

BCMB 489 Special Topics CRN 10295

Molecular Diagnostics

Course Outline: Fall 2020

Course Delivery: Online using Brightspace, Zoom and MS Teams
Class meets on Zoom every Tuesday 1:30-4:20 pm

INSTRUCTOR:

Dr. Paul Romaniuk

Office hours: Thursday 1:00-2:00 pm on Zoom

email: pjr@uvic.ca

Topics: This course is a guided exploration of molecular diagnostics in the context of the ongoing COVID-19 pandemic. We will focus specifically on tests that detect the presence of pathogen DNA or RNA in a patient sample. As a case study, we will follow the development of diagnostic tests in a research laboratory through specific examples drawn from Dr. Romaniuk's research. You will be given research data to analyze and draw conclusions from. The final project in the course is to plan a novel molecular diagnostic test.

Learning Objectives: This course will provide you with the ability to:

1. Describe and understand the different types of molecular diagnostic tests and how they are used.
2. Evaluate the performance criteria for molecular diagnostic tests both in the market and in development.
3. Understand the underlying technologies used in molecular diagnostic tests.
4. Evaluate data from different stages of developing a molecular diagnostic and select optimal conditions based on the data from each stage.
5. Produce a plan for developing a novel molecular diagnostic as part of a team.
6. Effectively search the published literature for relevant information.
7. Efficiently read and extract relevant information from sources you identify.
8. Use reflective thinking to identify what you know about a subject and what you need to learn next.

Format: This course will be delivered using a directed studies approach. It is a blend of synchronous (online class meeting) and asynchronous (study on your own time) learning with an emphasis on group/team-based learning. Most of the content of the course will come from student-lead research into aspects of molecular diagnostics guided by asynchronous materials and assignments posted on Brightspace. You will need to find research papers and any other information necessary to answer questions about molecular diagnostics. We will meet using Zoom on Tuesdays at 1:30 pm for approximately 50-80 minutes each week to discuss the asynchronous materials and to allow for some in-class group discussion. In addition to the in-class group work, you will participate in a separate weekly meeting outside of class set up by your group in Zoom or Microsoft Teams. **Because of the requirement for synchronized class time and group work, your attendance is mandatory. This course cannot be taken asynchronously. Attendance will be recorded at the beginning of each Tuesday class meeting, so it is important that you show up on time.**

Course Structure

Module 1 Overview of Molecular Diagnostics (MDx)

- Week 1 (September 9-15)
 - what is the definition of molecular diagnostic?
 - what basic technologies are used in nucleic acid-based MDx?
 - what testing strategies have been used in the covid pandemic?
 - what do you know and what do you need to learn about nucleic acid based MDx?
- Week 2 (September 15-22)
 - what are the key performance parameters used to determine testing quality?
 - how do these performance parameters affect the accuracy of the tests?
 - how many and what kinds of tests have been approved through the FDA "emergency use authorization" (EUA) process?
 - what went well and what didn't go well in the covid testing landscape?

Module 2 Developing a covid test - nucleic acid extraction

- Week 3 (September 22-29)
 - what are clinical sample types for covid testing?
 - how much virus is in these samples?
 - what are the challenges of trying to extract viral RNA from each sample?
- Week 4 (September 29-October 6)
 - how is a sample prep method developed?
 - analyzing data
- Week 5 (October 6-13)
 - how is a sample prep method optimized and validated?
 - analyzing data

Module 3 Developing a covid test - nucleic acid amplification

- Week 6 (October 13-20)
 - how do thermal cycling and isothermal amplification differ?
 - what are the different methods for isothermal amplification?
 - how is a target sequence chosen in a pathogen's genomic DNA or RNA?
 - how does target choice affect the specificity of a test?
- Week 7 (October 20-27)
 - how are candidate LAMP assays designed and tested?
 - how are the best LAMP assays optimized?
 - analyzing data
- Week 8 (October 27-November 3)
 - what are the effects of buffer and sample components on LAMP assay performance?
 - analyzing data

Module 4 Final Group Assignment

Produce a plan for developing a novel molecular diagnostic test

- Week 9 (November Nov3-17)
 - complete and present your outline for developing the plan
- Week 10 (November 17-24)
 - presentation of first draft of plan in class for peer feedback
- Week 11 (November 24-December 1)
 - presentation of final plan in class

Grading:

Category of Work	Due Dates	% of final grade
Low stake quizzes on course materials <ul style="list-style-type: none">• Course outline• Weekly videos	Every Tuesday at noon	10%
Short individual assignments <ul style="list-style-type: none">• small research assignments• reflective thinking discussion posts	Every Tuesday at noon	15%
Long individual assignments <ul style="list-style-type: none">• written assignment 1• written assignment 2	October 6 November 17	10% 10%
Contributions to group work <ul style="list-style-type: none">• Written contributions in advance	Every Friday at 5 pm	15%
Short group in-class presentations <ul style="list-style-type: none">• weekly or biweekly update on topics	Tuesday in class	20%
Final group project <ul style="list-style-type: none">• initial outline• draft plan presentation• final plan presentation	November 17 November 24 December 1	5% 5% 10%

Workload

- You will spend ~30 minutes per week before class watching powerpoint presentations of background information
- You will spend ~5-10 minutes per week answering low stake short answer quizzes on the presentations
- You will spend 15 minutes per week writing a reflective thinking post consisting of a point-form summary of the three take home lessons you learned from the videos or small research assignment and proposing one or more ideas of what you need to learn next
- You will spend ~15-20 minutes per week preparing a point-form summary of your group contribution and posting on Brightspace
- You will spend 60-80 minutes in class on Tuesdays. This time will be divided between answering questions that have arisen from the course materials, brief presentations on progress from each group, followed by discussion of what to learn next and then an initial meeting with your group to assign responsibilities for the weekly group week
- You will spend 1-2 hours per week in a second out-of-class group meeting to work on the weekly group assignment
- You will likely spend ~1-2 hours per week doing literature searches and other research into weekly topics

Anticipated total workload hours per week: 6-7

Note: The emphasis in this course is on thinking about questions that lead to ideas about molecular diagnostic testing and developing those ideas into an understanding of the key issues and processes. Most assignments require point-form or very short (several sentences) answers to a few questions. The exceptions are the two long individual assignments and the final group project. **There are no tests or exams in this course.**

UVic Grading Scheme

A ⁺	90 -100	B ⁺	77 - 79	C ⁺	65 - 69	F	< 50
A	85 - 89	B	73 - 76	C	60 - 64	N **	< 50
A ⁻	80 - 84	B ⁻	70 - 72	D	50 - 59		

** N grades

Students who have completed the following elements will be considered to have completed the course and will be assigned a final grade:

- *Weekly online quizzes are the only optional element in this course*
- *You must complete 80% of the short individual assignments*
- *You must complete both long individual assignments*
- *You must complete all of the individual contributions to group work*
- *You must complete all group work (short assignments and final assignment)*

Failure to complete one or more of these elements will result in a grade of “N” regardless of the cumulative percentage on other elements of the course. An N is a failing grade, and it factors into a student’s GPA as 0. The maximum percentage that can accompany an N on a student’s transcript is 49.

DEPARTMENT INFORMATION AND POLICIES

1. The Department of Biochemistry and Microbiology upholds and enforces the University’s policies on academic integrity. These policies are described in the current University Calendar. All students are advised to read this section.
2. Cell phones, computers, and other electronic devices must be turned off at all times during live class sessions unless being used for the purpose of connecting and engaging with the class.
3. No recordings of live lectures are permitted without permission of the instructor. Many online courses will be recorded by the instructor for accessibility for students unable to attend. If you do not wish to be recorded, contact your instructor to determine if alternative arrangements can be made.
4. Course materials, such as notes, problem sheets, quizzes, examinations, example sheets, or review sheets, may not be redistributed without the explicit written permission of the instructor.
5. Students are expected to be available for all exams. Instructors may grant deferrals for midterm examinations for illness, accident, or family affliction. Although students do not require documentation, students must contact their instructor and BCMB office (biocmicr@uvic.ca) with the reason for their absence within 48 hours after the midterm exam. The Department will keep a record of the absences. It is the responsibility of the student to ensure all required components are complete, and to arrange deferred exams/assignments with the instructor, which normally should occur within one week of the original exam date.
6. The Department of Biochemistry and Microbiology considers it a breach of academic integrity for a student taking a deferred examination to discuss the exam with classmates. Similarly, students who reveal the contents of an examination to students taking an examination are considered to be in violation of the University of Victoria policy on academic integrity (see current University Calendar). Students must abide by UVic academic regulations and observe standards of scholarly integrity (no plagiarism or cheating).

Online exams must be taken individually and not with a friend, classmate, or group, nor can you access notes, course materials, the internet, or other resources without the permission of the instructor. You are prohibited from sharing any information about the exam with others. Use of unauthorized electronic devices and accessing the internet and class material during exams is prohibited unless permission is granted by the instructor. Instructors may use Browser Lockdown Software to block access during classes and exams.

7. Deferral of a final exam must be requested with an Academic Concession form and submitted directly to Undergraduate Records. Deferred final exams for fall term courses will be arranged by the instructor. Deferred final exams or spring term courses will be arranged through Undergraduate Records and must be written before the end of the summer term as stipulated in the University Calendar.
8. Requests for review/remark of a midterm exam must be made within one week of the exam being returned.
9. The instructor reserves the right to use plagiarism detection software or other platforms to assess the integrity of student work.
10. Supplemental exams or assignments will not be offered to students wishing to upgrade their final mark
11. Anonymous participation in online classes is not permitted without permission of the instructor.

The current pandemic is placing added stressors- financial, mental, and physical- on everyone. Your wellbeing is of foremost importance. If you are experiencing difficulties coping, the University has resources to help. Reach out to [Counselling Services](#), [the Centre for Academic Communication](#), or [Learning Assistance Program for assistance](#).

Centre for Accessible Learning: Students with diverse learning styles and needs are welcome in this course. In particular, if you have a disability/health consideration that may require accommodations, approach the Centre for Accessible Learning (CAL) as soon as possible in order to assess your specific needs.

<https://www.uvic.ca/services/cal/index.php>

Course Experience Survey (CES)

We value your feedback on this course. Towards the end of term you will have the opportunity to complete a confidential course experience survey (CES) regarding your learning experience. The survey is vital to providing feedback to us regarding the course and our teaching, as well as to help the department improve the overall program for students in the future. When it is time for you to complete the survey, you will receive an email inviting you to do so. If you do not receive an email invitation, you can go directly to your [CES dashboard](#). You will need to use your UVic NetLink ID to access the survey, which can be done on your laptop, tablet or mobile device. We will remind you nearer the time but please be thinking about this important activity.