

(University of Choice)

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

(MAIN CAMPUS)

UNIVERSITY EXAMINATIONS (MAIN PAPER) 2017/2018 ACADEMIC YEAR

SECOND YEAR SECOND TRIMESTER EXAMINATIONS

FOR THE DEGREE OF BACHELOR OF MEDICAL LABORATORY SCIENCES

COURSE CODE: BML 227

COURSE TITLE: LABORATORY MANAGEMENT & Q.A.

DATE: JULY 2018

TIME:

INSTRUCTIONS TO CANDIDATES

This paper is divided into three sections, **A B** and **C**, carrying respectively: Multiple Choice Questions (**MCQs**), Short Answer Questions (**SAQs**) and Long Answer Questions (**LAQs**). Answer all questions.

TIME: 2 Hours

MMUST observes ZERO tolerance to examination cheating

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Q1. The estimate of the lowest concentration of an analyte that can be measured is known as?

- (a) Analytical sensitivity
- (b) Analytical specificity
- (c) Analytical measurement range
- (d) Analytical run

Q2. Tolerance limits for humidity as a quality control measure is established for which of the following equipment:

(a) Centrifuges

- (b) Water baths
- (c) Autoclaves
- (d) Refrigerators

Q3. In order to have a functioning lab quality management process there must be?

- (a) Equipment
- (b) Personnel
- (c) Established and implemented quality policies
- (d) All of the above

Q4. Personnel are the most important laboratory resource. They must:

- (a) Be competent, committed and motivated
- (b) Not engage in other activities other than laboratory work
- (c) Address management and oversight
- (d) Not be reminded of the importance of encouragement and motivation

Q5. Which of the following is the service guidelines for biosafety cabinets/laminar flow hoods:

- a) Check accuracy with standard weights of appropriate class at a predetermined frequency
- b) Check daily air flow and document the results to verify effectiveness
- c) Maintain and keep records to verify that back-up is in place
- d) Verify effective sterilization with an appropriate biological indicator weekly

Q6. You are required to store in the fridge reagent kits with the following recommended storage temperature ranges: ALT: 0 to 8°C, Rapid HIV: 3 to 10°C, Pregnancy Test: 2 to 25°C and Chemistry Controls: -10 to 6°C. The <u>optimal</u> fridge storage temperature for these kits would be defined as?

- (a) 2 to 8°C
- (b) 0 to 25° C
- (c) 3 to 6° C
- (d) -10 to 25°C

Q7. During centrifuge calibration, a digital tachometer displays a value of 3000rpm for a rotational speed set at 3200rpm by the manufacturer. How would you interpret these results?

- (a) Calibration has passed
- (b) Calibration has failed
- (c) Centrifuge should be recalibrated
- (d) Centrifuge should be validated and pass/fail criteria set

Q8. Select the best response regarding medical laboratory equipment:

- (a) Equipment shall have an SOP describing the use, preventive maintenance, cleaning and calibration
- (b) Equipment SOPs are not required if operator manuals are available for use

- (c) Labs should not have documented evidence of personnel training for the use, operation and maintenance of lab equipment
- (d) All of the above
- Q9. As a QMS, medical lab equipment management will involve the following element:
 - (a) Having the equipment chosen for you
 - (b) A system in place for equipment maintenance
 - (c) Installing the equipment yourself
 - (d) Assumption that the equipment works properly
- Q10. Proper management of laboratory purchases and inventory:
 - (a) Negates all working processes in the laboratory
 - (b) Clears all work backlog, reagents and equipment from lab benches
 - (c) Produces cost savings and ensures that supplies & reagents are available when needed
 - (d) Reduces the costs of testing, supplies and equipment
- Q11. This is the element of process control within a medical laboratory:
 - (a) Proper disposal of lab wastes
 - (b) Information management
 - (c) Customer care and service
 - (d) Method verification and validation
- Q12. In addition to technical competency, job performance evaluation may also consider:
 - (a) Quality of interpersonal communication
 - (b) Good clinical laboratory practice training
 - (c) Staff identification codes
 - (d) Adequate number of qualified personnel
- Q13. Careful management of laboratory information assures:
 - (a) Proper laboratory functions are met and achieved
 - (b) Accuracy and confidentiality is maintained
 - (c) That no staff or any other health provider may access the information
 - (d) Quality control for testing is met and achieved
- 14. This is a factor involved in the management of lab facilities and safety:
 - (a) Proper testing procedures
 - (b) Quality control procedures
 - (c) Minimizing risks and preventing hazards
 - (d) Elimination of risks and hazards
- Q15. The following is as a laboratory record:
 - (a) The laboratory Quality manual
 - (b) Standard Operating Procedures
 - (c) Un-reviewed test results
 - (d) External quality assurance and/or proficiency test results
- Q16. An example of a pre-analytic occurrence frequently seen in most laboratories is?
 - (a) Improper sample collection and storage
 - (b) Appropriate sample labeling
 - (c) Transporting samples under specified conditions
 - (d) Reagent or test kit storage under specified condition
- Q17. A laboratory document control plan will address the following:
 - (a) Proper testing procedures
 - (b) Ensure SOPs are procedurally accurate and relevant

- (c) Quality control procedures
- (d) Destructive elimination of risks and hazards
- Q18. The Deming's cycle in process improvement usually follows these steps:
 - (a) Act, Check, Do and Plan
 - (b) Check, Act, Plan and Do
 - (c) Plan, Do, Check and Act
 - (d) Plan, Check, Do and Act
- Q19. One of the standard operating procedures in laboratory specimen management is?
 - (a) Quality control
 - (b) Test results reporting
 - (c) Equipment operation and maintenance
 - (d) Tracking
- Q20. In laboratory testing, accuracy can be defined as:
 - (a) Measure of how close a tested value is to the true value
 - (b) Measurement of the scatter or random error between repeated measurements
 - (c) Estimate of the lowest concentration of an analyte that can be measured

(d) Specified interval bound by two limiting values that contains 95% of the values found in healthy individuals

SECTION B: Short Answer Questions (SAQs)

INSTRUCTIONS

- The section has five (5) questions, carrying a maximum total of forty (40) marks
- Answer all of them
- Q21. State what the laboratory safety training course would entail, at a minimum. (8 Marks)
- Q22. Enumerate any eight items that have to be in the laboratory personnel file (8 Marks)

Q23. Explain the laboratory information systems access and security. (8 Marks)

Q24. State the equipment service guidelines for lab refrigerator and freezer. (8 Marks)

Q25. List the basic laboratory safety and personal protective equipment (8 Marks)

SECTION C: Long Answer Questions (LAQs)

- The section has two (2) questions, carrying a maximum total of forty (40) marks
- Answer all of them

Q26. Document the standard format used to write laboratory SOPs.(20 Marks)Q27. Discuss audit trails and chain of custody in laboratory specimen management.(20 Marks)