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

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

NO BOOK TEST II

DURATION: ONE AND HALF HOUR

DATE: 12th MARCH 2020

TIME: 01.00 PM – 02.30 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.....

Name:
Address:

Part A: Multiple Choice Questions (10 marks)

1. A management requirement in ISO 15189 is given in
 - a) laboratory equipment.
 - b) accommodation and environmental conditions.
 - c) internal Audits.
 - d) Personnel.

2. Precision of laboratory managements can be measured by
 - a) correlation coefficient.
 - b) mean.
 - c) median.
 - d) standard deviation.

3. Westguard rule combination used to interpret two level control is correctly given in
 - a) $1_{2S} / 2_{2S} / R_{1S} / 3_{1S} / 12 X$
 - b) $1_{3S} / 2_{2S} / R_{4S} / 4_{1S} / 10X$
 - c) $1_{3S} / 2_{2S} / 6X / 3_{1S} / 9X$
 - d) $1_{3S} / 2_{2S} / 8X / 10X / 12X$

4. Duties of quality assurance manager does not include
 - a) technical validation of daily QC results.
 - b) take corrective actions.
 - c) to draw samples from the patients.
 - d) participate in management review meeting.

5. An example for systemic error includes
 - a) pipette contamination.
 - b) variations in incubation temperature.
 - c) bubbles of lines of reagents.
 - d) variation in line voltage.

6. Which of the following option is correct regarding QA and QC?
 - a) QC is an integral part of QA.
 - b) QA is an integral part of QC.
 - c) QA and QC are independent to each other.
 - d) QC may or may not depend on QA.

7. Which one of the following is not an Element of a QC programme?
- a) Establishing written policies and procedures, including corrective action.
 - b) Training senior laboratory staff only.
 - c) Ensuring complete documentation.
 - d) Reviewing quality control data.
8. A quality management system ensures
- a) Screening off sub clinical diseases.
 - b) The proper sample collection procedures.
 - c) Follow up of the disease condition.
 - d) Prevention of disease.
9. Which of the following statement is the best regarding laboratory audits?
- a) generates evidence to support, refute or develop a hypothesis.
 - b) increases overall knowledge and discovers best practice.
 - c) can identify areas that need to be prioritized and monitored.
 - d) compare current practices against an accepted standard.
10. One of the most powerful aspects to emerge from total quality management (TQM) is the concept of the internal customer and supplier. This means
- a) It is the responsibility of the executive in charge of TQM to manage internal customer-supplier relationships.
 - b) The product or service must be inspected prior to its delivery to the external customer.
 - c) Service Level Agreements must be in place to ensure standards are met.
 - d) Every part of the organization contributes to external customer satisfaction by satisfying its own internal customers.

Part B: Structured Essay Questions (80 marks)

Q 1

1.1 List three (03) objectives of quality management in a medical laboratory. (06 marks)

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1.2 List three (03) parameters that should be included in an equipment quality control program. (06 marks)

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1.3 "ISO 15189 is a comprehensive standard" explain this statement. (08 marks)

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(Total – 20 marks)

Registration No.....

Q 2

2.1 What is internal quality control (IQC)? (06 marks)

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2.2 Give three (03) instances where internal quality control should be run. (06 marks)

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2.3 Briefly explain why internal quality control is important for the laboratory management. (08 marks)

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(Total – 20 marks)

Q3

3.1 What steps you should follow when the daily quality control results are out of the range? (12 marks)

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3.2 What information should be included in a sample collection manual? (08 marks)

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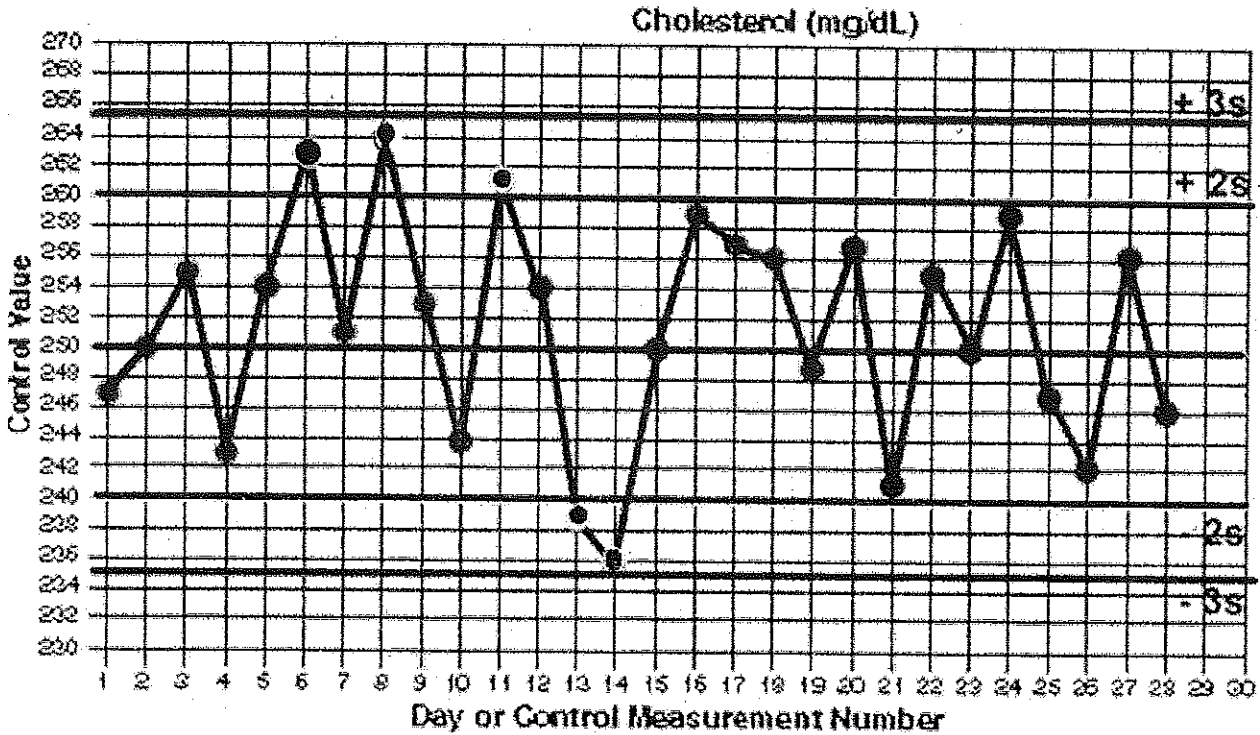
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(Total – 20 marks)

Q 4

You are provided with a Levey-Jenings chart for serum cholesterol over last 28 days



4.1 Find the mean and standard deviation. (06 marks)

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4.2 What are the westgard rules can be identified in this Levey-Jenings chart. (06 marks)

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4.3 Interpret the graph on daily basis. (08 marks)

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(Total – 20 marks)

Part C: Essay Question (10 marks)

1. Briefly explain how do you conduct an internal audit in one of a section of your laboratory?

(10 marks)

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ANSWER SHEET FOR PART A

1.

a	b	c	d
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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
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6.

a	b	c	d
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7.

a	b	c	d
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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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