

00135

INDEX NO:

**BACHELOR OF MEDICAL LABORATORY SCIENCES HONOURS
MDU6404- MEDICAL LABORATORY QUALITY MANAGEMENT AND
ACCREDITATION**

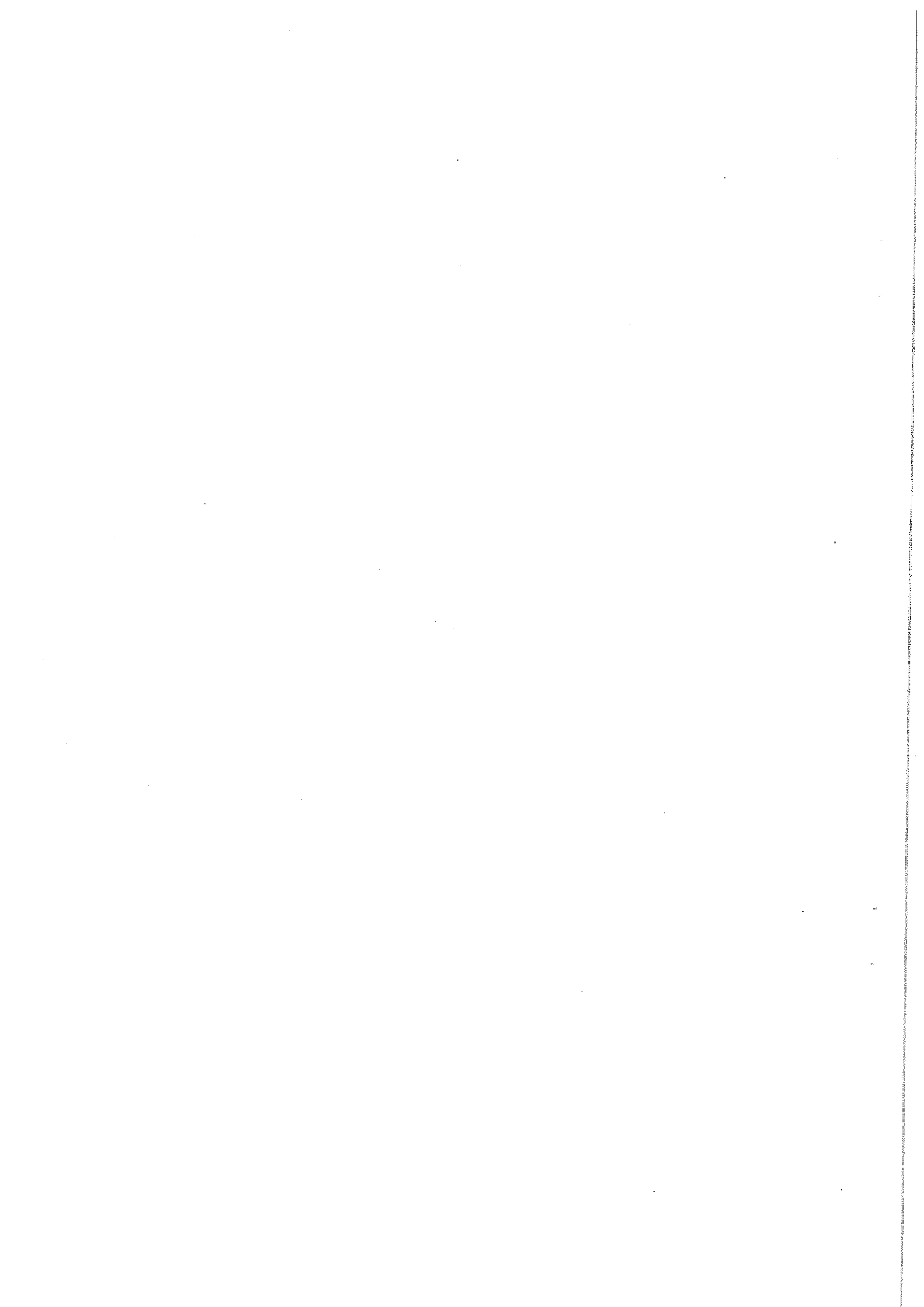
LEVEL 6

FINAL EXAMINATION

ACADEMIC YEAR 2020-2021

SEMESTER I

INDEX NO:



PART B – Structured Essay Questions (40 Marks)

1.

1.1 List three (03) managements aspects included in ISO15189:2012 standard. (03 marks)

- i.
- ii.
- iii.

1.2 List three (03) technical aspects included in ISO15189:2012 standard. (03 marks)

- i.
- ii.
- iii.

1.3 List four (04) quality system essentials given by GP26 guideline for implementation of quality management in medical laboratories. (04 marks)

- i.
- ii.
- iii.
- iv.

(Total: 10 Marks)

2.

2.1 Define “quality indicators”. (02 marks)

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INDEX NO:

2.2 List three (03) uses of quality indicator systems. (03 marks)

- i.
- ii.
- iii.

2.3 Illustrate the process of selecting quality indicator system for your laboratory. (05 marks)

(Total: 10 Marks)

3.0

3.1 List three (03) audit documents that will be used in an laboratory audit. (03 marks)

- i.
- ii.
- iii.

3.2 List three (03) responsibilities of the quality manager during audit process. (03 marks)

- i.
- ii.
- iii.

3.3 Write down four (04) main phases in conducting an audit giving activities performed in each step. (04 marks)

Phase/step	Activities
i.	
ii.	
iii.	
iv.	

(Total: 10 Marks)

4.0

4.1 Define the term performance appraisal. (02 marks)

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4.2 Outline the reflective procedure of performance appraisal. (05 marks)

INDEX NO:

4.3 List three (03) facts that are important to consider when establishing an evaluation method in performance appraisal. (03 marks)

- i.

 ii.

 iii.

(Total: 10 Marks)

PART C – Essay Questions (30 marks)

1. Assume that you are the quality manager of newly established ABC laboratory Pvt (Ltd). Few referring physicians reported that biochemical testing results shown to have an abnormality when compared with the previous reports of the same patient. Describe how you will address this situation using graphical illustrations of the management procedures/processes you have learnt. (15 marks)
2. Your lab manager asks you to create the new control range for the new lot of hematology control level 1. The following 20 hemoglobin values are gathered to determine the control limits.
 - a. Calculate and record the mean and the standard deviation for this set of values.

(04 marks)

4.2	4.0	4.6	4.1
4.7	4.9	4.7	4.2
4.3	4.7	4.9	4.7
4.4	4.6	5.0	4.8
4.4	4.0	4.5	4.4

- b. Given the results above, construct and label the Levey-Jennings Control chart with values for mean, -3SD, -2SD, -1SD, +1SD, +2SD, +3SD (06 marks)

- c. You are given the records of the first 10 days of Control 1 Hemoglobin results. Plot each data given below on your labeled chart (in above b.) and mark whether the controls are acceptable or "out- of control." (05 marks)

Day	mg/dl	Day	mg/dl
1	4.5	6	4.8
2	4.2	7	4.4
3	4.1	8	4.4
4	4.6	9	4.2
5	4.7	10	4.9

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00135