

A- COURSE TITLE, CODE, ACADEMIC YEAR:

Laboratory Management and Quality Control – CLS-601 – Level 1

B- COURSE INFORMATION:

Course Code	Course Title	Credit Units			Study Level	Pre-requisites
		Total	Theory	Practical		
CLS 601	Laboratory Management and Quality Control	2	2	0	1 ST level	None
Course Coordinator		Extension		Email Address		
Prof. Bandar A. Suliman		---		bsuliman@taibahu.edu.sa		

C- COURSE DESCRIPTION:

Students will gain competencies in the principles and practices of laboratory management and quality assurance in the clinical setting. They will acquire a thorough understanding of quality assurance and quality control procedures in clinical biochemistry, hematology, and microbiology, learning to quickly and effectively identify and correct errors using internal and external quality control tools to detect and address both random and systematic errors. Students will acquire knowledge and practical training in writing standard operating procedures, establishing reference ranges, and evaluating materials and methods used in the laboratory. They will also learn about various aspects of laboratory management, including personnel management, resource allocation, budgeting, and regulatory compliance, developing the necessary skills to effectively manage and ensure the quality of a clinical laboratory.

D- COURSE OBJECTIVES:

By the end of this course, the student should be able to:

1. Understand and apply the principles of laboratory management, including administrative processes, financial management, leadership styles, problem-solving, and decision-making in the clinical laboratory setting.
2. Define and discuss quality and its related terms, applying various quality control tools and methods in the main sections of clinical laboratories to ensure accurate and reliable results.
3. Analyze and interpret bio-statistical indicators to monitor and improve laboratory performance.
4. Develop and implement standard operating procedures (SOPs) in compliance with ISO/CBAHI standards and conduct laboratory audits to maintain quality and regulatory compliance.
5. Evaluate and optimize laboratory design, classification, and resource allocation to enhance efficiency and productivity in the clinical laboratory.

E- THEORY TOPICS:

Week	Theory Topic	Hours
1	Introduction to Laboratory Management	2
2	Quality Assurance and Quality Control Principles	2
3	Statistical Quality Control	2
4	Quality Control Tools, Troubleshooting, and Corrective Actions (Merged Topics)	2
5	Standard Operating Procedures (SOPs)	2
6	Method Evaluation and Validation	2
7	Establishing Reference Ranges	2
8	Section-Specific Quality Control Protocols I (Biochemistry & Hematology)	2
9	Section-Specific Quality Control Protocols II (Microbiology, Histopathology & Blood Bank)	2
10	ISO/CBAHI Standards and Document Control	2
11	Laboratory Audits (People, Sample, and Technical Management)	2
12	Financial Management and Budgeting	2
13	Leadership and Problem-Solving Strategies	2
14	Change Management in Clinical Laboratory Medicine	2

15	Revision & Final Exam Preparation	2
	Total	24

G- ASSESSMENT TASKS:			
#	Type of assessment task	Week	Total Grades
1	Continuous Assessments (Interactive Quizzes)	Week1-week10	15
2	Mid Term	Week8	20
3	Group Project (Quality Audit)	Week 10	25
4	Final exam	Week 15	40

H- LEARNING RESOURCES:	
Required textbook:	
- Lynne S. Garcia (Editor). Clinical Laboratory Management 2nd Edition Publisher: ASM Press; 2 edition (2013) ISBN-13: 978-1555817275 Publisher: ASM Press; 2 edition (November 15, 2013) - James O. Westgard (Author) Basic QC Practices: Training in Statistical Quality Control for Medical Laboratories 4th Edition (2016) Publisher: Westgard QC; 4 edition (August 1, 2016 ISBN-13: 978-1886958302	

I- STUDENT ACADEMIC COUNSELING 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 A. Suliman	bsuliman@taibahu.edu.sa

General policy and procedures

1) Attending policy:

- Students are encouraged to achieve 100% attendance rate 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 exceeding 25% will be banned from attending the final exam and disqualified from this course.

2) Midterm Exams

- The type and due date of exams are presented in the student course outline.
- If the student is absent from midterm exam with a legitimate reason, student 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 the student is absent from midterm exams without any legitimate reason, student will not be able to repeat the midterm exam.
- During exams, students must enter the classroom with ONLY a pen. No scientific materials or any electronic devices (e.g. MOBILE phones) are allowed in the class during exam period. Students who find scientific materials or MOBILE phones will be considered cheating.
- Cheating or attempt of cheating in **exams** can lead student to fail in the course

(المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)

3) 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 before 30 min from the starting time.
- Student must carry his/her national ID to enter the final exam.
- Cheating in exams students will not be excused and can fail in the course
- Cheating or attempting cheating in **Final exams** can lead students to:
 - Fail in the course (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)
 - Get excluded from the University for the next semester
 - Prohibited from entering summer term for that year.

4) Assignment

- Assignment MUST be submitted on due date.
- Students MUST refer to the assignment formatting 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 similarities index allowable %) is not accepted (المادة التاسعة من لائحة التأديب الطلابي بجامعة طيبة)
- Students should submit the Turnitin report with the assignment confirming the similarities index allowable % based on their level.

5) Similarity index

- Similarity index 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 similarity index:
 - Second year students (level 3 and 4) = **50%**
 - Third year students (level 5 and 6) = **40%**
 - Fourth year students (level 7 and 8) = **30%**
- Things considered similarity index or cheating:
 - Falsifying results of research studies.
 - Writing an assignment jointly and submitting it as the work of one individual unless it 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 students MUST be aware of the consequences for misconduct that can be severe, including exclusion from the University.

6) Late submission

- Assignment submitted after due date (4 pm) without approval of extension considered a late submission.
- A penalty will be applied based on the course instructor.

7) Failure to submit:

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



approved by the course instructor.

8) Assignment formatting guidelines:

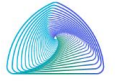
- Typed on A4 paper
- Font either Times New Roman 12pt or Arial 11pt
- Cover sheet has student number, email address, course name and code, course coordinator's name, word count, submission date and title.
- 1.5 line spacing
- Extra space between paragraphs
- Page numbers, with the introduction starting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

9) Assignment writing guidelines:

Assignment writing guidelines	
• Due date: Week 8 (Thursday), 4:00 pm • The aim: to assess students' level of competency in reading, understanding and summarizing medical mycology research articles. • Roles: Choose recent scientific research paper (NOT A REVIEW) published after 2014 • The Group written project: In groups of 3-5 write a 3-page report (excluding cover page, figures and references) discussing overcoming innovation barriers in a selected health sector or department • The Assignment: Your assignment 2024 is: Present a successful case of innovation in health while describing: gaps, barriers, framework, process, solution, application and outcome. • The Presentation: ○ Must construct a summary figure or table. ○ 10 slides (without front, Reference, thank you and question slide) • Turnitin report: You are required to submit your Turnitin report (confirming the allowable similarity index % based on your level) along with your assignment.	

10) Marking guide for assignments:

	Performance Indicator	Details	%
General criteria	Overall formatting	• Cover sheet (Assignment formatting guidelines)	10%
	Appropriate use of language	• Good choice of words • Grammar, spelling and punctuation. • Structure and organization of sentences	20%
	Correct choice of references, referencing style and citation	• Variety of books, journal articles and appropriate websites • Correct citation • Correct referencing style	10%
	Similarity index %	• Student should submit their Turnitin report with the assignment to confirm the allowable %.	



Course specific criteria	Clear understanding of the paper	• Correct hypothesis • Correct aims • Clear understanding to the background of the study • Summarizing the main findings correctly • Accurate understanding to the conclusion • Demonstrate valid points in the critical review	60%
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- Course specific criteria should be based on the type of assignment
- The table of the course marking guide for the assignment should be handed to the students as feedback on their assignment.
- Continuous assessments may include quizzes, internet searches, homework, exercises, class activity, scratch cards, presentations, group work, etc.
- Practical exams may contain hands-on experiments, laboratory work, simulations, or demonstrations.
- Written exams will include multiple-choice questions (MCQ), short essay questions, and long essay questions.

