BMD 513: Principles of Diagnostic Technology: Immunoassays

Course and Faculty Information

Course Description: The Principles of Diagnostic Technology: Immunoassays course is designed to achieve two major goals. The first is to introduce the student to the field of biomedical diagnostics through a series of lectures and readings providing a high level overview. This will bring preliminary familiarity to major areas and concepts in this field which will be covered in more detail in either this course or other courses offered in this Master's degree program. Second major goal is to introduce the development and implementation of immunoassays, the most prevalent class of diagnostic tests offered beyond the taking of vital signs. This will be achieved by first learning some of the relevant basic concepts in Immunology and followed by the descriptions of immunoassay formats, assay development, applications and bioethics.

Credits: 4

Prerequisites: degree- or nondegree-seeking graduate student; Credit is allowed for only BMD 513 or BMD 598 (Principles of Diagnostic Technology 2: Immunology)

Instructor: Carl Yamashiro, Ph.D.

Contact Info: carl.yamashiro@asu.edu; (480) 884-0348

Office Hours: By appointment arranged by email

Course Learning Outcomes

At the completion of this course, students will be able to:

1. Develop a preliminary understanding of the major areas in biomedical diagnostics
2. Apply key concepts of immunology relevant to immunoassay design and development
3. Identify the major immunoassay types
4. Describe assay standards for analysis and quality
5. Identify the major types of applications for immunoassays
6. Understanding bioethical issues to guide the design and utilization of immunoassays

Textbooks

There is one required text for this course: "The Immunoassay Handbook, Fourth Edition: Theory and applications of ligand binding, ELISA and related techniques". Edited by David Wild. 2013.

- ISBN-10: 0080970370
- ISBN-13: 978-0080970370

The text is available online from a variety sources such as Amazon and comes in several different formats including e-Text.

Course Access

Your ASU courses can be accessed by both my.asu.edu and myasucourses.asu.edu; bookmark both in the event that one site is down.

Computer Requirements

This is a fully online course; therefore, it requires a computer with internet access and the following technologies:

- Web browsers (Chrome, Mozilla Firefox, or Safari)
- Adobe Acrobat Reader (free)
- Adobe Flash Player (free)
- Webcam, microphone, headset/earbuds, and speaker
- Microsoft Office (Microsoft 365 is free for all currently-enrolled ASU students)
- Reliable broadband internet connection (DSL or cable) to stream videos.

Note: A smartphone, iPad, Chromebook, etc. will not be sufficient for completing your work in ASU Online courses. While you will be able to access course content with mobile devices, you must use a computer for all assignments, quizzes, and virtual labs.

Course Topics, Schedule & Grading

Activities used for assessment of course objectives include: participation in course discussions; exams and quizzes, and a practical final exam.

ACTIVITIES/ASSIGNMENTS • All assignments are due at **11:59 pm** on dates shown	**DUE DATE**
Getting Started	
Review: Course syllabus, course tour videos, and all pertinent course information	8/23/19
Post: • Initial post to Introduction to *Welcome and Introductions* Forum • Post response(s) to peers	 8/25/19 8/29/19

Complete: ● Browser Check ● Syllabus Quiz ● Academic Integrity Agreement	 8/23/19 8/23/19 8/25/19
Unit 1: An Introduction to Biomedical Diagnostics	
View: Unit 1 Introduction Important Learning Advice from your TA (there is no TA for this term's course but this can still be useful for the course and program)	8/24/19
Week 1: History of Biomedical Diagnostics	
Required Readings: 1. A brief history of medical diagnosis and the birth of the clinical laboratory (Berger) ● Part 1 - Ancient times through the 19th century ● Part 2 - Laboratory science and professional certification in the 20th century ● Part 3 - Medicare, government regulation and competency certification ● Part 4 - Fraud and abuse, managed care and lab consolidation 2. Laboratory Medicine in the 21st Century (Burke) **Supplemental Readings:** ● The History of Chemical Laboratory Equipment (Szabadvary) ● Clinical Chemistry through Clinical Chemistry: A Journal Timeline (Rej) ● Genetics and molecular biology in laboratory medicine, 1963-2013 (Whitfield) ● New Thinking on Clinical Utility: Hard Lessons for Molecular Diagnostics (Peabody, et al.) ● One Hundred Years of Drug Regulation: Where Do We Go from Here? (Woosley)	8/25/19
View: The History & Impact of Diagnostics, Personalized Medicine, and Companion Diagnostics (Aspinall)	8/26/19
Submit: Week 1 Quiz	8/28/19
Week 2: Disease	
Read:	8/31/19

• Hofmann-Apitius et al. 2015. Towards reforming the taxonomy of human disease. Nature Reviews Drug Discovery, 14: 75-76. • Lazarin et al. 2014. Systematic Classification of Disease Severity for Evaluation of Expanded Carrier Screening Panels. PLOS, 2014.	
View: Disease Lecture	9/1/19
Submit: Week 2 Quiz	9/4/19
Week 3: Technology	
Read: • (Frantzi, et al.) Clinical proteomic biomarkers: relevant issues on study design & technical considerations in biomarker development. (pp. 1-4 and 16-17) • (Durmaz, et al.) Evolution of Genetic Techniques: Past, Present, and Beyond (Sepulveda and Young) • The Ideal Laboratory Information System (pp. 1129-1130, and the first paragraph for each of the functionalities through the remainder of the article) • (Moore and McGrath) New technologies help labs tackle old diagnostics problems. • (Khosla) Technology will replace 80% of what doctors do.	9/7/19
View: Technology Lecture	9/8/19
Submit: Week 3 Quiz	9/11/19
Week 4: Applications	
Read: • Groves, E. (2010). From biomarkers to diagnostics: The road to success Click for more options . Quintiles white paper. The required reading for this article is pp. 3-7. The rest is optional reading. • Quality System (QS) Regulation/Medical Device Good Manufacturing Practices (web site) • Quality System Regulation (web site)	9/14/19
View: Applications Lecture	9/15/19
Post: • Initial post to Week 4 discussion • Response(s) to peers	 9/15/19 9/18/19

Submit: Unit I Exam	9/19/19
Unit 2: The Immune System	
View: Unit 2 Introduction	9/20/19
Week 5: An Introduction to the Immune System	
Read: • Cellular and Molecular Immunology Module1: Introduction, pp. 1-12 • INTRODUCTION TO IMMUNOLOGY I. The Normal Immune Response, pp. 1-7	9/21/19
Complete: Learning Object 1 ● Section 1: all ● Section 2: 2.1-2.2 ● Section 3: all ● Section 4: all	9/23/19
Submit: Week 5 Quiz	9/25/19
Week 6: The Innate Immune System and Adaptive Immunity	
Read: • Cellular and Molecular Immunology Module1: Introduction, pp. 13-32 • "Cell Types" which is a supplemental attachment to LO2 • "The Fundamentals of MHC" which is a supplemental attachment to LO3	9/29/19
Complete: ● Learning Object 2 ● Learning Object 3 ○ Section 1: all ○ Section 2: 2.1-2.2; 2.11-2.16	9/30/19
Submit: Week 6 Quiz	10/2/19
Week 7: The Science of Antibodies	
Read: Selected portions from the online series, What is Biotechnology? • Introduction to the Exhibition • Early Antibody Research • The Making of Monoclonal Antibodies • The Patent Saga • The First Clinical Applications of Monoclonal Antibodies	10/5/19

Complete: Learning Object 4	10/6/19
Post: ● Initial post to Week 7 discussion ● Response(s) to peers	 10/6/19 10/9/19
Submit: Unit 2 Exam	10/10/19
Unit 3: Immunoassays	
View: Unit 3 Introduction	10/11/19
Week 8: Immunoanalysis	

Read:
• The Immunology Handbook (textbook)
  ○ Chapter 1.2, Immunoassays for Beginners, pp. 7-10
  ○ Chapter 1.3, Immunoassay Performance Measures, pp 11-22, 25-26
  ○ Chapter 2.1, Immunoassay Configurations, p. 29, pp. 34-38, 50-56
  ○ Chapter 2.4, Lateral Flow Immunoassay Systems…, pp. 89-91
• Introduction to Flow Cytometry: A Learning Guide, by BD Biosciences: pp. 5-6, 9-11, 13-14, 16-18, 22-23, 26. The remainder of the document is optional reading.
	10/13/19

Complete: Learning Object 6	10/14/19
Submit: Week 8 Quiz	10/16/19
Week 9: Antibody Protection	

Read:
• The Immunology Handbook (textbook)
  ○ Chapter 3.1, Antibodies, pp. 249, 254-256, 261-263
  ○ Chapter 3.3, Separation Systems, pp. 287-295
  ○ Chapter 3.4, Conjugation Methods, pp. 301-305, 311-313
• Case Study 1: Development of monoclonal antibodies against *Listeria monocytogenes*.
• Affinity Chromatography
• Enzyme-Linked Immunoassay Formats
	10/20/19

Complete: Learning Object 7	10/21/19

Submit: Week 9 Quiz	10/23/19
Week 10: Recombinant Antibodies	
Read: • The Immunology Handbook (textbook) ○ Chapter 3.1, Antibodies, pp. 249, 254-256, 261-263 (review of material read from last week) • Case Study 2: Development of recombinant antibodies to algal-toxins • Introduction to cloning • Case Study 3: DiCAST – Innovation in drug discovery	10/27/19
Complete: Learning Object 8	10/28/19
Submit: Week 10 Quiz	10/30/19
Week 11: Antibodies - Diagnostic & Therapeutics	
Read: • The Immunology Handbook (textbook) ○ Chapter 3.1, Antibodies, pp. 254-256 (reread) • Scott, A.M., et al. (2012). Antibody therapy of cancer. Nature Reviews Cancer, 12: 278-287. • Byrne, H., et al. (2013). A tale of two specificities: Bispecific antibodies for therapeutic and diagnostics applications. Trends Biotechnol., 31: 621-632. • Brennan, J., et al. (2003). Production, purification and characterization of genetically derived scFv and bifunctional antibody fragments capable of detecting illicit drug residues. J. Chromatography, 786: 327-342. • Case Study 4: Development of prostate cancer-specific recombinant antibodies	11/2/19
Complete: Learning Object 9	11/3/19
View: More on Immunoassays and Review	11/3/19
Post: ● Initial post to Week 11 discussion ● Response(s) to peers	 11/3/19 11/6/19
Submit: Unit 3 Exam	11/7/19
Unit 4: Immunoassays 2	
View: Unit 4 Introduction	11/8/19

Week 12: Biosensors	

Read:
• The Immunology Handbook (textbook)
  ○ Chapter 4.1 Related Techniques – Qualification by Diffusion in Gel (1961-1977), pp. 342-344.
  ○ Chapter 4.1 Related Techniques – Quantification of Antigens by In-Gel Immunochemistry (1963-Present). pp. 345-347.
  ○ Chapter 6.2 Immunoassay Implementation – Point-of-Care Testing, pp. 455-463.
  ○ Chapter 2.11 Immunoassay Configurations – Immunological Biosensors, pp. 203-207.
• Case Study 5: The role of auto-antigens in colorectal cancer tissue Click for more options
• Case Study 6: Use of Biacore for high throughput antibody screening
	11/10/19

Complete: Learning Object 10	11/11/19
Submit: Week 12 Quiz	11/13/19
Week 13: Antibodies for Tumor Detection	
Read: ● The Immunology Handbook (textbook) ○ Chapter 9.13: pp. 833-838, 846-847 ● Article: Partin el al., Prostate-Specific Antigen as a Marker of Disease Activity in Prostate Cancer: Part 1, Cancer Network, 2002. ● Instructions for Completing the Final Practical Exam (in Canvas – Need to start to prepare the paper for the exam that is due on	11/17/19
Complete: Learning Object 11	11/18/19
View: • Writing using APA Style and Format	11/18/19
Submit: Week 13 Quiz	11/20/19
Week 14: Ethics and Course Summary	
Read: Osborne NJ, Payne D, Newman ML. Journal Editorial Policies, Animal Welfare, and the 3Rs	11/24/19
Complete: Learning Object 12	11/24/19

View: • Bioethics Supplement	11/25/19
Post: • Initial post to Week 14 discussion • Response(s) to peers	11/24/19 11/27/19
Submit: Unit 4 Exam	11/29/19
Week 15: Review	
Read: Review required readings	12/3/19
View: • Immunology Course Review	12/5/19
Submit: Course Evaluation	12/6/19
Submit: Final Practical Exam	12/7/9

Grading

Your grade will be determined based on the following grading schema:

Grade	Percentage	Points Range
A	94-100%	940-1000
A-	90-93.9%	900-939
B+	87-89.9%	870-899
B	83-86.9%	830-869
B-	80-82.9%	800-829
C+	77-79.9%	770-799
C	73-76.9%	730-769
C-	70-72.9%	700-729
D+	67-69.9%	670-699
D	63-66.9%	630-669

D-	60-62.9%	600-629
E	Below 60%	0-599

Submitting Assignments

All assignments, unless otherwise announced, MUST be submitted to the designated area of Canvas. Do not submit an assignment via email.

Assignment due dates follow Arizona Standard time. Click the following link to access the Time Converter to ensure you account for the difference in Time Zones. Note: Arizona does not observe daylight savings time.

Grading Procedure

Grades reflect your performance on assignments and adherence to deadlines. Grades on assignments will be available within 72 hours of the due date in the Gradebook.

Late or Missed Assignments

Notify the instructor **BEFORE** an assignment is due if an urgent situation arises and you are unable to submit the assignment on time.

Follow the appropriate University policies to request an accommodation for religious practices or to accommodate a missed assignment due to University-sanctioned activities.

Unauthorized late assignments will be assessed deductions of 15% of the total points for that assignment per day that it is past the due date.

Communicating With the Instructor

Community Forum

This course uses a discussion board called "Community Forum" for general questions and comments about the course. Prior to posting a question, check the syllabus, announcements, and existing posts. If you do not find an answer, post your question. You are encouraged to respond to the questions of your classmates.
Email questions of a personal nature to your instructor. You can expect a response within 72 hours.

Chat

The Chat tool in Canvas allows students and teachers to interact in real time. Use Chat only for informal course-related conversations unless your instructor informs you otherwise. Chat is not ideal for questions about assignments; instructors are not required to monitor it and conversations may be buried or lost.

Email

ASU email is an official means of communication among students, faculty, and staff. Students are expected to read and act upon email in a timely fashion. Students bear the responsibility of missed messages and should check their ASU-assigned email regularly.
All instructor correspondence will be sent to your ASU email account.

ASU Online Course Policies

View the ASU Online Course Policies

Student Success

To be successful:

- check the course daily
- read announcements
- read and respond to course email messages as needed
- complete assignments by the due dates specified
- communicate regularly with your instructor, TA and peers
- create a study and/or assignment schedule to stay on track

Drop and Add Dates/Withdrawals

This course adheres to a set schedule and may be part of a sequenced program, therefore, there is a limited timeline to drop or add the course (http://students.asu.edu/academic-calendar). Consult with your advisor and notify your instructor to add or drop this course. If you are considering a withdrawal, review the following ASU policies:

- Withdrawal from Classes (http://www.asu.edu/aad/manuals/ssm/ssm201-08html)
- Medical/Compassionate Withdrawal (http://www.asu.edu/aad/manuals/ssm/ssm201-09html)
- Grade of Incomplete (http://www.asu.edu/aad/manuals/ssm203-09.html)

Grade Appeals

Grade disputes must first be addressed by discussing the situation with the instructor. If the dispute is not resolved with the instructor, the student may appeal to the department chair per the University Policy for Student Appeal Procedures on Grades (https://catalog.asu.edu/appeal).

Student Conduct and Academic Integrity

ASU expects and requires its students to act with honesty, integrity, and respect. Required behavior standards are listed in the Student Code of Conduct and Student Disciplinary Procedures (http://www.asu.edu/aad/manuals/ssm/ssm104-01.html), Computer, Internet, and Electronic Communications policy (http://www.asu.edu/aad/manuals/acd/acd125.html), ASU Student Academic Integrity Policy (http://provost.asu.edu/academicintegrity), and outlined by the Office of Student Rights & Responsibilities (https://eoss.asu.edu/dos/srr). Anyone in violation of these policies is subject to sanctions.

Students are entitled to receive instruction free from interference by other members of the class (http://www.asu.edu/aad/manuals/ssm/ssm104-02.html). An instructor may withdraw a student from the course when the student's behavior disrupts the educational process per Instructor Withdrawal of a Student for Disruptive Classroom Behavior (http://www.asu.edu/aad/manuals/usi/usi201-10.html).
Appropriate online behavior (also known as *netiquette*) is defined by the instructor and includes keeping course discussion posts focused on the assigned topics. Students must maintain a cordial atmosphere and use tact in expressing differences of opinion. Inappropriate discussion board posts may be deleted by the instructor. The Office of Student Rights and Responsibilities accepts incident reports (https://eoss.asu.edu/dos/srr/filingreport) from students, faculty, staff, or other persons who believe that a student or a student organization may have violated the Student Code of Conduct.

Prohibition of Commercial Note Taking Services

In accordance with ACD 304-06 Commercial Note Taking Services (http://www.asu.edu/aad/manuals/acd/acd304-06.html), written permission must be secured from the official instructor of the class in order to sell the instructor's oral communication in the form of notes. Notes must have the note taker's name as well as the instructor's name, the course number, and the date.

Course Evaluation

Students are expected to complete the course evaluation. The feedback provides valuable information to the instructor and the college and is used to improve student learning. Students are notified when the online evaluation form is available.

Accessibility Statement

Disability Accommodations: Qualified students with disabilities who will require disability accommodations in this class are encouraged to make their requests to me at the beginning of the semester either during office hours or by appointment. Note: Prior to receiving disability accommodations, verification of eligibility from the Disability Resource Center (DRC) is required. Disability information is confidential.
Establishing Eligibility for Disability Accommodations: Students who feel they will need disability accommodations in this class but have not registered with the Disability Resource Center (DRC) should contact DRC immediately. Students should contact the Disability

Resource Center, campus-specific location and contact information (https://eoss.asu.edu/drc/contactus) can be found on the DRC website. DRC offices are open 8 a.m. to 5 p.m. Monday – Friday. Check the DRC website (http://eoss.asu.edu/drc) for eligibility and documentation policies.
Email: DRC@asu.edu
DRC Phone: (480) 965-1234
DRC FAX: (480) 965-0441

Title IX

Title IX is a federal law that provides that no person be excluded on the basis of sex from participation in, be denied benefits of, or be subjected to discrimination under any education program or activity. Both Title IX and university policy make clear that sexual violence and harassment based on sex is prohibited. An individual who believes they have been subjected to sexual violence or harassed on the basis of sex can seek support, including counseling and academic support, from the university. If you or someone you know has been harassed on the basis of sex or sexually assaulted, you can find information and resources at http://sexualviolenceprevention.asu.edu/faqs/students

Syllabus Disclaimer

The syllabus is a statement of intent and serves as an implicit agreement between the instructor and the student. Every effort will be made to avoid changing the course schedule but the possibility exists that unforeseen events will make syllabus changes necessary. Remember to check your ASU email and the course site often.