Ministry of Health of Ukraine
Poltava State Medical University
Department of Physiology

SYLLABUS

LABORATORY DIAGNOSTICS

Elective component

educational and professional level	the second (master's) level of higher education
field of knowledge	22 «Health Care»
specialty	222 «Medicine»
qualification educational	Master of Medicine
qualification professional	Doctor
educational and professional program	«Medicine»
form of training	full-time education
course and semester of study of academic discipline	IV course 7-8 semesters

Poltava - 2024

INFORMATION ABOUT TEACHERS

Surname, name, teacher (s), academic degree, academic title	Lyudmyla Vesnina - Doctor of Medical Sciences, Professor Tatiana Mamontova - Ph.D., as. prof. Oksana Shlykova - Ph.D. Olena Tkachenko - Ph.D.
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MAIN CHARACTERISTICS OF THE EDUCATIONAL DISCIPLINE

The volume of the discipline

Number of credits / hours - **3,0 / 90**, of which:
Lectures (hours) - **8**
Practical classes (hours) - **40**
Independent work (hours) - **42**
Type of control - **Credit**

The policy of the discipline is determined by the system of requirements that research and teaching staff impose on applicant for higher education in the study of the discipline «Laboratory Diagnostics» and is based on the principles of academic integrity (https://www.pdmu.edu.ua/n-process/department-npr/normativni-dokumenti).

Observance of academic integrity by applicant for higher education in the discipline involves:

- independent performance of educational tasks, tasks of current and final control of learning outcomes;
- links to sources of information in the case of the use of ideas, developments, statements, information;
- compliance with the law on copyright and related rights;
- providing reliable information about the results of their own educational or scientific activities, used research methods and sources of information.

Violation of academic integrity is: academic plagiarism, self-plagiarism, fabrication, falsification, writing off, deception.

For violation of academic integrity applicant for higher education may be prosecuted in accordance with regulations.

Applicants, studying the discipline «Laboratory Diagnostics», are *required to:*

- follow the schedule of the educational process and prevent non-fulfillment of the curriculum and individual curriculum without good reason, come to class on time, in accordance with the schedule
- comply with the requirements of labor protection, safety, industrial sanitation, fire safety, provided by the relevant rules and instructions;
- to comply with the requirements for the appearance (dress code) of persons approved by the decision of the Rector's Office of 29.08.2014.
- to maintain order in the classrooms, to treat the property of the department carefully and neatly (furniture, computer equipment, textbooks, teaching materials, equipment);
- not to take out things and various equipment from classrooms and departments without the permission of scientific and pedagogical workers, and in case of intentional damage - to compensate their cost in the order determined by the current legislation;
- observance moral and ethical principles stay in the space scientific research institute.

Applicants, studying the discipline «Laboratory Diagnostics», are *prohibited from:*

- leave the classroom during the lesson without the permission of the teacher;
- use a mobile phone and other means of communication and receive information without the teacher's permission;
- engage in extraneous activities, distract other applicants and interfere with the teacher;
- to use narcotic drugs, psychotropic substances and their analogues, alcoholic beverages at the department, to smoke on the territory of the department and to be in the department in a state of alcohol, drugs or other intoxication;
- to commit illegal and immoral acts that may create dangerous conditions for the health and / or life of others that degrade human dignity, to use profanity;
- conducting the educational process in special conditions (martial law, quarantine during a pandemic, etc.) is carried out with the help of distance learning technologies using the ZOOM, Google Meet, Google Classroom platforms.

Description of the academic discipline

Laboratory diagnostics is based on a combination of medical and biological components, providing a deep knowledge of modern information about research in the field of biomedical sciences and possession of modern methods of laboratory research of biological material. The assimilation of the material provides the acquisition of skills in working in a diagnostic laboratory and skills of analytical thinking for analyzing the results obtained in an amount sufficient for future practical activities.

The subject of the study of the discipline are modern methods of laboratory research of the human body functional states and various pathological processes.

Prerequisites and postrequisites of the academic discipline

The study of the academic discipline «Laboratory diagnostics» is based on the knowledge obtained by students of the second (master's) level of higher education in the study of medical biology, Latin language and medical terminology, deontology in medicine, medical and biological physics, medical chemistry, biological and bioorganic chemistry, physiology and pathophysiology, pharmacology, morphological disciplines and pathomorphology; integrates with the study of clinical disciplines, provides for the formation of skills to apply knowledge in laboratory diagnostics in the process of further education and professional activity.

Disciplines for the study of which knowledge, skills and abilities are required, acquired at the end of the study of this discipline:

- Internal medicine
- Surgery
- Obstetrics and gynecology
- Pediatrics
- Infectious diseases

The purpose and objectives of the academic discipline:

The purpose of studying the academic discipline «Laboratory Diagnostics» is mastering to applicants the second (master's) level of higher education algorithms and principles of laboratory research modern methods as part of the diagnostic process, the formation of sustainable skills of effective use of laboratory data in various pathological conditions and the ability to correctly interpret laboratory results in order to use the acquired knowledge in the study of the following clinical disciplines and future professional activities.

The main tasks of studying the discipline are:

- formation of a systematic approach to using the capabilities of laboratory diagnostics in a complex of diagnostic and therapeutic procedures
- determination of the diagnostic capabilities of a modern laboratory
- formation of skills to create a comprehensive laboratory examination, determination of indications and contraindications
- acquaintance with stages of laboratory researches
- confirmation of the importance of the preanalytical stage
- training in basic laboratory methods

- formation of skills of interpretation of results, estimation of erroneous data
- formation of an understanding of laboratory research standardization
- justification of the importance of studying laboratory diagnostics for other medical disciplines.

Competencies and learning outcomes according to the educational and professional program, the formation of which is facilitated by the discipline

Competencies according to the educational and professional program, the formation of which contributes to the discipline

Integral competence	
The ability to solve complex problems, including those of a research and innovation nature in the field of medicine. Ability to continue learning with a high degree of autonomy	
General competencies	
GC1	Ability to abstract thinking, analysis and synthesis
GC 2	Ability to learn and master modern knowledge
GC 3	Ability to apply knowledge in practical situations
GC 4	Knowledge and understanding of the subject area and understanding of professional activity
GC 6	Ability to make informed decisions
GC 7	Ability to work in a team
GC 10	Ability to use information and communication technologies
Special (professional, subject) competencies	
SC2	Ability to determine the required list of laboratory and instrumental studies and evaluate their results
SC3	Ability to establish a preliminary and clinical diagnosis of the disease
SC 16	Ability to maintain medical documentation, including electronic forms

Program learning outcomes according to the educational and professional program, the formation of which is facilitated by the discipline:

Assign and analyze additional (mandatory and optional) examination methods (laboratory, functional and/or instrumental) (according to list 4), patients with diseases of organs and body systems for differential diagnosis of diseases (according to list 2).

Learning outcomes for the discipline:

upon completion of the academic discipline study, applicant for higher education must

know:

- structure and organization of laboratory services
- modern diagnostic capabilities of laboratory research
- quality assurance system for laboratory research
- stages of laboratory research
- rules for preparing patients for laboratory tests
- rules for the receipt, transportation and storage of biological material for laboratory research
- algorithm for prescribing laboratory tests
- evaluation and interpretation of results
- assessment and interpretation of the causes of false results
- the use of laboratory diagnostics for various pathological conditions;

be able to:

- select the necessary laboratory tests and draw up diagnostic algorithms for the most common pathological conditions of organs and systems
- receive biological material and carry out its processing

- evaluate the quality of the preanalytical stage
- conduct basic laboratory tests
- interpret the results of the obtained laboratory tests
- evaluate and interpret the causes of erroneous results.

Thematic plan of lectures (by modules) with an indication of the main issues considered at the lecture

№	Topic	Number of hours
Module 1. Basic principles and approaches in modern laboratory diagnostics **Content module 1.** Modern laboratory organization. General clinical investigations		
1	Laboratory research importance for evidence-based medicine. Modern international laboratory service quality standards 1. The role of clinical laboratory diagnostics in modern medical practice, its structure. 2. Evidence-based medicine - concept, basic principles. 3. International standards of quality management system. 4. Quality infrastructure, its elements: technical regulation, supervision, inspection. 5. Legislation in the field of technical regulation. 6. The concept of a quality management system in medical laboratories of Ukraine. 7. Standardization. Representation of Ukraine in international and European standardization organizations. 8. State standard DSTU EN ISO 15189:2015	2
2	Modern laboratory work organization. Safety requirements 1. Laboratory support of medical care and its organization. 2. Stages of laboratory research. 3. Principles of laboratory equipment. Engineering equipment. 4. Laboratory equipment. 5. Risk factors. Safety in the laboratory. 6. General safety requirements when working in the laboratory. 7. Workplace organization. 8. Safety requirements in emergency situations	2
Content module 2. Clinical and laboratory research for the most common diseases diagnosis		
3	Modern approaches to inflammatory conditions laboratory diagnosis 1. Inflammation - types, form the main steps of the inflammatory response. 2. Pathogenetic mechanisms of inflammation. Exogenous and endogenous mediators of inflammation. 3. Early and late mediators of inflammation, methodical approaches to diagnosis. 4. Laboratory markers of neutrophils, respiratory burst. 5. Types of changes in the protein spectrum of blood plasma. 6. Proteins of the acute phase of inflammation, methodical approaches to diagnosis. 7. Pathological proteins, methodical approaches to diagnosis. 8. Methods of laboratory diagnosis of inflammatory processes	2
4	Modern molecular genetic methods role in conducting scientific research and practical medicine 1. Molecular genetic research methods. 2. Laboratory of molecular genetic research, features. 3. Polymerase chain reaction, principles of the method. 4. Sample preparation of biological material.	2

	5. Methods of setting, detection of polymerase chain reaction results. 6. Gene and protein expression, polymorphic gene variants, methods of determination. 7. Single nucleotide substitutions. 8. Diagnostic value of studies of expression and polymorphic variants of genes. 9. The concept of population research. Interpretation of results. 10. The role of molecular genetic methods in practical medicine and scientific research	
	Together	8

Seminars are not provided by the program.

Thematic plan of practical classes by modules and content modules with an indication of the main issues considered at the practical class

№	Topic	Number of hours
Module 1. Basic principles and approaches in modern laboratory diagnostics **Content module 1.** Modern laboratory organization. General clinical investigations		
1	Laboratory service organization bases 1. Laboratory diagnostics, the main sections of the discipline. 2. The purpose and objectives of laboratory diagnostics for theoretical and practical medicine. 3. The history of the development of laboratory medicine. 4. Organizational structure of laboratory services. Basic documentation. 5. Rules of organization, equipment and structures of material and technical support of various types laboratories. 6. Provision of medical equipment, laboratory furniture, reagents. 7. Principles of specialization of modern laboratory diagnostic services. 8. Features of the work organization in laboratory departments, the organization of interaction between departments. 9. Principles and forms of centralization of clinical laboratory research.	2
2	Laboratory tests quality control organization. Control and reference materials 1. Laboratory tests quality control as a laboratory operation basis. 2. General information about the quality management system. 3. Normative documents regulating the policy in the field of laboratory research quality. 4. The most important international standards for laboratory medicine. 5. Characteristics of factors affecting the result of clinical laboratory analysis. 6. Calibration, control and reference materials. Reference values of laboratory parameters. 7. Quality control methods of quantitative laboratory tests. 8. Quality control methods of qualitative and semi-quantitative laboratory tests. 9. Organization and carrying intralaboratory and external laboratory quality control	2
3	Modern principles of obtaining and preparing material for laboratory research. Laboratory safety 1. Preanalytical stage of laboratory research. 2. Major mistakes at the preanalytical stage. 3. Key aspects of quality control of preanalytical stage. 4. Factors of the preanalytical stage influencing the laboratory tests results. 5. Modern principles of obtaining and preparing biological material for	2

	laboratory research. 6. Types of biological material. Features of patient preparation and obtaining biological material. 7. Recommendations for the collection of blood, urine. 8. Conditions for biological material storage and transportation for laboratory research. 9. Features of the workplaces organization and safety in the laboratory. 10. Modern means of personnel protection. 11. Laboratory documentation on safety regulations	
4	Total clinical blood and urine tests 1. Name the conditions of the preanalytical stage of performing general clinical research of blood and urine. 2. Determination of erythrocyte blood parameters, reference values, diagnostic value. 3. Determination of blood platelets number, reference values, diagnostic value. 4. Qualitative and quantitative characteristics of leukocytes, calculation of leukocyte formula, reference values, diagnostic value. 5. Index of anisocytosis (RDW), erythrocyte indices: average erythrocyte volume (MCV), average concentration of hemoglobin in erythrocyte (MCHC), average hemoglobin in erythrocyte (MCH), reference values, diagnostic value in the anemias classification. 6. Histograms, clinical significance. 7. Modern methods of urine tests. Physico-chemical properties, methods of determination, diagnostic value. 8. Name the main parameters and methods for determining the organized urine sediment. Diagnostic value. 9. Name the main parameters and methods for determining the unorganized urine sediment. Diagnostic value. 10. Types of test strips for biochemical components detection by methods of «dry chemistry»	2
5	Hemostasis system disorders diagnosis. Coagulology general principles 1. Modern concepts of hemostasis. Mechanisms of vascular and platelet, coagulation hemostasis, fibrinolysis and anticoagulant system 2. Methodical approaches and principles of laboratory research of the hemostasis and fibrinolysis system state, their disorders. 3. Clinical significance of laboratory research of the hemostasis and fibrinolysis system state, anticoagulant system. 4. The reference values of laboratory parameters research of the hemostasis system, fibrinolysis, anticoagulant system and influences factors. 5. Modern methods of hemostasis research, principles of laboratory tests choice. 6. Features of the preanalytical stage in the hemostasis system research. 7. Preparation of biological material for hemostasis system research. 8. The choice of laboratory tests for the coagulation hemostasis research, depending on the coagulation phases. 9. Basic tests for assessing the state of the anticoagulant system and fibrinolysis	2
6	Human immune status, its evaluation. Flow cytometry method principles 1. Mechanisms of innate and adaptive immunity. 2. The importance of laboratory diagnostics of the immune status disorders for theoretical and practical medicine. 3. Laboratory approaches to the diagnosis of the immune status disorders. 4. Classification of immunological research levels and their clinical significance. 5. Reference values of the immune status indicators, factors of influence. 6. Features of the preanalytical stage in determining the immune system	2

	parameters. 7. Rules for the preparation of biological material. 8. Principles of flow cytofluorimetry method. 9. Use of membrane and intracellular markers in flow cytofluorometry. 10. Clusters of leukocyte differentiation, classification principles. 11. Diagnostic algorithms in the immune status study. 12. Clinical significance of the research of immune status indicators, interpretation of results	
7	Endocrine system state evaluation Enzyme immunoassay principles 1. Factors of humoral regulation, their characteristics and classification. 2. Hormones and neurohumoral regulation. The main mechanisms of hormones action. 3. Hypothalamo-pituitary system. The neurosecretory of the hypothalamus. The role of liberins and statins. 4. Adenopituitary gland, its hormones, their influence. Metabolic effects of growth hormone. GH secretion regulation circuit, circadian rhythms. 5. Thyroid gland, its hormones. Circuit of synthesis and secretion regulation of thyroxine (T4) and triiodothyronine (T3). 6. Hormones of the pancreas (insulin, glucagon, somatostatin), their influence on glucose metabolism. The hormonal regulation circuit for maintaining a constant blood glucose concentration. 7. Hormones of cerebral and cortical substances of the adrenal glands, their role in the organism, regulation of secretion. 8. Principles of enzyme immunoassay. 9. Hormones level determining by the enzyme immunoassay. Features of preanalytical stage of the endocrine system state research. 10. Principles of results interpretation	2
8	Reproductive system regulation central link disorders. Modern laboratory diagnostics 1. Sex glands, endocrine function. 2. Age features of the sex glands endocrine function. 3. Neurohumoral regulation of the reproductive system. Central and peripheral hormones. 4. Methodological approaches to assessing reproductive function. 5. Preanalytical stage. Features of appointment study of a sex hormones level. 6. Principles for assessing a woman's reproductive system by determining the peripheral hormones level. 7. Sex hormones, reference indicators. 8. Influence factors, data interpretation. 9. Change in the level of sex hormones depending on age. 10. Screening of pregnancy, clinical significance, interpretation of results	2
9	Tumor processes diagnostics modern principles Tumor markers, types 1. Biomarkers, tumor markers. The value of tumor markers in laboratory diagnostics. 2. Classification of tumor markers by chemical structure and biological functions. 3. Characteristics of the main terms in the definition of tumor markers. 4. Ideal tumor marker. 5. Clinical use of tumor markers. 6. Features of the preanalytical stage of oncological diseases research. 7. Characteristics of the gastrointestinal tract tumor markers. 8. Characteristics of the reproductive system tumor markers. 9. Characteristics of the urinary system tumor markers	2
10	Situational tasks solving on content module 1	2

Content module 2. Clinical and laboratory research for the most common diseases diagnosis		
11	Metabolic processes in the body and their evaluation by clinical and biochemical parameters. Acute phase proteins. Lipid metabolism 1. Protein metabolism in the human organism. 2. Proteins and protein fractions. 3. Specific proteins. Proteins as markers of the inflammation acute phase. 4. Reference values of protein metabolism indicators, factors of influence. 5. Features of the preanalytical stage in determining the protein metabolism indicators. 6. Peculiarities of lipid metabolism, main lipid fractions. 7. Reference values of lipid metabolism indicators, influencing factors. 8. Dysliproteinemia, typing of dyslipoproteinemia. 9. Clinical significance of the lipid metabolism indicators research. 10. Features of the preanalytical stage in determining the lipid metabolism parameters. 11. Basic research methods of protein and lipid metabolism indicators. 12. Principles of biochemical analyzer operation	2
12	Carbohydrate metabolism assessment. Carbohydrate metabolism disorders diagnosis principles 1. Carbohydrate metabolism in the human organism. 2. Carbohydrate metabolism regulation and its disorders. 3. The main indicators of carbohydrate metabolism. 4. Methods for determining the carbohydrates metabolism. 5. Determination of glucose in blood and urine, clinical significance. 6. Determination of glycosylated hemoglobin and clinical significance. 7. Determination of lactic acid and fructosamine and clinical significance. 8. Features of the preanalytical stage in determining the carbohydrate metabolism parameters. 9. Reference values of carbohydrate metabolism indicators, factors of influence. 10. Diagnostics principles of carbohydrate metabolism disorders, data interpretation	2
13	Body's immune status assessment by enzyme-linked immune-sorbent assay 1. Factors of humoral immunity. 2. Immunoglobulins - classification, role in immune defense. 3. Concept of cytokines, chemokines, adhesion factors. 4. Laboratory approaches to the determination of nonspecific and adaptive immune defense indicators. 5. Reference values of the immune status indicators, factors of influence. 6. Features of the preanalytical stage in determining the immune system parameters. 7. Diagnostic algorithms in the immune status research. 8. The clinical significance of the immune status indicators research	2
14	Allergy pathology. Modern views on the allergy diagnosis. Allergy molecular diagnosis principles 1. Allergies classification by the development rate and pathogenesis. 2. Characteristics of the main exo- and endoallergens types. 3. Cross-reactions. 4. Panallergens, panallergenic cross-reactions. 5. Features of laboratory approaches to the allergies diagnosis. 6. Specific clinical methods of allergy diagnostics. 7. Specific immune methods for allergy diagnostic. Molecular diagnostics of allergies. 8. Features of the preanalytical stage in determining the allergic inflammation	2

	indicators. 9. Features of results interpretation of the general and allergen-specific immunoglobulins E (IgE). 10. Reasons for the discrepancy between the results of clinical and laboratory diagnostics of allergies	
15	Human Basic helminthiases, their laboratory diagnosis 1. Human parasitic diseases. 2. The main classes of helminths, individual biological characteristics. 3. Features of laboratory algorithms for the diagnosis of helminthiasis. 4. General clinical and immunological methods for the helminthiasis research. 5. Immunoassay of antibodies, antigens, antibody avidity index. 6. Immune blotting, immunochromatographic analysis. 7. Indirect hemagglutination and indirect immunofluorescence reactions. 8. Features of nematodes laboratory diagnosis. 9. Features of trematodes laboratory diagnosis. 10. Features of cestodosis laboratory diagnostics. 11. Laboratory approaches to the protozoa diagnosis. 12. Features of laboratory diagnostics of the main protozoa	2
16	Molecular genetic research methods. Polymerase chain reaction, method principles 1. Molecular genetic research methods. 2. Polymerase chain reaction (PCR). 3. Definition and history of PCR discovery. 4. Rule E. Chargaff. 5. Amplification of DNA. 6. The main stages of DNA amplification. 7. Methods for the amplification products detection. 8. Components of the reaction mixture for PCR. 9. Organization of work in PCR laboratories. 10. Real time PCR. 11. PCR method advantages and disadvantages. 12. Quality control of PCR research	2
17	Modern molecular genetic methods role in practical medicine and scientific researches 1. Place of PCR in clinical laboratory diagnostics. 2. Methods for the nucleic acids (NA) isolation and purification. 3. The process of nucleic acids isolation by phenol-chloroform extraction. 4. Isolation of nucleic acids using various sorbents. 5. Determination of nucleic acids qualitative and quantitative indicators. 6. Determination of the DNA or RNA preparation purity. 7. Electrophoresis of nucleic acids in agarose gel. 8. Reverse transcription. 9. Polymerase chain reaction in real time (Real-Time PCR). 10. PCR for direct diagnosis and identification of infectious agents. 11. Methods for molecular typing of microorganisms based on PCR. 12. PCR for detection of drug resistance in microorganisms. 13. PCR advantages and disadvantages as a method for diagnosing infectious diseases. 14. Improvement of PCR technology	2
18	Immunohistochemical research methods. Immunohistochemical determination of surface and intracellular markers 1. Immunohistochemistry, determine, the main tasks. 2. Development history of immunohistochemistry. 3. Antibodies, types of antibodies. 4. Features of antibodies to antigen binding.	2

	5. Direct and indirect methods of immunohistochemistry. 6. The main stages of the immunohistochemical method, immunohistochemical protocol. 7. Preanalytical stage of immunohistochemical research. 8. Preparation of biological material. 9. Dewaxing and rehydration. 10. Antigen activation. 11. Blocking endogenous peroxidase or blocking enzymes	
19	Immunohistochemical methods role in practical medicine and scientific researches 1. Quality control of the immunohistochemical research. 2. Positive and negative controls, principles of use. 3. Diagnostic capabilities of the immunohistochemical method. 4. Main immunological markers. 5. Classification principles of surface and membrane markers. 6. Interpretation of the immunohistochemical research results. 7. The clinical significance of bases markers. 8. Methodological approaches to the use of immunohistochemistry in scientific research	2
20	Laboratory research of biological fluids 1. Laboratory research of urine 2. Laboratory research of saliva 3. Laboratory research of cerebrospinal fluid 4. Laboratory research of other biological fluids Credit	2
	Total	40

Independent work

№	Content	Number of hours
1	Preparation for practical classes – theoretical preparation and development of practical skills	20
2	Elaboration of topics that are not included in the classroom lesson plan:	
2.1	The history of the laboratory medicine development. Prospects for improving the laboratory service in Ukraine 1. The main stages of laboratory diagnostics 2. Historical aspects of the laboratory diagnostics development 3. The first centers of laboratory diagnostics in Ukraine 4. Modern stages of development of laboratory medicine in Ukraine 5. Promising directions of the laboratory service development	6
2.2	Normative documents in the health care system that regulate the work of the laboratory: resolutions, orders, instructions 1. Concept of regulatory documents, general characteristics 2. Normative base of laboratory medicine 3. Basic regulations concerning the organization of the laboratory service 4. Orders of the Ministry of Health, which regulate the work of the laboratory service 5. Instructions on the organization of the laboratory service	6
2.3	The history of the polymerase chain reaction discovery 1. The main stages of the molecular genetic research development 2. The significance of the DNA structure discovery 3. Nucleotides. Chargaff's rule 4. DNA polymerase. The significance of the Taq polymerase discovery	5

	5. Prospective directions for the development of molecular genetic research	
2.4	Basic concepts of molecular biology 1. Principles of DNA and RNA structure 2. Functions of DNA and RNA 3. DNA replication 4. Direct and reverse transcription 5. Regulation of transcription	5
	Total	**42**

Individual tasks

1. Making thematic tables.
2. Review of modern educational literature on topics:

- modern methods of laboratory research, diagnostics of diseases from the leading sections of clinical medicine;
- age characteristics of the cellular composition of tissues, organs and biological fluids and substrates in health and disease.

The list of questions that a student of higher education must learn when studying an academic discipline (form of control - credit):

1. Meaning, goals, tasks and place of clinical laboratory diagnostics in the development of theoretical and practical medicine.
2. Rules of organization, equipment and structures of material and technical support of laboratories of various types.
3. Organization of quality control of laboratory research.
4. Normative documents that regulate policy in the field of quality of laboratory research.
5. Characterization of factors affecting the result of clinical laboratory analysis. Control and reference materials.
6. The system of guaranteeing the quality of laboratory research. Internal laboratory quality control.
7. Modern principles of obtaining and preparing material for laboratory research. Types of biological material. Obtaining plasma and blood serum.
8. Stages of the laboratory cycle. Preanalytical stage. Basic requirements for the organization.
9. Peculiarities of workplace organization and safety techniques in the laboratory.
10. Modern means of personnel protection.
11. Principles of hematology analyzer operation.
12. General clinical examination of blood. Modern issues of laboratory diagnosis of anemia.
13. Physico-chemical properties of urine and morphological features of the elements of urine sediment.
14. Methods of hemostasis research. A modern perspective on basic coagulogram tests.
15. Laboratory diagnosis of immune status disorders. Principles of the flow cytofluorimetry method. Use of membrane and intracellular markers.
16. Basic principles of enzyme immunoassay.
17. Assessment of the state of the endocrine system. Principles of interpretation of results.
18. Modern concepts of laboratory diagnosis of tumors. Oncomarkers, types. Data interpretation.
19. Laboratory diagnosis of violations of the central link of regulation of the reproductive system.
20. Metabolic processes in the body and their assessment using clinical and biochemical indicators. Acute phase proteins. Methods of determination of proteins and amino acids.
21. Clinical-diagnostic value of blood determination: cholesterol, triglycerides, free fatty acids. Methods of determination of lipids.
22. Principles of biochemical analyzer operation.
23. Clinical and diagnostic value of determination of glucose in blood and urine. Principles of diagnosis of carbohydrate metabolism disorders, data interpretation.
24. Use of immunological diagnostics in clinical practice. Assessment of the body's immune status by enzyme-linked immunosorbent assay.

25. Indicators of innate and acquired immunity. Phagocytosis, NST-test.
26. Allergic pathology. Types of allergic processes. Modern views on the diagnosis of allergies.
27. Principles of molecular allergy diagnosis.
28. Human helminthiasis. Laboratory diagnosis of helminth infections.
29. Rules and requirements for organizing the work of the molecular genetic research laboratory.
30. Polymerase chain reaction, principles of the method.
31. Preparation of a sample of biological material. Ways of setting the reaction. Detection of polymerase chain reaction results. Polymerase chain reaction control.
32. Expression of genes and proteins, polymorphic variants of genes, methods of determination. Single nucleotide substitutions.
33. Diagnostic value of studies of expression and polymorphic variants of genes.
34. Immunohistochemical research methods.
35. Direct and indirect methods of immunohistochemistry. Concept of monoclonal and polyclonal antibodies.

Teaching methods

- verbal (lecture, explanation, story, conversation, instruction)
- visual (observation, illustration, demonstration)
- practical (interpretation of laboratory data, compilation of a diagnostic algorithm for laboratory tests, implementation of the research method)
- explanatory-illustrative or information-receptive (provision of ready-made information by a research and pedagogical worker and its assimilation by education applicants)
- thematic discussions
- analysis of specific situations
- partial search, research methods.

Assessment forms and methods

A scientific-pedagogical employee necessarily evaluates the success rate of a higher education student in each lesson on a four-point (traditional) scale.

Evaluation criteria are defined by the working curriculum in the discipline «Laboratory Diagnostics», which is approved by the Academic council of the Dentistry faculty of PSMU (Table 1).

Assessment of success is integrated (all types of higher education applicants work are evaluated both in preparation for the lesson and during the lesson) according to the criteria that are communicated to them at the beginning of the discipline. Conversion of the current grade, set on the traditional 4-point scale, to multi-point in each lesson is not carried out.

Table 1

Criteria for assessing knowledge of education applicants:

For a 4-point scale	**Estimation in ECTS**	**Assessment criteria**
5 excellent	A	The higher education applicant shows special creative abilities, is able to acquire knowledge independently, without the help of the teacher finds and processes the necessary information, is able to use the acquired knowledge and skills for decision-making in unusual situations, convincingly argues answers, independently reveals own talents and inclinations, possesses not less than 90% knowledge of the topic both during the survey and all types of control
4 good	B	The higher education applicant is fluent in the studied amount of material, applies it in practice, freely solves exercises and problems in standardized situations, independently corrects errors, the number of which is insignificant, has at least 85% knowledge of the topic both during the survey and all types control
	C	The higher education applicant is able to compare, summarize, systematize information under the guidance of a lecturer, in general, independently apply it in

		practice, control their own activities; to correct mistakes, among which there are significant, to choose arguments to confirm opinions, has at least 75% knowledge of the topic both during the survey and all types of control
3 satisfactory	D	The higher education applicant reproduces a significant part of the theoretical material, shows knowledge and understanding of the basic provisions, with the help of a lecturer can analyze the educational material, correct mistakes, among which there are a significant number of significant ones. Has at least 65% knowledge of the topic both during the survey and all types of control
	E	The higher education applicant has educational material at a level higher than the initial, a significant part of it reproduces at the reproductive level. Has at least 60% knowledge of the topic both during the survey and all types of control
2 unsatisfactory	FX	The higher education applicant has the material at the level of individual fragments that make up a small part of the material. Has less than 60% knowledge of the topic both during the survey and all types of control
	F	The higher education applicant has the material at the level of elementary recognition and reproduction of individual facts, elements, has less than 60% knowledge of the topic both during the survey and all types of control

The **credit** is conducted at the last practical lesson based on the results of the current assessment. This type of final control does not involve any additional written work or testing in the last lesson.

The condition for obtaining credit is:

• practice of all missed classes;

• average current grade in the discipline not lower than «3,00»

Learning outcomes are assessed on a two-point scale (credited / not credited) and a multi-point scale. The average score for current activity is converted into points on a 200-point scale, according to the recalculation table (Table 2).

The maximum number of points that can be obtained by the student in the discipline - 200. The minimum number of points that must be scored by the student - 122.

Learning outcomes – «grade point average» and «scores» received by the applicant should be entered in the academic journal. If the student fulfills the conditions for obtaining credit, the teacher puts in the test sheet «credited» and the number of points scored by the student for the discipline.

In the case when the average grade for the discipline is below «3,0», the higher education applicant does not receive credit. The teacher enters in the first test sheet «not credited» and the number of points scored by the higher education applicant for the discipline. The teacher submits the statement to the dean's office on the day of the last lesson. Applicants who have a current grade point average below the grade of «3» must eliminate academic debt by the beginning of the next semester, otherwise the applicant may be expelled as not having completed the curriculum.

Table 2

Average grade for current progress (A)	Grade for current progress from the module (A*24)	Grade for PMK with module (A*16)	Grade for the module and / or exam (A*24 + A*16)	Estimation in ECTS	By 4-point scale
1	2	3	4	5	6
2	48	32	80	F FX	2 unsatisfactory
2,1	50	34	84		
2,15	52	34	86		
2,2	53	35	88		
2,25	54	36	90		
2,3	55	37	92		
2,35	56	38	94		
2,4	58	38	96		
2,45	59	39	98		
2,5	60	40	100		

2,55	61	41	102		
2,6	62	42	104		
2,65	64	42	106		
2,7	65	43	108		
2,75	66	44	110		
2,8	67	45	112		
2,85	68	46	114		
2,9	70	46	116		
2,95	71	47	118		
3	72	50	122	E	3 satisfactory
3,05	73	50	123		
3,1	74	50	124		
3,15	76	50	126		
3,2	77	51	128		
3,25	78	52	130	D	
3,3	79	53	132		
3,35	80	54	134		
3,4	82	54	136		
3,45	83	55	138		
3,5	84	56	140	C	4 good
3,55	85	57	142		
3,6	86	58	144		
3,65	88	58	146		
3,7	89	59	148		
3,75	90	60	150	C	4 good
3,8	91	61	152		
3,85	92	62	154		
3,9	94	62	156		
3,95	95	63	158		
4	96	64	160	B	
4,05	97	65	162		
4,1	98	66	164		
4,15	100	66	166		
4,2	101	67	168		
4,25	102	68	170		
4,3	103	69	172		
4,35	104	70	174		
4,4	106	70	176		
4,45	107	71	178		
4,5	108	72	180	A	5 excellent
4,55	109	73	182		
4,6	110	74	184		
4,65	112	74	186		
4,7	113	75	188		
4,75	114	76	190		
4,8	115	77	192		
4,85	116	78	194		
4,9	118	78	196		
4,95	119	79	198		

5	120	80	200		

System of current and final control

Control measures for assessing the educational activities of higher education applicants include the current control of knowledge, skills and abilities.

Control measures are based on the principles of: compliance with higher education standards; use of a standardized and unified diagnostic system aimed at the application of knowledge; definition of evaluation criteria; objectivity and transparency of control technology.

Control methods:

• verbal control;
• written control;
• test control;
• practical check.

Types of control

Preliminary (initial) control is carried out at the first practical lesson by using test control of basic training of education applicants.

Current control is carried out during practical classes, which assess the knowledge of theoretical and practical material in the form of:

• solving situational tasks;
• structured written works;
• structured control of practical skills and abilities
  – assessment of knowledge and skills to analyze the results of laboratory tests,
  – ability to form the purpose of research,
  – ability to form a diagnostic algorithm for certain types of pathologies,
  – knowledge of types of laboratory tests.

Final control is used to test and evaluate knowledge, skills and abilities in the discipline.

The form of the final control of progress - **Credit.**

Methodical support

1. Thematic plans of lectures, practical classes for students of higher education
2. Recommended literature
3. Videos
4. Lectures
5. Test, control tasks and situational tasks for practical classes.
6. Methodical materials for work during practical classes.

Recommended literature

Basic

1. Tietz Textbook of Laboratory Medicine (Tietz Textbook of Clinical Chemistry and Molecular Diagnostics). N. Rifai (Author). - Saunders, 7th edition, 2022. – 1584 p.
2. A.M. Van Leeuwen, M.L. Bladh. Textbook of Laboratory and Diagnostic Testing: Practical Application of Nursing Process at the Bedside. - F.A. Davis Company, 2016. – 792 p.
3. C.C. Chernecky, B.J. Berger. Laboratory Tests and Diagnostic Procedures, - Saunders, 6th Edition, 2013. - 1232 p.
4. Young D.S, editor. Effects of preanalytical variables on clinical laboratory tests. - Washington, DC: AACC Press, 2007. – 1982 p.
5. B.J. Bain. Blood Cells: A Practical Guide. - 5 th Edition, Oxford: Wiley-Blackwell, 2015, 504 p.

Additional

1. Mamontova T.V., Mishchenko I.V., Vesnina L.E., Kaidashev I.P. Basic Laboratory hematology Principles: Manual - Poltava, PSMU, Навчальний посібник. – 2022.
2. B.J. Bain, I. Bates, M.A. Laffan S., Dacie JV, Lewis SM. Dacie and Lewis Practical Haematology. - 11th ed. London: Churchill Livingstone, 2011.
3, Doucette LJ. Mathematics for the clinical laboratory, 2nd ed. Philadelphia, PA: Saunders Co., 2011.

Information resources
Videos on laboratory diagnostics
Electronic textbooks
Tietz Clinical Guide to Laboratory Tests - E-Book (4th ed.)
Multimedia presentations
https://en.wikipedia.org/
National Center for Biotechnology Information: www.ncbi.nlm.nih.gov
Gene base www.ncbi.nlm.nih.gov/gene

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