

A- COURSE TITLE, CODE, ACADEMIC YEAR:

Quality Assurance & Laboratory Management- MLT (458) – 1443 H

B- COURSE INFORMATION:

Course Code	Course Title	Credit Units			Study Level	Pre-requisites
		Total	Theory	Practical		
MLT458	Quality Assurance & Laboratory Management	2	2	-	8 th	None
Course Coordinator		Extension		Email Address		
Prof. Bandar Suliman		-		bsuliman@taibahu.edu.sa		

C- COURSE DESCRIPTION:

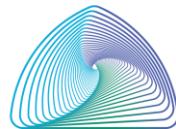
By the end of the course, the students will gain competencies in management and quality assurance of the clinical laboratory. The students will be trained to interpret control charts. They will acquire understanding of the managerial-organizational communication control charts, knowledge quality assurance of clinical chemistry, hematology, blood bank, microbiology, parasitology, and histopathology. The students will acquire knowledge and be practically trained how to write standard operating procedures, and will come to be capable to detect random and systematic errors, and will acquire knowledge about leadership style and group effectiveness.

D- COURSE OBJECTIVES:

1. The students will acquire understanding of the control charts
2. The students will acquire knowledge quality assurance of clinical chemistry, hematology and microbiology.
3. The students will acquire knowledge and will be practically trained in how to write standard operating procedures.
4. The students will come to be capable to detect random and systematic errors.
5. The students will state problem solving & decision-making process,
6. financial management and laboratory accreditation
7. The students will compare internal quality control with external quality assessment.

E- THEORY TOPICS:

Week	Theory Topic	Contact Hours
1	Medical Lab Quality Assurance Overview	2
2	Pre-analytical, Analytical Phase & Post-analytical Phases	2



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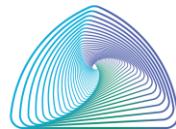


3	Control Charts & Reference Intervals	2
4	Response of Control Rules to Errors	2
5	POCT & Use of Patient Data for QC	2
6	Standard Operating Procedures (SOPs)	2
7	Quality Control in Hematology	2
8	Quality Control in Microbiology	2
9	Quality Control in Histopathology	2
10	Quality Control in Blood Bank	2
11	Quality Control in Parasitology	2
12	Reference range	2
13	QC assessment	2
14	External Quality Assurance, ISO & Laboratory Accreditation	2
15	Revision	2

F- COURSE LEARNING OUTCOMES:

#	Course Learning Outcomes	Assessment tools
1.1	Define quality, quality assurance, quality control and point of care testing	Continuous Assessment + Midterm + Final
1.2	Define the following: random error, systematic error, reference value, clinical sensitivity, clinical specificity, predictive value of a laboratory test and calculate each.	Continuous Assessment + Midterm + Final
1.3	Outline the tasks involved in methods evaluation, including statistical measures that must be performed	Continuous Assessment + Midterm + Final
2.1	Explain the need for control charts in the clinical laboratory and describe how to enter data on a control chart	Continuous Assessment + Midterm + Final
2.2	List and explain the Westgard rules for the interpretation of laboratory control data	Continuous Assessment + Midterm + Final
2.3	Apply the Westgard rules to actual control data and determine what actions must be taken to correct out of limit control values	Continuous Assessment + Midterm + Final
3.1	Adopt the multi-disciplinary health team approach to solve patient's problems	Continuous Assessment
3.2	Respect the role of all the services, members, and staff involved in providing health care to the patient	Continuous Assessment

G- ASSESSMENT TASKS:



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#	Type of assessment task	Week	Total Grades
1	Assignment (SOP Draft)	5	10
2	Midterm Exam (MCQs Only)	8	20
3	Continuous Assessment (Quiz)	Cont.	30
4	Final Exam	17	40

H- LEARNING RESOURCES:

- Ratliff T. (2014). The Laboratory Quality Assurance System: A Manual of Quality Procedures and Forms 3rd Edition ISBN-13: 978-0471269182 ISBN-10: 0471269182.
- ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I ([Link](#))

I- STUDENT ACADEMIC COUNSELLING AND SUPPORT:

IF YOU REQUIRE INDIVIDUAL ACADEMIC CONSULTATION AND SUPPORT RELATED TO THE COURSE, THE TEACHING STAFF ARE AVAILABLE DURING THE INDICATED OFFICE HOURS BELOW

Tutor name	Contact information
Prof. Bandar Suliman	bsuliman@taibahu.edu.sa
Dr. May Alsayb	msayb@taibahu.edu.sa

J-ASSIGNMENT WRITING GUIDELINES

Due date: (week 10 - Thursday) no later the 2:00 pm.

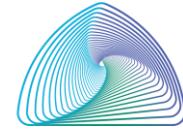
The assignment for this course will be a written Standard Operating Procedure (SOP) for a specific process or procedure

The SOP should be as follows:

- Not less than **250 words** in length in 1-2 page
- The structure of the SOP model should be strictly followed (see the example below)
- The file should be submitted as a PDF file using “Blackboard”
- All students must READ the instructions of PLAGIRISM and assignment should not exceed more than 30% plagiarism.
- Writing the assignment jointly and sumitting it as the work for one individual is UNACCEPTED.

For example, of a model SOP please review the link below

<https://app.box.com/s/4bjinpvrcebc6bmga9e>



GENERAL POLICY AND PROCEDURE

A. Attending policy:

- A 100% attendance rate is required during this course.
- Any absence requires an official acceptable excuse (NO later than 2 weeks).
- Student who is absent reach 10% is required to contact immediately his/her advisory supervisor and sign first warning form.
- Student who is absent reaching 15% is required to contact immediately his/her advisory supervisor and sign the second warning form.
- Students who are absent reaching 25% will be banned from attending the final exam and disqualified from this course.

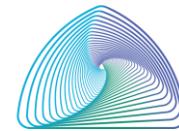
B. Quizzes and Exams

- The type and due date of quizzes and exams are presented in the student course outline.
- If absent from midterm exams or quizzes for a legitimate reason, students may apply for a postponed examination. However, the head of the department is responsible for making the final decision about accepting the student request.
- If absent from midterm exams or quizzes without any legitimate reason, students will not be able to repeat the midterm exam or quizzes.
- During exams and quizzes, students must enter the classroom with ONLY a pen. No scientific materials or MOBILE phone are allowed in the class during exam period. Students who find scientific materials or MOBILE phones will be considered cheating and will fail the exam.
- Cheating or attempt of cheating in **Quizzes or exams** student will not be excused and will fail in the course
(المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)

C. Final exam:

- Students are not allowed to enter the final exam after 30 min from the starting time.
- Students are not allowed to leave the final exam 30 min from the starting time.
- Student must carry his/her national ID to enter the final exam.
- Cheating in Quizzes or exams students will not be excused and will fail in the course
- Cheating or attempt of cheating in **Final exams** student will not be excused and will
 - 1- Fail in the course
(المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)
 - 2- Get excluded from the University for the next semester
 - 3- Prohibited from entering summer term for that year.

D. Assignment



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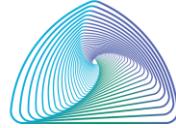
- Assignment MUST be submitted on due date even if the student is absent.
- Students MUST refer to the assignment formatting guidelines, writing guidelines and marking guide in each course outline.
- Assignments are returned with the marking guide to students within three weeks unless otherwise advised.
- Cheating in assignment (e.g. exceeding the plagiarism allowable %) ZERO in their assignment (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)
- Cheating in assignment for the second time, student will not be excused and will fail in the course (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)

E. Plagiarism

- Plagiarism is a practice of taking someone else's work and presented as your own, such as quoting or paraphrasing someone else's words, works or research findings, without acknowledgement and referencing the source.
- Allowable % of plagiarism: 30%
- Things considered plagiarism or cheating:
 - Falsifying results of research studies.
 - Writing an assignment jointly and submitting it as the work of one individual unless it is ~~is~~ clearly designated a group project.
 - Helping someone else to commit any dishonest act such as those listed above.
 - Quoting someone else's words without referencing
 - Copy/paste someone else's work without paraphrasing.
- The student MUST be aware of the consequences for misconduct that can be severe, including exclusion from the University.
- Cheating in assignment (e.g. exceeding the plagiarism allowable %) student will take ZERO in their assignment (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)
- Cheating in assignment for the second time, student will not be excused and will fail in the course (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)

F. Late submission

- Assignment submitted after due date (4 pm) without approval of extension considered a late submission.
- A penalty of 5% per day for the total mark available for that assessment for each day it is late must be imposed.
- Students cannot avoid a late penalty by e-mailing their assessments to the faculty, unless online submission is an approved submission method for that piece of assessment.



G. Assignment extension – Special considerations

- Student affected by serious illness or other factors outside of his/her control can apply for special consideration.
- Students must fill in a (**special consideration form**) and attach the supporting documents to submit a request for approval of late submission of assignments to the course coordinator.
- A student should not wait for their results to come out before applying for special consideration.
- Applications for special consideration will be assessed, where possible, within three working days of submission.
- Notification of the outcome of any application will be communicated by email to the student's email address.

H. Failure to submit

- Students who fail to submit their course assignment will get ZERO in their assignment, unless a request for extension is submitted.

I. Assignment formatting guidelines:

- Typed on A4 paper
- Font either Times New Roman 12pt or Arial 11pt
- Cover sheet has student number, email address, course name and code, course coordinator's name, word count, submission date and title.
- 1.5-line spacing
- Extra space between paragraphs
- Page numbers, with the introduction starting on page one
- Referencing using Vancouver referencing or ABI:
- The assignment must include accurate citation referencing
- The assignment must include accurate reference list correct
- Must check spelling and grammar before submission
- There should be enough references included (1 reference/100 words suggested)