UNIVERSITY OF JAFFNA, SRI LANKA

FACULTY OF ALLIED HEALTH SCIENCES

SECOND YEAR SECOND SEMESTER EXAMINATION IN BScHons (MLS)- 2020

MLSLQ 2243 LABORATORY MANAGEMENT AND QUALITY ASSURANCE

Date: 20.01.2023   Time: 2 hours

ANSWER ALL SIX QUESTIONS.

ANSWER EACH PART IN SEPERATE ANSWER BOOKS

PART A

1.

1.1 Name **four (4)** standardization bodies which provide accreditation
of clinical laboratories.   (20 Marks)

1.2 Briefly describe the steps used in the accreditation process of a clinical
Laboratory.   (30 Marks)

1.3 Briefly describe **two (2)** international standards used for accreditation of a
Laboratory.   (30 Marks)

1.4 State **five (5)** benefits of obtaining accreditation of a clinical laboratory.

(20 Marks)

2.

2.1 Briefly explain the Laboratory Information Management System (LIMS).

(20 Marks)

2.2 Explain how sample management could be carried out using LIMS.   (40 Marks)

2.3 Tabulate the advantages and disadvantages of LIMS in a clinical laboratory.

(40 Marks)

3. Laboratory Quality Management System is a standardized procedure and practice contributing to the overall quality of laboratory test results.

   3.1 List **ten (10)** quality system essentials used in quality management system model.
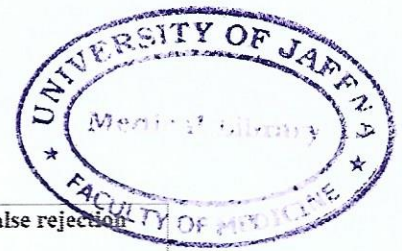
   (20 Marks)

   3.2 The external quality assessment (EQA) report of the alkaline phosphatase (ALP) obtained in 2022 is given below. Estimate the Total %Bias of the laboratory.

   (20 Marks)

Month	Mean of comparison	Lab result
January	214.413	226
February	131.177	133
March	192.59	199
April	125.861	129
May	167.023	165
June	445.102	443
July	57.205	64
August	164.032	154
September	319.152	321
October	227.893	235
November	524.897	561

   3.3 The internal quality control (IQC) report of ALP indicated the mean and standard deviation of 208.15 and 4.0, respectively. Estimate the precision of the laboratory.

   (20 Marks)

   3.4 Calculate the sigma value of the ALP by assuming the total allowable error (TEa) of ALP is $\pm 30\%$. **(20 Marks)**

   3.5 Briefly explain how you would select the most suitable Westgard QC rules for ALP (Westgard Sigma Rule table is given separately) **(20 Marks)**

Table/ Figure 8: Hypothetical sigma values for different Westgard rules [20]

Sigma	Westgard rules	Levels of control	Measurements	p error detection	P false rejection
6.0	$1_{3.5s}$	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	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	2	2	0.91	0.03
3.8	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	2	2	0.86	0.03
3.6	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	2	2	0.79	0.03
3.4	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	2	2	0.65	0.03
3.2	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	3	2	0.48	0.03
3.0	$1_{3s}/2\,2_{2s}/R\,4_s/4_{1s}$	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

PART B

4.

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

4.2 Management is a continuous process. Explain this statement. (25 Marks)

4.3 Briefly explain the three levels of management. (25 Marks)

4.4 Explain the factors that are reshaping and redefining the manager's job.

(30 Marks)

5.

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

5.2 Differentiate between 'proactive planning' and 'reactive planning'. (25 Marks)

5.3 Briefly explain the following innovative approaches to planning:

   5.3.1 Stretch goals (15 Marks)

   5.3.2 An intelligence team (15 Marks)

5.4 Explain why planning does not always bring the intended benefits. (25 Marks)

6.

    6.1 What do you mean by the term 'decentralized filing system'?   **(20 Marks)**

    6.2 State any three advantages and disadvantages of decentralized filing system.

        (20 Marks)

    6.3 Briefly explain the stages in records management.   **(30 Marks)**

    6.4 'An organization may face some consequences for not having a proper

        system for records management'. Explain.   **(30 Marks)**