Part B: Structured Essay Questions (40 marks)

Q1

1.1 In a laboratory testing "error" and "uncertainty" are two distinct concepts. Explain this statement. (02 Marks)

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1.2 List three (03) characteristics of method validation. (03 Marks)

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1.3 You are tasked with evaluating a new diagnostic test for detecting a specific biomarker associated with a rare disease. In your validation study, you have tested the new assay on a panel of 500 samples, including 200 from patients known to have the disease and 300 from healthy individuals. After analyzing the results, you found that the test correctly identified 180 of the diseased individuals and correctly ruled out 280 of the healthy individuals.

Calculate the sensitivity and specificity of the diagnostic test based on the above findings? (05 Marks)

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(Total 10 marks)

Q2

2.1 List four (04) characteristics of a good Standard Operating Procedure (SOP). (02 Marks)

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2.2 Write three (03) functions of Laboratory Information System. (03 marks)

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2.3 Compare the computerized information system and paper-based information system under the following categories. (05 Marks)

	Computerized information system	Paper-based information system
Confidentiality		
Availability and accessibility		
Security and protection		
Communication		
Storage		

(Total 10 marks)

Q3

1.1 Define the term "strategy" in the context of organizational management (03 Marks)

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1.2 List three (03) performance standards (03 Marks)

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3.3 Outline the process that involves conducting a comprehensive performance appraisal. (04 Marks)

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(Total 10 marks)

Q4

1.1 Define the term "corrective action". (02 Marks)

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1.1 List the four (04) steps that are involved in the process of root cause analysis (RCA). (04 Marks)

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4.3 Briefly describe two (02) advantages of analyzing quality indicators alongside RCA findings in medical laboratories. (04 Marks)

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(Total 10 Marks)

Part C: Essay Question. (30 marks)

Question 01

A biochemistry analyzer is purchased for your working laboratory without assessing the laboratory's specific workflow needs. (15 Marks)

a. Explain the consequences that arise due to improper selection of the above equipment.
b. Suggest potential measures to address those challenges.

Question 02

Explain the strategies that a laboratory manager can employ to maximize both efficiency and effectiveness in the operations of a laboratory. (15 Marks)

(Total 30 Marks)

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