



الجمهورية اليمنية  
وزارة التعليم العالي والبحث العلمي  
جامعة ٢١ سبتمبر للعلوم الطبية والتطبيقية  
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Republic of Yemen  
Ministry of Higher Education & Scientific Research  
**21 SEPTEMBER UMAS**  
Faculty of Laboratory medicine  
Department of HEMATOLOGY  
Unit of Development & Quality assurance

Republic of Yemen  
Ministry of Higher Education & Scientific Research  
**21 SEPTEMBER UNIVERSITY of MEDICALS &  
APPLIED SCIENCES**



Faculty of Laboratory medicine..

Department of Hematology

Course Specification of **Quality Control. Assurance and biosafety in medical lab**

Course No. (03,03,337)

2022/2023



## Course name: Quality Control

I. Course Identification and General Information:				
1	Course Title:	Quality Control. Assurance and biosafety in medical lab		
2	Course Code & Number:	03,03,337		
3	Credit Hours:	Theory Hours		
		Lecture	Exercise	Practical
		2	0	2
3			Credit Hours	3
4	Study Level/ Semester at which this Course is offered:	Third Level / 1 <sup>st</sup> Semester		
5	Prerequisite (if any):	Hematology		
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. Boshra Al-absi		
13	Date of Approval:	2023/3/11		

## II. Course Objectives and Learning Outcomes (description, objective, course learning outcome)



<b>A. Course Description:</b>
This course will cover basic concepts of quality management such as quality management system, quality planning, quality controlling, quality assurance, quality improvement in medical laboratories. Also, it provides information about quality assurance in hematology laboratory.

III. Course Intended Learning Outcomes (CILOs)		Referenced PILOs
<b>A. Knowledge and Understanding: Upon successful completion of the course, students will be able to:</b>		
a1	understand the concepts of quality management, quality assurance and quality control.	A1
a2	Recognize laboratory organization, regulations, accreditation, method evaluation.	A2
a3	summarize quality assurance in hematology lab.	A3
<b>B. Intellectual Skills: Upon successful completion of the course, students will be able to:</b>		
b1	perform quality assurance and quality control in medical laboratory.	B1
b2	assess the precision and accuracy of lab test results	B2
b3	recognize errors in lab results and correct them.	B3
<b>C. Professional and Practical Skills: Upon successful completion of the course, students will be able to:</b>		
c1	demonstrate ethical and professional behavior, interest, enthusiasm, and willingness to learn as seen through active participation.	C1,
c2	act responsibly and reliably as measured by punctuality, attendance, dependability, and quality of work.	C2
<b>D. Transferable Skills: Upon successful completion of the course, students will be able to:</b>		
d1	Relate laboratory organization, regulations, accreditation, method evaluation.	D1

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
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a1	understand the concepts of quality management, quality assurance and quality control.	Lectures	Exams
a2	understand laboratory organization, regulations, accreditation, method evaluation.	Lectures	Exams
a3	summarize quality assurance in hematology lab.	Lectures	Exams

(B) Alignment Course Intended Learning Outcomes of Intellectual Skills to Teaching Strategies and Assessment Strategies:

	Course Intended Learning Outcomes	Teaching strategies	Assessment Strategies
b1	perform quality assurance and quality control in medical laboratory.	Lectures, Laboratory practical	Home work
b2	assess the precision and accuracy of lab test results	Lectures, Laboratory practical	Home work
b3	recognize errors in lab results and correct them.	Lectures, Laboratory practical	Home work

(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	demonstrate ethical and professional behavior.	Lectures, Laboratory practical	Practical exam
c2	demonstrate interest, enthusiasm, and willingness to learn as seen through active participation.	Lectures, Laboratory practical	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	Relate laboratory organization, regulations, accreditation, method evaluation.	Lectures, Laboratory practical,	Practical exam, seminars

NO.	Units/Topics List	Number of Weeks	Contact hours	Learning Outcomes (CILOs)
1	Quality management system model, terminology of quality assurance and	1	2	a1, b1

	its objectives			
2	Phases of quality assurance program: pre-analytical	1	2	a1, b1
3	Phases of quality assurance program: pre-analytical	1	2	a2, a1, b2
4	Pre-analytical errors in Hematology lab	1	2	a1, a3, b1, b3, c1
5	Internal quality control and quality control materials	1	2	a2, a3
6	Mid-term exam	1	1	a1, a3, b1, b3, c1
7	Phases of quality assurance program: analytical	1	2	a2, a3, b1, b2, c1
8	Monitoring of analytical quality by using statistical methods and control charts	1	2	a2, a3, b1, c1
9	Interpreting Quality Control Data and Westgard rules	1	2	a2, a1, b1, c1
10	Phases of quality assurance program: post-analytical	1	2	a2, b1, c1
11	Quality Assurance in hematology lab	1	2	a2, a3, b1, c1
12	External Quality Control (EQA)	1	2	a2, a3, b3
13	Sources of error in hematology lab	1	2	a2, a1, b1, c1
14		1	2	a2, a1, b1, c1
	Final Theoretical	1		
	<b>Number of Weeks /and Units Per Semester</b>	<b>14</b>	<b>27</b>	

**B - Practical Aspect: (if any)**

NO.	Tasks/ Experiments	Number of Weeks	Contact hours	Learning Outcomes
1	Laboratory safety	1	2	c1, c2,d1
2	Quality control in blood sampling and collection	1	2	c1, c2,d1
3	Common instruments, glassware and chemical in hematology lab	1	2	c2,d1
4	Quality assurance in preparation of common	1	2	c1, c2

	hematological reagents			
5	Micropipette calibration	1	2	c1, c2
6	Lab equipment maintenance	2	2	c1, c2
7	Standard calibration curve of hemoglobin	1	2	c1, c2,d1
8	Mean and standard deviation for Hb and PCV determination	1	2	c2,d1
<b>Number of Weeks /and Units Per Semester</b>		<b>9</b>	<b>16</b>	

#### V. Teaching Strategies of the Course:

1-	Lectures:
2-	practical session
3-	<b>seminars</b>

#### 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	<b>Midterm Exam</b>	8	20	20%	a1,a2,b1,b2,b3,c1
2	<b>Practical exam</b>	14	30	30%	a1,a2,b1,b2,c1,c2,d1
3	<b>Final Exam</b>	16	50	50%	a1,a2,b1,b2,c1,d1
	Total		100	100%	



### VIII. Learning Resources:

#### 1- Required Textbook(s)

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|----|---|
| 1- | WHO- 2011- Laboratory Quality Management System: handbook |
| 2- | Barbra j.Bain ,Imel...Elsevier (2017)                     |

#### 2- Essential References.

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|----|--|
| 1- | Shirlyn McKenzie, Kristin Landis-Piwowar, Linne Williams (2019). Clinical Laboratory Hematology, 4th Edition, Pearson Publishers. ISBN-13: 978-0134709390; ISBN-10: 013470939X |
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#### 3- Electronic Materials and Web Sites etc.

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| 1- | <a href="https://www.britannica.com/science/blood-biochemistry">https://www.britannica.com/science/blood-biochemistry</a> |
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### IX. Course Policies:

<b>Class Attendance:</b>	
1	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.
<b>Tardiness:</b>	
2	-If the student dose not attend for more than 6 times, the student will be obligated to withdrew from the course
<b>Exam Attendance/Punctuality:</b>	
3	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.
<b>Assignments &amp; Projects:</b>	
4	Assignments and projects must be submitted on time. Students who delay their assignments or projects shall lose the mark allocated for the same.
<b>Cheating:</b>	
5	



	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	<b>Forgery and Impersonation:</b> 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	<b>Other policies:</b> 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