



1. Module identification code.	
Name of the institution:	Universidad Autónoma de Nuevo León
Name of the school:	School of Medicine
Name of the degree program:	Clinical Chemistry
Name of the course (learning unit):	Clinical biochemistry
Total number of class hours-theory and practice:	120 hours
Class hours per week:	6 hours
Independent study:	30
Course modality:	Face-to-face instruction
Module level:	Sixth semester
Core/elective module:	Core
Curriculum area:	ACFP-F
UANL credit points:	5
Create date:	September 15 th , 2018
Date of last amendment made:	January 21 th , 2022
Person(s) responsible for the design and amendment of the module:	Dr. E. Diana Guadalupe Robles Espino





2. Presentation:

The learning unit of Clinical biochemistry is composed of four phases, which integrate and provide the foundations for students to perform adequately in a Clinical biochemistry laboratory.

During phase 1: Basics of Quality Control, students will learn to identify the causes of variability that affect analytical methods in the Clinical biochemistry laboratory. They will also verify the analytical performance of qualitative methods and be able to interpret the results of both internal and external quality control.

Subsequently, in phase 2: Laboratory Tests in the Diagnosis, Control, and Monitoring of Glucose, Lipid, and Protein metabolism disorders, students will analyze the pathophysiological foundations that support these tests as well as the applicable analytical methodologies. At the same time, they will execute traditional manual methods in the Clinical biochemistry laboratory for the determination of glucose, cholesterol, and total proteins. Among the competencies that students will acquire in this phase, they will be able to interpret tests useful in diagnosing disorders of glucose and lipid metabolism and correlate them with the most common diagnoses.

In phase 3: Clinically important enzymes, students will analyze the pathophysiological foundations of enzymes as biochemical markers, as well as the applicable analytical methodologies. They will also carry out traditional manual methods for enzyme determination. In this phase, students will be able to interpret alterations in the results of different enzymes and correlate them with the most likely diagnosis.

Finally, in phase 4: Tests that Evaluate Liver and Kidney Function, Electrolyte Balance, and Acid-Base Status, students will analyze the pathophysiological foundations of tests for diagnosing kidney and liver disease, as well as disorders in electrolyte and acid-base balance. Additionally, they will analyze the methodological foundations of these tests and interpret results and their clinical correlation. They will also execute traditional manual methods for the determination of bilirubin, urea, creatinine, and general urine examination.

To ensure that students achieve these learning objectives, activities will be developed that promote meaningful learning and provide evidence demonstrating the competencies acquired, which in turn will enable them to develop an integrative learning product consisting of solving quality control cases, verifying methods, and interpreting results along with their clinical correlation.

3. Purpose:

Contribute to achieving the graduate profile by developing the necessary professional competencies to perform in the Clinical Laboratory through the execution of biochemical analysis methods, as well as the interpretation and validation of patient results.

This learning unit is related to Biochemistry, which provides the foundations of human metabolism; to Physiology, which offers knowledge of the function of organs and systems in the human body; and to Pathology, which introduces the concepts of disease. All of this knowledge is integrated into Clinical biochemistry to correlate laboratory tests with patient diagnosis. Additionally, it is related to Instrumental Analysis, which provides knowledge about the analytical methodologies on which the various determination methods in the Clinical biochemistry laboratory are based.

Within the learning units of more advanced semesters, there is a connection with Clinical pathology, Selected topics, and Professional practice, providing the necessary knowledge for interpreting and validating patient results, the basics of quality control, and the technical skills required for performing biochemical analyses.

Clinical biochemistry collaborates in promoting three general competencies of UANL; it encourages logical, critical, and proactive thinking by analyzing situations typical of work in the clinical laboratory, allowing for informed decision-making regarding sample management and the quality of laboratory results. During this learning unit, discussion spaces are created around the challenges facing our society in health matters, particularly in laboratory diagnostics, fostering interventions with a critical attitude, human commitment, and professionalism to seek the best alternatives for each situation.

Additionally, it promotes conflict resolution among the multidisciplinary health team through dialogue, negotiation, and mediation via case simulations. It collaborates with specific competencies by executing biochemical analysis of blood and urine samples for clinical diagnosis, interpreting results from biochemical profiles in correlation with patient diagnosis, and applying quality control tools to ensure the reliability of laboratory results.





4. Competences of the graduate profile

General competences to which this module (learning unit) contributes:

Instrumental skills:

5. To use logical, critical, creative and proactive thinking to analyze natural and social phenomena that allow them to make relevant decisions in their sphere of influence with social responsibility.

Personal and social interaction skills:

10. To intervene in the face of the challenges of contemporary society at the local and global level with a critical attitude and human, academic and professional commitment to contribute to consolidating general well-being and sustainable development.

Integrative skills:

14. To resolve personal and social conflicts, in accordance with specific techniques in the academic field and in their profession for appropriate decision-making.

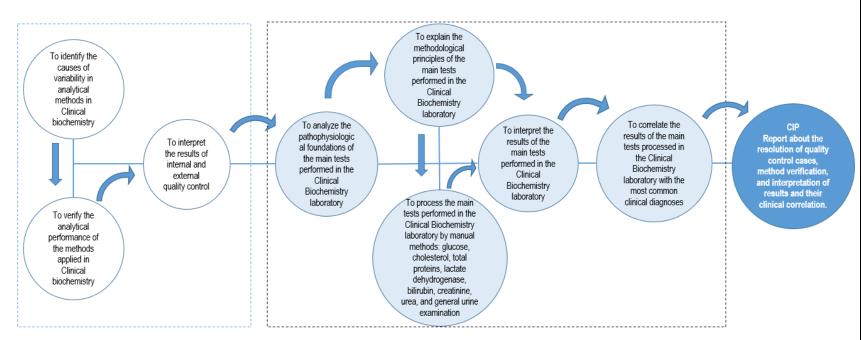
Specific competences of the graduate profile to which this module (learning unit) contributes:

- 2. To execute physical, chemical and/or biological procedures in the collection, handling, storage and analysis of samples to contribute to a reliable clinical, toxicological, chemical, food, forensic and environmental diagnosis.
- 6. To interpret the results of analyses based on established criteria that allow timely and pertinent decision-making in clinical, toxicological, chemical, food, forensic, and environmental diagnosis.
- 7. To guarantee the reliability of the analytical results obtained by applying quality control guidelines as established by laboratory policies for correct decision-making.





5. Course roadmap:



Phase 1: Basics of Quality Control

- Phase 2: Laboratory Tests in the Diagnosis, Control, and Monitoring of Disorders of Glucose, Lipid, and Protein Metabolism.
- Phase 3: Clinically Important Enzymes.
- Phase 4: Tests that Evaluate Liver and Kidney Function, Electrolyte Balance, and Acid-Base Status





6. Structuring into stages or phases: Stage 1: Basics of quality control Component(s) of the competence:

- To interpret the results of internal and external quality control based on the criteria of Westgard rules and an external quality program to identify systematic and random errors, and establish corrective measures that ensure the reliability of laboratory results.
- To verify the analytical performance of quantitative methods applied in the Clinical biochemistry laboratory regarding accuracy, precision, and linearity to evaluate whether they meet the established quality requirements.

Evidence of student learning	Performance criteria	Learning activities	Content	Resources
Internal and external quality control case study report.	Submit the handwritten report in PDF format by teams on the MS Teams platform: Includes:	The professor explains the contents of the phase through electronic presentations, infographics and examples of the different topics during the sessions. During the sessions, the professor intersperses questions throughout the presentations to keep the students' attention. The student individually answers the Quality Control booklet provided by the professor outside the classroom. The student individually asynchronously creates a comparative table of the different types of control materials in the format indicated by the professor and submits it on the	 Object of study of Clinical biochemistry. Disciplines related to Clinical biochemistry. Types of samples analyzed in Clinical biochemistry exams and collection methods. Clinical biochemistry laboratory process: preanalytical, analytical and post-analytical stage. Precision, veracity and accuracy. Quality Assurance and Quality Control. Control materials and calibrators. Parametric statistics: Mean, mode, median, standard deviation and coefficient of variation. Types of distribution of 	Classroom with audiovisual equipment: Projector, overhead projector, computer, audio system. Clinical Laboratory of the University Hospital. Teaching laboratory equipped for laboratory practices. Computer equipment with Microsoft Office and Internet connection. Moodle, ExamSoft and MS Microsoft Teams platform. Free-to-use electronic presentations prepared by the teacher.

Bibliographic references.

Only one member of the team will upload the evidence to the platform on the established date.

platform indicated by the data populations. professor.

The student asynchronously and as a team creates a report on the resolution of a statistics problem assigned by the professor and submits it on the platform indicated by the professor.

The professor presents cases of interpretation of and internal external Quality Control through electronic presentations and infographics.

The student individually participates in group discussions about the interpretation of the cases during class.

The professor explains the laboratory practices through infographics and/or audiovisual media. student individually and asynchronously reviews the laboratory practices and performs them during the corresponding synchronous session.

The student individually and asynchronously performs the report of the

following laboratory practices and delivers them on the platform indicated by

the teacher.

 Precision and veracity in the clinical laboratory. (Accredited learning 1.1)

- · Internal cuality control. Systematic and random error.
- Trends and shifts.
- · Levey Jennings graphs.
- Westgard rules.
- External quality control.
- quality External assessment programs.

Video

Chapter 3: Levey-Jennings Charts & Westgard's Rules

Book excerpts:

González (2019). Chapter 1: Preanalytical phase. Obtaining specimens.

Basic Lessons on Quality Control in the BIO-RAD Laboratory.

Digital readings:

Internal quality control vs external quality control.

Free reference sources:

QCNet. QC Education.

PACAL. Quality assurance program.

in t	leasurement of precision he clinical laboratory. ccredited learning ivity1.2)	
ser Lev (Ad	Preparation of a control rum and construction of a vey Jennings graph. ccredited learning civity1.3)	

Evidence of student learning	Performance criteria	Learning activities	Content	Resources
2. Verification report of quantitative analytical methods.	The verification report is carried out as a team and delivered as a Word or Excel document on the MS Teams platform with a cover page on the date established by the teacher. Must contain: Total Error Calculations. CV Selection Total Error Calculation. Selection of quality requirement for each method. Analysis of the performance of each method in terms of precision, truthfulness and accuracy. Conclusions about what the causes of the	The teacher explains the contents of the phase through electronic presentations, infographics and examples of the different topics during the sessions. The student carries out, as a team and during class, the verification of the performance of truthfulness, precision and accuracy of an analytical method with data provided by the teacher. The teacher explains the laboratory practices through infographics and/or audiovisual media. The student individually and asynchronously reviews the laboratory practices and carries them	Quality requirements and total error. Verification of quantitative analytical methods in the clinical laboratory. Accuracy verification. Verification of truthfulness. Accuracy check. Linearity verification.	Digital readings: Guide for the validation and verification of quantitative examination procedures used by the EMA clinical laboratory. Free reference sources: Westgard QC.

verification results may	out during the	
be.	corresponding	
Only one team member	synchronous session.	
will upload the evidence	The student individually	
to the platform on the	and asynchronously	
established date.	completes the report of the	
	following laboratory practices and delivers them	
	on the platform indicated	
	by the teacher.	
	Characteristics of a	
	prototype	
	spectrophotometric	
	method used in	
	Clinical	
	Biochemistry.	
	(Accredited	
	learning	
	activity1.4)	
	 Measuring linearity 	
	in a quantitative	
	analytical method in	
	Clinical	
	Biochemistry.	
	(Accredited	
	learning activity	
	1.5)	
	The student individually completes the content	
	knowledge exam	
	corresponding to phase 1	
	on the date indicated by the	
	teacher. (Accredited	
	learning activity 1.6)	





Phase 2: Laboratory tests in the diagnosis, control and monitoring of glucose, lipid and protein metabolism diseases. Component(s) of the competence:

Interpret the results of tests for the diagnosis of glucose, lipid and protein metabolism diseases, considering the patient's clinical picture, clinical sensitivity and specificity and the analytical methodologies used, to correlate laboratory findings with the most probable clinical diagnoses.

Evidence of student learning	Performance criteria	Learning activities	Content	Resources
Case report on clinical resolution of glucose, lipid and protein metabolism diseases.	Performed as a team. Complete the case in the format provided by the teacher. Includes cover with team member information. Answer in handwriting each of the criteria established in the case format, digitize it and upload it to the MS Teams platform on the date assigned by the teacher. Consider clinical data and laboratory results for clinical correlation of results. Only one team member will upload the evidence to the platform on the established date.	The teacher explains the contents of the phase through electronic presentations, infographics and examples of the different topics during the sessions. During the sessions, the teacher intersperses questions throughout the presentations to keep the students' attention. The student participates individually in group discussions about the interpretation of the cases during class. The teacher explains the laboratory practices through infographics and/or audiovisual media. The student individually and asynchronously reviews the laboratory practices and carries them out during the	 Generalities of glucose and metabolism. Colorimetric and enzymatic methods for determining blood glucose. Oral glucose tolerance test. Postprandial glucose. Glycosylated hemoglobin. Glucose in urine. Clinical importance of glucose and glycosylated hemoglobin determination. Hyperglycemia and hypoglycemia. Criteria for the diagnosis of Diabetes Mellitus and Gestational Diabetes. 	Classroom with audiovisual equipment: Projector, overhead projector, computer, audio system. Clinical Laboratory of the University Hospital. Teaching laboratory equipped for laboratory practices. Computer equipment with Microsoft Office and Internet connection. Moodle, ExamSoft and MS Microsoft Teams platform. Free-to-use electronic presentations prepared by the teacher.

corresponding synchronous session.

The student individually and asynchronously completes the report of the following laboratory practices and delivers them on the platform indicated by the teacher:

- Determination of glucose. (Accredited learning activity 2.1)
- Determination of cholesterol. (Accredited learning activity 2.2)
- Protein determination. (Accredited learning activity 2.3)

The student individually completes the content knowledge exam corresponding to phase 2 on the date indicated by the teacher. (Weighted Activity 2.4)

- Generalities of protein chemistry and metabolism.
- Total protein and albumin function, normal values and clinical significance.
- Determination of proteins by methods: Kjeldahl, Biuret and refractive index.
- Determination of albumin by dye fixation methods.
- Estimation of total proteins and albumin in other body fluids: urine and cerebrospinal fluid.
- Generalities of chemistry and metabolism of triglycerides and cholesterol.
- Principles for lipid analysis.
- Determination of triglycerides, cholesterol and their clinical importance:
- Serum lipoproteins, their determination and clinical importance.
- Dyslipidemias

Book excerpts:

Gonzalez (2019).

Chapter 14: Glucose metabolism: diabetes mellitus. Hypoglycemia.

Chapter 15. Lipid metabolism.

Dyslipidemias.

Chapter 16. Study of serum proteins.

Digital readings:

Canalizo (2013). Diagnosis and treatment of dyslipidemias.

González (2013).
Hemoglobin A1c: A
reliable and accurate test
for diabetes care? A
prospective study in
Mexico. Revista Salud
Pública de México





Phase 3. Enzymes of clinical importance. Component(s) of the competence:

Interpret the results of clinically important enzymes according to their sensitivity and specificity, considering the patient's clinical picture and the analytical methodologies used, to correlate laboratory findings with the most probable clinical diagnoses.

Evidence of student learning	Performance criteria	Learning activities	Content	Resources
4. Portfolio of enzymes of clinical importance.	Create a portfolio as a team that includes: Conceptual map of the assigned topic Key concepts of the topic. Hierarchy of concepts. Summary of the topic Includes: Cover, index, introduction, content: (pathophysiology, basis of the analysis method, sample collection conditions, analysis procedure, clinical correlation, conclusions, and bibliography) Submit the conceptual map and the summary in a single document in PDF format, on the MS Teams platform on the date indicated by the teacher.	The teacher explains the contents of the phase through electronic presentations, infographics and examples of the different topics during the sessions. During the sessions, the teacher intersperses questions throughout the presentations to keep the students' attention. The student asynchronously and as a team, prepares the portfolio of enzymes of clinical importance. The student individually and asynchronously completes the readings recommended by the teacher.	 Sensitivity and specificity of enzymes. Determination of enzyme activity in the clinical laboratory. Origin, reaction it catalyzes, isoenzymes, determination method, interferences, sample conditions, reference values and clinical correlation of: Lactate dehydrogenase (LDH), Aspartate aminotransferase (AST), Alanine aminotransferase (ALT), Acid 	Classroom with audiovisual equipment: Projector, overhead projector, computer, audio system. Clinical Laboratory of the University Hospital. Teaching laboratory equipped for laboratory practices. Computer equipment with Microsoft Office and Internet connection. Moodle, ExamSoft and MS Microsoft Teams platform. Free-to-use electronic presentations prepared by the teacher. Free-to-use electronic presentations prepared by students. Book excerpt González (2019). Chapter 17. Enzymes.

Seminar Presentation:	The teacher explains the	phosphatase	Video
Create a digital presentation with a maximum of 12 slides that includes the points highlighted in the summary, which is uploaded to the MS Teams platform one day before the presentation.	laboratory practice through infographics and/or audiovisual media. The student individually and asynchronously reviews the laboratory practice and performs it during the corresponding synchronous session.	(ACP), Alkaline phosphatase (ALP), Lipase (LIP), Amylase (AMY), Gamma glutamyltransferase (GGT) and Creatine kinase (CK).	Enzyme kinetics
Present in the classroom on the date and time indicated by the teacher within a maximum time of 15 minutes. Only one member of the team will upload the evidence to the platform on the established date.	The student individually and asynchronously completes the laboratory practice report and submits it on the platform indicated by the teacher. • Determination of Lactate dehydrogenase LDH (Accredited learning activity 3.1)		
	The student individually solves the content knowledge exam corresponding to phase 3 (Accredited learning activity 3.2)		





Phase 4. Tests that evaluate liver and kidney function, electrolyte and acid-base balance.

Component(s) of the competence:

Interpret the results of tests that evaluate liver and kidney function, electrolyte and acid-base balance, considering the patient's clinical picture, the clinical sensitivity and specificity of the tests and the analytical methodologies used, to correlate laboratory findings with the most likely clinical diagnoses.

Evidence of student	Performance criteria	Learning activities	Content	Resources
5. Case report on clinical resolution of tests evaluating liver and kidney function, electrolyte and acid-base balance.	Complete the project as a team and submit it in PDF format on the MS Teams platform on the date scheduled by the teacher. Includes in the report: • Front page • Identification of abnormal parameters identified in the case, both clinical and laboratory. • Definition of medical terms found in the case. • Probable diagnosis and its pathophysiological basis. • Highlights the tests that allow diagnosis considering clinical	The teacher explains the laboratory practices through infographics and/or audiovisual media. The student individually and asynchronously reviews the laboratory practices and carries them out during the corresponding synchronous session. The student individually and asynchronously completes the report of the following laboratory practices and delivers them on the platform indicated by the teacher: • Determination of bilirubin. (Accredited learning activity 4.1)	determination in the laboratory by Maloy-Evelyn, Jendrassik-Groff methods and direct spectrophotometry (bilirubinometers).	Classroom with audiovisual equipment: Projector, overhead projector, computer, audio system. Clinical Laboratory of the University Hospital. Teaching laboratory equipped for laboratory practices. Computer equipment with Microsoft Office and Internet connection. Moodle, ExamSoft and MS Microsoft Teams platform. Free-to-use electronic presentations prepared by the teacher. Book excerpts: Gonzalez (2019): Chapter 6: Water and electrolytes.

- sensitivity and specificity.
- Indicates tests that are not relevant to the diagnosis.
- Mention other useful tests for diagnosis that have not been performed.
- Literature.
- Only one team member will upload the evidence to the platform on the established date.

- Determination of urea. (Accredited learning activity 4.2)
- Creatinine determination.

(Accredited learning activity 4.3)

 General Urine Examination.

(Accredited learning activity 4.4)

The student individually completes the content knowledge exam corresponding to phase 4 on the date indicated by the teacher. (Accredited learning activity 4.5)

- glomerular filtration: inulin, creatinine and urea clearance. Non-protein blood nitrogen: urea nitrogen, creatinine, uric acid.
- Tests that measure tubular function:
 Pamnihippurate clearance,
 phenolsulfophthalein (PSP) test, specific gravity, osmolarity, and concentration and dilution tests.
 Calcium and phosphate.
- Characteristics of urine. General urine examination and its importance in clinical diagnosis.

• Electrolytes:

- Methods for determining sodium, chlorine and potassium in blood, urine and body fluids.
- Sampling conditions for electrolyte determination.
 Clinical significance

Chapter 7: Blood gases and acid-base balance.

Chapter 9: Biochemical study of renal function.

Chapter 23: Biochemical study of liver function and integrity.

Laboratory results reports.

	of electrolyte determination. • Acid-base balance and arterial gases: Respiratory and metabolic alkalosis and acidosis. • Blood gas analysis and sampling conditions. Determination of blood gases and their clinical utility.	
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Phase	Evidence and accredited learning activities	Weighing
Phase	Evidence 1. Internal and external quality control case study report.	4 points
1	Evidence 2. Verification report of quantitative analytical methods.	4 points
28%	Accredited learning activity 1.1 Practice report: Precision and accuracy in the clinical laboratory.	2 points
	Accredited learning activity 1.2 Practice report: Measuring precision in the clinical laboratory.	2 points
	Accredited learning activity 1.3 Practice report: Preparation of a control serum and construction of a Levey - Jennings graph.	2 points
	Accredited learning activity 1.4 Practice report: Characteristics of a prototype spectrophotometric method used in Clinical Biochemistry.	2 points
	Accredited learning activity 1.5 Practice report: Measurement of linearity in a quantitative analytical method of Clinical Biochemistry.	2 points
	Accredited learning activity 1.6 Phase 1 Knowledge test	10 points
Phase 2	Evidence 3. Report on the resolution of clinical cases of glucose, lipid and protein metabolism diseases.	4 points
18%	Accredited learning activity 2.1 Practice report: Determination of glucose.	2 points
	Accredited learning activity 2.2 Practice report: Determination of cholesterol.	2 points
	Accredited learning activity 2.3 Practice report: Determination of total proteins.	2 points
	Accredited learning activity 2.4 Phase 2 Knowledge test	8 points
Phase	Evidence 4. Portfolio of enzymes of clinical importance.	4 points
3 14%	Accredited learning activity 3.1 Practice report: Determination of lactate dehydrogenase	2 points
	Accredited learning activity 3.2 Phase 3 Knowledge test	8 points

Phase 4	Evidence 5: Report of resolution of a clinical case of tests that evaluate liver and kidney function, electrolyte and acid-base balance.	4 points
20%	Accredited learning activity 4.1 Practice report: Determination of Bilirubin.	2 points
	Accredited learning activity 4.2 Practice report: Determination of urea.	2 points
	Accredited learning activity 4.3 Practice report: Creatinine determination.	2 points
	Accredited learning activity 4.4 Practice Report: General Urine Examination	2 points
	Accredited learning activity 4.5 Phase 4 Knowledge test	8 points
PIA 20 %	Assessment of quality control case resolution, method verification and interpretation of results and clinical correlation.	20 points
	Total	100 points

8. Course integrative project/product:

Assessment of quality control case resolution, method verification and interpretation of results and clinical correlation.





9. References:

Bishop, M. (2019). Química Clínica: Principios, procedimientos y correlaciones. Estados Unidos. McGraw-Hill.

González, A. (2019). Principios de Bioquímica Clínica y Patología Molecular. España: editorial Elsevier.

Fernández - Espina, C. y Mazziota, D. (2005). Gestión de la Calidad en el Laboratorio Clínico. Argentina: editorial Médica panemericana.

Henry, J.B. (2007). El Laboratorio en el Diagnóstico Clínico. España: Editorial Marbán. Hickman, P.E. (Ed). (2009).

Methods in clinical chemistry. [CD-ROM]. EUA: Pesce Kaplan Publishers.

Kaplan, L.A. y Pesce, A.J. (1993). *Química clínica: técnicas de laboratorio, fisiopatología, métodos de análisis: teoría, análisis y correlación.* Argentina: editorial Médica panamericana.

Robles, D.G. y Sánchez, M. (2020). Manual de Prácticas de Bioquímica Clínica. México: Facultad de Medicina, UANL.

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