This Standard Operating Procedure (SOP) template is provided as an example and contains suggested contents for laboratory SOPs. It was adapted from a template initially designed by the HIV Vaccine Trial Network (HVTN). The template must be modified for use to fit the needs of your laboratory. General components and key areas are included in the template to provide guidance and assistance. The below table shows the recommended sections to include in each document type.

**Suggested Contents for Laboratory Policies and Procedures**

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| --- | --- |
|   | **Document Type** |
| **Suggested Section** | **Policy Documents** | **Process Flow Charts/Tables** | **Analytical Quantitative** | **Analytical Qualitative** | **Nonexamination Procedures** |
|
| Purpose | X | X | X | X | X |
| Principle/Scope | X | X | X | X | X |
| Policy | X |   | Insert specific requirements where applicable |
| Process |   | X |   |   |   |
| Supporting Documents | X | X |   |   |   |
| Equipment |   |   | X | X | As needed |
| Reagents/media |   |   | X  | X | As needed |
| Supplies |   |   | X  | X  | X  |
| Safety Precautions |   |   | As needed | As needed | As needed |
| Sample type/volume |   |   | X | X |   |
| Calibration |   |   | X | As needed |   |
| Quality Control |   |   | X | X | X |
| Procedure |   |   | X | X | X |
| Reporting Results |   |   | X | X | X |
| Interpretation |   |   | X | X | X |
| Procedural Notes |   |   | X | X | As needed |
| Limitations |   |   | X | X |   |
| Calculations |   |   | X | As needed |   |
| Reference Range |   |   | X | As needed |   |
| Critical Values |   |   | X | As needed |   |
| References | X |   | X | X | X |
| Related Documents |   |   | X | X | X |
| Appendices |   |   | X | X | X |

Reference: CLSI. *Quality Management System: Development and Management of Laboratory Documents;* *Approved Guideline-Sixth Edition.* CLSI document QMS02-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2013.

COVER & SIGNATURE PAGES:

1. *Lab name* and *physical address* should appear on all documentation (header).
2. *Title* of SOP should appear on all pages (header)
3. *Author(s)* provide identification and reference for qualification to write the SOP.
4. *Approved by* provides authority to implement the SOP.
5. *Revision History* provides a system to track changes and reasons for change.
6. *Distributed copies* provides a system to remove obsolete copies and distribute current copies.
7. *SOP Annual Document Review* provides documentation that management (laboratory director or designee) reviews the SOPs at least once per year.
8. *SOP number*, *version number* and *effective date* (footer).
9. *Page numbers* (1 of total number of pages) insures that pages are not skipped or missing.
10. *Signature table* for reading, understanding and agreeing to follow the SOP provides documentation that the appropriate staff received training and are aware of the lab requirements.
11. If you do not have any information for a particular section, section enter N/A following the title of the section.
12. This template is designed for a quantitative analytic procedure. Refer to the table on page 1 to determine the appropriate sections for qualitative and non-analytical procedures.

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| Approved By | *Name, Title* | *Signature* | *Date* |
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| Revision History | *Version # [0.0]* | *Revision Date* | *Description (notes)* |
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| Bi-annual Review | *Name, Title* | *Signature* | *Date* |
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***I acknowledge that I have read, understand and agree to follow this SOP.***

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PRINCIPLE: Describe the principle or rationale for the assay procedure.

AUTHORITY & RESPONSIBILITY:

1. The Director (or his/her designee) of the Laboratory Program, the Laboratory QA Program Manager and the International Laboratory Program Manager have the authority to establish this procedure.
2. The Principal Investigator/Laboratory Manager is responsible for the implementation of this procedure and for ensuring that all appropriate personnel are trained.
3. All technologists and technicians working on clinical trial studies are responsible for reading and understanding this SOP prior to performing the procedures described.

SPECIMEN:

Patient Preparation: List any preparation required for patients, such as ‘patient should be fasting’. If no preparation is required, list as ‘none”

Specimen Type: List acceptable specimens for your facility, such as serum, EDTA plasma, EDTA whole blood.

Optimum/Minimum Specimen Volume: List the optimum specimen volume that allows for the original testing plus repeat testing and temporary storage, if needed. Include the minimum volume required to perform the assay for reference (in case of difficult or short phlebotomy draws).

Handling Conditions: Include temperature requirements and any special precautions. For example: Store sample at room temperature (15-30 °C) until delivered to lab. Protect from light. Deliver to lab within 2 hours of collection.

Unacceptable Specimens: List conditions that would make the specimen unacceptable for testing such as:

1. Unlabeled or mislabeled specimens will be rejected.
2. Specimens collected in sodium heparin tubes are NOT to be used for this assay.
3. Gross hemolysis (3-4+) or clotted samples are NOT to be used for this assay.

EQUIPMENT: List the equipment and materials needed to perform this assay.

PRECAUTIONS: Briefly describe universal precautions used for all laboratory procedures and mention any additional procedures that are specific for the test.

MATERIALS/DISPOSABLES: List disposable items and materials needed such as PPE, pipettes

REAGENTS: List reagents including preparation instructions, storage requirements, expiration dating and handling requirements. Indicate where reagent information should be documented (ie. reagent logs)

CALIBRATION: List calibration materials, preparation, frequency, procedure and documentation. Include performance requirements for calibration (acceptable and unacceptable).

QUALITY CONTROL: List control materials, preparation, frequency and documentation. Include performance requirements, acceptable and repeat criteria, out-of-range action, quality control logs and review.

PROCEDURE: List each step in the order that it is to be done. Include all details necessary to correctly perform the assay. Indicate where information such as readings and indicators are recorded as needed.

CALCULATIONS: List all calculations required. Include examples as appropriate.

REPORTING RESULTS:

Interpretation of Results: Indicate how the results are read and/or interpreted.

Reporting Format: Indicate how results are to be reported, including units. Be specific such as how many decimal points or non-reactive vs. negative.

Procedure for Abnormal/Unexpected Results: Indicate what an abnormal or unexpected result might be and list any action to be taken. For example: an optical density reading within an equivalent area might require repeat testing in duplicate. Include how the repeat testing is interpreted.

Reference (normal) Range: List reference range(s) for the assay. Include age, sex and population references as appropriate.

Linear/Analytical Range: List the assay’s linear range. Indicate action to be taken if results are outside the linear limits (high or low). If specimens may be diluted to bring within the linear range, list the dilution method and diluent to be used. Include calculations and acceptable analytical range based on dilutions.

Critical Values: If applicable, indicate critical value level and what to do if a critical value is obtained.

PROCEDURAL NOTES: List additional information applicable to assay or troubleshooting.

LIMITATIONS: Include information detailing limitations of the procedure. For example: do not use sodium heparin plasma. Heparin is known to interfere with the assay.

REFERENCES: List sources of information, such as instrument manuals, that may assist with the procedure.

APPENDICES: Attach supporting documents such as package inserts, forms, log sheets or charts.