THE OPEN UNIVERSITY OF SRI LANKA
25 APR 2025
EXAMINATION DIVISION

00072

THE OPEN UNIVERSITY OF SRI LANKA

FACULTY OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

ACADEMIC YEAR 2024/2025 – SEMESTER I

BACHELOR OF MEDICAL LABORATORY SCIENCES HONOURS

MDU6404 – MEDICAL LABORATORY QUALITY MANAGEMENT AND ACCREDITATION

FINAL EXAMINATION **DURATION: 03 HOURS**

DATE: 25th April 2025 TIME: 9.30 AM – 12.30 PM

Part B: Structured Essay Questions (40 marks)

Q1

1.1 Define the term "Method validation". (02 Marks)

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1.2 Compare the quality control (QC) materials and calibrators under the following categories.

(03 Marks)

	QC materials	Calibrators
Purpose		
Composition		
Frequency of use		

1.3 Illustrate the steps for implementing and maintaining a QC programme in a medical laboratory. (05 Marks)

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(Total 10 Marks)

Q2.

2.1. Define the term "Lean Management". (02 Marks)

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2.2 List **four (04)** common causes of process bottlenecks that lead to irregular workflow in Lean management. (04 marks)

i.....

ii.....

iii.....

iv.....

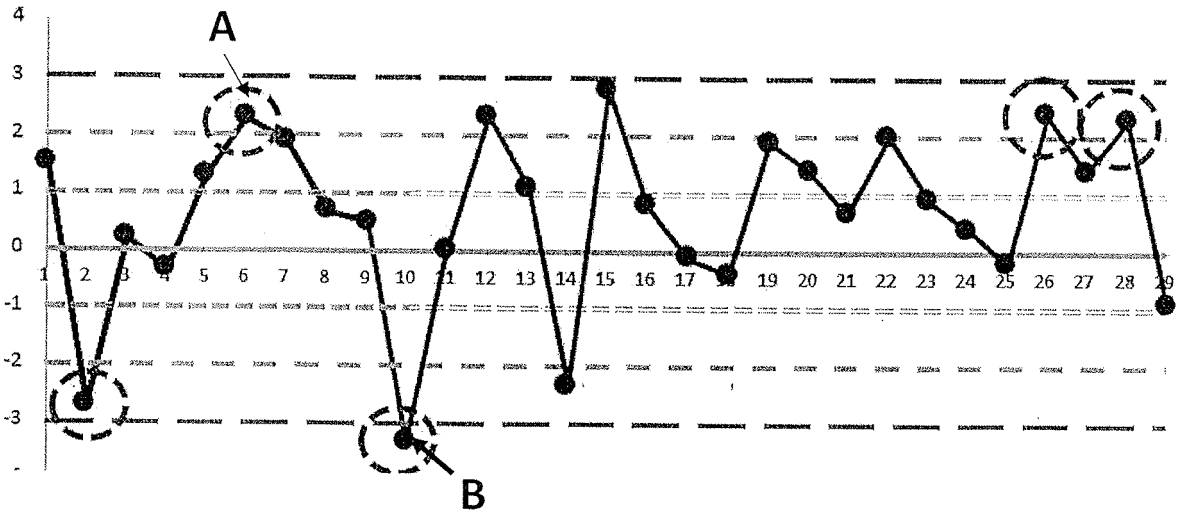
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2.3 State **four (04)** types of waste in an organization, providing **one (01)** example for each. (04 Marks)

Type of waste	Example
i.	
ii.	
iii.	
Iv	

(Total 10 Marks)

Q3. A Levy jenny chart maintained for a particular test is given below.



3.1 Identify the type of error, and Westgard rule associated with points A and B. (02 Marks)

	Type of error	Westgard rule
A		
B		

3.2 List **three (03)** reasons that could lead to a violation at point B in the process. (03 Marks)

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3.3 Briefly describe the steps involved in creating a quality control (QC) chart for a laboratory test. (05 Marks)

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(Total 10 Marks)

Q4.

4.1 Compare the terms "procurement" and "purchasing". (03 Marks)

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4.2 List **three (03)** consequences associated with improper specification and selection of laboratory equipment. (03 Marks)

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4.3 Briefly describe the purpose of bidding documents in procurement. (04 Marks)

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(Total 10 Marks)

Part C: Essay Question. (30 marks)

Question 01

Imagine you are a laboratory manager overseeing both established and newly developing laboratories. Explain the main steps that you would follow to ensure efficient operations in the laboratory. (15 Marks)

Question 02

Discuss the general features of a Laboratory Analytical Operational Information System in laboratory management. (15 Marks)

(Total 30 Marks)

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