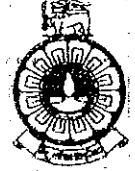


00036

THE OPEN UNIVERSITY OF SRI LANKA
FACULTY OF HEALTH SCIENCES
DEPARTMENT OF MEDICAL LABORATORY SCIENCES
ACADEMIC YEAR 2018/2019 – SEMSETER I

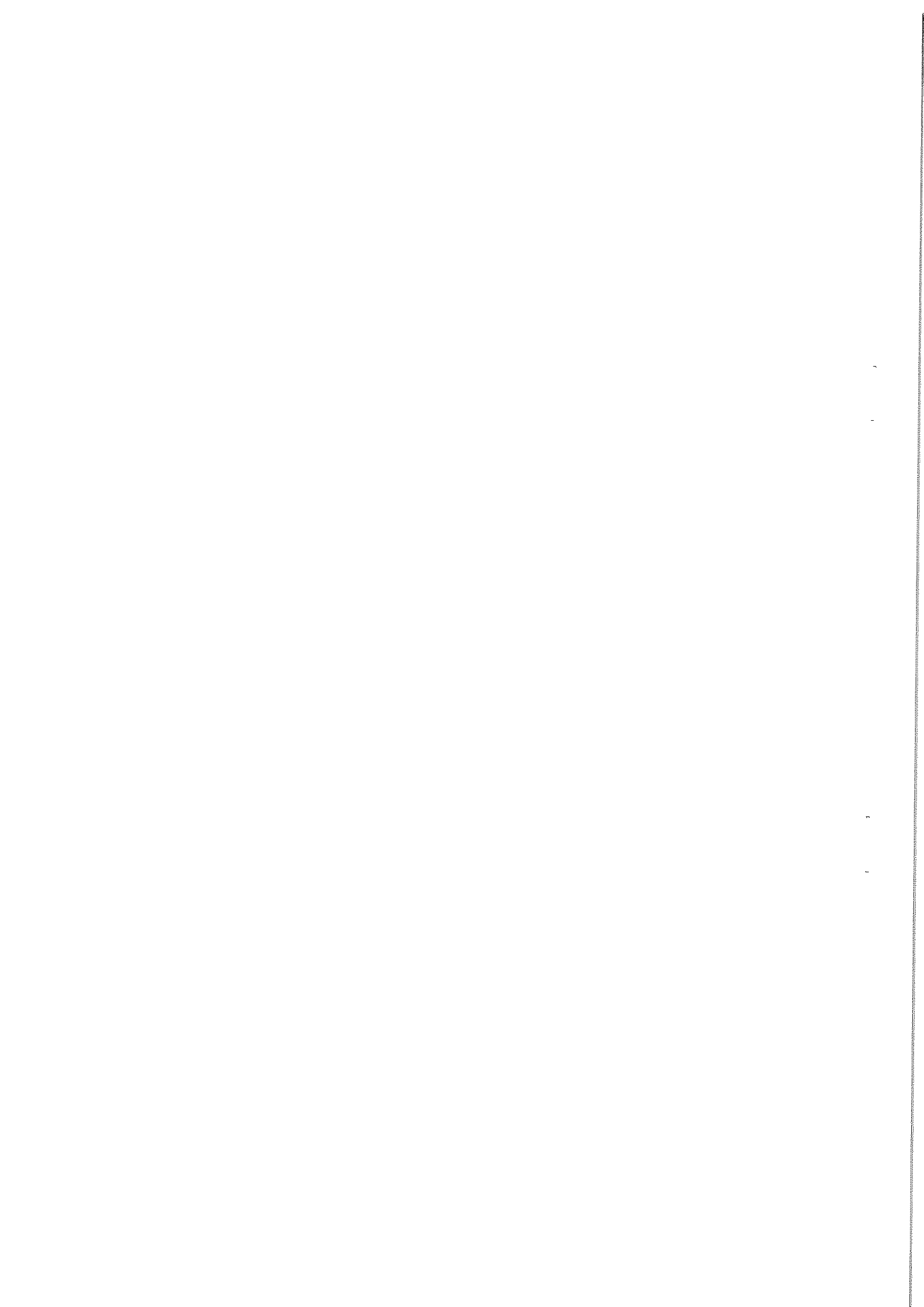


BACHELOR OF MEDICAL LABORATORY SCIENCE HONOURS
MDU6404 – MEDICAL LABORATORY QUALITY MANAGEMENT &
ACCREDITATION
FINAL EXAMINATION

DURATION: THREE HOURS

DATE: 01st MARCH 2019

TIME: 09.30 AM – 12.30 PM



Part B: Structured Essay Questions (40 marks)

Q 1

1.1 Write the objectives of analytical method validation?

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(2 marks)

1.2 Write FIVE (5) performance characteristics that are investigated during analytical method validation.

I
II.....
III.....
IV.....
V

(5 marks)

1.3 Write THREE (3) quality assurance activities conducted in a medical testing laboratory.

I
II
III

(3 marks)

(Total – 10 marks)

Q 2. Given below is a proficiency testing result of glucose testing received by a medical laboratory. Answer the questions based on the result given below.

Analysis Unit	Your result	Number of participants	General mean	CV%	Bias%	Z-score	Comment
Glucose g/l	105	315	101	6.2	4.0	0.64 (satisfactory)	Random error

2.1 Comment on the proficiency testing result obtained by the laboratory?

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(5 marks)

2.2 Write TWO (2) examples of possible random errors occur in analytical measurements

I

II

(2 marks)

2.3 How a laboratory can minimize random errors?

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(3 marks)

(Total – 10 marks)

Q 3

3.1 Write FIVE (5) documents/records that should be maintain for automated clinical chemistry analyzer machine used in a laboratory?

- I
- II
- III
- IV.....
- V

(5 marks)

3.2 Write FIVE (5) activities conducted during pre-analytical phase.

- I
- II
- III
- IV.....
- V

(2.5 marks)

3.3 Write FIVE (5) activities conducted during post-analytical phase.

- I
- II
- III
- IV.....
- V

(2.5 marks)

(Total – 10 marks)

Registration No..... 00046

Q 4

4.1 Mention three key elements of lean management system

- I.....
- II.....
- III.....

(3 marks)

4.2 Briefly describe one of above element.

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(3 marks)

4.3 Briefly discuss “process bottle neck” considering any process in a clinical laboratory as an example.

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(4 marks)

(Total – 10 marks)

Part C: Short Essay Questions (30 marks)

Q 1 (Write answers in a separate answer book)

Assume that your laboratory has issued an incorrect blood glucose test report of a patient and the referring medical officer has complained you of the erroneous report.

- 1.1 Describe the activities you would carry out to address this problem. (10 marks)
- 1.2 Explain the difference between root cause analysis and an internal audit (5 marks)

(Total – 15 marks)

Q 2 (Write answers in a separate answer book)

- 2.1 Discuss the total financial budget of your clinical laboratory for the next financial year (2019/2020) as the chief executive officer of the laboratory. (15 marks)

(Total – 15 marks)

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