

1.	Subject	QUALITY CONTROL IN A MEDICAL BIOCHEMISTRY LABORATORY			
2.	Code	MLD – 312			
3.	Study program:	Three-year professional studies of medical laboratory diagnostics			
4.	Conducted by	UKIM – Medical faculty Department of Biochemistry and Clinical Biochemistry			
5.	Degree of education (first or second cycle)	First cycle			
6.	Academic year/semester	III/V	7	Credits	2
8.	Professor	Head of the Department: Prof. d-r Jasna Bogdanska The lessons are held by all the Department members			
9.	Prerequisite	Fulfilled condition for enrollment into third year			
10.	Goals	<p>The students get acquainted with the system of providing quality in a medical biochemistry laboratory. Quality control in the pre-analytical phase. Types of obstacles during measuring. Analytical phase – inaccuracy and imprecision control. Equipment and tools control. Reagents control. Quality inner-control. Post-analytical control. Quality handbook. Outside control of work quality.</p> <p><i>Knowledge and understanding:</i></p> <p>After the subject program the students will be able to:</p> <ul style="list-style-type: none"> • Actively use all valid laboratory documents and records according to the standard MKC EN ISO 15189 • Document the introduced actions of quality control • Introduce the actions defined in the pre-analytical professional standards which start with the doctor's request for a laboratory analysis, continue with patient preparation, taking a primary sample, transport to the laboratory or a referral laboratory and finish with the action of analytical analysis. • Use with certainty the recommended analytical methods for preparing analyses according to a good professional training • Actively participate in applying inner and outside quality control in medical biochemistry laboratory • Provide follow up into all phases of the laboratory process • Reduce the frequency of laboratory mistakes • Provide safety and health of patients, personnel and visitors • Discover lack of conformity and manage it. Suggest correctional and preventative measures and ways of improving the work • Protect the confidentiality of patients' data • Send the quality indicators to the system of quality management which aids the health protection of patients <p><i>Skills and knowledge:</i></p> <p>By mastering the subject content, the student will be able to:</p> <ul style="list-style-type: none"> • Manage a patient during taking biological sample • Acting according to the referral and the biological material in the pre-analytical phase 			

		<ul style="list-style-type: none"> • Using laboratory documents in routine work • Writing imprecision control diary • Writing inaccuracy control diary • Preparing serum pool • Applying equipment and tools control
11	.	<p>Content summary:</p> <p>Theoretical lessons:</p> <ul style="list-style-type: none"> • Defining quality management in a medical biochemistry laboratory • Work process: pre-analytical, analytical, post-analytical phase of the work process • Pre-analytical phase: <ul style="list-style-type: none"> - Patient preparation - Acting according to the referral - Patient management when taking the biological material - Closed system of taking blood sample (vacuum test-tube and additives) - Quality control/quality indicators in the pre-analytical phase • Analytical phase <ul style="list-style-type: none"> - Types of mistakes during measurement - Inaccuracy and imprecision control - Equipment and tool control - Reagents control - Inner quality control (using control samples) - Quality control/quality indicators in the analytical phase • Post-analytical phase <ul style="list-style-type: none"> - Defining TAT (turn-around time) - Declaring critical values - Quality control/quality indicators in the post-analytical phase • Laboratory information system (LIS) • Outside control of the work quality • Using laboratory documents in routine work (creating standard operational procedures (SOP), work instructions, instructions) • Using the Quality handbook <p>Practical lessons:</p> <ul style="list-style-type: none"> • Adopting techniques for taking vein blood • Adopting techniques for taking capillary blood <p>Blood – serum separation/plasma – analytical actions:</p> <ul style="list-style-type: none"> • Equipment and tools control • Reagents control • Inaccuracy and imprecision control
12	.	<p>Teaching methods:</p> <p><i>Teaching activity:</i> Theoretical lessons, seminars, laboratory work, guided individual learning at home, consultations</p> <p><i>Student's activity:</i> Attending theoretical lessons, practicing skills through independent laboratory work, homework assignments, writing a paper, mastering techniques for constructive criticism and analysing someone else's work, presenting a paper or subject content, mastering techniques for summarizing and concise expression.</p> <p>Working in a laboratory and independent performance of 50 phlebotomies with guidance</p> <p><i>Ways of passing the exam</i></p>

	Check of knowledge in writing. Condition for attending the exam: work in a laboratory with a minimum number of phlebotomies under guidance; paper		
13	Total classes:	60	
14	Organization		
15	Types of teaching activities	15.1	Lessons: theoretical classes
		15.2	Laboratory practical lessons
16	Other types of activities	16.1	
		16.2	Self-supporting practice
		16.3	Learning at home
17	Knowledge assessment		Points
	17.1	Paper/project (oral/written presentation)	1 – 5 points
	17.2	Active participation	Theoretical lessons 1 – 5 points Practical lessons 9 – 15 points The student can miss only 2 practical lessons Independent performance of the laboratory tasks, calculating the results and writing them in a laboratory diary in a form of a laboratory report which must be filled according to the given instructions and must be approved by an assistant/professor
	17.3	Final exam Written part (theoretical and practical lessons test)	Practical part: 24 – 40 points Theoretical part: 21 – 35 points
18	Grading criterion (points/grades)	Up to 59	5 (five) F
		60-68	6 (six) E
		69-76	7 (seven) D
		77-84	8 (eight) C
		85-92	9 (nine) B
		93-100	10 (ten) A
19	Requirements for obtaining a signature and attending the final examination	<p>To obtain a signature, the student must gain minimum points from attending the theoretical lessons, practical lessons and seminars</p> <p>To attend the final exam, the student must pass the mid-term exams. In the exam session, the student first must pass the mid-term exams.</p> <p>The practical exam is independent from the mid-term exams and is passed if the student gets 60% of the total number of points.</p> <p>To attend the oral exam, the student must pass the mid-term exams and the practical exam.</p> <p>The final grade is formed according to the grading criterion, and is based on the sum of the points of all the activities.</p>	
20	Language	Macedonian	

.			
21	Method of evaluating the quality of the lessons	Students anonymous evaluation of the lessons, the teachers and the collaborators.	
22	Literature:		
	22.1	Mandatory literature	
		1.	Laboratory Quality Management System Handbook (ISBN 978 92 4 154827 4) Version 1.1, WHO, Available at https://apps.who.int/iris/bitstream/handle/10665/44665/9789241548274_eng.pdf , 2011
		2.	Quality Management in a Medical Laboratory, analyzing demands and revised questionnaire for self-evaluation, Ines Vukasovic, Medicinska Naklada, 2016
		3.	Macedonian Standard MKC EN ISO 15189:2013, Medical Laboratories: Special Quality and Competence Requests (ISO 15189:2012, Standardization Institute of the Republic of North Macedonia, 2013
		4.	Medical Biochemistry Exercises Practicum for the students of general medicine, Topuzovska Sonja, Bogdanska Jasna, Bosilkova Gordana, Gerakarovska Marija, Efremova Aaron Snezana, Kavrakova Julijana, Korneti Petraki, Kostovska Irena, Krstevska Marija, Labudocikj Danica, Tosheska Trajkovska Katerina, Cekovska Svetlana
	22.2	Additional literature	
		1.	