

## 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](#)**

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Teaching: Clinical biochemistry and clinical molecular biology

SSD: BIO/12

Numberi CFU: 2

Teacher: [Massimo Pieri](#)

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Teaching: Data processing systems

SSD: ING-INF/05

Numero di CFU: 1

Nome docente: [Paolo Montanari](#)

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Teaching: Statistics for Experimental Research

SSD Teaching: SECS-S/02

Number of CFU: 1

Teacher name: [Simone Lanini](#)

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Teaching: Technical Sciences of Laboratory Medicine

SSD: MED/46

CFU Numbers: 2

Professor's name: [Marianna Aragri](#)

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### PREREQUISITES

For a proper understanding, the student should have the basic knowledge of cell biology, biochemistry, physiology and general pathology. It would be desirable for the student to know the basics of cell biology, molecular biology and biochemistry: such as the structure of a gene, proteins and DNA replication. In order to understand the topics illustrated, it is necessary to have acquired the knowledge imparted in the Information Technology course.

### LEARNING OBJECTIVES

The essential objectives of the Clinical Biochemistry and Clinical Molecular Biology and Applied Statistics course are the knowledge of traditional and innovative methodologies used in the

laboratory for the determination of different proteins in the clinical biochemistry laboratory. These objectives will be achieved through lectures and interactive teaching activities, intended to facilitate learning and improve the ability to address and resolve 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 objective of the course Statistics 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 teaching will also deal with issues relating to test comparison and the fundamental aspects of study designs for biomedical diagnostic research. These objectives will be achieved through lectures and practical examples illustrating the methodology of some scientific studies published in medical literature. The purpose of the Laboratory Technical Sciences module is to provide students with the main knowledge on the pre-analytical, analytical and post-analytical phases of the diagnostic processes of laboratory medicine, with particular attention to clinical biochemistry exams, including the neonatal diagnosis. The main educational objectives of the clinical biochemistry course are the acquisition by the student of basic knowledge on the clinical-diagnostic significance of some of the laboratory tests that form the "clinical-chemical profile". These objectives will be achieved through lectures and interactive teaching activities, intended to facilitate learning and improve the ability to address and resolve the main diagnostic questions of the clinical biochemistry laboratory.

At the end of the course, students will have acquired the fundamental concepts of applying the scientific method to the study of biomedical phenomena (choice and measurement of parameters, evaluation of errors), they will be able to describe the physical phenomena of complex systems using suitable mathematical tools, will know the scientific basis of medical procedures and the operating principles of equipment commonly used for diagnostics and therapy, as well as to provide the student with the skills necessary to understand the key role that Information Technology (IT) plays for today's society and, in particular, in the context of the technical-healthcare professions. At the end of the "Information Processing Systems" module, the student will have acquired the skills necessary to understand the role played by information systems and database management systems in the field of technical healthcare 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 have to:

- Know and explain traditional and innovative methodologies used in the laboratory of clinical biochemistry and molecular biology.

- Know and understand laboratory analytical data
- Know what computer systems are and why they are needed
- Know the different types of computer systems commonly adopted in companies and their purposes
- Know the development cycle (life cycle) of a computer system
- Have a basic understanding of programming languages and coding
- Know the different approaches to software development (object-oriented, structured, etc.)
- Have a basic understanding of databases and database management systems
- Calculate and interpret the accuracy of a diagnostic test
- Calculate and interpret the predictive value of a diagnostic test
- Calculate and interpret the likelihood of a diagnostic test
- Knowing how to use Bayes' theorem
- Know how to compare a test with a golden standard
- Know how to compare an index test with the reference test through paired measures (McNemar test)
- Knowing how to recognize and interpret a cohort study applied to medical diagnostics
- Knowing how to recognize and interpret a case control study applied to medical diagnostics
- Knowing how to recognize and interpret a comparative study for paired measures applied to medical diagnostics
- Knowing how to recognize the difference between comparative studies to measure accuracy and studies to measure clinical outcome.
- 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
- Know and understand bad analytical data
- Know and explain the main hematological parameters
- Have knowledge of the correct terminology to be used in laboratory medicine
- Have knowledge and ability to understand the quality of a biological sample
- Have knowledge of the parameters that can influence the pre-analytical phase in the field of hematological investigations and clinical biochemistry - Knowledge of the main methods used for genetic analyzes
- Have knowledge of the diagnostic techniques to be applied in the field of clinical biochemical investigations
- Have knowledge and understanding of the stages of analytical processes in laboratory investigations, with the ability to intervene in solving analytical problems
- Have knowledge and understanding of the main types of tests to be used in neonatal diagnosis.

### **Applying knowledge and understanding**

At the end of the course the student will be able to:

- use the laboratory knowledge acquired for the autonomous study of aspects relating to the field of clinical biochemistry and molecular biology, to which the student will dedicate himself in the context of his professional activity;
- how to apply the knowledge and technologies learned in the course to real application contexts
- use the knowledge acquired for autonomous study of aspects relating to medical diagnostics and relate with knowledge of the causes with other professionals in the sector.
- apply the main theoretical notions, relating to the basic techniques, considered essential to facilitate the understanding and acquisition of professional skills which will be experienced in a clinical chemistry laboratory.
- Know and apply the principles that regulate the various stages of analytical processes in investigations of clinical biochemistry and molecular biology.
- Know and apply in practice the main differences between the different diagnostic tests in the field of hematological diagnosis.
- Know and apply in practice the differences between the various diagnostic tests in the field of neonatal diagnosis
- Be able to understand and use the correct terminology in the field of Healthcare Information Systems, so as to be able to collaborate in their development.

### **Communication skills**

At the end of the course the student should know:

- use scientific terminology, specific to the clinical biochemistry laboratory and the basic techniques of molecular biology.
- evaluate and compare different Health Information Systems. specific scientific terminology appropriately
- theoretical, scientific and professional knowledge in the study of biological and biochemical parameters in biological samples, using appropriate scientific terminology
- Knowing how to describe the analytical processes in hematological investigations, clinical biochemistry and molecular biology, using scientific terminology appropriate to the specific context of diagnosis
- adequately describe a diagnostic process of laboratory medicine, demonstrating that you have learned an appropriate scientific language for the purpose of correct and rigorous communication
- Use specific scientific terminology appropriately.

### **Making judgements**

At the end of the course the student will have to:

- Know the main techniques for determining clinical biochemistry and molecular biology tests and their clinical interpretation.
- Have adequate knowledge and competence to be familiar with information systems, database management systems and their life cycles
- Have learning skills useful for deepening information technology aspects in the technical-health field.

- Carry out general evaluations on the potential of diagnostic tests both in healthcare and in clinical research.
- Carry out general assessments relating to the topics covered in clinical biochemistry
- Synthesize and correlate the various topics
- Have a critical ability on the use of laboratory tests, for diagnosis in the fields of clinical biochemistry, hematology and molecular biology
- Carry out general assessments relating to the topics covered.

**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: sensitivity, 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**

- Variability and laboratory results: Organization of the clinical analysis laboratory; biological, pre-analytical and analytical variability; specificity and sensitivity
- Main techniques and methodologies used in clinical chemistry
- Biological material separation techniques
- Principles and Techniques of Hematology and Coagulation
- Plasma proteins and protidograms
- Laboratory tests for the study of liver and kidney function
- The laboratory in diabetes mellitus and cardiovascular diseases
- Molecular investigations in neonatal diagnosis

### **COURSE STRUCTURE**

The teaching of Clinical Biochemistry and Clinical Molecular Biology is structured in 20 hours of frontal teaching, divided into 2 or 3 hour lessons based on the academic calendar. Frontal teaching includes theoretical lessons with interaction and the projection of videos on the topics covered.

The teaching method of the "Information Processing Systems" course involves the carrying out of frontal lessons for a total of 10 hours on both theoretical and applied topics, with reference to real case studies.

The Statistics for Experimental Research course is structured in 10 hours of frontal teaching, divided into 2-hour lessons. Frontal teaching includes theoretical lessons and seminars on practical examples (analysis of studies published in medical literature).

The Teaching of Laboratory Technical Sciences is structured in 20 hours of frontal teaching, divided into lessons of 2 or 4 hours according to the academic calendar. Frontal teaching includes theoretical lessons with interaction. In addition, intermediate tests are foreseen which will be communicated to the students in advance.

### **COURSE GRADE DETERMINATION**

The verification of the students' preparation will take place with a written exam followed by an oral exam for the teaching 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 scored at least a minimum of 18/30 points.

The verification of learning of the "Information processing systems" module consists of a written and an oral part. The written part will consist of 10/15 multiple choice questions. The oral part consists of a question on the topics of the program.

The verification of the students' preparation of the Statistics for Experimental Research course will take place with an oral exam. The oral test will consist of 3 questions, the first of which on a topic chosen by the student. During the test, the knowledge of purely theoretical elements may be verified, the calculation of parameters or the interpretation of study results may be requested. During the oral exam, the Examining Commission will evaluate the Student's ability to apply the

knowledge and will ensure that the skills are adequate to interpret the fundamental parameters for evaluating the accuracy of a diagnostic test in the medical field.

The exam of the Laboratory Technical Sciences module will take place in oral mode, and as an object of the exam it will focus on the educational program. The examination of the module will take place as an integral part of the entire integrated course. The evaluation criteria considered will be: acquired knowledge, independent judgement, communication skills and learning ability. The exam will be passed with a grade of at least 18/30

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

The final evaluation derives from the weighted average of the various modules and the exam can be passed with a score of 18/30.

The examination will be overall evaluated according to the following criteria:

Not suitable: significant deficiencies and/or inaccuracies in knowledge and understanding of the topics; limited analysis and synthesis skills, frequent generalizations

18-20: just sufficient knowledge and understanding of the topics, with possible imperfections; sufficient analytical, synthesis and independent judgment skills.

21-23: knowledge and understanding of routine topics; correct analysis and synthesis skills with coherent logical argumentation.

24-26: reasonable knowledge and understanding of the topics; good analytical and synthesis skills with rigorously expressed arguments.

27-29: complete knowledge and understanding of the topics; remarkable analytical and synthesis skills. Good independent judgement.

30-30L: excellent level of knowledge and understanding of the topics. Remarkable analytical and synthesis skills and independent judgement. Arguments expressed in an original way

## **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 teaching, the student will be given the opportunity to participate in seminars and the opportunity to view videos in order to improve learning. The topics of the activities are not subject to examination.

#### **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](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 (Oxford Statistical Science Series) 1st Edition ISBN-13: 978-0198565826 ISBN-10: 0198565828

##### **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 email:

Prof. Massimo Pieri

email [massimo.pieri@unicamillus.org](mailto:massimo.pieri@unicamillus.org)