



UNIVERSITY OF JAFFNA
FACULTY OF ALLIED HEALTH SCIENCES
SECOND YEAR SECOND SEMESTER EXAMINATION IN BScHons (MLS) -2021
MLSLQ 2243 LABORATORY MANAGEMENT AND QUALITY ASSURANCE

Date:09.08.2023

Time: 2 Hours

ANSWER ALL SIX QUESTIONS.

ANSWER EACH PART IN SEPARATE ANSWER BOOKS

PART A

1. The External Quality Assessment (EQA) report of the creatinine received from a hospital laboratory is given below. The Internal Quality Control (IQA) report of creatinine shows the Mean and Standard deviation of 4.089 and 0.054, respectively. The Total Allowable Error (TEa) of creatinine of the above laboratory is set up as $\pm 15\%$.

EQA report of creatinine from January to November 2022

Month	Mean of comparison	Lab result
January	4.603	4.69
February	1.551	1.54
March	4.25	4.29
April	1.382	1.42
May	10.9	11.44
June	3.51	3.58
July	0.877	0.89
August	3.5	3.51
September	7.85	7.57
October	4.87	5.1
November	3.93	3.92

1.1. Define the followings,

- 1.1.1. Accuracy (05 Marks)
- 1.1.2. Precision (05 Marks)
- 1.1.3. Bias (05 Marks)

1.2. Estimate the Total % Bias and Precision for creatinine of the above laboratory (30 Marks)

1.3. Calculate the Sigma value and choose the most suitable Westgard QC rules for creatinine to the above laboratory (Westgard Sigma Rule table is given below)

(25 Marks)

Sigma	Westgard rules	Levels of control	Measurements	p error detection	P false rejection
6.0	1_{3s}	2	1	0.98	0.01
5.8	$1_{3.5s}$	2	1	0.98	0.00
5.6	1_{3s}	2	1	0.97	0.00
5.4	1_{3s}	2	1	0.94	0.00
5.2	1_{3s}	2	1	0.91	0.00
5.0	$1_{2.5s}$	2	1	0.96	0.03
4.8	$1_{2.5s}$	2	1	0.93	0.03
4.6	1_{3s}	2	1	0.92	0.01
4.4	$1_{2.5s}$	2	1	0.96	0.04
4.2	$1_{2.5s}$	2	1	0.92	0.04
4.0	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	2	2	0.91	0.03
3.8	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	2	2	0.86	0.03
3.6	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	2	2	0.79	0.03
3.4	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	2	2	0.65	0.03
3.2	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	3	2	0.48	0.03
3.0	$1_{3s} / 2_{2s} / R_{4s} / 4_{1s}$	3	2	0.36	0.02

Source: Schoenmakers CHH, Naus AJM, Xvermeer HJ, Loon DV and Steen5 G. Practical application of Sigma Metrics QC procedures in clinical chemistry. Clin Chem Lab Med 2011;49(11):1837-1843

1.4. Outline the following QC rules,

1.4.1. Control rule 2_{2s} (10 Marks)

1.4.2. Control rule R_{4s} (10 Marks)

1.4.3. Control rule 1_{3s} (10 Marks)

2. Write notes on

2.1. Youden plot. (25 Marks)

2.2. Receiver operating characteristic (ROC) curve. (25 Marks)

2.3. Inventory in a clinical laboratory. (25 Marks)

2.4 Steps in buying an equipment for a clinical laboratory (25 Marks)

3.

3.1. Name four (4) accreditation bodies providing accreditation to clinical laboratories.

(10 Marks)

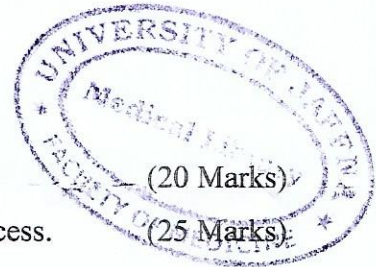
3.2. Briefly describe two (2) accreditation standards.

(40 Marks)

3.3. Outline the process of obtaining accreditation for a clinical laboratory (30 Marks)

3.4. List five (5) benefits of obtaining accreditation for a clinical laboratory (20 Marks)

PART B



4.

4.1 What do you understand by the term 'planning'? (20 Marks)

4.2 Explain why management is considered as a multi-dimensional process. (25 Marks)

4.3 Differentiate between 'efficiency' and 'effectiveness'. (25 Marks)

4.4 Explain whether management is a science or an art. (30 Marks)

5.

5.1 What is meant by the term 'records management'? (20 Marks)

5.2 Briefly explain the steps in the records management process. (25 Marks)

5.3 Differentiate between 'centralized filing system' and 'decentralized filing system'. (25 Marks)

5.4 While records management may appear simple, it entails much more than just filing papers. Explain any five records management challenges. (30 Marks)

6.

6.1 What do you understand by the term 'information system'? (20 Marks)

6.2 State why companies rely on e-business applications. (20 Marks)

6.3 Briefly explain the areas of knowledge important for managers to understand information systems. (30 Marks)

6.4 Explain the managerial challenges of information technology that organizations face today. (30 Marks)