Degree in Biomedical Laboratory Techniques

Teaching: Clinical biochemistry and clinical molecular biology and applied statistic
SSD: BIO/12 ; Ing-Inf/05 ; Secs-s/02 ; Med/46
Number CFU: 6
Teacher: Massimo Pieri   **e-mail:massimo.pieri@unicamillus.org**

Teaching: Clinical biochemistry and clinical molecular biology
SSD: BIO/12
Numberi CFU: 2
Teacher: Massimo Pieri   e-mail:massimo.pieri@unicamillus.org

Teaching: Data Processing Systems
SSD: Ing-Inf/05
Numberi CFU: 2
Teacher:Paolo Bocciarelli   e-mail: paolo.bocciarelli@unicamillus.org

Teaching: Statistics for Experimental Research
SSD Teaching: SECS-S/02
Number of CFU: 1
Teacher name: Simone Lanini   e-mail: simone.lanini@unicamillus.org

Teaching: Technical Sciences of Laboratory Medicine
SSD Teaching: MED / 46
Number of CFUs: 2
Teacher name: Alessia Cabrini   e-mail: alessia.cabrini@unicamillus.org

PREREQUISITES

For a proper understanding, the student should have the basic knowledge of cell biology, biochemistry, physiology and general pathology.

LEARNING OBJECTIVES

For the course of Clinical Biochemistry and Clinical Molecular Biology, knowledge of traditional and innovative methodologies used in the laboratory for the determination of different proteins in the clinical biochemistry laboratory are essential objectives. These objectives will be achieved through lectures and with interactive teaching activities, associated with facilitating learning and improving the ability to face and solve the main diagnostic questions of the clinical biochemistry laboratory. The course aims to provide the student with the skills necessary to understand the role played by information systems and database management systems, illustrating the development process. It is an essential goal of the Statistics course for Experimental research to learn the knowledge of the essential elements for the interpretation of the accuracy and predictive values of a diagnostic test. This course will also deal with issues relating to the comparison of tests and the fundamental aspects of study designs for biomedical research for diagnostics. These objectives will be achieved

through lectures and practical examples illustrating the methodology of some scientific studies published in the medical literature. Knowledge of the methods for selecting and managing independently the analytical processes for the various analysis techniques, applying laboratory safety principles and biomedical laboratory activities as an entity represent internal health system.

The main educational objectives of the clinical biochemistry course are acquired by the student of basic knowledge on the clinical-diagnostic significance of some of the laboratory tests that control the "chemical-clinical profile". These objectives will be achieved through lectures and with interactive teaching activities, associated with facilitating learning and improving the ability to face and solve the main diagnostic questions of the clinical biochemistry laboratory.

At the end of the course, students will know the fundamental concepts of the application of the scientific method to the study of biomedical phenomena, the scientific bases of medical procedures and the principles of operation of the equipment used for diagnostics and therapy, as well as supplying the student with the skills provided understanding the key role that Information Technology (IT) plays for today's society and, in particular, required by the technical-health professions.

EXPECTED LEARNING RESULTS
The expected learning outcomes are consistent with the general provisions of the Bologna Process and the specific provisions of Directive 2005/36 / EC. They are found within the European Qualifications Framework (Dublin descriptors) as follows:

LEARNING OUTCOMES
knowledge and understanding
At the end of this teaching the student will need to know:
- Know and explain traditional and innovative methodologies used in the laboratory of clinical biochemistry and molecular biology.
- Understand the analytical laboratory data.
- what information systems are and why they are needed
- several types of information systems commonly found in organizations and their purpose
- information system development life cycle
- a basic knowledge on programming languages and coding
- the different approaches to software development (Object Oriented, structured programming, etc.)
- a basic knowledge on databases and database management systems
- to calculate and to assess the accuracy of a diagnostic test;
- to calculate and to assess the predictive values of a diagnostic test;
- to calculate and to assess the likelihood ratios of a diagnostic test;
- to use the Bayes theorem;
- to compare a test with a golden standard;
- to compare an index test with the standard reference by using paired measures (McNemar test);

- to recognize and to assess a cohort study for diagnostic medical research;
- to recognize and to assess a case control study for medical research in the diagnostic field;
- to recognize and to assess a paired comparative diagnostic study;
- to assess the difference between studies for measuring accuracy and studies for measuring clinical outcomes.
- Know and explain the pre-analytical phase in the Clinical Biochemistry laboratory
- Know and explain the concepts of treatment and conservation of biological materials
- Know and explain the main analytical measurement techniques
- Knowing how to understand and understand the wrong analytical data
- Know and explain the main hematological parameters.

Applying knowledge and understanding
- At the end of the course the student will be able to use the acquired laboratory knowledge for an in-depth study related to the field of clinical biochemistry and molecular biology, to which the student will dedicate himself in the professional activity.
- how to apply the knowledge and techniques explained in the course to real cases
- At the end of the course, the student will be able to use the knowledge acquired for assessing independently main research issues related to the specific field of diagnostic medicine and for relating to other professionals in a proper way.
- apply the main theoretical notions, related to the basic techniques, considered essential for
  facilitate the understanding and acquisition of professional skills that you will experience within a clinical chemistry lab.

Communication skills
Furthermore, at the end of the course the student must be able to :
- use scientific terminology, specific in the clinical biochemistry laboratory and in the basic techniques of molecular biology.
- how to appropriately use the terminology which refers to information systems and databases
- know how to use properly specific scientific terminology.
- acquire theoretical, scientific and professional knowledge in the study of biological and biochemical parameters in biological samples, using an appropriate scientific terminology

Making judgements
At the end of the course, the student must be able to :
- learn the main techniques for determining clinical biochemistry and molecular biology tests and their clinical interpretation.
- knowledge and competency to be familiar with information systems, databases management systems and their relevant development life cycle
- basic knowledge for judging general issues for the application of diagnostic tests to clinical practice and medical research.
- carry out rough assessments relating to the topics covered in clinical biochemistry

These expected learning outcomes are measurable with the final assessment.

COURSE SYLLABUS
Clinical biochemistry and clinical molecular biology

➢ Proteins: functions in all biological liquids and methods of determination.
➢ Clinical biochemistry of the liver and kidney.
➢ Glucose Homeostasis.
➢ The emergency laboratory.
➢ Heart markers and drugs of abuse.
➢ Clinical biochemistry of cerebrospinal fluid.
➢ DNA sequencing techniques.

Data Processing Systems

➢ Introduction to Information Systems
➢ Information System types
➢ The lifecycle of Information Systems
➢ Overview of Database and Database Management System (DBMS)

Statistics for Experimental Research

➢ Diagnostic accuracy: sesistivity, specificity and pre-test probability
➢ Predictive values: negative predictive values, positive predictive values and prevalence
➢ Positive likelihood and negative likelihood
➢ Bayes theorem
➢ Gold Standard, Reference Tests and Index Tests
➢ Target population, study population, target situation and target condition
➢ McNemar test
➢ Diagnostic cohort studies
➢ Case control study for research in diagnostics medicine
➢ Paired comparative studies for research in diagnostics medicine
➢ Clinical outcome studies (benefit studies)

Technical Sciences of Laboratory Medicine

➢ Pre-analytical variability (treatment and conservation of biological materials). - The laboratory error.
➢ General characteristics of measurement techniques.
➢ The techniques of separation of biological material.
➢ The main measurement techniques used in a clinical chemistry laboratory (photometry, spectrophotometry, chromatography, fluorimetry, turbidimetry, nephelometry, electrophoresis and signs of serology)
➢ laboratory investigations of carbohydrate, lipid and nitrogen metabolism
➢ Hematologic parameters: glycaemia, hemoglobin, glycated hemoglobin, lipidemia, bilirubin, azote-mia, uricemia, transaminase.
➢ Principles and Techniques of Hematology and Coagulation. molecular investigations, application of PCR in clinical biochemistry

COURSE STRUCTURE

The course of **Clinical biochemistry and clinical molecular biology** is structured in 20 hours of frontal teaching, divided into lessons of 2 or 3 hours according to the academic calendar. The lesson will include theoretical lessons with video projections on the topics covered.

The course of **Data Processing Systems** is structured around a set of topics illustrated during classes, which deal with both theory and application, with reference to concrete case studies.

The course of **Statistics for Experimental Research** is structured in 10 hours lectures, divided into 2-hour lessons. The lessons will include theoretical lectures and seminars on practical examples (analysis of peer-reviewed studies published in medical literature).

The course of **Technical Sciences of Laboratory Medicine** is structured in 20 hours of frontal teaching, divided into lessons of 2 or 3 hours according to the academic calendar. The lectures will include theoretical lessons with interaction and video projections on the topics covered. At the beginning of each lesson there will be a summary of the previous lesson in order to verify the correct   understanding   by   the   students.

COURSE GRADE DETERMINATION

The verification of the preparation of the students will take place with a written exam followed by an oral exam for the course of **Clinical biochemistry and clinical molecular biology**. The written test will consist of questions with multiple choice answers. To access the oral exam the student must have totaled at least a minimum of 18/30 points.

The acquisition of the expected learning results for the teaching of the Data Processing System will be ascertained through tests carried out in the classroom in written mode via multiple choice quiz, (on-the-way tests).

Final assessment will be carried out by an oral test for the course **Statistics for Experimental Research**. The oral test will consist of three questions, the first of which on a topic chosen by the student. The test will assess the knowledge of purely theoretical topics, the calculation of parameters or the interpretation of study results. During the oral test, the Commission will assess the student's ability to apply the knowledge learned and to ensure that the skills are adequate for interpreting the fundamental parameters of a medical diagnostics. According to the Dublin parameters the test will assess the student's ability for making judgments, communication skills and learning skills.

The verification of the preparation of the students will take place with a written exam for the course **Technical Sciences of Laboratory Medicine** . The written test will consist of 30 questions with multiple choice answers, for each correct answer a point will be assigned. The final score of the written test will be given by the sum of the partial scores assigned to each question answered correctly. To access the oral exam the student must have totaled at least a minimum of 18 points.

During the oral exam the Examining Commission will assess the student's knowledge and the skills learned during the course. The following will also be assessed: making judgments, communication skills and learning skills as indicated in the Dublin descriptors.

In the evaluation, knowledge and comprehension skills have a weight equal to 40%, applied knowledge and comprehension skills of 40% and judgment autonomy of 20%

In the final assessment, the weighted average of the teaching modules will be made

OPTIONAL ACTIVITIES
Clinical biochemistry and clinical molecular biology
In addition to the teaching activity, the student will be given the opportunity to participate in any ECM courses relevant to the topics covered. The topics of the activities are not subject to examination. Acquisition of the hours allocated occurs only with a mandatory frequency of 100% and suitability is provided.
Data Processing Systems
No optional activities
Statistics for Experimental Research
In addition to the lessons, the student will be given the opportunity to participate in practical sessions to expand specific topics already covered during the lessons. These activities (maximum 2 sessions for no more than 3 students) are optional and do not constitute exam subject. This session will be held on the request of at least 2 students. The acquisition of allocated hours takes place only with a mandatory frequency of 100% and is expected to be eligible.
Technical Sciences of Laboratory Medicine
In addition to the teaching activity, the student will be given the opportunity to participate in any ECM courses relevant to the topics covered. The topics of the activities are not subject to examination. Acquisition of the hours allocated occurs only with a mandatory frequency of 100% and suitability is provided.

READING MATERIALS

Clinical biochemistry and clinical molecular biology
The student will be provided with educational material, such as notes and presentations.

Data Processing Systems
Deborah Morley and Charles S. Parker, *Understanding Computers: Today and Tomorrow (16th edition)* - Cengage Learning

Statistics for Experimental Research
The Design of Diagnostic Studies - Reading material for an internetbased course Werner Vach, Veronika Reiser, Izabela Kolankowska, Susanne Weber Copyright University of Freiburg, 2014 https://www.offenehochschule.uni-freiburg.de/ordner/data/doc/knowledge_translation/dokumentation-diagnosekurs

Margaret Sullivan Pepe The Statistical Evaluation of Medical Tests for Classification and Prediction

Technical Sciences of Laboratory Medicine
 The student will be provided with educational material, such as notes and presentations

RESPONSIBLE AVAILABILITY
Students are received by appointment by writing to the following numbers:
Prof. Massimo Pieri
 email massimo.pieri@unicamillus.org