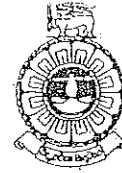


Sample



03

THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCES
ACADEMIC YEAR 2019/2020 – SEMESTER I

BACHELOR OF MEDICAL LABORATORY SCIENCE HONOURS
MDU6404 – MEDICAL LABORATORY QUALITY MANAGEMENT &
ACCREDITATION

10/

NO BOOK TEST 01

DURATION: ONE AND HALF HOUR

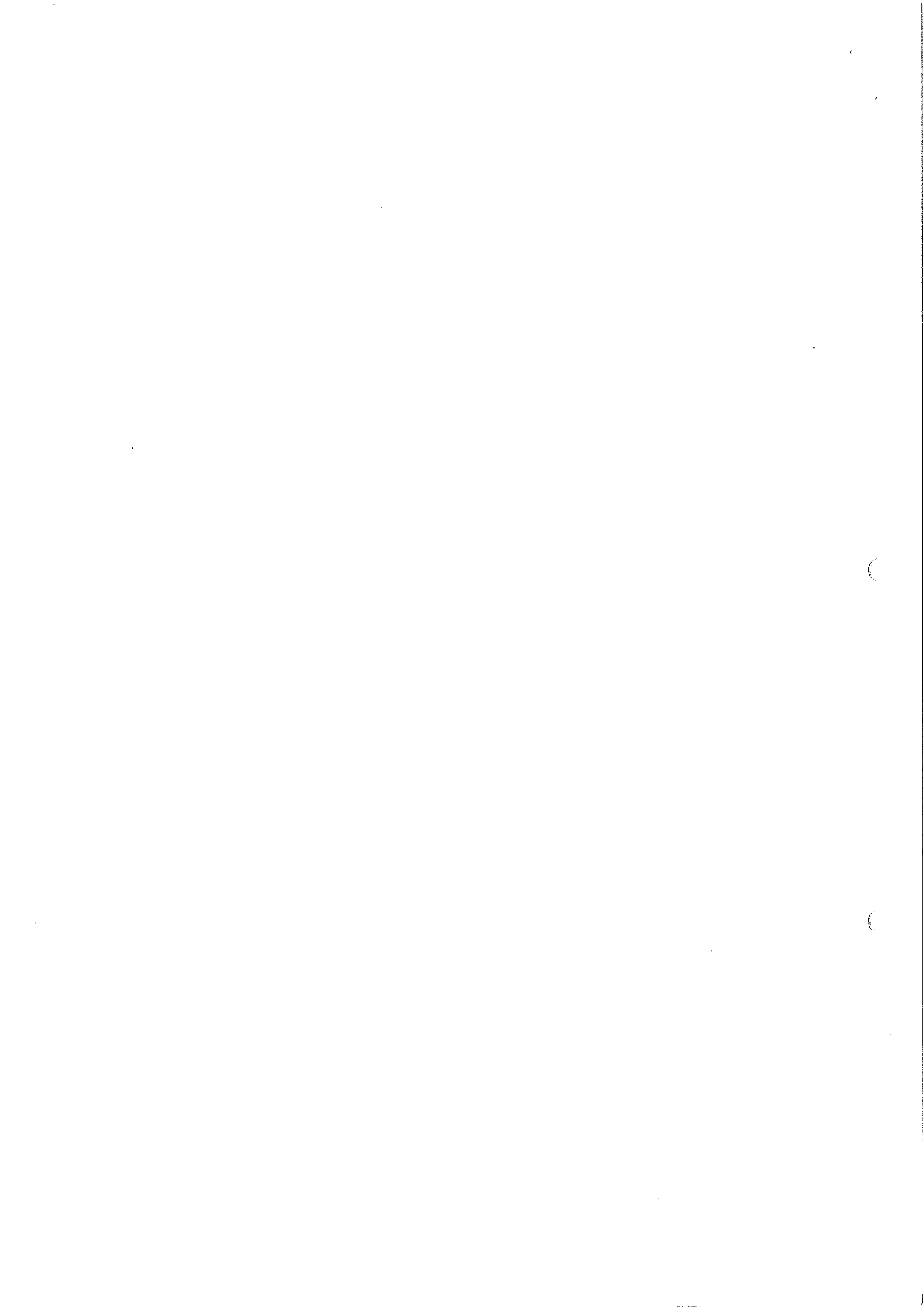
DATE: 19th FEBRUARY 2020

TIME: 02.00 PM -- 03.30 PM

REGISTRATION NO:

IMPORTANT INSTRUCTIONS/ INFORMATIONS TO CANDIDATES

- This question paper consists of 09 pages with 10 Multiple Choice Questions (Part A), 04 Structured Essay Questions (Part B) and 01 Essay Question (Part C).
- Write your Registration Number in the space provided.
- Answer ALL questions.
- Multiple Choice Questions (Part A): Indicate answers in the answer sheet provided by placing a cross (X) in INK in the relevant cage. (answers in pencil will NOT be marked)
- Structured Essay Questions (Part B): Write answers within the space provided.
- Essay Question (Part C): Answer the question on the provided papers.
- Do not remove any page/part of this question paper from the examination hall.
- Mobile phones and any other electronic equipment are NOT allowed. Leave them outside.



Registration No.....

Part A: Multiple Choice Questions (10 marks)

1. Accuracy is defined as
 - a) degrees of closeness of test value to the true value.
 - b) degrees of closeness of a repeated value to the true value.
 - c) degrees of closeness of repeated value to each value.
 - d) degrees of closeness of a known value to the true value.

2. Which of the following statement is **TRUE** regarding external quality assessment?
 - a) Proficiency testing is a synonym for EQA.
 - b) It is a measure of precision of laboratory measurements.
 - c) EQA is more used in developed countries.
 - d) EQA is more focused on continues improvement.

3. A feature of random error includes,
 - a) Predictability.
 - b) Ability to detect easily.
 - c) Ability to detect by means of measurement of variance.
 - d) Ability to detect by means of measurement of accuracy.

4. In deciding which tests and test methods are appropriate to use in a laboratory depend on;
 - a) costs involved.
 - b) expertise of laboratory personal.
 - c) specimen collection techniques involved.
 - d) communication and transport links that exist.

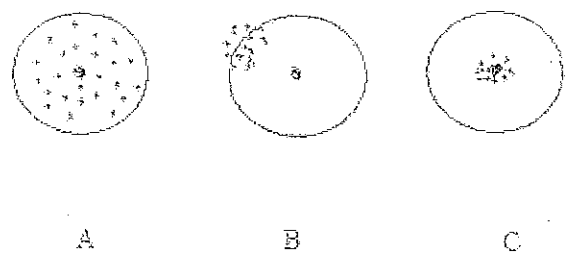
5. In a method, validation accuracy is measured by
 - a) Running 10 replicates of 2 levels of quality control (QC) samples and calculate within run standard deviation.
 - b) Gathering 21 results; 7 results in each of 3 separate runs and calculate within run standard deviation.
 - c) Performing test on known value substance and compare results to expected value.
 - d) Assessing manufacturer's claim

6. The rationale for implementing an overall quality management system in the laboratory is to
 - a) prevent any possibility of testing error.
 - b) differentiate between qualitative and quantitative methods.
 - c) prevent potential errors in the laboratory's path of workflow.
 - d) help to ensure that testing performed by the laboratory is accurate and reliable.

- 7. When most of the samples received by your laboratory are haemolysed, you have to improve
 - a) post analytical phase.
 - b) pre analytical phase.
 - c) post analytical phase and analytical phase.
 - d) external quality control programme.

- 8. Unassayed quality control materials can be used to
 - a) Determine the accuracy of test results.
 - b) Determine the precision of test results.
 - c) Determine both accuracy and precision of test results.
 - d) To calibrate the analyzers.

- 9. Situation B given below compared to situation A and C, is



- a) Accurate
 - b) Precise but inaccurate
 - c) Accurate and precise
 - d) Imprecise and inaccurate
-
- 10. The laboratory director of a medical laboratory shall not be responsible for
 - a) Provision of safe laboratory environment.
 - b) Selection and monitoring of laboratory instruments.
 - c) Provision of continuous professional development opportunities to laboratory staff.
 - d) Provision of second opinion for suspected test results.

Registration No.....

Part B: Structured Essay Questions (80 marks)

Q 1

1.1 Give four (04) responsibilities of quality manger in a medical laboratory. (04 marks)

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1.2 State six (06) components include in a standard operating procedure. (06 marks)

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1.3 Briefly explain the importance of maintaining standard operating procedure in quality management. (10 marks)

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(Total – 20 marks)

Registration No.....

Q 2.

2.1 List three (03) purpose of laboratory quality control. (06 marks)

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2.2 What is the difference between assayed and unassayed QC materials? (04 marks)

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2.3 Give five (05) instances when internal quality control samples are usually run in a laboratory. (10 marks)

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(Total – 20 marks)

Registration No.....

Q.4.

4.1 What is quality assurance? (04 marks)

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4.2 List four (04) objectives of quality assurance program? (08 marks)

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4.3 What are the precautions that a laboratory should take for minimizing the pre-analytical errors in a medical laboratory? (08 marks)

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(Total – 20 marks)

Part C: Essay Question (10 marks)

1. Discuss the essential components of a quality system in a medical laboratory? (10 marks)

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Registration No.....

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NO BOOK TEST 01

ANSWER SHEET FOR PART A

1.

a	b	c	d
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2.

a	b	c	d
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3.

a	b	c	d
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4.

a	b	c	d
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5.

a	b	c	d
---	---	---	---

6.

a	b	c	d
---	---	---	---

7.

a	b	c	d
---	---	---	---

8.

a	b	c	d
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9.

a	b	c	d
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10.

a	b	c	d
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