

MINISTRY OF HEALTH OF UKRAINE
ODESSA NATIONAL MEDICAL UNIVERSITY

Department of occupational pathology and functional diagnostics

«APPROVED»



Vice-rector for scientific and pedagogical work
Eduard BURIACHKIVSKYI

"01" September 2023

WORKING PROGRAM OF ELECTIVE DISCIPLINE

"BASICS OF CLINICAL AND LABORATORY DIAGNOSTICS"

Level of higher education: second (master's degree)

Field of knowledge: 22 "Health care"

Specialty: 222 "Medicine"

Educational and professional program: Medicine

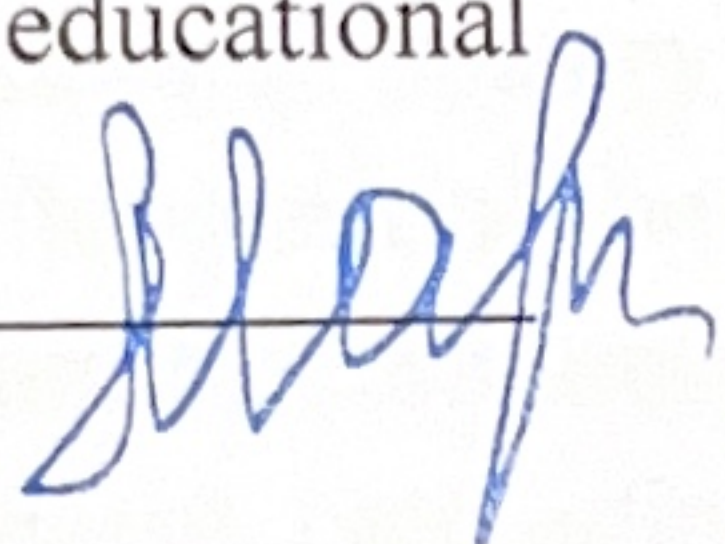
2023

The working program is compiled on the basis of the educational and professional program "Medicine" for the training of specialists of the second (masters) level of higher education in the specialty 222 "Medicine" field of knowledge 22 "Health care", approved by the Academic Council of ONMedU (Minutes No. 8 dated June 29 2023).

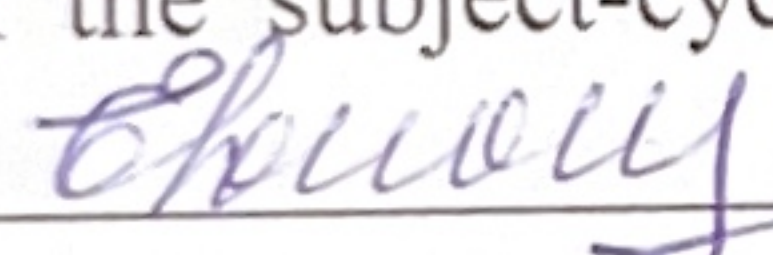
Authors: MD, Prof. Ignatiev O.M., Ph.D, Associate Professor Oparina T.P., Ph.D., Associate Professor Panyuta O.I., Ph.D., Associate Professor Zagorodnaya L.I., Ph.D., Associate Professor Yamilova T.M., assistant Dobrovolskaya O.O.

The working program is approved at the meeting of the department of occupational pathology and clinical laboratory diagnostics, Minutes No. 1 dated August 30, 2023.

Head of the department  Oleksandr IGNATIEV

Approved by the guarantor of educational and professional program  Valerya MARICHEREDA

Approved by the subject-cycle commission for therapeutic disciplines of ONMedU, Minutes No.1 dated August 31, 2022.

Head of the subject-cycle commission for therapeutic disciplines of ONMedU  Olena VOLOSHYNA

occupational diseases and functional diagnostics and plithisiopulmology
Revised and approved at the meeting of the department, Minutes No. 7 dated 04/09 2023 year.

Head of Department  Oleksandr IGNATIEV

Revised and approved at the meeting of the department, Minutes N_ dated " _ " _ 202_ year.

Head of Department _____ Oleksandr IGNATIEV

1. Description of the discipline

Name indicators	Field of knowledge, specialty, specialization, higher level	Characteristics of education disciplines
The total number of: Credits: 3.0 Hours: 90 Content modules: 6	Branch of knowledge 22 "Health care" Specialty 222 "Medicine" Level of higher education second (master's)	<i>Full-time education</i> <i>Elective discipline</i>
		<i>Year of study: 5</i> <i>Semesters IX- X</i> <i>Lectures (0 hours)</i> <i>Seminar classes (0 hours)</i> <i>Practical classes (30 hours)</i> <i>Laboratory (0 hours)</i> <i>Independent work (60 hours)</i> <i>Individual orders (0 hours)</i> <i>The form of final control – test</i>

2. The purpose and tasks of the educational discipline, competences, program learning outcomes.

The purpose of studying a selective discipline is the formation, assimilation and systematization of knowledge and skills from the analytical and clinical foundations of laboratory diagnostics, which will allow planning, organizing, independently conducting and interpreting laboratory studies of biological material; to rationally use laboratory algorithms for various forms of pathology.

The tasks of the discipline are the following:

- 1) providing applicants of high education with knowledge regarding the appointment of a laboratory examination of a patient, the use of laboratory research data in preclinical diagnostics, differential diagnosis, control of treatment and prognosis of the development of the most common diseases;
- 2) provision of knowledge regarding diagnostic procedures that are most often used in the practice of clinical laboratories;
- 3) provision of knowledge regarding the principles of constructing diagnostic search algorithms for the most frequent pathological conditions and clinical syndromes, as well as requirements for conducting research within evidence-based medicine.

The process of studying the discipline is aimed at forming elements of the following **competencies**:

General competencies:

- GC1. Ability to abstract thinking, analysis and synthesis
- GC3. Ability to apply knowledge in practical situations
- GC4. Knowledge and understanding of the subject area and understanding of professional activity
- GC6. Ability to make informed decisions
- GC10. Ability to use information and communication technologies
- GC16. The ability to evaluate and ensure the quality of the work performed

Special competencies are:

- SC1. Ability to collect medical information about the patient and analyze clinical data
- SC2. Ability to determine the necessary list of laboratory and instrumental studies and evaluate their results
- SC3. Ability to establish a preliminary and clinical diagnosis of the disease
- SC8. Ability to determine tactics and provide emergency medical care
- SC10. Ability to perform medical manipulations
- SC16. Ability to maintain medical documentation, including electronic forms
- SC21. The ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments on health care problems and related issues to specialists and non-specialists, in particular to people who are studying
- SC24. Adherence to ethical principles when working with patients and laboratory animals
- SC25. Adherence to professional and academic integrity, to be responsible for the reliability of the obtained scientific results
- SC28. Ability to apply fundamental biomedical knowledge at a level sufficient to perform professional tasks in the field of health care

Program learning outcomes (PLO) are:

PLO 1. Have thorough knowledge of the structure of professional activity. To be able to carry out professional activities that require updating and integration of knowledge. To be responsible for professional development, the ability for further professional training with a high level of autonomy.

PLO 2. Understanding and knowledge of basic and clinical biomedical sciences, at a level sufficient for solving professional tasks in the field of health care.

PLO 3. Specialized conceptual knowledge that includes scientific achievements in the field of health care and is the basis for conducting research, critical understanding of problems in the field of medicine and related interdisciplinary problems.

PLO 4. Identify and identify leading clinical symptoms and syndromes (according to list 1); according to standard methods, using preliminary data of the patient's history, data of the patient's examination, knowledge about the person, his organs and systems, establish a preliminary clinical diagnosis of the disease (according to list 2).

PLO 5. Collect complaints, history of life and diseases, evaluate psychomotor and physical development of the patient, state of organs and systems of the body, based on the results of laboratory and instrumental studies, evaluate information regarding the diagnosis (according to list 4), taking into account the age of the patient.

PLO 6. To establish a final clinical diagnosis by making a reasoned decision and analyzing the received subjective and objective data of clinical, additional examination, carrying out differential diagnosis, observing the relevant ethical and legal norms, under the control of the managing physician in the conditions of the health care institution (according to the list 2).

PLO 7. 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).

PLO 14. Determine tactics and provide emergency medical care in emergency situations (according to list 3) in limited time in accordance with existing clinical protocols and treatment standards.

PLO 17. Perform medical manipulations (according to list 5) in the conditions of a medical institution, at home or at work based on a previous clinical diagnosis and/or indicators of the patient's condition by making a reasoned decision, observing the relevant ethical and legal norms.

PLO 21. Search for the necessary information in the professional literature and databases of other sources, analyze, evaluate and apply this information.

PLO 24. To organize the necessary level of individual safety (own and the persons he cares for) in case of typical dangerous situations in the individual field of activity.

PLO 25. It is clear and unambiguous to convey one's own knowledge, conclusions and arguments on health care problems and related issues to specialists and non-specialists.

PLO 27. Communicate freely in the state language and in English, both orally and in writing to discuss professional activities, research and projects.

As a result of studying the discipline, the applicant *should know*:

- Classification and systematic approaches to modern laboratory methods of research and the possibility of their use in the practical activity of a doctor;
- Principles of interpretation of the results of the clinical and laboratory examination of the patient;
- Patterns of changes in clinical and laboratory indicators under the influence of various drugs to control the effect of drugs;

be able:

- conducting the most common clinical and laboratory analyzes of patients;
- build diagnostic search algorithms depending on the purpose of the study, the patient's condition and the capabilities of the laboratory;
- to provide an assessment of the received research results;
- identify signs of errors in laboratory diagnostics.

3. Content of the educational discipline "Basics of clinical and laboratory diagnostics".

Content module 1. Organization of laboratory service, principles of clinical laboratory work, accuracy, reliability, sensitivity of research. Quality control of laboratory research.

Topic 1. Introduction to laboratory diagnostics

The subject and tasks of the course of clinical laboratory diagnostics. History of the development of clinical laboratory diagnostics. Characteristics of the material for research. Methods of obtaining material for clinical and laboratory methods of research. Requirements for work in clinical diagnostic laboratories.

The role of clinical and laboratory methods of examining the patient as criteria for the effectiveness and safety of drug therapy. Ways of possible influence of drugs on laboratory indicators. The value of laboratory diagnostics in the practical activity of a doctor.

Content module 2. Laboratory research by types of research (general clinical, biochemical), laboratory diagnosis of emergency conditions, algorithm for the study of endocrine organs.

Topic 2. General clinical research

General information about the composition of the studied liquids - blood, urine, etc.. Basic clinical indicators. General information about the formation of indicators in the body. Factors affecting research results. Morphology and functions of cells. Normal content in components in general clinical studies. Quantitative methods. Indicators of pathological conditions. Some of the most significant indicators and research methods. The main pharmacological groups of drugs that cause "pathological" changes in research and the mechanisms of false results.

Topic 3. Biochemical research

Indicators of protein, fat, carbohydrate metabolism, homeostasis and hemostasis: platelets, blood coagulation factors. Blood collection and processing technique for biochemical research. Methods of determination and clinical and diagnostic value of indicators. Lipidogram. Proteinogram. Types of coagulograms. DVZ syndrome. The effect of drugs on hemostasis indicators.

Topic 4. Meaning and research of enzymes, hormones and vitamins in diseases of internal organs. Research of enzymes and hormones. Clinical significance of hormone levels.

Topic 5. Examination algorithm for endocrine diseases. Sugar profile.

Topic 6. Main syndromes – anemia, inflammation, leukemia and others.

Content module 3. Algorithms of laboratory tests for diseases of individual systems and organs.

Topic 7. Algorithms of laboratory research of individual organs and systems. Physiological features of the formation of indicators in the human body. Principles of collection and stages of research of material from individual organs and systems - bone system, urinary system, hepatobiliary system, etc. Research algorithm. Features of the main indicators of the analysis depending on the age of the person and various physiological conditions (pregnancy, hypothermia, excessive physical and mental stress). Clinical and diagnostic value of tissue and organ research in various diseases. The importance of the functional state of organs - bones, kidneys, liver, etc. - as a criterion for the effectiveness and safety of drug therapy.

4. The structure of the educational discipline

Subject	Number of hours	
	Total	including

		lectures	seminars	practical	laboratory	IWS
<i>Content module 1. Organization of laboratory service, principles of clinical laboratory work, accuracy, reliability, sensitivity of research. Quality control of laboratory research.</i>						
Topic 1. Introduction to clinical laboratory diagnostics as a discipline. Principles of laboratory research. General information about the accuracy, reliability, sensitivity and specificity of research. Quality control of laboratory research	6	0	2	0	0	4
Total by module 1	6	0	2	0	0	4
<i>Content module 2. Laboratory studies by research types, laboratory diagnosis of emergency conditions, studies of proteins, fats, carbohydrates, homeostasis, enzymes, hormones. Examination for endocrine diseases, sugar profile.</i>						
Topic 2. General clinical research. Definition, components, current status. Research automation	6	0	2	0	0	4
Topic 3. Biochemical studies of the metabolism of proteins, fats, carbohydrates, homeostasis and hemostasis: platelets, blood coagulation factors	6	0	2	0	0	4
Topic 4. Meaning and research of enzymes, hormones and	6	0	2	0	0	4

vitamins in diseases of internal organs.internal organs.						
Topic 5. Examination algorithm for endocrine diseases. Sugar profile.	7	0	2	0	0	5
Topic 6. Main syndromes - anemia, inflammation, leukemia, et al	6	0	2	0	0	4
Total by module 2	31	0	10	0	0	21
<i>Content module 3. Algorithms of laboratory tests for diseases of individual systems and organs.</i>						
Topic 7. Algorithms of laboratory examination of individual organs and systems.	8	0	4	0	0	4
Total by module 3	8	0	4	0	0	4
Total	45	0	16	0	0	29

5. Topics of lectures/seminars/practical/laboratory classes

5.1. Lectures are not provided.

5.2. Seminar classes are not provided

5.3. Topics of practical classes.

№	Topics of practical classes	Number of hours
1	Topic 1. Introduction to clinical laboratory diagnostics as a discipline. Principles of laboratory research. General information about the accuracy, reliability, sensitivity and specificity of research. Quality control of laboratory research	2
2	Topic 2. General clinical research. Definition, components, current status. Research automation	2
3	Topic 3. Biochemical studies of the metabolism of proteins, fats, carbohydrates, homeostasis and hemostasis: platelets, blood coagulation factors	2
4	Topic 4. Meaning and research of enzymes, hormones and	2

	vitamins in diseases of internal organs.	
5	Topic 5. Examination algorithm for endocrine diseases. Sugar profile.	2
6	Topic 6. Main syndromes - anemia, inflammation, leukemia, et al	2
7	Topic 7. Algorithms of laboratory examination of individual organs and systems.	2
8	Topic 7. Algorithms of laboratory examination of individual organs and systems.	2
	Total	16

6. Independent work of the applicants of higher education

№	Topics for applicants' independent work	Number of hours
1	Topic 1. Introduction to clinical laboratory diagnostics as a discipline. Principles of laboratory research. General information about the accuracy, reliability, sensitivity and specificity of research. Quality control of laboratory research Preparation for the seminar class 1.	4
2	Topic 2. General clinical research. Definition, components, current status. Research automation. Preparation for the seminar class 2.	4
3	Topic 3. Biochemical studies of the metabolism of proteins, fats, carbohydrates, homeostasis and hemostasis: platelets, blood coagulation factors Preparation for the seminar class 3.	4
4	Topic 4. Meaning and research of enzymes, hormones and vitamins in diseases of internal organs. Preparation for the seminar class 4.	4
5	Topic 5. Examination algorithm for endocrine diseases. Sugar profile. Preparation for the seminar class 5.	5
6	Topic 6. Main syndromes - anemia, inflammation, leukemia, et al. Preparation for the seminar class 6.	4
7	Topic 7. Algorithms of laboratory examination of individual organs and systems. Preparation for the seminar class 7.	4
	Total	29

7. Teaching methods

A practical class is a type of educational class in which the teacher conducts a discussion on predetermined problems, for which applicants prepare abstracts of speeches on the basis of individually completed tasks (abstracts, essays, etc.), testing, solving situational tasks.

At the practical classes, the teacher assesses the quality of the applicants' performance of individual tasks, their activity in the discussion, the ability to formulate and defend their position, etc.

Independent work with recommended basic and additional literature, with electronic information resources, preparation for practical classes.

8. Forms of control and evaluation methods (including criteria for evaluating learning outcomes)

Current control: oral survey, testing, solution of situational clinical tasks, assessment of activity in class.

Final control: credit test

Assesment of the current learning activity at the practical classes:

1. *Assesment of theoretical knowledge on the subject of the lesson:*

- methods: survey, solving a situational clinical problem
- maximum score – 5, minimum score – 3, unsatisfactory score – 2.

2. *Assessment of practical skills:*

- the ability to correctly prescribe and interpret the results of laboratory and instrumental examination, justify the diagnosis based on the analysis of clinical and auxiliary examination methods.

- maximum score – 5, minimum score – 3, unsatisfactory score – 2.

The grade for one practical session is the arithmetic average of all components and can only have a whole value (5, 4, 3, 2), which is rounded according to the statistical method.

Criteria for current assessment in class:

«5»	The applicant is fluent in the material, takes an active part in discussing and solving a situational clinical problem, confidently demonstrates practical skills and interpretations of clinical, laboratory and instrumental research data, expresses his opinion on the subject of the class, demonstrates clinical thinking.
«4»	The applicant has a good command of the material, participates in the discussion and solution of a situational clinical problem, demonstrates practical skills in the interpretation of clinical, laboratory and instrumental research data with some errors, expresses his opinion on the subject of the class, demonstrates clinical thinking.
«3»	The applicant does not have sufficient knowledge of the material, takes part in the discussion and solution of the situational clinical problem without confidence, demonstrates practical skills during the interpretation of clinical, laboratory and instrumental research data with significant

	errors.
«2»	The applicant does not master the material, does not take part in the discussion and solution of the situational clinical problem, does not demonstrate practical skills in the interpretation of laboratory research data.

Independent extra curricular work of the applicants is assessed at the appropriate practical session or at the final control with the mandatory display of the procedure of this type of control in the work program.

Final score. Test is given to the applicant, who completed all tasks of the work program of the academic discipline, took an active part in practical classes, completed and defended an individual assignment and has an average current grade of at least 3.0 and has no academic debt.

9. Distribution of points received by the applicant.

The obtained average score for the academic discipline for applicants, who have successfully mastered the work program of the academic discipline is converted from a traditional four-point scale to points on a 200-point scale, which is shown in the table:

Conversion table of a traditional assessment into a multi-point scale

National score for the discipline	Points
«5» (excellent)	185-200
«4» (good)	151-184
«3» (satisfactory)	120-150
«2» (unsatisfactory)	Less than 120

A multi-point scale (200-point scale) characterizes the actual success of each applicant in learning the educational component. The conversion of a traditional assessment into a 200-point assessment is performed by the information and technical department of the University. According to the obtained points on a 200-point scale, the achievements of the applicants are evaluated according to the ECTS rating scale. Further ranking according to the ECTS rating scale evaluates the achievements of the students in the educational component, who are studying in the same course of the same specialty, according to the points they received. The ECTS scale is a relative-comparative rating that establishes the applicant's belonging to the group of the best and worst among the reference group of fellow students (faculty, specialty). An "A" grade on the ECTS scale cannot be equal to an "excellent" grade, and a "B" grade to a "good" grade, etc. When converting from a multi-point scale, the limits of grades "A", "B", "C", "D", "E" on the ECTS scale do not coincide with the limits of grades "5", "4", "3" on the traditional scale.

Acquirers who received grades "FX" and "F" ("2") are not included in the list of ranked acquirers. The grade "FX" is awarded to students who have obtained the minimum number of points for the current learning activity, but who have not passed the final examination. A grade of "F" is assigned to students who have attended all classes in the discipline, but have not received an average score (3.00) for the current academic activity and are not admitted to the final examination.

Applicants, who study in one course (one specialty), based on the number of points scored in the discipline, are ranked on the ECTS scale as follows:

Criteria for determining the ECTS scores

Evaluation of ECTS	Statistical indicator
«A»	is the best 10% of applicants
«B»	next 25% of applicants
«C»	next 25% of applicants
«D»	next 25% of applicants
«E»	last 10% of applicants

10. Methodological support

- Working program of the discipline
- Syllabus
- Methodological recommendations for practical classes
- Methodological recommendations for independent work of higher education applicants
- Multimedia presentations
- Situational clinical tasks
- Electronic bank of test tasks by subdivisions of the discipline
- Educational and methodical literature

11. Questions for the final control

1. The value of clinical laboratory research. Historical sketch of the development of the laboratory service. The role of clinical and laboratory-instrumental methods of patient research as criteria for the effectiveness and safety of drug therapy.
2. Organization and conduct of laboratory tests during outpatient admission;
3. Organization and conduct of laboratory tests during inpatient treatment;
4. Organization and conduct of laboratory tests during the provision of emergency care;
5. Peculiarities of laboratory research in telemedicine;

6. Characteristics of the method of laboratory diagnostics - accuracy, reliability.
7. Quality control of laboratory research;
8. The concept of general clinical blood analysis. General rules and blood collection technique.
9. Clinical syndromes in the general blood test;
10. Value of the general clinical analysis of urine. Principles of collection and stages of urine research.
11. Analysis of sputum. Principles of collection and research stages;
12. Coprogram. Principles of collection and stages of research. Feces on the eggs of helminths.
13. Study of punctates and other liquids.
14. Biochemical examination of blood. Hemostasis and blood coagulation. The total number of platelets and their morphology.
15. Research of blood glucose. Sugar profile.
16. Study of blood lipids. Lipidogram.
17. Research of blood protein. Proteinogram. Nonspecific indicators of inflammation.
18. Study of the coagulation system. Coagulogram.
19. Principles of hormone research.
20. Algorithm of laboratory examination of the bone system.
21. Algorithm of laboratory examination of the renal system.
22. Algorithm for laboratory examination of the function of the hepatobiliary system;
23. Algorithm of laboratory examination of reproductive function.
24. The effect of drugs on the physical properties of the test.
25. The effect of drugs on the chemical properties of the test.
26. Influence of drugs on the analytical properties of the test.
27. Prevention of false results in laboratory practice.

12. Recommended literature

Main (basic):

1. Robinson A.T. Pathology — The Beginnings of Laboratory Medicine: First in a Series, Laboratory Medicine. 2021. Vol. 52. No 4. P. e66–e82.
2. West J., Atherton J., Costelloe S.J., Pourmahram G., Stretton A., Cornes M. Preanalytical errors in medical laboratories: a review of the available methodologies of data collection and analysis. Ann Clin Biochem. 2017. Vol.54, No 1. P. 14-19.

3. Yu H.E., Lanzoni H., Steffen T., Derr W., Cannon K., Contreras J., Olson J.E. Improving Laboratory Processes with Total Laboratory Automation. *Laboratory Medicine*. 2019. Vol.50, No1. P. 96–102.
4. McKenzie S.B., Bergeron J.D., Landis-Piwowar K., Williams L. *Clinical Laboratory Hematology*, 4-th edition, 2019. 350 p.
5. Cascio M.J., DeLoughery T.G. Anemia: Evaluation and Diagnostic Tests. *Med Clin North Am*. 2017. Vol.101, No 2. P. 263-284.
6. Pfeiffer C.M., Looker A.C. Laboratory methodologies for indicators of iron status: strengths, limitations, and analytical challenges. *Am J Clin Nutr*. 2017. Vol. 106, Suppl 6. P.1606S-1614S.
7. Brunzel N.A. *Fundamentals of Urine & Body Fluid Analysis*, 5th Edition, 2021. 448 p.
8. de Haas V., Ismaila N., Zhang L. Initial Diagnostic Workup of Acute Leukemia: ASCO Clinical Practice Guideline Endorsement Summary of the CAP and ASH Guideline. *J Oncol Pract*. 2019. Vol. 15, No 2. P. 101-105.
9. Jakšić B., Pejša V., Ostojić-Kolonić S., et al. Guidelines for Diagnosis and Treatment of Chronic Lymphocytic Leukemia. *Krohem B-CII* 2017. *Acta Clin Croat*. 2018. Vol. 57, No 1. P.190-215.
10. Gulati G. *Blood cell Morphology: Grading Guide*, 2nd Edition. 2017. 98 p.
11. Celkan T.T. What does a hemogram say to us? *Turk Pediatri Ars*. 2020. Vol. 55, No 2. P.103-116.

Additional:

1. Dusilnicka I., Krala E., Cholewinska P., Radwan-Oczko M. The Use of Saliva as a Biosample in the Light of COVID-19. *Diagnostics*. 2021. Vol. 11. P. 1769.
2. Tiongco R.E., Bituin A., Arceo E., Rivera N., Singian E. Salivary glucose as a non-invasive biomarker of type 2 diabetes mellitus. *J Clin Exp Dent*. 2018. Vol. 10, No 9. P. e902-e907.
3. Palladino M. Complete blood count alterations in COVID-19 patients: A narrative review. *Biochem Med (Zagreb)*. 2021. Vol. 31, No 3. P.030501.
4. Oyaert M., Delanghe J.. Progress in Automated Urinalysis. *Ann Lab Med*. 2019. Vol. 39, No 1. P. 15-22.

5. Wada H., Yamamoto A., Tomida M., et al. Proposal of Quick Diagnostic Criteria for Disseminated Intravascular Coagulation. J. Clin. Med. 2022. Vol. 11. P. 1028.

6. Ahmad S., Maqbool A., Srivastava A., Gogoi S., Siddiqui F.A., Panwar S. Urine Analysis Revisited: A Review. Annals of International Medical and Dental Research. 2018. Vol. 5, No 1.P. 22-32.

7. Methodical recommendations for seminar classes and IWS/ composed by The Department of occupational diseases and functional diagnosis, 2022.

13. Electronic information resources

1. Official website of the WHO <https://www.who.int>

2. Website of the All-Ukrainian Association of Laboratory Diagnostics
<http://acclmu.org.ua>

3. Information and educational environment info.onmedu
[https://info.odmu.edu.ua/chair/occupational diseases and functional diagnostics/files](https://info.odmu.edu.ua/chair/occupational_diseases_and_functional_diagnostics/files).