Cairo University - Faculty of Medicine
Clinical and Chemical Pathology Department

MD Compulsory Course – General Laboratory Medicine [CCP922G]

General Laboratory Medicine Course Specification
MD Degree in Clinical and Chemical Pathology

Program on which the course is given: Doctorate in Clinical and Chemical Pathology
Department offering the program: Clinical and Chemical Pathology Department
Department offering the course: Clinical and Chemical Pathology Department
Course code: CCP922G
Element of the program (Compulsory/Elective): Compulsory course
Academic year: 2015-2016
Date of approval: July 2015
Credit points: 10 Credit points
Course duration: 30 weeks
Teaching hours: Theoretical 70% and Practical 30%
Course Coordinators:

- Prof. Samia Rizk
- Prof. Lamia Mansour

I. AIM OF COURSE

The general laboratory course for doctorate degree in clinical and chemical pathology is designed to prepare candidates with the general knowledge, skills and attitudes necessary to manage clinical laboratories including principles of total quality management, laboratory accreditation, advanced laboratory technologies and instrumentation, and molecular pathology. It also acquaints the trainees with the principles of good laboratory practice and medical research.

II. INTENDED LEARNING OUTCOMES

A. **Knowledge and Understanding:**

By the end of the program the candidate should be able to:

1. Explain the principles and essential elements required of laboratory quality management systems.
2. Describe different systems of laboratory accreditation.
3. Describe the organization and operation of modern laboratory services, as compliant with international standards
4. Explain the principles and applications of biostatistics in clinical laboratories
5. Explain principles and requirements of research ethics, professionalism in laboratory medicine
6. Describe the organization and elements of a research protocol, study designs, analysis and publications.
7. Explain the principles and applications of recent laboratory technology in laboratory practice and research

B. Intellectual Skills:

By the end of the program the candidate should be able to:

1. Analyze and solve laboratory diagnostic errors & problems applying his quality knowledge
2. Provide consultant advisory services, regarding the clinical usefulness, interpretation, and limitations of advanced laboratory techniques
3. Provide consultant opinion regarding the application of molecular pathology in subspecialty
4. Critically analyze research papers
5. Effectively access pertinent scientific literature
6. Integrate new information in an ongoing fashion into diagnostic decision-making
7. Plan and organize a research study

C. Professional and Practical Skills:

By the end of the program the candidate should be able to:

1. Effectively and timely recognize laboratory system errors while deciding the standard corrective action.
2. Properly use the laboratory information system in routine laboratory practice and management.
3. Apply molecular pathology to diagnosis and management in subspecialty
4. Perform advanced laboratory techniques according to subspecialty
5. Monitor the performance of laboratory processes according to quality measures

D. General and Transferable Skills:

By the end of the program the candidate should be able to:

1. Apply leadership and teamwork skills required to implement laboratory policies.
2. Communicate effectively orally and in writing
3. Demonstrate competent use of information technology including the use of word processing, databases, statistical programs, laboratory and hospital information systems
4. Contribute to the continuous development and training of laboratory staff, through mentoring, supervision and appraisal.
5. Expand and enhance their own knowledge and abilities through adopting life-long learning practices.

III. COURSE CONTENT

i. **General Laboratory Medicine**

ii. **Main topics: Students will receive presentations or group discussions about recent advances in the following subjects:**

Principles of Medical Research

1. Study designs in medical research
2. The research question, and hypothesis testing
3. The research protocol
4. Sampling, and sample size estimation
5. Statistical analysis of results
6. Ethics in medical research

Principles of Laboratory Management

1. Laboratory certification and accreditation.
2. Laboratory total quality management principles.
3. Process control.
4. The lean and six sigma, as quality improvement tools.
5. External quality control and proficiency testing.
6. The laboratory information system.
7. Health and safety in the clinical laboratory.

Biostatistics in Clinical Labs

1. Method validation and verification
2. Diagnostic value of lab tests.
3. Reference intervals, decision limits and diagnostic cutoff values.

Molecular Genetics, Cytogenetics, and Molecular Pathology

1. Basic concepts in molecular pathology.
2. Gene mutation and repair.
3. Cell division and cell cycle.
4. Chromosomal anomalies.
5. Modes of inheritance and personalized medicine.
6. Gene expression.
7. Epigenetics.
8. Oncogenesis.
9. Population genetics and genetic counselling.
10. DNA sequencing, NGS, and bioinformatics.
11. Cytogenetics and molecular cytogenetic techniques.
12. PCR and hybridization techniques.
13. Real time PCR. Microarray HRM
14. Good clinical laboratory practice(GCLP) for molecular based tests used in diagnostic labs
15. Molecular diagnosis of infectious diseases.

Advanced Laboratory Techniques

1. Protein separation: principles, application, and interpretation
2. Flow cytometry: principles, techniques, instrumentation, interpretation, and application

iii. **Course contents:** Distribution of course contents

SUBJECTS	Lectures/ Tutorials (hrs)	Practical (hrs)	Total (hrs)	% of Total
Principles of medical research	22	25	47	24.1
Principles of laboratory management	22	25	47	24.1
Biostatistics in clinical labs	10	15	25	12.8
Molecular genetics, Cytogenetics, and Molecular Pathology	45	20	65	33.4
Advanced Laboratory Techniques	6	5	11	5.6
Total	**105**	**90**	**195**	**100**

IV. TEACHING METHODS

The course will be managed through the following teaching/learning methods:

- Observation of, assisting and discussion with Senior Medical Staff

- Task specific on job training
- Observation of laboratory methods
- Practical bench work
- Appropriate post-graduate education courses (interactive lectures and online courses)
- Interaction with clinical staff in seminar discussions and specific courses e.g.
    - workshops
    - Journal club
    - Laboratory medicine conferences
- Independent assignments: on various course topics
- Personal study

Lecture/ Session Timetable:

Interactive lecture/sessions are given once a week during the academic year.

V. LIST OF REFERENCES

- Course notes
- Essential books (text books):
    - WHO quality text book
    - Tietz Textbook of Clinical Chemistry and Molecular Diagnostics
- Web sites
    - Research ethics online course: by NIH

      URL: http://phrp.nihtraining.com/users/login.php
    - Health in Numbers: Quantitative Methods in Clinical and Public Health Research: By Harvard School of Public Health

      https://www.edx.org/course/harvardx/harvardx-ph207x-health-numbers-354

VI. TEACHING AND LEARNING FACILITIES

- Lecture halls provided with a white board
- Audio-visual aids (data-show, slide projection)
- Postgraduate labs and hospital labs

VII. ASSESSMENT

Assessment criteria:

The prerequisite for sitting to the final exam is 75% attendance of the lectures and fulfilling all the credit points specified for the scientific activities, the training program and the elective course which should be registered in the log book.

Assessment tools:

- Continuous assessment is carried throughout the course and registered in the logbook. Approval of satisfactorily training will be built on accurate and systematic observation by the senior staff supervisor
- Final summative examination will be carried at the end of the course. .

Assessment schedule: The final exam is held twice per year in May and November.

Examination description:

a) Written (40%): one paper of 3 hours duration including: short essay questions, comparative aspects question and MCQs
b) Practical (30%): includes detailed procedures observation and assessment, interpretation of laboratory test results, proper interpretation and reporting on provided cases.
c) Oral (30%): by a board of at 3 -4 senior professor staff members

Weighing of assessment

Exams	Marks	Intended Learning Outcomes
Written	200	A1- 7, B1-3
Oral	150	A1- 7, B1-3, D2
Practical	150	B1-B4, C1, C3-5, D3
Total	600	

Head of Department

Prof. Fatma El Mougy