

Clinical Performance Objectives in Immunology
Department of Medical and Research Technology
University of Maryland School of Medicine
Spring 2015

Upon completion of the **Clinical Immunology** rotation, the MLS student will be able to:

I. SPECIMEN HANDLING AND PROCESSING/LABORATORY SAFETY

1. Following departmental protocol, demonstrate safe work practices by:
 - a. Wearing personal protective equipment (PPE) as required.
 - b. Handling and disposing of contaminated materials according to standard precautions.
 - c. Handling chemicals according to safety procedures.
2. State the specimen collection and handling requirements for each immunologic test.
3. Evaluate patient specimens for acceptability in terms of patient identification, hemolysis, lipemia and test volume requirements, according to established laboratory policy.
4. If patient specimens are determined to be unacceptable, identify the correct resolution.

II. QUALITY CONTROL AND QUALITY ASSURANCE

1. Prepare controls and reagents within acceptable QA limits.
2. Aliquot, using appropriate technique, control samples into designated areas (tubes, wells, or analyzer cups) for each assay performed.
3. Using established criteria, determine whether or not available controls and reagents are acceptable for use according to lab protocol.
4. Recognize all critical values obtained during patient testing as abnormal.
5. Communicate critical values immediately to clinical instructor.
6. State the confidentiality policy of the facility during testing procedure and reporting in accordance with HIPAA guidelines.
6. Observe basic laboratory computer applications where relevant.
7. Review quality control data for a minimum of three (3) different immunology assays performed in the laboratory.

8. Evaluate quality control data according to established laboratory guidelines.
9. Discuss appropriate actions for unacceptable control results.

III. CORE KNOWLEDGE AND SKILLS

1. Demonstrate pipetting technique in accordance with manufacturers' instructions using all available types of pipettes.
2. Pipette reagents and samples accurately.
3. Calculate all specimen dilution concentrations with 100% accuracy.
4. To the satisfaction of the clinical instructor:
 - a. Demonstrate how to correctly calculate both serial and non-serial dilutions.
 - b. Given sensitivity and specificity data on three (3) immunologic assays (from package inserts) choose the most appropriate method to reliably determine patient results for a given analyte.
 - c. Perform one (1) serial dilution to set up for an immunologic assay.

IV. IMMUNOLOGY ASSAY METHODOLOGIES/INSTRUMENTS

1. Discuss the theories/principles of operation of the following assays:
 - Direct immunofluorescence
 - Indirect immunofluorescence
 - ELISA (EIA) sandwich technique
 - Western blot
 - FPIA
 - Flow cytometry
2. Identify the common immunological application of the: fluorometer, chemiluminometer, photometer and fluorescence microscope.
3. Perform if available, the following assays to the satisfaction of the clinical instructor: Latex agglutination, Hemagglutination, EIA.
4. Observe, if available on site, the following assays: Immunodiffusion, Direct and indirect immunofluorescence, FPIA, Flow cytometry.
5. If available, load QC and patient samples on an automated analyzer according to standard operating procedures.

6. If available, perform one (1) automated analyzer start-up procedure according to established laboratory protocols.
7. If available, interpret quality control on an automated assay, matching the clinical instructors' result with 100% accuracy.

V. BACTERIAL SEROLOGY: NON TREPONEMAL (VDRL, RPR) TREPONEMAL (FTA-ABS), STREPTOZYME, LYME DISEASE

1. To the satisfaction of the clinical instructor:
 - a. Discuss the theory/principle of each test.
 - b. Correlate the disease manifestations with expected test results for each assay.
 - c. Explain the significance of reactive, weakly reactive and non-reactive results in the RPR test.
 - d. Discuss instances where false positive and false negative RPR and FTA-ABS reactions might be expected to occur.
 - e. Perform RPR assay QC/calibration techniques (temperature, needle, rotator) according to lab protocol.
 - f. Interpret with 100% accuracy a minimum of 10 RPR screening tests.
 - g. Perform a minimum of 2 RPR titers on previously reactive specimens, matching the technologist's results within +/- one dilution factor.
 - h. Compare & contrast the RPR and FTA-ABS assays for syphilis in terms of sensitivity, specificity, use in diagnosis, and use in monitoring therapy.
 - i. Discuss or perform the Streptozyme assay on a minimum of 2 specimens.
 - j. Discuss or perform the screening and/or confirmatory western blot for Lyme Disease on a minimum of two (2) specimens.

VI. VIRAL SEROLOGY - HEPATITIS A-C, EBV, HIV, RUBELLA, CMV, HERPES

1. Correlate viral markers with clinical disease for the following: Hepatitis A, B, C; EBV; HIV; Rubella; CMV.
2. List the viral markers used to screen blood donor units.
3. Discuss or perform a hepatitis assay.
4. Explain the theory/principle of screening tests for infectious mononucleosis.
5. Perform a minimum of five (5) screening tests for infectious mononucleosis, matching the technologist's results with 100% accuracy.

6. If available, using the laboratory's standard operating procedure manual as a reference, discuss the process of setting up, performing and interpreting an HIV antibody screen with your clinical instructor.
7. Discuss how ELISA and Western blot tests are used to diagnose HIV infection.
8. Discuss the TORCH panel with regard to its use and clinical significance.

VII. AUTOIMMUNITY ASSAYS– ANA, CRP, C3, C4, RF, THYROID ANTIBODIES

1. Observe, perform or discuss the following:
 - ANA assay (both fluorescence and enzyme methods)
 - CRP
 - C3
 - C4
 - RF
 - Thyroid antibodies
2. When given electronic images or slides, visually identify the following ANA patterns: homogeneous, peripheral (rim) speckled, nucleolar, and centromere.
3. When given electronic images or slides, correlate the ANA patterns seen with the following disease states: SLE, Sjögrens Syndrome, Mixed Connective Tissue Disease (MCTD), Progressive Systemic Sclerosis (Scleroderma) and CREST Syndrome.
4. If available on site, resolve technical, instrument, and/or physiologic causes of problems or unexpected test results for each assay performed to the satisfaction of the clinical instructor.

PROFESSIONAL QUALITIES

1. Arrive at the laboratory on time and return from lunch/breaks on time.
2. Adhere to the established student uniform policy of the MLS program.
3. Notify the clinical supervisor of any unavoidable absences prior to the scheduled arrival time and make arrangements to make up the time on a mutually convenient date.
4. Demonstrate the ability to follow verbal and written instructions including written protocols and procedures and ask pertinent questions.

5. Communicate in a constructive, professional manner (i.e. polite, considerate, pleasant and unhurried) with members of the laboratory and hospital staff, peers and patients.
6. Organize work in a logical sequence.
7. Complete work and assignments within established deadlines.
8. With the approval of the clinical instructor, demonstrate the initiative to perform tasks without being reminded.
9. Demonstrate constructive utilization of all training time by examining available study materials during periods of time not devoted to instruction.
10. Demonstrate flexibility in changes to the scheduled daily learning activities due to laboratory staffing, emergencies, etc.
11. Demonstrate the ability to recognize and admit mistakes or discrepancies in laboratory protocols and/or results and, take appropriate corrective measures, including seeking help and notifying staff when needed.
12. Demonstrate the ability to accept professional constructive criticism regarding work.
13. Maintain the confidentiality of all patient information at all times in accordance with HIPPA regulations. This applies to patients or other unauthorized individuals and extends beyond the confines of the clinical setting.
14. Adhere to all published safety regulations in the laboratory.
15. Demonstrate professionalism in attitude, appearance and work ethic 100% of the time.
16. Adhere to standards and regulations regarding proper access and utilization of institutional computers.
17. Adhere to policies of the affiliate regarding the use of ALL electronic devices, including but not limited to, portable music players such as MP3 and Smart/cell phones.