General Information	**BACELOR DEGREE IN BIOTECHONOLOGIES**
Title of the subject	Molecular diagnostics and quality control
Degree Course (class)	Industrial and Agri-Food Biotechnologies (L-2)
ECTS credits	8
Compulsory attendance	yes
Language	Italian with english slides
Academic year	2020/2021

Subject Teacher	
Name and Surname	Alessandra Castegna
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Place and time of reception	Campus, Via Orabona 4, Palazzo di Farmacia, 1° piano, giovedì ore 13.00 080-5442322

ECTS credits details	Discipline sector (SSD)	Area
	BIO/12	

Study plan schedule	Year of study plan	Semester
	third	second

Time management	Lessons	Laboratory	Exercises	Total
CFU	7	1		8
Total hours	175	25		200
In-class study hours	56	12		68
Out-of-class study hours	119	13		132
Clinical Biochemistry and Molecular Biology				

Syllabus	
Prerequisites / Requirements	
Biochemistry and molecular biology knowledge is not mandatory but strongly advised	
Expected learning outcomes (according to Dublin descriptors)	
Knowledge and understanding	Through the use of various bibliographic sources (scientific literature, current events), the student will be stimulated to acquire essential tools for their profession, with particular reference to the following specific objectives: • to know the tools of quality control • to know the ISO standards and the quality management system applied to production processes • to know the methodologies of clinical biochemistry and molecular diagnostics, starting from the treatment of the samples. • to know the biochemical-molecular technologies related to human diagnostics.

Applying knowledge	The course aims to provide the methodological approaches and basic techniques for the professional needs of the biotechnologist with particular emphasis on the most relevant aspects to enter the job market and achieve professional success. In detail, the main objectives are: • to acquire the skills to move safely in a clinical diagnostic laboratory and the manual skills required for this. • to apply the knowledge and elements necessary to manage laboratory quality control. • to apply the knowledge and elements necessary to implement a quality management system.
Making informed judgments and choices	• To demonstrate the ability to evaluate the type of treatment and analysis (methods) to be applied based on the analytical sample. • to demonstrate judgment in process quality control strategies.
Communicating knowledge	• To demonstrate the ability to evaluate the type of treatment and analysis (methods) to be applied based on the analytical sample. • To demonstrate judgment in process quality control strategies.
Capacities to continue learning	The course will provide the student with the ability to develop an autonomous and continuous study for updating, through the use of texts, scientific publications in the sector, measuring himself with new information, not necessarily provided by a teacher. Through lectures and laboratory experiences, the student will be stimulated to face specific problems linked to the development of their professional expertieses, in order to develop problem solving strategies. The student will be encouraged to actively participate in the learning and updating actions planned by the study course.
Study Program	
Content	Part I: General concepts of diagnostics. General laboratory diagnostics. Definition, limits and purposes of laboratory diagnostics. Strategies in requesting laboratory tests and related logic schemes. Organic liquids: blood, urine, cerebrospinal fluid, general

	considerations, physical properties and chemical composition. The collection and conservation of biological materials. Pre-analytic treatment: whole blood, plasma and serum tests; anticoagulants and their use. Sources of analytical variability and impact on the interpretation of results. Biological variability. Lab error. Quality control: control of pre-analytical variables and related procedures; control of analytical variables; internal and external quality control; use of stable control materials; choice of reference materials; general principles of control charts. Evaluation of the diagnostic value of a test: diagnostic sensitivity; diagnostic specificity; positive or negative predictive value; diagnostic efficiency; reference values. Part II: Process and product quality control. Sources of variability and factors that influence the production process. Quality certification of processes and products. ISO standards. Statistical process control theory. Tools of the statistical process control. Control charts for variables and attributes. Part III: Biochemical and molecular biology methodologies applied to molecular diagnostics. PCR. Molecular hybridization, in situ PCR, competitive PCR, quantitative PCR, real-time PCR. Methods for typing known mutations: oligo hybridization (ASO), allele specific PCR (ASA), Minisequencing; Ligase test (OLA), RFLP, ARMS; Related applications (Fragile X Syndrome). Methods for the identification of new mutations: dHPLC, TGGE / DGGE, SCCP, TRFLP, sequencing and related applications. High-throughput mutation detection and genotyping: REAL-TIME HRM. Protein-arrays. Use of antibodies, aptamers and small molecules. Immunometry. ELISA. RIA. Engineered binding proteins. SELDI-TOF. Diagnostic proteomics. Mass spectrometric analysis for diagnostic purposes. ESI and MALDI ionization techniques. Relative quantification techniques of the proteome. ICAT, ITRAQ. Study of post-translational modifications by mass spectrometry. Protein fingerprinting from LC-MS and LC-MS / MS analysis. Use of MASCOT and PROFOUND. Laboratory experience: extraction of metabolites from biological samples and quantification by mass spectrometric analysis.
Bibliography and textbooks	Principi di Biochimica clinica (Spandrio-Sorbona)
Notes to textbooks	
Teaching methods	Lectures and lab sessions
Assessment methods	Oral exam

(oral, written, ongoing assessment)	
Evaluation criteria (describe criteria for each of the above expected outcomes)	Final oral exam on molecular diagnostics topics. Students must be able to express the concepts related to the topics of the course using an appropriate language also in the choice of scientific terms that must be consistent with the terminology of the discipline. Students need to know the following topics: - Biochemical and molecular biology methodologies applied to molecular diagnostics. - treatment of the analytical sample. - process quality control tools, quality management system and ISO STANDARDS.
Further information	