QUALITY CONTROL AND ASSURANCE IN A BIOMEDICAL LABORATORY	
GENERAL INFORMATION	
Course teacher	Asst. Prof. Vatroslav Šerić, MMedBiochem, PhD
Associates	Asst. prof. Vesna Horvat, MMedBiochem, PhD Asst. Prof. Sanja Mandić, MMedBiochem, PhD Marija Milić, MMedBiochem, PhD Tara Rolić, MMedBiochem
Study programme	Graduate University Study of Medical Laboratory Diagnostics
Course status	mandatory
Year of study, semester	2nd year, 3rd semester
ECTS credits	**4**
Form of teaching (number of classes)	Lectures: 25; Seminars: 20
Expected number of students attending the course	20

1. COURSE DESCRIPTION

Course objectives

Introduce students to general principles of quality control system and international standards for medical laboratories; Introduce students to basic principles of development and validation of analytical methods and equipment maintenance; Introduce students to the manner of implementing and assuring quality control in a laboratory; Introduce students to the application of biological variation in the process of defining analytical objectives of quality and assessment of test results.

Course entry requirements and competencies needed for the course

Completed courses at the Undergraduate Study Programme of Medical Laboratory Diagnostics or equivalent bachelor's degree (baccalaureate)

Learning outcomes at study programme level

1.2, 2.1, 2.3, 2.4, 2.5, 2.6, 3.1, 3.2

Expected learning outcomes at course level

After attending lectures and completing seminars, studying independently and passing the exam, the students will be able to:

1. explain the principles of the quality control system and international standards for medical laboratories.
2. apply knowledge on biological variations when defining analytical objectives of quality and assessment of test results.
3. use appropriate laboratory technologies and methods for processing and analysing materials, as well as for working on complex automated analysers in general-purpose and specialised biomedical laboratories.
4. critically assess, find solutions and solve specific laboratory problems arising in different work environment.s
5. implement and assure quality control in a laboratory.

Course content

Lectures: Methods of establishing and managing a quality control system: Quality control, quality assurance and quality management; quality of structures, processes and results; ISO standards 9001:2000, EN ISO 17025:1999 and EN ISO 15189:2003; Application of ISO standards in clinical and laboratory practice; Laboratory process quality assurance: from referral to interpretation of results; Medical laboratories accreditation; Quality indicators - laboratory errors. Implementation and interpretation of analytical quality control: Internal analytical quality control; External quality assessment; Advantages of participation in external (foreign) quality control; Understanding of basic statistical concepts in regular quality control (mean value, coefficient of variation, standard

deviation, median, quartile). Evaluation of measuring instruments: Stages in evaluation of automated analysers (selection, clinical and laboratory evaluation, cost-effectiveness); Assessment of laboratory needs and selection of optimum analyser compatible with the structure of existing equipment; Evaluation procedures for automated analysers; Validation, verification and evaluation of measuring instruments; precision, specificity, sensitivity and accuracy; significance of regular checks – calibration of automated analysers, measuring instruments (spectrophotometers, scales) and other equipment (pipettes, cuvettes, thermometers); Test methods and control of reagents (quantitative and qualitative). Effect of biological variation on laboratory test results: Components of biological variation (interindividual, intraindividual, individuality index); Assessment methods for laboratory results of clinically relevant body fluid components (population reference values, individual reference values), models for preparation of reference intervals; reference interval width; glossary of reference values; transfer of reference values to new analytical conditions; determining of analytical objectives of quality based on biological variation components (target values for precision, bias and allowable total error).

Seminars: Quality assurance of the laboratory process: from the referral to the interpretation of the results. Internal analytical quality control; Advantages of involvement in external (foreign) quality controls; Validation, verification and evaluation of measuring instruments; precision, specificity, sensitivity and accuracy; the importance of regular checking - calibration of automatic analyzers, measuring instruments (spectrophotometers, balances) and other (pipettes, cuvettes, thermometers) equipment; Methods of testing and control of reagents and reagents (quantitative and qualitative). Pre-analytical and analytical criteria for the harmonization of the results of laboratory tests at the national and international level. Overview of other factors that can affect the final result: patient preparation, sampling, storage and transport. Patient safety: goals, measures and implementation method.

Forms of teaching

Lectures; seminars; seminar work

Students' responsibilities

Attendance is obligatory throughout all course forms, and the student has to attend all the exams. Student absence of up to 30% is considered acceptable in each teaching form. Practical work and seminars that were not completed have to be taken in the form of colloquiums. The student has to attend all forms of exams required.

Monitoring students' work *(Connecting learning outcomes, teaching methods and evaluation)*

Teaching activity	ECTS	Learning outcome	Student activity	Evaluation methods	Grade points	
					Min.	Max.
Attending classes	0.25	1-5	Attendance,	Attendance records	2	5
Seminar paper	1.75		Seminar paper	Writing and presenting seminar paper	18	45
Final exam	2	1-5	Studying for final exam	Written exam	30	50
Total	**4**				**50**	**100**

Evaluation of written part of final exam

Percentage of correct answers (%)	Grade points
60.00-64.99	30
65.00-69.99	33
70.00-74.99	36
75.00-79.99	39
80.00-84.99	42
85.00-89.99	45
90.00-94.99	48
95-100	50

Formulating the final grade:
Grade points achieved in classes are combined with points achieved in the final exam. Grading in the ECTS system is absolute grading and represents one's final achievement. Grades are numerically expressed as follows: A – excellent (5): 80-100 grade points; B – very good (4): 70-79.99 grade points; C – good (3): 60-69.99 grade points; D – sufficient (2): 50-59.99 grade points

Assigned reading (available in the library and in other media)

Title	Number of copies in the library	Availability in other media
EN ISO 15189, Medical laboratories — Requirements for quality and competence.		Yes

Further reading

1. European Committee for Clinical laboratory standards (ECCLS): Manual for evaluation of instruments, procedures and test reagents
2. C. Ricos, V. Alvarez, F. Cava, JV Garcia-Lario, CV Hernández Jiménez, et al., "Biological variation and desirable quality specifications. The 2004 update", http://www.westgard.com/guest26.htm
3. Hammer-Plećaš A, Čvorišćec D, Stavljenić-Rukavina A. Analitička kontrola u medicinsko-biokemijskom laboratoriju. Biochemia Medica 1995; 1:37-45

Quality assurance methods that ensure the acquisition of exit competencies

Anonymous, quantitative, standardised students' opinion survey on the course and teacher's work, carried out by the Quality Assurance Office of the Faculty of Medicine in Osijek.