

4. Responsibilities

- List personnel who are authorized or responsible for performing the test and evaluating test results for reporting.

5. References

- List relevant documents, guidelines, or literature that support or relate to the test (e.g., ISO standards, method references, manuals).

6. Definitions

- Define technical terms or abbreviations used.

7. Materials and Equipment

- List all required materials, reagents, and equipment, including specifications, vendor and part number, and preparation steps.

8. Safety and Precautions

- Include PPE requirements, hazard information, and handling/disposal instructions.

9. Procedure

- Detailed, step-by-step instructions for performing the test.
- Include timing, volumes, conditions (e.g., temperature, pH, equipment speed), and critical control points.

10. Quality Control

- Describe how to validate results, run controls, and handle deviations or unexpected results.

11. Data Recording and Reporting

- Specify how and where to record observations and results.
- Include formats or templates if applicable.

12. Deviation, Non-Compliance and Troubleshooting

- Address how deviations or non-compliance with the procedure will be handled.
- List common problems and how to resolve them.

13. Appendices

- Include diagrams, flowcharts, checklists, calibration logs, or example data sheets.

14. Review and Revision

- Specify how the SOP will be reviewed and revised periodically.