

## Degree in Biomedical Laboratory Techniques

### INTEGRATED TEACHING: Clinical Biochemistry, Clinical Molecular Biology and Applied Statistics

SSD : BIOS-09/A; IINF-05/A; STAT-01/B; MEDS-26/A

CFU : 6

TEACHER RESPONSIBLE: Marianna Aragri EMAIL: [marianna.aragri@unicamillus.org](mailto:marianna.aragri@unicamillus.org)

Teaching: Clinical Biochemistry and Clinical Molecular

BiologySSD: BIOS-09/A

Name of teacher: [Verena Damiani](#) e-mail: [verena.damiani@unicamillus.org](mailto:verena.damiani@unicamillus.org)

Numero di CFU: 2

Teaching: Information processing

systemsSSD: IINF-05/A

Name of teacher: [Paolo Montanari](#) e-mail: [paolo.montanari@unicamillus.org](mailto:paolo.montanari@unicamillus.org)

Numero di CFU: 1

Teaching: Statistics for Experimental

ResearchSSD: STAT-01/B

Name of teacher: [Lucilla Rava](#) e-mail: [lucilla.rava@unicamillus.org](mailto:lucilla.rava@unicamillus.org)

Numero di CFU: 1

Teaching: Science Laboratory Medicine

TechniquesSSD MEDS-26/A

Name of teacher: [Marianna Aragri](#) e-mail: [marianna.aragri@unicamillus.org](mailto:marianna.aragri@unicamillus.org)

Numero di CFU: 2

### PREREQUISITES

Although there are no prerequisites, basic concepts of protein structure, basic concepts of biology, physiology, biochemistry and chemistry are required. 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 taught in the Information Technology course.

### OBIETTIVI FORMATIVI

The teaching of Clinical Biochemistry and Clinical Molecular Biology and Applied Statistics has as its essential objectives the knowledge of traditional and innovative methodologies used in the laboratory for the determination of various proteins in the clinical biochemistry laboratory. These objectives will be achieved through lectures and interactive teaching activities designed to facilitate learning and improve the ability to address and solve the main diagnostic questions of the clinical biochemistry laboratory. The teaching aims to provide students with the necessary skills to understand the role played by information systems and database management systems, illustrating their development process.

It is an indispensable objective of the teaching 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 cover topics relating to the comparison of tests 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 the medical literature. The aim of the Laboratory Techniques module is to provide students with the main knowledge of the pre-analytical, analytical and post-analytical phases of diagnostic processes in laboratory medicine, with a focus on clinical biochemistry tests, including neonatal diagnosis. The main educational objectives of the teaching of clinical biochemistry are the acquisition by the student of basic knowledge of the clinical-diagnostic significance of some of the laboratory tests that form the 'chemical-clinical profile'. These objectives will be achieved through lectures and interactive teaching activities, designed to facilitate learning and improve the ability to address and solve the main diagnostic questions of the clinical biochemistry laboratory.

By the end of the course, students will have acquired the fundamental concepts of the application of 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 appropriate mathematical tools, they will know the scientific basis of medical procedures and the operating principles of the equipment commonly used for diagnostics and therapy, and they will be able to provide students with the necessary skills to understand the key role that Information Technology (IT) plays in today's society and, in particular, in the field of technical-health professions. At the end of the module 'Information Processing Systems', the student will have acquired the skills necessary for understanding the role played by information systems and database management systems in the context of the technical-health professions.

## EXPECTED LEARNING OUTCOMES

**Knowledge and understanding. By the end of this teaching the student will be able 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 used in companies and their purposes
- Know the development cycle (life cycle) of a computer system
- Have a basic knowledge of programming languages and coding
- Know the different approaches to software development (object-oriented, structured, etc.)
- Define the research objective
- Collect data in a useful way for their analysis
- Calculate the sample size and power of the study
- Describe the data and represent them graphically
- Calculate summary measures
- Calculate measures of estimation uncertainty
- Make comparisons between groups
- Study correlation between variables
- Assess associations between variables and their cause-effect relationship
- Calculate the risk of an event
- Apply survival analysis methods
- Know and explain the pre-analytical phase in the Clinical Biochemistry laboratory
- Know and explain the concepts of handling and storage of biological materials

- Know and explain the main analytical measurement techniques
- Know and understand incorrect analytical data
- Know and explain the main haematological 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 may influence the pre-analytical phase in haematological investigations and clinical biochemistry- Have knowledge of the main methods used for genetic analysis
- Have knowledge of the diagnostic techniques to be applied in the field of clinical biochemistry 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

### **Ability to apply knowledge and understanding**

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

- use the laboratory knowledge acquired for the autonomous investigation of aspects relating to the field of clinical biochemistry and molecular biology, to which the student will devote himself/herself in the context of his/her professional activity
- how to apply the knowledge and technologies learned in teaching to real-life application contexts
- use the knowledge acquired for the autonomous investigation of aspects relating to medical diagnostics and relate in an informed manner with other professionals in the sector
- apply the main theoretical notions, relating to basic techniques, considered indispensable to facilitate the understanding and acquisition of professional skills of which they will gain experience within a clinical chemistry laboratory.
- To know and apply the principles governing the various phases of analytical processes in clinical biochemistry and molecular biology investigations.
- To know and apply in practice the main differences between the various diagnostic tests in the field of haematological diagnosis.
- To know and apply in practice the differences between the different diagnostic tests in the field of neonatal diagnosis
- To be able to understand and use the correct terminology in the field of Health Information Systems, so as to be able to collaborate in their development.

### **Communication skills**

By the end of the course, the student should know how to

- use scientific terminology specific to the clinical biochemistry laboratory and the basic techniques of molecular biology.
- Evaluate and compare different Health Information Systems.
- Know how to apply specific scientific terminology appropriately
- theoretical, scientific and professional knowledge in the study of biological and biochemical parameters in biological samples, using appropriate scientific terminology
- to be able to describe analytical processes in haematological investigations, clinical

biochemistry and molecular biology, using scientific terminology appropriate to the specific diagnostic context

- adequately describe a diagnostic process in laboratory medicine, demonstrating that they have learnt appropriate scientific language for the purpose of correct and rigorous communication
- Use specific scientific terminology appropriately.

### **Autonomy of judgement**

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

- Know the main determination techniques of clinical biochemistry and molecular biology tests and their clinical interpretation.
- Have adequate knowledge and competence to be familiar with computer systems, database management systems and their life cycles
- Have learning skills useful for the in-depth study of IT aspects in the health-technical field.
- Make general assessments of the potential of diagnostic tests in both care and clinical research.
- Carry out general assessments of the topics covered in clinical biochemistry
- Synthesise and correlate the various topics
- Have a critical capacity on the use of laboratory tests for diagnosis in the fields of clinical biochemistry, haematology and molecular biology
- Make outline evaluations related to the topics covered.

## **SYLLABUS**

### **Clinical Biochemistry and Molecular Biology**

- Proteins and their functions in biological fluids; analytical methods for protein determination.
- Clinical biochemistry of the liver and kidney.
- Glucose homeostasis.
- Cardiac biomarkers and drugs of abuse.
- Water-electrolyte balance and acid-base equilibrium.
- Clinical molecular biology investigations.
- DNA sequencing techniques.

### **Information processing systems**

- Introduction to Information Systems
- Types of Information Systems
- The Life Cycle of Information Systems
- Healthcare Information Systems
- Overview of Databases and Database Management Systems (DBMS)

### **Statistics for Experimental Research**

- **Fundamentals of Epidemiology**
- Introduction to epidemiology
- Ratios, proportions, and rates
- Frequency measures: prevalence, incidence density, cumulative incidence
- Association measures: relative risk (RR) and odds ratio (OR)
- **Types of Epidemiological Studies**
- Descriptive epidemiology: case reports, prevalence studies, correlation studies

- Analytical epidemiology:
- Observational studies: cohort, case-control, cross-over
- Experimental studies: randomized controlled trials (RCTs)
- **Study Validity**
- Bias
- Confounding
- Effect modifiers
- **Multivariate statistic**
- Multivariate statistical inference
- Simple and multiple linear regression models
- Simple and multiple logistic regression models
- **Survival Analysis**
- Kaplan-Meier method
- Logrank test
- Cox proportional hazards model
- **Diagnostic Test Evaluation**
- Sensitivity
- Specificity
- Positive predictive value (PPV) and negative predictive value (NPV)
- Positive and negative likelihood ratios (LR+ and LR-)
- ROC curve
- Serial and parallel testing
- **Practical Applications**
- Data analysis and visualization using JASP

#### **Science Laboratory Medicine Techniques:**

- 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
- Principles and Techniques of Hematology and Coagulation
- Emergency management in the laboratory
- Molecular investigations in prenatal and neonatal diagnosis

#### **TEACHING METHODS**

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

The teaching of 'Information Processing Systems' includes lectures for a total of 10 hours of frontal teaching, divided into lessons of 2 and 3 hours, on both theoretical and applied topics, with reference to real case studies.

The teaching of Statistics for Experimental Research is structured in 10 hours of face-to-face teaching, divided into lectures of 2 and 3 hours. Frontal teaching includes theoretical lectures and seminars on practical examples (analysis of studies published in the medical literature). The Laboratory Techniques course consists of 20 hours of face-to-face teaching, divided into lectures of 2 or 3 hours depending on the academic calendar. Frontal teaching includes theoretical lectures with interaction. In addition, intermediate examinations are planned, which will be communicated to the students in advance.

## **METHODS OF VERIFYING LEARNING**

The verification of the students' preparation will take place by means of a written examination followed by an oral test for the teaching of Clinical Biochemistry and Clinical Molecular Biology. The written test will consist of a number of questions based on the weight of the CFUs of the various disciplines, with multiple-choice answers. To be admitted to the oral examination, the student must have scored at least a minimum of 18/30 points. More specifically, the questions for the disciplines of Information Processing Systems and Statistics for Experimental Research comprise 10 quizzes each, conversely for the disciplines of Technical

Laboratory Science and Clinical Biochemistry and Clinical Molecular Biology, 20 questions each. During the oral test, the examining board will assess the student's knowledge and skills acquired during teaching, as well as autonomy of judgement (making judgements), communication skills (communication skills) and learning skills (learning skills) according to the Dublin descriptors.

The exam is passed with a minimum grade 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**

Ciaccio M. Trattato di Biochimica Clinica e Medicina di Laboratorio, 1st Edition, 2021, EdiSES Università. The student will be provided with educational material, such as notes and presentations.

#### **Data Processing Systems**

Book Deborah Morley and Charles S. Parker, *Understanding Computers: Today and Tomorrow (16th edition)*

- Cengage Learning

#### **Statistics for Experimental Research**

Notes provided by the teacher. Book: Armitage P., Berry G., Statistica Medica, metodi statistici per la ricerca in Medicina, (III edizione), Mc Graw-Hill Libri Italia, Milano 1996

### **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.ssa Marianna Aragri

email [marianna.aragri@unicamillus.org](mailto:marianna.aragri@unicamillus.org)