TECHNICAL UNIVERSITY OF MOMBASA

FACULTY OF APPLIED AND HEALTH SCIENCES

DEPARTMENT OF MEDICAL SCIENCES

UNIVERSITY EXAMINATION FOR:

DMLS

AML 2105: GOOD CLINICAL LABORATORY PRACTICE.

END OF SEMESTER EXAMINATION

SERIES: DECEMBER 2016

TIME: 2 HOURS

Instructions to Candidates

You should have the following for this examination

-Answer Booklet, examination pass and student ID

This paper consists of Choose Nochoose Sect/Quest. AttemptChoose instruction.

Circle the correct answer in section A.

Section A

1. Good clinical practices are?
   A. Protocols developed by the ICH clinical practice and clinical research
   B. Protocols to be followed during manufacturing of drugs
   C. Only applicable to no-ethical health and safety studies
   D. Procedures governing the design of trials involve ding human participants

2. The main role of referral laboratories is?
   A. Carry out normal assays
   B. Develop laboratory standards
   C. Offer consultancy services
   D. Standardize laboratory test kits

3. The highest tier of biomedical laboratory in Kenya comprises of the following laboratory
   A. Research
   B. Specific disease
   C. Medical college
   D. Provincial hospital

4. The following are important reasons for the provision of staff rest area and lounge
   A. Storage of food stuffs and drinks
   B. Storage of food stuffs and drinks
   C. A rest area for laboratory staff
   D. So as to have a separate administrative work area

5. Facilities must maintain GCLP standards in the employment of staff. Employers must therefore develop standards for the following
   A. Protocols for employment of adequate staff
   B. Non-documented protocols for staff retention
   C. Amorphous regulation of staff training
   D. Established protocols for staff retraining

6. The duration for periodic staff evaluation may be
   A. Determined by the employees
   B. Determined by individual laboratories
   C. Determined by the national accreditation agency
   D. Done only once in each year

7. Personnel files for staff may contain the following
   A. Comprehensive CV
   B. Copies of relevant qualifications
   C. Copy of marriage certificate
   D. Up-to-date information of other employees health status

8. The types of tests to be done in a facility may be determined according to
   A. The laboratory equipment
   B. The laboratory manager
   C. The employee curriculum vitae
   D. The SOPs

9. Standard organization for microbiological assay should be checked for?
   A. Potency
   B. Sterility
   C. Colour
   D. Activity

10. The following information should be contained in the primary specimen collection manual
   A. Equipment trouble shooting protocol
   B. Patient preparation before sample collection
   C. Specimen handling
   D. Reagent labels

11. The analyst work sheet contains the following except?
    A. Date of analysis
    B. Time of collection
    C. Findings and results
    D. Clinicians signature

12. The following items are core to the test report
    A. Normal range or values for test result
    B. Specimen rejection criteria
    C. Clear report with minimum errors
    D. An interpretation of the results

13. The following name as must be present to ascertain the validity of a report
    A. Reporting authority
    B. Report transporters name
    C. Patients name
    D. Phlebotomist's name

14. The key arrears of patient data management in the laboratory include.
    A. Patient details
    B. Findings of analyses
    C. Inspection reports
    D. Immediate destruction of raw data

15. Specimen to be rejected may be defined as?
    A. Those meeting the normal acceptable threshold for quality
    B. Those collected without following the laid down sops
    C. All specimens collected by qualified staff irrespective of sops
    D. Critical samples that may be difficult to obtain fresh

16. When should data entry begin in the laboratory?
    A. Before patient is discharged
    B. After specimen collection
    C. As soon as a registration number is assigned
    D. As soon as the report is ready

17. Which one of the following is an item of a standard operating procedure?
    A. Batch number
    B. Equipment size
    C. Title
    D. Laboratory size

18. Which one is a type of SOPs in respect to occupational health and safety of medical laboratory personnel?
    A. Post exposure treatment protocol
    B. Staff appointment protocols
    C. Staff vaccination protocol
    D. Participation in histological quality control protocol

19. In the medical laboratory, safety must be directed towards?
    A. Environmental protection only
    B. Staff protection only
    C. Protection of staff and environment
    D. Patient protection only

20. Which principles govern the medical personnel?
    A. Principle of malfeasance
    B. Principle of beneficence
    C. Principle of institutional arrangement
    D. Principle of a risk maximization

21. What is quality assurance?
    A. A process that does not guarantee quality laboratory results
    B. A process that adopts all necessary procedures for error minimization
    C. Quality assurance is synonymous to internal quality control
    D. Quality assurance is a management headache

22. Which one of the following special amenities in the laboratory is a basic GCLP requirement?
    A. Power supply
    B. Uninterrupted power supply
    C. Good quality water
    D. Specimen collection area

23. How are laboratory services graded by WHO?
    A. An integral part of manufacturing practice
    B. A main ingredient in provision of essential clinical services
    C. Non-essential component of disease surveillance and clinical research
    D. An integral part of disease surveillance and treatment monitoring

24. Which one of the following document must be upgraded regularly during the entire period of employment?
    A. Copy of appointment letter
    B. Reference letter from previous employer
    C. Employees health status
    D. Copies degrees

25. Which one of the following is an item on the reagent labels?
    A. Name of the patient
    B. Date of test request
    C. Reagent concentration
    D. Type of specimen to be used

26. Which one of he following charts should the daily quality control values be plotted on?
    A. Ghent's chart
    B. Levy Jenning's chart
    C. Field's chart
    D. Graham's chart

27. Which one of the following is not an alternative QC measure for tests without QC materials?
    A. Random retesting of chosen specimen
    B. Replicate testing of specimen using the same machine
    C. Replicate testing of specimen using different methods and different machine
    D. Correlation of test result with other parameters

28. Which one of the following is a measure to ensure good use of SOPs in the laboratory?
    A. SOPs must be available at the work bench
    B. SOPS must be locked up all the time to ensure safety
    C. SOPs must be filled in the laboratory in-in-charge's office
    D. The language of the SOPs must be technical as possible

29. A quality assurance programme is a managerial concept illustrated by Deming's cycle with the following component
    A. Planning
    B. Doing
    C. Wrecking
    D. Cleaning

30. Which one of the following statement is true during staining?
    A. QC should be run with every new stain lot
    B. QC should be run once a week
    C. QC should be done by junior staff only
    D. None of the above

31. The duration for periodic staff evaluation may be
    A. Determined by the employees
    B. Determined by individual laboratories
    C. Determined by the national accreditation agency
    D. Done only once in each year

32. Which one of the following is not a scope of GCLP?
    A. Infrastructures
    B. Personnel
    C. Equipment
    D. Laboratories

33. Which was the first international guideline research involving human participants?
    A. Declaration of Helsinki
    B. Declaration of Japan
    C. Nuremberg code
    D. WHO ethical code

34. What is the objective of a quality audit?
    A. To prevent errors
    B. To catch staff doing wrong things
    C. To provide separate archives of data, reports and sample
    D. To ensure staff are following SOPs

35. Which one of the following may result upon restriction of laboratory access?
    A. Prevent false positive results
    B. Prevent wastage of resources
    C. Prevent false negative results
    D. Preventing interference to sample, equipment or results

36. Whose function is the proper storage of trial records and data?
    A. Study sponsor
    B. Facility manager
    C. Principal investigator
    D. Archivist

37. Why should laboratory staff wear closed shoes?
    A. Allow easy breakage of glassware
    B. Keep the feet warm and smart
    C. Protect the foot from biohazard spillage and chemicals
    D. Avoid being sent away by the laboratory manager

38. What is the context of a study protocol?
    A. How to process proficiency panels
    B. Trial objectives, purpose and design
    C. Review of past studies
    D. Procedures for laboratory safety

39. Which one of the following should be trained in the use of equipment?
    A. Sponsor
    B. Laboratory management
    C. Quality assurance manager
    D. Laboratory staff

40. The CRF is defined as
    A. Case report form
    B. Clinical record form
    C. Clinical Record form
    D. Combined records form

Section B

41. Discuss the contents of standard operating procedures (SOPs) **(20marks)**

42. Explain facilities and equipment as requirements in GCLP **(10marks)**

43. Explain the declaration of Helsinki **(10marks)**

44. Describe the levels of laboratory services **(20marks)**