TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

CERTIFICATE IN MEDICAL LABORATORY SCIENCES

AML1109 : GOOD CLINICAL LABORATORY PRACTICE

SPECIAL/SUPPLEMENTARY EXAMINATION

SERIES: AUGUST 2017

TIME: 3 HOURS

DATE: Pick Date Sep 2017

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of **TWO** Section(s). Attempt ALL questions.

Circle the correct answer in section A.

Section A

1. Which one of the following is not a section included in a standard operating procedure

   a. Safety instructions

   b. Reagents

   c. Donor details

   d. Related SOPs

2. Which one of the following is not a factor to consider when installing new laboratory equipment

   a. Maintenance

   b. Cost of the personnel to run the tests

   c. Installation requirements

   d. Performance evaluation

3. Which one of the following defines the characteristics of an individual mandated to carry out quality analysis in a laboratory set up

a. Individuals appointed to QA functions should have the ability to understand the basic concepts under- lying the activities being monitored.

b. They should be a part of the study team

c. They can be picked from andy department within the institution

d. They should be from an independent institution

4. Which one of the following does not undergo a laboratory standardisation process

a. Reference material

b. Initial measurement procedure

c. Reference measurement procedure

d. Secondary measurement procedure

5. Which one of the following is a method of assessing laboratory needs using the quantification procedure

a. Consumption based

b. Assessment of postulated reactions to be carried out

c. Assessment of the number of reactions the kit can carry out

d. Life span of the kit

6. Quantification provides information for all of the following except

a. Estimating annual budget requirements.

b. Allowing for better planning.

c. Making decisions and monitoring performance of the inventory management system.

d. Assessing the rate of consumption for quality analysis

7. Which one of the following is not a factor to consider when installing new equipment

a. Requirements for disposing it

b. Process of troubleshooting

c. Size of the lab

d. Maintenance schedule recommended

8.Which one of the following is a characteristic of a laboratory whose air supply is maintained by constant volume mechanism

a. The volume of air supply changes in respect to environmental changes

b. It has few controls to maintain

c. It is expensive to design

d. It is easy to relocate the equipment within the lab

9. Which one of the following is not a tool used to manage stock

a. Standardised forms

b. Card systems

c. Log books

d. Data charts

10. Which one of the following information is found recorded in a store recording system

a. Expiry date

b. Lot number

c. Quantity of each kit

d. SOP number

11. Which one of the following is not used to classify microorganisms into the various risk groups

a. Morphology of the organism

b. Pathogenicity of the organism

c. Mode of transmission,

d. Host factors

12. Which one of the following is not a characteristic used to classify ignitable waste

a. Liquid wastes with a flashpoint less than 60 C (140 F)

b. Non-liquid wastes that are capable of causing fire through friction, reaction with moisture, or spontaneous chemical changes

c. Ignitable compressed gases

d. Those that are capable of detonation or explosive reaction

13. All of the following are guidelines that are used when carrying out procedures in bio-safety lab 1 and 2 except.

a. Pipetting by mouth must be strictly forbidden.

b. Materials must not be placed in the mouth.

c. A written procedure for the clean-up of all spills must be developed and followed.

d. Laboratory protective clothing must be of the type with solid-front or wrap-around gowns

14. Which one of the following is not a chemical germicide that can b used for disinfection in a laboratory

a. Sodium chloride

b. Alchohol

c. Chlorine dioxide

d. Formaldehyde

15. Which one of the following is not a personal protective equipment item used in a laboratory

a. Gloves

b. Laboratory coat

c. Shoes

d. Mask

16.All laboratory employees must be trained on the proper use of personal protective equipment prior to starting work in the laboratory. Which one of the following is not included in that training

a. How to properly wear PPE

b. Types of PPE

c. What are the limitations of PPE

d. The proper care, maintenance and disposal of PPE

17. Which one of the following is not a characteristic of a quality man agent pal

a. Be developed and maintained by an individual or a group of individuals that is (are) part the testing personnel of the laboratory, if practical and possible

b. Be integrated with the institutional Quality Assurance

c. Detail an operational plan that describes the goals and objectives of the QM program

d. Be accessible to all staff

18. Which one of the following is a type of Quality assurance inspection

a. Personnel-based

b. Institution-based

c. Study-based

d. Protocol-based

19. Which one of the following is not a document found in a testing laboratory

a. Personal protective equipment policy

b. Personnel policies

c. Job description

d. Organisation chart

20. Which one of the following is not a function of the document control plan

a. Maintain a master list of the people responsible of reviewing the SOPs.

b. Ensure SOPs are procedurally accurate and relevant.

c. Keep the authorisation process standardised/consistent, limiting approvals to laboratory management.

d. Review SOPs annually and document the review.

21.The laboratory should operate appropriate QC procedures to ensure the quality and accuracy of all aspects of the work performed and reported. Which one of the following is not an aspect whereby quality control features are applied

a. Within analytical batch acceptance criteria

b. External proficiency scheme results

c. Production of analytical plans and consistency with clinical protocol

d. Presentation of the results

22. Chain of custody is important when dealing with trial samples for the following reasons except.

a. For sample identification and traceability at all times.

b. Monitoring sample storage areas.

c. To ensure the integrity of the stored samples.

d. For easy documentation in the laboratory records

23. Which one of the following will result to mishandling of specimen

a. Use of one test requisition per specimen

b. Labelling each specimen with the patient's name, date and time of collection, or site.

c. Write the number of specimens on the test requisition.

d. Submitting the specimen separately from the requisition.

24. Which one of the following is not a good organisation practice

a. Provision of adequate physical facilities and qualified staff.

b. Planning of studies and allocation of resources.

c. Definition of staff responsibilities and training of staff.

d. Assuring that results become part of accepted scientific knowledge.

25.Which one of the following is not a compulsory equipment for laboratory personnel safety

a. Sink

b. Portable eye wash

c. Sand bucket

d. Oxygen detector

26.The laboratory must maintain a system for providing and maintaining clinical trial data records and reports. These records and reports may include the following except

a. Specimen tracking forms

b. Chain-of-custody documents

c. Data summaries

d. Laboratory reports

27.Which one of the following is a method of treating biological waste when disposing it off

a. Washing

b. Inceneration

c. Autoclaving

d. Heating

28. The planning/resource allocation system required by GLP is captured on a document called the master schedule. Which one of the following is not a characteristic of a master schedule

a. The system is not included in an SOP.

b. The person responsibile for its maintenance and updating are defined.

c. The various versions of the master schedule are approved and maintained in the archive as raw data.

d. Distribution is adequate and key responsibilities are identified

29. Which one of the following is a characteristic of a laboratory training system

a. It may be informal i.e among colleagues.

b. There is no standard format that defines it.

c. One cannot perform a historical reconstruction training through the archived documents

d. The training schedule is described in a standard operating procedure

30. Which one of the following is a way in which equipment maintenance can be carried out

a. Preventive maintenance

b. Frequent servicing

c. Proper calibration using the right standards

d. Keeping up to date records of maintenance schedules

31.Biological Safety Program provides guidance to facilitate safe and responsible research with biological agents. Which one of the following is not a part of the program

a. Emergencies and exposures

b. Radiation safety

c. Biological toxins

d. Shipping and receiving of biological material

32. One of the following is not included in the label of a test item

a. Test item name.

b. Batch number.

c. Expiry date.

d. Name of the carrier.

33. Which one of the following is not a characteristic of a study protocol

a. Identification

b. Standard operating procedures to be used

c. Title

d. Statement purpose

34.Which one of the following is not a goal of a good laboratory design

a. Energy efficiency

b. Comfort

c. Space

d. Safety

35. Which one of the following is not a type of an audit that can be carried out on a study

a. Study-based inspections/audits.

b. Facility/Systems-based inspections/audits.

c. Process-based inspections/audits

d. Personnel inspections

36. Carrying out an audit of the laboratory procedures or studies is very important. Which one of the following document is not included in an audit

a. Standard operating procedure

b. Laboratory notebook

c. Study plan

d. Manuscript published from the study

37.All of the following define good laboratory conduct except

a. All analysis or evaluation of trial samples must be performed in accordance with the clinical protocol

b. Samples should be uniquely identified at every stage of the analysis.

c. Samples can be analysed at any given point even if its not in the timeframe as determined at the time of method validation

d. All data generated during the conduct of the laboratory work should be recorded directly

38.Which one of the following is not an importance of inspecting laboratories

a. To ensure that all the equipment are working properly

b. Raise level of awareness for lab personnel

c. Opportunity for additional training

d. Health and safety check of laboratory facilities

39. Which one of the following is not a component of an analytical report

a. Identification of the analytical work by a descriptive title and identification number .

b. The start and completion dates of the laboratory work.

c. Presentation of the results

d. Sample of the standard operating procedure

40. Which one of the following is not part of a laboratory report

a. Introduction

b. Background

c. Objectives of the experiment

d. Equipment list

Section B

41.

a) Define good laboratory practice (5 marks)

b) A master schedule is a document that captures planning/resource allocation system required by good laboratory practice. Discuss areas that should be included in a master schedule (15 marks)

42.

a) Describe quality assurance and discuss the three types of inspection in a quality assurance programme (10 marks)

b) Discuss the qualifications of a quality assurance personnel (10 marks)

43.

a) Safety training is an important component for all laboratory staff. Discuss what it entails (10 marks)

b) Outline the contents of a laboratory analytical report