

Quality Assurance & Lab Management Academic Assignment

"Drafting a Standard Operating Procedure (SOP)"

1) Project Overview

Imagine you are the Quality Supervisor in a moderate-to-large sized hospital laboratory. As part of maintaining accreditation and quality requirements, your laboratory director has requested that you draft a new Standard Operating Procedure (SOP) for a specific pathology test of your choice (e.g., Glucose, CBC, Lipid Profile). Your goal is to write concise, unambiguous, step-by-step instructions so that a colleague with limited experience, but basic understanding, can successfully reproduce the test unsupervised.

2) Learning Objectives

This assignment is designed to assess and develop the following Course Learning Outcomes (CLOs) as per the MLT458 course specifications:

- **CLO 1.5:** Discuss how to write standard operating procedures.
- **CLO 4.3:** Communicate ideas and arguments effectively.
- **Vision 2030 Alignment:** Elevating healthcare quality and laboratory reliability to meet national and international accreditation standards (e.g., ISO 15189, CBAHI).

3) Design Requirements

3A. Content (Message) Your SOP must follow the exact 10-point structural model outlined in Lectures 7 & 8:

1. **Name of Test:** Ensure correct WHO or international nomenclature.
2. **Value of Test:** State clinical/public health reasons and any limitations.
3. **Principle of Test:** Briefly state the technology and chemical reaction used.
4. **Specimen:** Identify type, collection requirements (volume, container, additives), stability/storage, delivery instructions, and rejection criteria.
5. **Equipment & Reagents:** List necessary items to collect, analyze, and store the specimen.
6. **Controls:** List positive/negative controls and their sources.
7. **Method for Test:** Describe in a numbered sequence how to perform the test, including calibration and calculations.
8. **Results & Interpretations:** Specify units, format, accepted reference ranges, target turnaround time (TAT), and actions for seriously abnormal results.
9. **Sources of Error:** Summarize common causes of incorrect results (e.g., lipemic samples, poor mixing).
10. **References:** List main sources (books, manufacturer leaflets, WHO guidelines).

3B. Document Control & Appendices

- **Document Control Notation:** Each page of the SOP must include a header or footer with: Short Title/ID #, Rev. #, Date, and Page X of Y.
- **Appendices:** You must include separate sections for:

- **Appendix A (Reagents):** Preparation method, hazards (MSDS), storage, and stability.
- **Appendix B (Equipment):** Model, instructions, and maintenance/QC schedules.
- **Appendix C (Health & Safety):** Decontamination, chemical safety, and first aid procedures.

3C. Technical Specifications

- **Length:** Not less than 250 words, contained within 1-2 pages.
- **Font & Spacing:** Typed on A4 paper, using Times New Roman 12pt or Arial 11pt, with 1.5-line spacing and extra space between paragraphs.
- **Cover Sheet:** Must include student number, email address, course name and code, course coordinator's name, word count, submission date, and title.
- **Referencing:** Vancouver referencing style is required. Ensure accurate citation throughout the text and a correct reference list at the end (at least 1 reference).

4) Evaluation Rubric

Criteria	Description	Weight
Formatting & Document Control	Adherence to cover page, font, spacing rules, and strict inclusion of Document Control notation (ID, Rev, Date, Page #).	20%
Content Completeness	Accurate and logical inclusion of all 10 mandated SOP sections (Name, Principle, Specimen, Method, Results, etc.).	40%
Clarity & Language	Clear, unambiguous, step-by-step instructions. Implied use of "you" without explicitly stating it. Free of spelling/grammar errors.	20%
Appendices & Referencing	Proper inclusion of Appendices A, B & C, and strict adherence to Vancouver referencing style.	20%

5) Submission Requirements

- **File Format:** Submit as a PDF file via the Taibah LMS "Blackboard".
- **Academic Integrity:** Writing the assignment jointly and submitting it as individual work is UNACCEPTED. Plagiarism must not exceed 30%. Exceeding this limit constitutes cheating and will result in a ZERO.
- **Delivery:** Upload your video file to Taibah LMS "[Blackboard](#)".
- **Due date:** Thursday 11-Dec-2025; no later than 2:00 PM.