

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

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, using laboratory policy.
4. If patient specimens are determined to be unacceptable, state the resolution.

II. **QUALITY CONTROL AND QUALITY ASSURANCE**

1. Prepare controls and reagents within acceptable QA limits.
2. Using established criteria, determine whether or not available controls and reagents are acceptable for use according to lab protocol.
3. Recognize all critical values obtained during patient testing as abnormal.
4. Report critical values immediately to clinical instructor.
5. 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. Explain how to correctly calculate both serial and non-serial dilutions.
  - b. Explain the concept of lattice theory in antigen/antibody reactions: prozone, equivalence, post zone (and how that might impact patient test results).
  - c. Determine corrective action that is needed upon recognizing when prozone has occurred.
  - d. Discuss the five classes of human immunoglobulins in terms of physical structure, biological activity and location(s).
  - e. Compare and contrast primary and secondary immune responses
  - f. Define the functions of the following cell types in regard to their role(s) in the humoral or cellular immune systems: neutrophil, monocyte, macrophage, eosinophil, basophil, B lymphocyte, T<sub>H</sub> lymphocyte, T<sub>C</sub> lymphocytes and NK cells.
  - g. Compare and contrast the terms sensitivity and specificity.

### IV. **IMMUNOLOGY ASSAY METHODOLOGIES/INSTRUMENTS**

1. Discuss the theories/principles of operation of the following assays:
  - Latex agglutination
  - Hemagglutination
  - immunodiffusion
  - Direct immunofluorescence
  - Indirect immunofluorescence
  - ELISA (EIA) sandwich technique
  - Western blot
  - FPIA
  - RIA
  - 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, RIA, Flow cytometry.

**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. Observe or discuss an HIV antibody screen.
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.