

2023/2024. ACADEMIC YEAR	
PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)	
<b>Full (Hungarian) name of the subject:</b> KLINIKAI KÉMIA ÉS LABORATÓRIUMI DIAGNOSZTIKA	
<b>Program:</b> Undivided program (pharmaceutical)	
<b>Schedule:</b> Full-time	
<b>Short name of the subject:</b> Labordiagnosztika alapjai	
<b>English name of the subject:</b> Clinical Chemistry and Laboratory Diagnostics (theory)	
<b>German name of the subject:</b> Klinische Chemie und Labordiagnostik	
<b>Type of registration:</b> <u>obligatory</u> /obligatory elective/elective/criteria requirement	
<b>Neptun code of the subject:</b> GYKLM1082E1A	
<b>Responsible Department:</b> Department of Laboratory Medicine	
<b>Responsible tutor</b>  dr. Barna Vásárhelyi  <b>Contact information:</b> - phone: +36 20 666 3246 - email: vasarhelyi.barna@med.semmelweis-univ.hu	<b>Title, academic degree:</b>  Medical doctor, Director, Ph.D., D.Sc.
<b>Name of the persons responsible for the teaching of the subject:</b>  Barna Vásárhelyi  Ibolya Kocsis  Györgyi Molnár-Világos  Zsófia Szabó  Adrienne Fehér  Gellért Karvaly	<b>Title, academic degree:</b>  Professor of medicine, specialist of laboratory medicine, Ph.D., D.Sc.  Pharmacist, specialist of laboratory medicine, Ph.D.  Pharmacist, specialist of laboratory medicine  Pharmacist, specialist of laboratory medicine, Ph.D.  Medical doctor, specialist of laboratory medicine, specialist of hematology and hemostasis  Pharmacist, Ph.D.
<b>Class per week:</b>  Theory: 2 Practice: 0	<b>Credit point(s):</b>  2
<b>Professional content, intent of acquirement and it's function in order to implement the goals of the program:</b>  Discussion of the role of laboratory tests in clinical decision-making, with particular regard to areas requiring pharmaceutical knowledge.	

**Short description of the subject:**

Pharmacists encounter questions related to laboratory diagnostics several times during their daily work. A general request from laymen concerns the proper conduction of home tests (e.g. blood sugar, blood fat level), and the interpretation of laboratory results. In clinical care, there is a particularly high demand for the appropriate interpretation of laboratory findings with a focus on the effects and side effects of drugs. The pharmacist's approach represents a significant added value in this respect. Therapeutic drug level monitoring is a separate field in which pharmacists play a prominent role.

The clinical diagnostic laboratory also relies on the knowledge of pharmacists. A special qualification (specialist of laboratory medicine) is acquired by experts working in his field.

In the lectures the main aspects of reporting laboratory tests, the most frequently performed analytical procedures, and the interpretation of test results are presented.

The following topics are addressed with a special focus:

- point-of-care tests performed at the patient's bedside (in pharmacies),
- major tests employed for investigating the diseases of individual organ systems,
- clinical laboratory analysis of the pharmacodynamic effects of drugs,
- therapeutic drug monitoring,
- clinical laboratory quality assurance.

In the lectures, the theoretical background of the topics listed in the "Topics of theoretical classes" section will be presented and illustrated.

In the framework of the course, clinical diagnostic laboratory visits will be arranged in a pre-organized way, and the application of point-of-care tests performed at the patient's bedside, in the pharmacy, or by the patients for self-checking will be demonstrated (2x70 minutes, 2x1.5 theoretical classes).

The discussion of laboratory test reports will be conducted to help students with the better understanding and proper application of the acquired knowledge (4 theoretical classes).

**Course data**

Recommended term	Contact hours (lecture )	Contact hours (practice )	Contact hours (seminar)	Individual lectures	Total number of contact hours/semester	Normal course offer	Consultations
semester 5	28	--	--	--	28	<u>Autumn semester*</u> Spring semester Both semesters (* Please underline)	--

<b>Program of semester**</b>
<b>Topics of theoretical classes (pro week):</b> 1. Introduction: the scope, position and functions of laboratory diagnostics in healthcare organisations 2. Blood collection procedure, types of blood collection tubes, and examples of their use. Preanalytical factors which affect laboratory results 3. Major laboratory analytical procedures and analytical systems used in clinical diagnostic laboratories. Quality assurance 4. Point-of-care tests, tests available for pharmacy self-monitoring 5. Interpretation of laboratory findings, basics of the statistical evaluation of test results. Data-oriented clinical laboratory: the importance of bioinformatics 6. Laboratory diagnosis of inflammation. Acute phase reaction 7. Liver function tests 8. Urinalysis 9. Diagnosis of tissue injury 10. Laboratory diagnosis of tumours. Molecular biology tests in the laboratory 11. Endocrinology tests: diagnosis of metabolic disorders (diabetes, hyperlipidaemia) 12. Endocrinology tests: thyroid hormones, adrenal and sex hormones 13. Therapeutic drug monitoring: basic concepts, pharmacokinetic principles, aims, factors influencing the fate of the drug in the body 14. Therapeutic drug monitoring: the role of laboratory tests in the implementation of individualised drug therapy. Precision pharmacotherapy software 15. Drugs influencing laboratory test results. Clinical drug testing 16. Fundamentals of clinical toxicology and its laboratory implications 17. Immunological tests: autoimmunity 18. Immunological tests: hypersensitivity reactions, allergy tests, and immunodeficiency conditions 19. Blood count elements. Anaemias. Iron deficiency 20. Basics of blood grouping 21. Haemostasis tests. Anticoagulant monitoring 22. Discussion of laboratory test reports 23. Discussion of laboratory test reports 24. Discussion of laboratory test reports 25. Discussion of laboratory test reports 26-28. Laboratory visit, demonstration of point-of-care tests
<b>Topics of practical classes (pro week):</b> None.
<b>Schedule of consultations:</b> No additional consultations will be scheduled.
<b>Course requirements</b>
<b>Prerequisites:</b> Physiology II Biochemistry II
<b>Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup:</b> Attendance at lectures in accordance with the Study and Examination Regulations in force at the Faculty of Pharmacy
<b>The grading method; the conditions for getting the signature; the number, topic(s) and date(s) of the mid-term assessments (reports, term tests, and the process in which they contribute to the final grade; and the possibility of their retake or their upgrading retake (as provided in §§ 25-28 of the STUDY AND EXAMINATION REGULATIONS):</b> The grade is based on the end-of-semester colloquium (attainable score: 50), as follows: 46 – 50 points: excellent, 41 – 45 points: good, 36 – 40 points: average, 31 – 35 points: sufficient, 30 points or below: insufficient. There is no midterm partial performance evaluation.
<b>Number, topics and dates of tests during the semester, opportunities of makeup and improvement of results***:</b> None

<p><b>Requirements of signature(as provided for in STUDY AND EXAMINATION REGULATIONS § 29):</b></p> <p>No special criteria have been set.</p>
<p><b>Number and type of projects students have to perform independently during the semester and their deadlines:</b></p> <p>No individual projects are required.</p>
<p><b>Type of the semester-end examination:</b>      signature*/practical grade*/semi-final*/final*          (* Please underline)</p> <p><b>Examination requirements:</b></p> <p>The scope, position and functions of laboratory diagnostics in healthcare organisations. Blood collection procedure, types of blood collection tubes, and examples of their use. Preanalytical factors which affect laboratory results. Major laboratory analytical procedures and analytical systems used in clinical diagnostic laboratories. Quality assurance. Point-of-care tests, tests available for pharmacy self-monitoring. Interpretation of laboratory findings, basics of the statistical evaluation of test results. Data-oriented clinical laboratory: the importance of bioinformatics. Laboratory diagnosis of inflammation. Acute phase reaction. Liver function tests. Renal function tests. Urinalysis. Diagnosis of tissue injury. Laboratory diagnosis of tumours. Molecular biology tests in the laboratory. Endocrinology tests: diagnosis of metabolic disorders (diabetes, hyperlipidaemia). Endocrinology tests: thyroid hormones, adrenal and sex hormones. Therapeutic drug monitoring: basic concepts, pharmacokinetic principles, aims, factors influencing the fate of the drug in the body. Therapeutic drug monitoring: the role of laboratory tests in the implementation of individualised drug therapy. Precision pharmacotherapy software. Drugs influencing laboratory test results. Clinical drug testing. Fundamentals of clinical toxicology and its laboratory implications. Immunological tests: autoimmunity. Immunological tests: hypersensitivity reactions, allergy tests, and immunodeficiency conditions. Elements of blood count. Anaemias. Iron deficiency. Basics of blood grouping. Haemostasis tests. Anticoagulant monitoring.</p>
<p><b>Form of the semester-end examination:</b>      written*/oral*/combined examination/practical examination/the assessment of completing project work          (according to STUDY AND EXAMINATION REGULATIONS 30.§)*      (* Please underline)</p>
<p><b>The possibility and conditions for offering grades:</b></p> <p>None</p>

**A list of the basic notes, textbooks, resources and literature that can be used to acquire the knowledge necessary to master the curriculum and to complete the assessments, with exact description about which of them is required to acquire which part of the syllabus (e.g. description based on topics)), as well as the main technical and other aids and study aids that can be used:**

Topic	Presentation material
The scope, position and functions of laboratory diagnostics in healthcare organisations	Barna Vásárhelyi: Trace reading in healthcare (presentation)
Blood collection procedure, types of blood collection tubes, and examples of their use. Preameritcal factors which affect laboratory results	Barna Vásárhelyi: Trace reading in healthcare (presentation)
Major laboratory analytical procedures and analytical systems used in clinical diagnostic laboratories	Györgyi Molnár-Világos: Major analytical procedures employed in clinical laboratories (presentation)
Quality assurance	Györgyi Molnár-Világos: Quality management in the laboratory (presentation)
Point-of-care tests, tests available for pharmacy self-monitoring	Ibolya Kocsis: Diagnostic analysis directly at patient's bed. Point-of-care testing (POCT) (presentation)
Interpretation of laboratory findings, basics of the statistical evaluation of test results	Barna Vásárhelyi: Questions of postanalytical phase (presentation)
Data-oriented clinical laboratory: the importance of bioinformatics	Barna Vásárhelyi: Questions of postanalytical phase (presentation)
Laboratory diagnosis of inflammation. Acute phase reaction	Zsófia Szabó: Laboratory diagnosis of inflammation, acute phase reactants, ainfectious diseases (presentation)
Liver function tests	Ibolya Kocsis: Evaluation of liver function (presentation)
Renal function tests	Ibolya Kocsis: Urine studies - monitoring of kidney function (presentation)
Urinalysis	Ibolya Kocsis: Urine studies - monitoring of kidney function (presentation)
Diagnosis of tissue injury	Barna Vásárhelyi: Metabolic disorders 2 (presentation)
Laboratory diagnosis of tumours	Barna Vásárhelyi: Tumor markers: principles and their clinical use (presentation)
Molecular biology tests in the laboratory	Béla Blaha: Nucleic acid-based molecular diagnostics (presentation)
Endocrinology tests: diagnosis of metabolic disorders (diabetes, hyperlipidaemia)	Ibolya Kocsis: Labordiagnostical examination of metabolic disorders (presentation). Barna Vásárhelyi: Metabolic disorders 2 (presentation)
Endocrinology tests: thyroid hormones, adrenal and sex hormones	Ibolya Kocsis: Labordiagnostical examination of metabolic disorders (presentation).
Therapeutic drug monitoring: basic concepts, pharmacokinetic principles, aims, factors influencing the fate of the drug in the body	Gellért Balázs Karvaly: Therapeutic drug monitoring (presentation)
Therapeutic drug monitoring: the role of laboratory tests in the implementation of individualised drug therapy	Gellért Balázs Karvaly: Therapeutic drug monitoring (presentation)
Precision pharmacotherapy software	S. Goutelle, J-B. Woillard, T. Buclin, et al. Parametric and nonparametric methods in population pharmacokinetics: experts' discussion on use, strengths, and limitations. J Clin Pharmacol 2022; 6: 158-170.
Drugs influencing laboratory test results	Gellért Balázs Karvaly: Therapeutic drug monitoring (presentation)
Clinical drug investigations	Gellért Balázs Karvaly: Therapeutic drug monitoring II. (presentation)
Fundamentals of clinical toxicology and its laboratory implications	Gellért Balázs Karvaly: Therapeutic drug monitoring II. (presentation)
Immunological tests: autoimmunity	Gellért Balázs Karvaly: Therapeutic drug monitoring II. (presentation)
Immunological tests: hypersensitivity reactions, allergy tests, and	Zsófia Szabó: Immunological tests I. Laboratory diagnosis of autoimmune disease (presentation)
	Zsófia Szabó: Immunological tests II. Hypersensitive reactions, allergy tests,

In the case of a subject lasting more than one semester, the position of the teaching/research department on the possibility of parallel enrolment and the conditions for admission\*\*\*\*:

yes\*/no\*/on and individual assesment basis\* (\* Please underline)

The course description was prepared by::

Prof. Dr. Barna Vásárhelyi, dr. Gellért Balázs Karvaly