MASENO UNIVERSITY

UNIVERSITY EXAMINATIONS 2013/2014

SECOND YEAR SECOND SEMESTER EXAMINATIONS FOR THE DEGREE OF BACHELOR OF SCIENCE IN MEDICAL LABORATORY SCIENCE WITH INFORMATION TECHNOLOGY

(CITY CAMPUS - DAY)

PMT 220: QUALITY CONTROL AND ASSURANCE

Date: 16th July, 2014 Time: 5.30 - 7.30 p.m.

INSTRUCTIONS:

- **Answer ALL questions in Section A and B.**
- **Answer Question 1 (ONE) COMPULSORY and ANY OTHER question in Section C.**

Second Semester Exams 2013/2014
Bachelor of Science in Medical Laboratory Science with IT

Kisumu City Campus

PMT 220: QUALITY CONTROL AND ASSURANCE

Section A
Answer ALL the questions in sections (10 marks)

1. Which of the following statement does not describe quality assurance in biomedical laboratory?
   A. It is an on-going planned process of evaluating the quality of laboratory activities and services
   B. It enables the institution to assure itself but not necessarily its clients that all tests and others services meet the standard.
   C. It is the responsibility of the quality assurance department
   D. It provides confidence that quality requirements are fulfilled
2. A medical laboratory accreditation covers the following **except**:
   A. Materials tested or measured in the laboratory
   B. The personnel and not necessarily the equipment and used in outlined procedures
   C. The procedures or methods used
   D. Quality assurance of the test
3. The following terms are fundamental to understanding the utility of clinical tests. Which term is TRUE?
   A. Sensitivity and specificity are characteristic of the test and the disease prevalence respectively.
   B. Negative predictive value (NPV) helps the clinicians to answer the question 'How likely is it that the patient does not have the disease given the test is positive?'
   C. Specificity of a clinical test refers to the ability of a test to identify those with the disease
   D. A test with high specificity results into many patients who are disease free being told of the possibility that they have disease.
4. Which one of the following is NOT the responsibility of the a test facility trail staff:
   A. Ensuring that that personnel understand their functions
   B. All staffs are responsible for following instructions given in trial protocol and SOPs.
   C. All staff are responsible for recording raw data promptly and accurate and in compliance with the laid-down guidelines
   D. All staff should be aware of those guidelines that apply to their work
5. Standard operating procedures (SOPs) should always be kept updated so as to:
   A. Cover the emerging issues in a particular laboratory test
   B. Ensure it is easy to follow by new laboratory staff or students on laboratory training
   C. Make the SOP appealing to patients
   D. Make it detailed in the nature of its description

6. Which of the following statements is true about bio-medical laboratory accreditation based on quality;
    A. It includes assessment of the personnel and equipment in the laboratory
    B. It is not an indicator of the competence of a laboratory to perform a specified range tests
    C. It deals exclusively with terminology and symbols used in a particular production process
    D. It is the sole responsibility of the laboratory manager to ensure accreditation is achieved

7. For quality assurance, handling of specimen and their storage plays an important role in the results that are obtained. To ensure this, the laboratory management should do the following except;
    A. Have a system for tracking samples as they move through the laboratory.
    B. Establish and implement a policy for sample storage and sample disposal.
    C. Maintain sample integrity and assure that all regulations and requirements are met.
    D. Allow samples to be handled by any the laboratory staff
8. The following is NOT a standard laboratory safety
    A. Storing chemicals in fume hoods
    B. Using of PPE
    C. Limiting access to the laboratory
    D. Prohibiting sandals and open-toed shoes to be worn while working in the laboratory
9. Which of the following does not relate to Good Clinical Laboratory Practice?
    A. Involves international ethical and scientific quality standard for designing, conduction and reporting trials that involve use of human subjects
    B. Product evaluation and registration
    C. Is aimed at promoting the quality and validity of test data
    D. Not concerned with promoting confidentiality in scientific research
10. A biomedical laboratory quality control is;
    A. A continuous or on-going planned process of evaluating the quality of laboratory activities
    B. The organizational structure, responsibilities, processes, procedures and resources for implementing quality
    C. A system which designed to verify that all tests and laboratory services satisfy the predetermined requirement
    D. Focused on providing confidence that quality requirements are fulfilled

Section B (30 marks)

Answer ALL the questions in this section

1) Discuss any **FIVE** specifications that should be given by laboratory management to ensure quality in handling of specimen/samples for laboratory tests (10 marks)

2) **a).** Outline **FOUR** main aspects of accreditation that must be considered by a laboratory management to ensure quality of services that it provides (4marks)

b). Define and briefly explain the following terms as applied in quality control and assurance in a biomedical setting (6marks)

i. Standard operating procedure
ii. False negative results
iii. Laboratory Quality Management

3) Describe factors that might lead to failure in the quality levels of a diagnostic or biomedical laboratory. (10marks)

SECTION C (30 marks)

Answer ANY TWO questions in this section. Question 1 is COMPULSORY

1. A group of students conducted a clinical test to determine HIV-1 prevalence in a population of men commercial sex-workers in Kisumu County. One thousand individuals were tested for HIV-1. 15% of the sex workers had HIV-1 infection. The sensitivity of the test kit was ⅔. The test also had a specificity of 53%.

   i. Define the following terms
      Sensitivity (**1 mark**)
      Specificity (**1 mark**)
      Positive predictive value (**1 mark**)
      Negative predictive value (**1 mark**)
   ii. Determine the number of sex-workers that had
      True positive results (**1 mark**)
      False negative results (**1 mark**)
      False positive results (**1 mark**)
      True negative results (**1 mark**)
   iii. Calculate the;
      Negative Predictive value (**2 marks**)
      Positive Predictive Value (**2 marks**)
   iv. Comment on the utility of the test kit for HIV-1 diagnosis (**3 marks**)

2. Describe in details the principles of Good Clinical Laboratory Practice. **(15 marks)**

3. Explain in details how quality control and assurance benefits a medical/pharmaceutical laboratory. **(15 marks)**