Republic of Yemen

Ministry of Higher Education & Scientific Research

21 SEPTEMBER UNIVERSITY of MEDICALS & APPLIEED SCIENCES

Faculty of Laboratory medicine..

Department of MICROBIOLOGY & IMMUNOLOGY

Course Specification of **Molecular Diagnostics**
Course No. (03.02.333)
2022/2023

I. Course Identification and General Information:

1	**Course Title:**	**Molecular Diagnostics**			
2	**Course Code & Number:**	**03.02.333**			
3	**Credit Hours:**	**Theory Hours**			
		Lecture	**Exercise**	Practical	**Credit Hours**
		2	0	2	3
4	**Study Level/ Semester at which this Course is offered:**	4th year and 2nd semesters			
5	**Pre –Requisite (if any):**	molecular biology and genetics			
6	**Co –Requisite (if any):**	None			
7	**Program (s) in which the Course is Offered:**	Bachelor in laboratory medicine			
8	**Language of Teaching the Course:**	English			
9	**Study System:**	semester			
10	**Mode of Delivery:**	Regular			
11	**Location of Teaching the Course:**	University Campus			
12	**Prepared by:**	Dr. Ghamdan Ahmed Altahish			
13	**Date of Approval:**	2022-2023			

II. Course Description:

Introducing the students to the range of molecular technologies available for laboratory diagnosis and management of infections Covering the following subjects Amplification-based techniques; design, practice and application, Traditional and developing sequencing technology, Molecular typing, Bioinformatics and Molecular approaches to diagnosis and management of infection .

III. Alignment Course Intended Learning Outcomes with program outcomes		
III. Course Intended Learning Outcomes (CILOs)		**Referenced PILOs**
A. Knowledge and Understanding: ***Upon successful completion of the course, students will be able to:***		
a1	**Explain** the diagnostic approach for common genetic disorders such as: cancer, hematological disorders and infectious diseases. and importance in forensic and paternity testing	**A1**
a2	Compare different isolation methods of nucleic acid extraction and	**A1**

	amplification and sequencing	
a3	**Demonstrate** the principle and procedures of nucleic acid electrophoresis and hybridization including Southern and Northern blots, FISH and DNA chip technology and DNA cloning.	**A2**
a4	**Discuss the** advanced knowledge of basic molecular techniques such as the principle of PCR, reverse transcriptase PCR, real time PCR and DNA sequencing	**A3**
B. Intellectual Skills: ***Upon successful completion of the course, students will be able to:***		
b1	**Interprets** results in context of other laboratory and clinical data, and relates the trouble shoot problems as they occur and determine possible causes.	**B1**
b2	**Correlate** molecular diagnostic techniques with the diagnosis of microbiological, hematological and genetic disorders and cancer.	**B2**
b3	**Monitors** disease progress and therapeutic efficacy with molecular diagnostic techniques & compares and selects appropriate molecular diagnostic methods.	**B3**
C. Professional and Practical Skills: ***Upon successful completion of the course, students will be able to:***		
c1	Perform extracts, purifies, quantifies and stores DNA and RNA for analysis from different sources	**C1**
c2	practice molecular detection of fungal, viral and bacterial pathogens, also in detection of mutation of some cancer and genetic disorders using molecular techniques as PCR and FISH	**C2**
c3	**Perform** and distinguish the results of PCR and RT-PCR, real time PCR, electrophoresis and hybridization techniques & Perform quality assurance in the molecular diagnostic laboratory.	**C3**
D. Transferable Skills: ***Upon successful completion of the course, students will be able to:***		
d1	**Establish** life-longs elf-learning required for continuous professional development & Present information clearly in written, electronic and oral forms.	**D1**
d2	**Establish** effective interpersonal relationship to Communicate ideas and arguments. and ability to Work as a part of team	**D3**
d3	**Develop** critical and analytical thinking to recognize errors and solve problems of diagnostic molecular biology which are used in research and diagnostic laboratories	**D2**

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IV. Alignment Course Intended Learning Outcomes with Teaching Strategies and Assessment methods:			
(A) Alignment Course Intended Learning Outcomes of Knowledge and Understanding to Teaching Strategies and Assessment Strategies:			
	Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
a1	**Explain** the diagnostic approach for common genetic disorders such as: cancer, hematological disorders and infectious diseases. and importance in forensic and paternity testing	Lectures	Exam
a2	Compare different isolation methods of nucleic acid extraction and amplification and sequencing	Lectures	Exam
a3	**Demonstrate** the principle and procedures of nucleic acid electrophoresis and hybridization including Southern and Northern blots, FISH and DNA chip technology and DNA cloning.	Lectures	Exam
a4	**Discuss the** advanced knowledge of basic molecular techniques such as the principle of PCR, reverse transcriptase PCR, real time PCR and DNA sequencing	Lectures	Exam
(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and			

Assessment Strategies:			
b1	Interprets results in context of other laboratory and clinical data, and relates the trouble shoot problems as they occur and determine possible causes.	Teaching strategies	Assessment Strategies
b2	**Correlate** molecular diagnostic techniques with the diagnosis of microbiological, hematological and genetic disorders and cancer.	Lectures, practical Lectures	Exam, practical exam
b3	**Monitors** disease progress and therapeutic efficacy with molecular diagnostic techniques & compares and selects appropriate molecular diagnostic methods.	Lectures, practical Lectures	Exam, practical exam
C Alignment Course Intended Learning Outcomes of Professional and Practical Skills to Teaching Strategies and Assessment Strategies:			
	Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
c1	Perform extracts, purifies, quantifies and stores DNA and RNA for analysis from different sources	Lab experiments	Practical Exam
c2	practice molecular detection of fungal, viral and bacterial pathogens, also in detection of mutation of some cancer and genetic disorders using molecular techniques as PCR and FISH	Lab experiments	Practical Exam
c3	**Perform** and distinguish the results of PCR and RT-PCR, real time PCR, electrophoresis and hybridization techniques & Perform quality assurance in the molecular diagnostic laboratory.	Lab experiments	Practical Exam
(D) Alignment Course Intended Learning Outcomes of Transferable Skills to Teaching Strategies and Assessment Strategies:			
	Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
d1	**Establish** life-longs elf-learning required for continuous professional development & Present information clearly in written, electronic and oral forms.	Lectures	Exam
d2	**Establish** effective interpersonal relationship to Communicate ideas and arguments. and ability to Work as a part of team	Practical session	Practical Exams
d3	**Develop** critical and analytical thinking to recognize errors and solve problems of diagnostic molecular biology which are used in research and diagnostic laboratories	Lectures	Seminars

Course Content:

A – Theoretical Aspect:

Order	Units/Topics List	Sub Topics List	Number of Weeks	contact hours	Learning Outcomes
1	Basic molecular biology:	Nucleic acid structure, replication, transcription, translation, DNA damage, mutagenesis.	1	2	a1,a2,b1
2	DNA extraction	Sample source, DNA extraction protocols, assessment of quality and quantity, storage	1	2	a1,a2,b2
3	RNA extraction	Sample source, RNA extraction protocols, assessment of quality and quantity, storage	1	2	a1,a2,b2
4	Blotting techniques:	Identification Hybridization, blotting and probe. Types, procedures and uses of **blotting** techniques Southern, northern and dot/slot blot; RFLP: (Principles. steps. Reaction Components and Applications)	1	2	a1,a2,b2
5	In situ nucleic acid hybridization & DNA Microarray	FISH: (Principles steps Reaction Components Applications) DNA chip (Principles steps. Reaction Components applications)	1	2	a1,a2,b2

6	PCR	Principles steps reaction Components Variants of the PCR Applications optimization of PCR reactions, contaminants, analysis and verification of PC R products nested, multiplex and hot start PCR	1	2	a1,a2,b2
7	Reverse transcriptase PCR,	Principles steps reaction Components Applications	1	2	a1,a2,b2
8	Med tem		1	2	
9	Electrophoretic	Principles steps reaction Components Applications	1	2	a1,a3,b2
10	Real time PCR	Principles steps reaction Components Applications	2	4	a1,a4,b2
12	DNA sequencing methods,	, applications of DNA sequencing in the clinical laboratory. Principles steps reaction Components Applications	1	2	a1,a2,b2
13	Gene Cloning	Principles steps reaction Components Applications	1	2	a1,a2,b2
14	Diagnosis of genetic disorders:	Application of molecular diagnostic in diagnosis of cancer, hematological disorders, and infectious diseases	1	2	a1,a3,b2
15	Final exam		1	2	a1,a3,b2
Number of Weeks /and Units Per Semester			**15**	**30**	

B - Practical Aspect: (if any)				
Order	**Tasks/ Experiments**	**Number of Weeks**	**contact hours**	**Learning Outcomes**
1	Sterile technique, pipetting, preventing contamination	**1**	**2**	**c1,c2,d1**
2	DNA extraction from plasma and bacteria	**1**	**2**	**c1,c2,d3**
3	DNA quantification and purification	**1**	**2**	**c1,c3,d2**
4	PCR set up	**1**	**2**	**c1,c3,d2**
5	Analyze PCR product using agarose gel electrophoresis and interpret results	**1**	**2**	**c1,c3,d3**
6	RNA extraction	**1**	**2**	**c1,c3,d3**
7	Setting up RT-PCR reaction	**1**	**2**	**c1,c3,d2**
8	Analyze RT-PCR results and troubleshoot	**1**	**2**	**c1,c2,d3**
9	Analyze PCR product using agarose gel electrophoresis and interpret results	**1**	**2**	**c1,c2,d2**
Number of Weeks /and Units Per Semester		**9**	**18**	

V. Teaching Strategies of the Course:	
1-	Lectures
2-	Practical session
3-	Seminars

VI. Assessment Methods of the Course:	
No	**Assignment**
1	Written Exams (Short Essays) and Quizzes
2	Multiple Choice Questions (MCQ)
3	Practical Exams (PE)

VII. Assignments:

No.	Assessment Method	Week Due	Mark	Proportion of Final Assessment	Aligned Course Learning Outcomes
1	**Midterm Exam**	8	20	20%	a1,a2,b1,b2,c1
2	**Practical exam**	14	30	30%	a1,a2,b1,b2,c1,d1,c2,c3
3	**Final Exam**	16	50	50%	a1,a2,b1,b2,c1
	Total	100		100%	

IX. Learning Resources:

· Written *in the following order: (Author - Year of publication – Title – Edition – Place of publication – Publisher).*

1- Required Textbook(s) (maximum two).	
1-	Brooker, R. J. (2009). *Genetics: Analysis & principles*. New York, NY: McGraw-Hill.
2-	Coleman, W. B., & Tsongalis, G. J. (1997). *Molecular diagnostics: For the clinical laboratorian*. Totowa, NJ: Humana Press.
3	Glick, B. R., Pasternak, J. J., & Patten, C. L. (2010). *Molecular biotechnology: Principles and applications of recombinant DNA*. Washington, DC: ASM Press.
2- Essential References.	
1-	Lela Buckingham and Maribeth Flaws. Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 2nd edition. ISBN-13: 978-0-8036-2677-5
2-	Lela Buckingham and Maribeth Flaws , Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 2007, ISBN-13: 978-0-8036-1659-2, ISBN-10: 0-8036-1659-7 ISBN-10: 0-8036-1659-7
3.	Lela Buckingham and Maribeth Flaws , Molecular Diagnostics: Fundamentals, Methods and Clinical Applications, 2007, ISBN-13: 978-0-8036-1659-2, ISBN-10: 0-8036-1659-7 ISBN-10: 0-8036-1659-7
3- Electronic Materials and Web Sites *etc*.	
1-	http://www.asmusa.org\
2-	http://www.phage.org/black09.htm
3-	http://www.microbe.org/microbes/virus_or_bacterium.asp
4-	http://www.microbelibrary.org
	http://www.bact.wisc.edu/Bact330/330Lecturetopics

XI. *Course Policies:*

1	**Class Attendance:** Class Attendance is mandatory. A student is considered absent and shall be banned from taking the final exam if his/her absence exceeds 25% of total classes.
2	**Tardiness:** -If the student dose not attend for more than 6 times, the student will be obligated to withdrew from the course
3	**Exam Attendance/Punctuality:** No student shall be allowed to the exam hall after 30 minutes of the start time, and shall not leave the hall before half of the exam time has passed.
4	**Assignments & Projects:** Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.
5	**Cheating:** Cheating is an act of fraud that results in the cancelation of the student's exam or assignment. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
6	**Forgery and Impersonation:** Forgery/Impersonation is an act of fraud that results in the cancelation of the student's exam, assignment or project. If it takes place in a final exam, the penalties stipulated for in the Uniform Students' Bylaw (2007) shall apply.
7	**Other policies:** The University official regulations in force will be strictly observed and students shall comply with all rules and regulations of the examination set by the Department, Faculty and University Administration