TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

DEGREE

AML 4101 : GOOD CLINICAL LABORATORY PRACTICE

END OF SEMESTER EXAMINATION

SERIES: Select series 2016

TIME: 3 HOURS

DATE: Pick Date May 2016

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of Choose No Section(s). Attempt ALL questions.

Circle the correct answer in section A.

Section A

Section A (30 Marks)

1. Entry in the following laboratory is highly restricted_____

   a) Biosafety level 3

   b) HIV diagnostic laboratory

   c) Teaching laboratory

   d) Biosafety level 4

   e) Laboratory for cholera studies

2. Persons or Institutions who fund health research projects are referred to as_____

   a) Bill Gates

   b) Sponsor

c) County governments

d) WHO

e) Principle investigator

3. Services offered by the laboratory are internationally recognized if the laboratory _____

a) Acquire ISO certification

b) Is approved by KEMRI

c) Has a license

d) Is in a level 5 hospital

e) Can carry out all biomedical tests

4. The following statements are correct about the consent forms except the form must _____

a) Be understood by participants

b) Show compensation

c) Be Signed by participant

d) Indicate risks involved

e) must be in Kiswahili or English language

5. Clinical trial samples are collected by any of the following except the?

a) Principle investigator

b) Nurse

c) Technologist

d) Sponsor

e) Research student

6. Minutes of the ethical review committee are signed by

a) The Imam

b) The priest

c) The chairman

d) The participants

e) The laboratory director

7. Which of the following can be foud in the MSDS

a) Heavy objects

b) Bacteria

c) Acids

d) Sharps

e) Syringes

8. The following is not advisable to wear when carrying out centrfugation

a) Long sleeved laboratory coat

b) Neck tie

c) Hand gloves

d) goggles

e) Metallic watch

9. The manufactures instruction on a kit can be used as _____

a) SOP

b) Job aid

c) Laboratory policy

d) External quality control document

e) Experimental protocol

10. Which one of the following shows formal communication in the laboratory

a) Work schedules

b) Time tables

c) SOPs

d) Laboratory organizational charts

e) Manuals

11. Exposure to UV radiation is prevented by

a) Switching the UV when no one is present

b) Wearing double laboratory coats

c) Wearing gloves

d) Using for short periods

e) Consuming large amounts of fluids

12. Which of the following statements is not found in the material quality control SOP?

a) Expired materials can used in case of emergency

b) Proper storage

c) Use of positive quality control

d) Use of negative quality control

e) Results of quality control material is indicated

13. Biohazards symbols can be found in all of the following except

a) Biosafety cabinets

b) Entrance of Biosafety levels

c) On Packages transporting biological specimens

d) Entrance of Scientific conference hall

e) Laboratory waste bags

14. Patient specimen request form must contain the following except

a) Marital status

b) Age of patient

c) Signature of Clinician

d) Date

e) Name of health facility

15. Withdrawal of study participants is indicated in_____

a) SOPs

b) Specimen request form

c) Consent forms

d) The proposal

e) references

16. Which one of the following is used by laboratory staff to protect confidentiality of patients?

a) Initials of patient name

b) Surname of patient

c) Codes

d) Name of specimen only

e) Date of specimen

17. A chart written by laboratory staff to assist them in carrying out routine work is the_____

a) Laboratory manuals

b) SOPs

c) Manufactures instructions

d) Job aid

e) Reference chart

18. Which of the following regulation is used for transport of infectious materials from Brazil to Kenya

a) Zika control regulations

b) IATA regulation

c) CDC regulations

d) WHO guidelines

e) Public Health Cap 242

19. In which one of the following Biosafety levels, infection is acquired through ingestion

a) Food microbiology laboratory

b) Biosafety level 3 laboratory

c) Teaching laboratory

d) Biosafety level 2 laboratory

e) Biosafety level 4 laboratory

20. To upgrade county laboratories the most important exercise is to ____

a) Educate members of staff
b) Employ experts
c) Build new laboratories
d) Carry out a gap analysis
e) Write proposals

21. Laboratory testing personnel can perform the following except

a) Log in equipment performance
b) Apply coding of specimen
c) Develop a Quality Management Program
d) Disinfect the workbench
e) Attend seminars

22. SOPs are owned by_____?

a) Laboratory director
b) patients
c) Laboratory staff
d) The authors
e) The institution

23. One of the earliest researches which failed in good clinical practice was

a) Ebola study
b) Discovery of penicillin
c) Cholera studies
d) HIV research
e) Tuskegee syphilis study

24. Speed failure in a centrifuge is audited by reviewing

a) Company documents
b) Inventory book

c) Equipment logs

d) SOPs

e) Control charts

25. The most sensitive specimen in the clinical laboratory is the

a) Blood sample

b) Typhoid samples

c) Frozen samples

d) Cerebral Spinal fluid

e) Sputum

26. All proposals which handle human specimens are cleared by

a) The cabinet secretary of health

b) Universities

c) Scientific steering committees

d) KMLTTB

e) Ethical Review Boards

27. Aliquots of clinical specimen are prepared for_____

a) Economic purpose

b) archiving

c) labeling

d) to save space

e) training students

28. The role of the sponsor in clinical trials is_____

a) To employ scientists

b) To ship in reagents

c) To report to the WHO

d) To provide quality assurance

e) To provide financial support

29 . The first document to refer to if laboratory equipment is shifted is the

a) Inventory

b) Work sheet

c) Transport files

d) Audit reports

e) Equipment maintenance records

30. What action is taken if unlabelled specimen is received?

a) Report the clinician to the Laboratory director

b) Process specimen and indicate not labeled

c) Accept specimen and search for the patient

d) Test specimen but withhold results

e) Reject the specimen

Section B

Question 31.

a) Describe the types of laboratory hazards (10 Marks)

b) Define the following

i. The ethical review committee (6 marks)

ii. The scientific steering committee (4 marks)

Question 32

Discuss in details the main documents required to carry out clinical trials and good laboratory procedures (20 Marks)