

# Medical Laboratory Science Program

**2021 Clinical Practicum Composite Manual** 

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## I. <u>INTRODUCTION</u>

The Clinical Practicum Rotation completes the final component of the student's professional phase of study. The practicum purposes to enhance the student's application of the clinical laboratory sciences theory and practical skills. Each clinical rotation site and department is designed to enhance the student's entry-level competencies.

The following rotations are:

Clinical Chemistry includes manual chemistry, instrumentation and

special chemistry

Clinical Hematology includes hematology and homeostasis

Clinical Immunohematology includes immunohematology and donor procedures

Clinical Microbiology includes bacteriology, mycology, parasitology,

virology, serology and molecular diagnostics

Urinalysis included as a part of Chemistry or Hematology

# II. <u>ORIENTATION</u>

Students will be given an orientation to each facility during the first days of the rotation or prior to the rotation. The following items will be included in the orientation.

- A. Introduction to Personnel
- B. Overview of Departmental Organization
- C. Explanation of Safety Regulations
- D. Review of Professional Performance Expectations
- E. Review of Grading and Attendance Policy

## III. MEDICAL LABORATORY SCIENCE PROGRAM GOALS

The Medical Laboratory Science Program goals reflect the general philosophy and mission of Morgan State University. The goals of the Medical Technology Program are:

- 1. To comply with the accrediting agency standards and other policies to maintain an accredited Medical Laboratory Science program.
- 2. To develop and implement a curriculum, which prepares medical laboratory scientists with entry- level competencies, who accept and fulfill the roles of health care pratitoneers in diverse clinical laboratory settings or other related vocations.
- 3. To provide a professional and supportive environment or setting so as to encourage the graduate to obtain national certification as a Medial Laboratory Scientist (MLS).
- 4. To encourage the development of positive attitudes, behavior, interaction and communication among other health care professionals, other students and the general public.
- 5. To develop effective tools, programs and activities to recruit and retain students and persons interested in the MLS program and profession.

# IV. CAREER ENTRY COMPETENCIES

Upon completion of the Medical Laboratory Science Program, the graduates will be able to:

- 1. Perform the full range of clinical laboratory tests in the clinical laboratory.
- 2. Participate in the development and evaluation of test systems and interpretive algorithms.
- 3. Evaluate and correlate laboratory results for accuracy and clinical conditions and make corrective actions if needed.
- 4. Utilize quality assurance to monitor procedures, equipment and technical competency for the pre-analytical, analytical and post-analytical phase of testing.
- 5. Communicate and exhibit professional and ethical behavior with other health-care professionals and the community.
- 6. Comply with established laboratory safety and governmental regulations.
- 7. Demonstrate educational principles and practices to educate/train individuals for and about the profession.
- 8. Apply the principles of laboratory management such as administration, human resource management, financial, operations, regulatory compliance, critical pathways and marketing.
- 9. Evaluate published laboratory articles (studies) using research design skills and practices for possible implementation.
- 10. Obtain national certification as a Medical Laboratory Scientist and pursue employment in the medical laboratory field or a related field with the goal of continued professional development and improvement.

## V. TEACHING METHODS

Students will experience the following teaching activities and instructional aids:

- A. Lectures
- B. Computer-Assisted Materials
- C. Case Studies
- D. Performance of Laboratory Tests
- E. Demonstrations
- F. Continuing Education's Programs

### VI. EDUCATION POLICY

#### A. <u>Attendance Policy</u>

Student attendance in all areas of the clinical rotation is required. Students must be present five (5) days a week and eight (8) hours a day. Specifics of the scheduled times for each clinical rotation will be imparted by the different clinical instructors. Three (3) late arrivals will constitute an absence. Three (3) absences for the clinical practicum will constitute a failure for the practicum. Students will have to complete all of the assigned days for the practicums regardless of the academic status. Absence during any of the clinical rotations requires notification to the affiliate Clinical Coordinator and the Program Director (Dr. Diane Wilson, 443-885-3611) before the scheduled workday. The missed times will be made up at the discrepancy of the clinical instructors.

#### B. Working Hours

Students are scheduled to receive clinical education for eight (8) hours daily. The actual scheduled hours will vary depending on the clinical rotation site. The conventional time for the clinical laboratory science education is between 7:00 a.m. and 4:30 p.m., however, other scheduled times may be included for the different clinical rotation sites. Students will be given a work hour schedule. Each clinical rotation site will give the students a 30-minute lunch break. Students are expected to be on time and in the area assigned. Students must receive instruction from the Clinical Instructor before leaving the work area.

#### C. Inclement Weather

Inclement weather is defined as any weather conditions (snow, sleet, flooding, etc.) which may be averse to the students' mobility to the clinical rotation sites. If the University is having classes, students are expected to report to the clinical rotation site at the scheduled time. If the University is closed, the students should contact the Clinical Coordinator about not attending the clinical rotation site. The students must also communicate the absence(s) to the Program Director. Students are also responsible for all make up materials during the absent days.

#### D. Dress Code

Each student is encouraged to present a professional appearance and demeanor at all times. Students must adhere to the dress code established by the specific clinical rotation site and Morgan State University Medical Technology Program. Although each clinical rotation site has its own policy on the dress code, the following Morgan State University dress code guidelines must be followed during each clinical rotation unless it is not accepted by the clinical rotation site.

- 1. A white laboratory coat and appropriate dress clothing are highly recommended. Each clinical rotation laboratory site will furnish the OSHA required laboratory jacket. No blue jeans clothing or sweatshirts (with words) can be worn at any of the clinical rotation sites. Clothing items must cover all parts of the upper body (i.e., parts of the body above the knee).
- 2. Name tags/badges will be worn at all times.
- All hairstyles, which extend below the shoulder, must be tied back with an appropriate hair item.
- 4. Open-toed shoes, sandals, fabric sneakers, jeans, sweatshirts, caps and sunglasses are not permitted.
- Small post earrings which do not extend below the ear are acceptable.
   Males are not allowed to wear earrings in the laboratory settings didactic or clinical rotation. Long necklaces or dandling bracelets are not acceptable.
- 6. Body piercings and tattoos should be covered.
- 7. No pagers or cellular phones are permitted.

# E. Student Laboratory Responsibility

Each clinical laboratory rotation experience will enhance the student's integration of theory and practical skills. Students will perform actual laboratory testing under the supervision of the Clinical Instructor. Students cannot perform laboratory testing or report laboratory results without the supervision or co-signature of the Clinical Instructor.

Service Work is defined as the student performing the work for the assigned instructor. The MLS program does not condone Service work during the clinical rotation practicum. If employment opportunities are present for the students during the clinical rotation experience, the student will comply with all of the steps of the human resource department in obtaining the employment. Students will not be assigned to a clinical practicum site for any clinical practicum in which they are employed.

## F. <u>Laboratory Safety</u>

Students are expected to adhere to all of the safety regulations and guidelines for each clinical rotation site. Students are also required to wear a face shield while handling any biological specimens.

#### Student Accident Procedure

The Woolford Health Center and the Program recommend the following steps for handling an accident involving a student at the clinical rotation site.

- 1. Assist the student following employee's accident protocol.
- 2. Transport the student to the clinical rotation site's designated employees' health location.
- 3. Notify Program Director (443-885-3611) or Program Office (443-885-4469).
- 4. Obtain the Incident Report within 24 hours of the accident.
- 5. Submit the Incident Report to the Program Office and Woolford's Infirmary within 24-48 hours of the accident (443-885-1677 1700 E. Coldspring Lane, Baltimore, MD 21251).
- 6. Inform the student to report to the Program Office (if medically possible) on the same day of the accident.

### G. Grading

Evaluation of the student performance for each clinical rotation site is based on the following:

- 1. 50%-Clinical Practicums Component; 50%-MSU Campus Component. The student is required to make a grade of 75% on all components.
- 2. **Practicum Component** Daily laboratory performances, written examinations, reports, practical examinations and other forms of evaluation as deemed by the Clinical Instructor.
- 3. An outline of the grading format and schedule of evaluations will be given to the students.
- 4. For each 4-week rotation, an affective performance evaluation will be conducted at mid-rotation and at the completion of the rotation to guide the student in developing his/her professional growth.
- 5. Campus Component Pre-Rotation-15%; Weekly Assessments-15%; Post-Rotation Examinations-20%. The weekly assessments will be completed prior to taking the Post-Rotation Examination.

6. A final grade of **Pass or Fail** will be given. Students must attain an average minimal grade of **75%** on all didactic and graded laboratory performances to receive a final grade of **PASS**.

# H. Evaluations

Each student will be asked to perform an objective evaluation of each discipline for his/her clinical rotation site. The forms will be submitted to the students by the Program Director or the Education Coordinator. The results from the forms will be compiled and submitted to the respective Clinical Instructor.

## I. Professional Behavior

During the clinical rotations, all students are expected to perform as health care professionals in the hospital setting. The students are to respect and conform to departmental rules and policies as well as the policies of Morgan State University. Remember, this clinical experience offers you the opportunity not only to gain experience in the different disciplines, but also to present yourself as a potential employee at the various sites.

## J. Confidentiality

During your clinical rotation experiences, you will have access to patient information and patient laboratory results generated in the clinical laboratory setting. Although you may be excited that you are now able to correlate laboratory results to certain conditions, **remember names**, **laboratory results and suggested diagnoses are STRICTLY CONFIDENTIAL.** You cannot interpret or discuss laboratory results with the person who had the test performed. In addition, laboratory results and information for patients should not be discussed outside of the laboratory (e.g., cafeteria, home).

# VII. CLINICAL LABORATORY ROTATION AFFECTIVE OBJECTIVES

During the clinical rotation setting, the student will do the following:

- 1. Attend the scheduled clinical education rotations work sessions at the designated times.
- 2. Exhibit a willingness to complete all of the assigned tasks on time.
- 3. Comply with the rules and guidelines of the department.
- 4. Respond to constructive criticism in a positive proactive manner.
- 5. Offer assistance to other departmental personnel for the needed laboratory tasks and projects.
- 6. Seek assistance and guidance when needed in the laboratory setting.
- 7. Maintain the laboratory working area in a clean and organized manner.
- 8. Comply with the departmental policies on reporting unknown results.
- 9. Maintain patient result confidentiality.
- 10. Choose to understand the significance of the role of the clinical laboratory scientist in the health care profession.
- 11. Support and attend clinical laboratory science continuing education programs.
- 12. Develop positive strategies for coping with stressful experiences.
- 13. Maintain confidence and assurance in the operation of the various clinical laboratory instruments.
- 14. Comply with all the assigned student laboratory responsibilities.
- 15. Cooperate with instructors and other laboratory personnel to create a positive and efficient work environment.

## VIII. <u>CLINICAL AFFILIATE FACULTY - CLINICAL COORDINATORS</u>

- Mary Sadlowski, MT (ASCP)
   Greater Baltimore Medical Center
- 2. Suzy Nicol, MS, MT (ASCP), SBB Johns Hopkins Bayview Medical Center
- 3. Lorraine Blagg, MT (ASCP) SBB The Johns Hopkins Hospital
- 4. Ruth Umali, MT(ASCP)
  The Johns Hopkins Hospital
- 5. Paula C. Mister, MS, MT, SM (ASCP) <sup>CM</sup> The Johns Hopkins Hospital
- 6. Justina M. Pangallo, MLS (ASCP), SBB MedStar Good Samaritan Hospital
- 7. Marie Ziobro, MS, MT (ASCP), CQA, (ASQ) Mercy Medical Center
- 8. Raynese Richards Saint Agnes Healthcare
- 9. Diana Macfarlane, BS MLS III HEW University of Maryland Medical Center
- 10. Theresa Marolda, MT (ASCP) VA Medical Center-Baltimore

#### MLS 422- CLINICAL PERFORMANCE OBJECTIVES IN HEMATOLOGY

Upon completion of the Hematology Clinical Rotation, the MLS student will be able to:

# I. Specimen Handling and Processing

- 1. Comply with the standard operating procedure for specimen handling and distribution.
- 2. 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.
- 3. Accept only specimens that meet standard laboratory protocol.
- 4. Describe corrective measures for samples that are lipemic, icteric or contain paraproteins.
- 5. Describe corrective measures for samples that are rejected due to quantity not sufficient, wrong anticoagulant, cold agglutinin, clotted, hemolyzed, improper patient identification, or improper tube collected.
- 6. Describe how to handle suboptimal fluid samples.

## II. Quality Control, Quality Assurance, Regulatory Issues

- 1. Evaluate Quality Control results according to criteria established for each test.
- 2. Describe the various periodic (daily, weekly) maintenance routine for each piece of equipment used during clinical rotations.
- 3. Observe basic computer applications where relevant.
- 4. Document instrument maintenance and quality control.
- 5. Complete all work within established turn around time.

- 6. Report critical and discrepant results to clinical instructor/supervisor
- 7. State the confidentiality policy of the facility during testing procedures and reporting according to HIPPA guidelines.
- 8. Describe the process used to implement a new lot number of control material.

## III. <u>Technical Procedure for Hematology</u>

- 1. Operate automated hematology instrumentation with minimal supervision and within acceptable ranges.
- 2. Perform non-automated hematology testing with minimal supervision and within acceptable ranges.
- 3. Using the automated hematology analyzer, perform a minimum of <u>40</u> CBC's and differentials.
- 4. Recognize abnormal flags on automated instrumentation.
- 5. Recognize all critical values and/or discrepant results on CBC's and differentials.
- 6. Report all critical values and/or discrepant results on CBC's and differentials to the clinical instructor.
- 7. Identify the corrective actions necessary for abnormal automated results.
- 8. Differentiate between normal and abnormal scattergram (plot) patterns.
- 9. Identify normal(reference) values for the following routine assays:

WBC count RBC indicesRBC count platelet count

• Hemoglobin Sedimentation rate

• Hematocrit Reticulocyte count

- 10. Demonstrate proper technique in preparing peripheral smears for microscopic examination to the satisfaction of the clinical instructor.
- 11. Evaluate a minimum of <u>20-25</u> peripheral blood smears for acceptable cellular distribution and staining to the satisfaction of the clinical instructor.

- 12. Perform a minimum of <u>20-25</u> peripheral smears with a combination of normal and abnormal results with 95% proficiency.
- 13. Prepare a minimum of 20-25 platelets estimates, agreeing with instruments counts within 20%.
- 14. Identify abnormal red cell morphologies to include: microcytes, macrocytes, ovalocytes, spherocytes, target cells, sickle cells, schistocytes, burr cells, teardrops, acanthocytes, and rouleaux.
- 15. Grade abnormal red cell morphologies according to laboratory guidelines.
- 16. Identify qualitative white cell inclusions to include: toxic granulation, toxic vacuolization, Dohle bodies, and Auer rods.
- 17. Identify red cell inclusions to include: Howell Jolly bodies, Pappenheimer bodies, basophilic stipling, siderotic granules, and Heinz bodies.
- 18. Grade hypochromia and polychromasia according to laboratory guidelines.
- 19. Given a peripheral smear or kodachrome slide, identify the stages of immature white cells.
- 20. Given a peripheral smear or kodachrome slide, identify the stages of immature red blood cells.
- 21. Correct the WBC count for nucleated red blood cells according to laboratory guidelines.
- 22. Given a peripheral smear or kodachrome slide, recognize, but not speciate, malarial forms.
- 23. Recognize abnormal platelet morphology.
- 24. Perform **or** discuss reticulocyte counts. If performed, the results should be within 20% of technologist-recorded result.
- 25. Explain the principle of the ESR and factors which might interfere with accurate results.
- 26. Perform an ESR with minimum supervision and within QC guidelines.
- 27. Describe or perform a sickle cell screen (solubility test).
- 28. Interpret a sickle cell screen according to laboratory guidelines.
- 29. Associate abnormal hematological results with possible pathology.

- 30. Given electrophoretic patterns, recognize the normal and abnormal hemoglobin patterns on electrophoresis at pH 8.6 (A, F, S, C, A<sub>2</sub>, E, H, Barts and Lepore).
- 31. Assist in the proper preparation, staining, and review of bone marrow aspirate.
- 32. Discuss the use of cytochemistry for classification of acute leukemias.
- 33. Discuss the use of flow cytometry in the classification of acute leukemias.
- 34. Compare and contrast the chronic and acute leukemias in terms of onset and major cell type.
- 35. Discuss the myleoproliferative and myelodysplastic disorders with reference to FAB and WHO classification, and hematologic lab findings.
- 36. Perform at least two (2) body fluid manual cell count and differential according to standard operating procedures.
- 37. Recognize cells specific to each body fluid type to include:
  - Histiocytes,
  - Mesothelial cells
  - Malignant cells
  - Macrophages with inclusion
  - Crystals
  - Bacteria
  - Yeast

#### IV. <u>Technical Procedures for Coagulation</u>

- 1. Perform a minimum of <u>10</u> Prothrombin times and Partial thromboplastin times.
- 2. Discuss the principles of the following procedures and the reagents used
  - PT
  - PTT
  - Thrombin time
  - Quantitative fibrinogen
  - D-dimer
  - POC testing
- 3. Describe or perform:
  - Quantitative fibrinogen
  - Thrombin time
  - FSP
  - D-dimer matching technologist results.
  - Describe the laboratory testing used to monitor anticoagulant therapy.

- 4. Describe possible pathologic complications of anticoagulant therapy.
- 5. Describe the intrinsic and extrinsic coagulation pathways.
- 6. Propose appropriate laboratory test to identify factor deficiencies.
- 7. Perform minor troubleshooting procedures of available coagulation reagent.
- 8. Identify common pre-analytic variables that may adversely impact patient results, including:
  - storage
  - type of anticoagulant
  - short draw
  - clotted sample
  - Hematocrit >55
  - lipemia
  - hemolysis
- 9. Describe possible pathologic complications of anticoagulant therapy, including LMWH, heparin, coumadin, and other market available anticoagulants.
- 10. When given patient history and coagulation test results, correlate thrombotic disorders with available patient history and coagulation test results.
- 11. In addition to the procedures listed above, discuss the principle, clinical significance, and reagents used for the following coagulation tests:
  - Factor assays
  - Mixing studies
  - Lupus anticoagulant (anticardiolipin assay)
  - Factor 5 Leiden
  - Protein S
  - Protein C
  - Antithrombin assay
- 12. Describe possible pathologic complications of anticoagulant therapy.

#### MLS 432-CLINICAL PERFORMANCE OBJECTIVES IN IMMUNOHEMATOLOGY

Upon completion of the Blood Bank rotation, the MLS/MT student will be able to:

# I. Specimen Handling and Processing

- 1. Following departmental protocol and 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. Identify the types of blood samples and collection tubes appropriate for routine testing in the blood bank.
- 3. Determine the acceptability of a sample for compatibility testing based on sample age, sample appearance and institutional policy.
- 4. List the minimum information required for labeling samples for blood bank testing.

### II. Quality Assurance/Quality Control and Regulatory Issues

- 1. Perform daily quality control for routine testing according to the operating procedures of the laboratory with 100% accuracy.
- 2. Recognize discrepant results in routine ABO, Rh and antibody screen testing with 100% accuracy.
- 3. Report all discrepant results to the clinical instructor.
- 4. List the quality control activities that are performed monthly, quarterly, biannually and annually.
- 5. Perform or observe basic laboratory computer applications where relevant.
- 6. State the patient confidentiality policy of the facility that complies with HIPPA guidelines for testing and reporting procedures.
- 7. List the accrediting and inspection agencies that monitor blood banks and transfusion services.

## III. Routine Technical Procedures – ABO/Rh, Ab Screen and DAT

- 1. Using a "0 to 4+" scale, grade macroscopic agglutination reactions within  $\pm$  1 agglutination grade of the instructor.
- 2. Prepare a 3-5% red cell suspension as needed for tube testing.
- 3. Label test tubes for routine testing according to laboratory procedure without error.
- 4. Perform ABO and Rh testing on a minimum of 25 samples with 100% accuracy.
- 5. Interpret the results of ABO and Rh testing without error.
- 6. Perform weak D testing on designated patient samples when available. (optional)\*
- 7. Perform ABO confirmatory testing on a minimum of <u>20 donor segments</u> with 100% accuracy.
- 8. Suggest a plan of action for the preliminary investigation of the following ABO discrepancies:
  - Hypogammaglobulinemia
  - Cold reacting alloantibody
  - Cold reacting autoantibody
  - Subgroup of A with anti-A1
  - Mixed field agglutination
- 9. Identify mixed field agglutination in <u>2</u> samples to the satisfaction of the clinical instructor.
- 10. Perform antibody screening on a minimum of  $\underline{20}$  samples to the satisfaction of the clinical instructor.
- 11. Explain the next step/s to be taken to investigate a positive antibody screen.
- 12. Compare and contrast direct and indirect antiglobulin testing with regard to principle, procedure and application
- 13. Identify sources of false negative and false positive error in antiglobulin testing.
- 14. Perform DAT and DAT Battery on a minimum <u>2</u> samples to the satisfaction of the clinical instructor.
- 15. Discuss alternatives in routine testing such as gel and solid phase.

# IV. Routine Technical Procedures - Cross Matching and Transfusion Management

- 1. Label test tubes for routine compatibility testing according to laboratory protocol without error.
- 2. Perform the appropriate cross match procedure, immediate spin (IS) or Full (IAT), on a minimum of <u>10</u> samples when given the relevant patient information and the policy of the laboratory.
- 3. Discuss the criteria and policies of electronic cross match.
- 4. Select the most appropriate donor units to cross match with a patient when ABO specific red cells are available and when not available.
- 5. Select the most appropriate donor units when the patient presents with:
  - single alloantibody
  - multiple alloantibodies
- 6. Interpret the results of cross matching with 100% accuracy.
- 7. Explain possible causes of an incompatible cross match.
- 8. Discuss the policies for emergency release and massive transfusion.
- 9. Discuss special transfusion donor units to include

Sickle Cell Irradiated CMV Negative Washed

- 10. Distinguish ABO and Rh-related HDN according to clinical and serologic presentation.
- 11. Perform or discuss the prenatal (mother) and postnatal (mother and newborn) serologic workups for managing cases of HDN.
- 12. Observe or discuss the procedures for RhIg administration including candidate selection, FMH screening, and dosage determination.
- 13. Compare and contrast the following adverse reactions to transfusion with regard to cause, classic signs & symptoms, and serologic investigation (if applicable):

Immediate Hemolytic Urticarial
Delayed Hemolytic Anaphylactic
Febrile Non-hemolytic Bacterial Sepsis

TRALI (optional) Volume Overload (optional)

- 14. Recommend approaches for future transfusion in patients who have experienced the transfusion reactions listed above.
- 15. Perform or describe a minimum of  $\underline{1}$  transfusion reaction work-up.
- 16. Compare and contrast warm and cold reacting autoantibodies with regard to serologic presentation, related testing and transfusion approaches.

## V. Reference Procedures

- 1. Perform routine antibody identification panels on a minimum of  $\underline{5}$  samples according to the acceptable precision of the laboratory.
- 2. Interpret the results of routine and selected cell panels to determine the specificity of single and multiple antibodies (simple).
- 3. Perform or discuss the following reference techniques to assist in antibody identification.
  - Selected cell panel
  - Red cell (antigen) phenotyping
  - Enhancement media (PEG & LISS)
  - Acid Elution
  - Pre-warmed technique
  - Enzyme treatment
  - Neutralization
  - Adsorption
  - Saline replacement
  - Cold panel
- 4. Compare and contrast the serologic characteristics of antibodies to the following blood group systems:

Rh Kell
Kidd Duffy
MNSs Lewis
Lutheran I

5. List <u>5</u> antigens of low incidence and <u>5</u> antigens of high incidence.\*

## VI. <u>Donor /Components/Product Disposition</u>

- 1. Discuss the physical and medical criteria used in the selection of the following blood donors:
  - Allogeneic
  - Autologous
  - Directed
  - Therapeutic (optional)
- 2. Describe, and, if available, perform the processing of a donor to include:
  - Donor history
  - Physical exam
  - Donor acceptability
  - Proper unit collection and handling
- 3. Identify the blood bank serology and viral marker testing required on all allogeneic, autologous and directed units.
- 4. Explain the preparation of the following components from whole blood:
  - Packed red blood cells
  - Fresh frozen plasma
  - Random platelets
  - Cryoprecipitate
- 5. Identify the shelf life, storage requirements and therapeutic use of:

Packed red blood cells
Platelets (random & single donor)
Frozen red blood cells
Irradiated red blood cells
Factor VIII & IX concentrates
Fresh frozen plasma
Cryoprecipitate
Leuko reduced red blood cells
Washed red blood cells
Rh Immune globulin

- 6. Review the daily inventory and inspection of blood products.
- 7. Issue or observe the issue (release) of a minimum of  $\underline{5}$  blood products for administration.

#### MLS 411-CLINICAL PERFORMANCE OBJECTIVES IN CLINICAL CHEMISTRY

Upon completion of the Clinical Chemistry rotation the student will be able to:

### I. Laboratory Safety

- 1. Comply with the standard operating procedure (SOP) for specimen handling distribution, and storage including correct triage of specimen for in house and send out laboratory testing.
- 2. Demonstrate safe work practices following departmental protocol by the following
  - 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.
- 3. Dispose of waste according to laboratory protocol.
- 4. Describe the evacuation plan for the laboratory.

## II. Specimen Handling

- 1. Check for correct identification/labeling of specimens according to the current National Patient Standard from JCAHO.
- 2. Identify specimens that may be unsuitable for analysis due to incorrect anticoagulant used hemolysis, lipemia, icteric, clot, and/or air bubbles present.
- 3. Evaluate specimens for appropriate anticoagulant, collection time, and site of collection.
- 4. Explain corrective measures for unacceptable specimens.
- 5. Prepare a minimum of <u>20</u> specimens for analysis by centrifugation and separation of cells from serum/plasma.
- 6. Describe the process for archiving and retrieving patient specimens including the correct specimen storage requirements for each analyte.
- 7. Observe a flow path for specimen collection and processing (manual method will used if total automation is present).

## **III.** Quality Assurance

- 1. Explain the purpose of the quality control program.
- 2. Document results of calibration, performance, and maintenance checks, malfunctions and corrections without error.
- 3. Observe basic LIS computer applications where relevant.
- 4. Comply with regulatory issues.
- 5. State the confidentiality policy of the facility during testing procedures and reporting according to HIPAA guidelines.
- 6. Explain the components of total quality management of the clinical laboratory.
- 7. Write a procedure for an analyte according to the NCCLS guidelines.

### **IV.** Performance of Procedures

#### A. Analytical Principles

- 1. Observe the sample path or flow in a minimum of  $\underline{2}$  instruments.
- 2. Discuss the theoretical principle for each analytical methodology.
- 3. Recognize interfering substances for each procedure performed.
- 4. Recognize common malfunctions of the instrument.
- 5. Describe the effect of interfering substances for each procedure performed.
- 6. Define the following methodologies:
  - End-point spectrophotometry
  - Kinetic spectrophotometry
  - Ion-selective electrodes
  - Osmometry
  - Electrophoresis
  - Chemiluminesecence
  - Immunoassay
  - Fluorescent polarization
- 7. Classify 20 different assays to their methodologies

#### B. Maintenance

- 1. Performa routine maintenance checks.
- 2. Describe the various periodic maintenance procedures for the different instruments and maintenance sheets.

#### C. Reagent Preparation

- 1. Prepare reagents, calibrators, and control material within the acceptable Q & A limits for 10 different assays.
- 2. Pipet reagents and samples correctly.

## D. Quality Control and Calibration

- 1. Perform calibrations.
- 2. Evaluate the validity of the standardization/calibration of the instrument.
- 3. With 100% accuracy, identify all control results that are not within the accepted quality control limits.
- 4. State possible reasons, if QC results are not within the limits (e.g., outside instrument limitations).
- 5. Discuss appropriate actions for unacceptable control results.
- 6. Observe documentation of corrective actions for unacceptable control values.

#### E. Testing of Samples

- 1. Prepare dilutions with 100% accuracy.
- 2. Perform testing for the equivalent amount of time for one work shift at a minimum with acceptable results and within the laboratory's timeframe specified for stat and/or routine turnaround time.
- 3. Demonstrate the ability to organize workflow.
- 4. Describe or demonstrate basis trouble-shooting skills for the common malfunctions.

## V. Interpretation and Reporting of Results

1. Recognize reference serum intervals and critical values for the following tests:

Glucose Blood urea nitrogen

Total protein Creatinine
Sodium Total bilirubin
Potassium Cholesterol
Chloride Blood gases

- 2. Identify all patient values that are significantly different (e.g. risk values, critical values, analytical errors) and bring these to the attention of the technologist immediately.
- 3. According to laboratory protocol document investigative and corrective action for discrepant results.
- 4. Determine need for repeat analysis on unacceptable reportable ranges.
- 5. Determine whether results fit the expected pattern with respect to previously obtained results on same test or other test results on same patient.
- 6. Evaluate a **minimum of 50 patient results** according to laboratory protocol.
- 7. Perform and interpret 10 routine calculations to include dilutions, anion gap, 24 hour urine, creatinine clearance, and LDL with 100% accuracy.
- 8. Correlate laboratory data with clinical implications with 75% accuracy. This includes:

Cardiac enzymesLiver enzymesBlood gases

Bilirubin
Protein
Iron
Lipids

Glucose
 Electrolytes
 Tumor markers
 Endocrine function
 Blood urea nitrogen
 Therapeutic Drugs

• Drugs of Abuse

- 9. State the difference between the analytical measurement range (AMR) and clinically reportable range (CRR).
- 10. Correlate abnormal results to possible disease states with 80% accuracy.

#### MLS 441- CLINICAL PERFORMANCE OBJECTIVES IN MICROBIOLOGY

Upon completion of the Clinical Microbiology rotation, the MT student will be able to:

## I. SPECIMEN HANDLING AND PROCESSING

- 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.
  - d. Properly using the biological safety cabinet when processing specimens
- 2. List criteria for evaluating specimens and requisitions for acceptability using laboratory-defined criteria.
- 3. Apply proper specimen handling to microbiological specimens to the satisfaction of the clinical instructor in regards to:
  - a. Timeliness
  - b. Appropriateness of specimen submitted for analysis requested
  - c. Safety and security of collection system
  - d. Completeness of essential patient information
- 4. Document rejected specimens according to laboratory's procedures for specimen rejection.
- 5. Given any routine specimen for culture:
  - a. State the collection system, storage conditions, and acceptable length of storage.
  - b. Explain the selection and use of appropriate primary culture media for initial plating.
  - c. State the proper incubation temperature and atmosphere conditions for each medium.
- 6. Given plating instructions and media selection criteria:
  - a. Process a **minimum of 20 bacterial specimens** of different types and prepare smears for Gram stain (if appropriate), to the satisfaction of the clinical instructor.
  - b. Demonstrate proper aseptic technique and streaking method, obtaining isolated colonies.

# II. QUALITY CONTROL, QUALITY ASSURANCE AND REGULATORY ISSUES

1. State the purpose of quality control in the microbiology laboratory.

- 2. Perform or state the daily or weekly maintenance checks on equipment (e.g. refrigerators, incubators, water baths, and instruments) with 100% accuracy.
- 3. Perform quality control procedures (e.g. stains, media, biochemical tests, antisera, and susceptibility tests) with 100% accuracy.
- 4. Record all QC results with 100% accuracy.
- 5. Report divergent results to instructor and suggest corrective actions.
- 6. Observe basic laboratory computer operations where relevant.
- 7. State the patient confidentiality policy of the facility during testing procedures and reporting, according to HIPAA guidelines.

### III. BACTERIOLOGY

- 1. Perform Gram stains on a **minimum of 15 samples**, including both direct smears and cultured colonies, following established laboratory procedures.
- 2. Evaluate stained smears for stain quality, according to established criteria.
- 3. Read a **minimum of 15 direct Gram smears**, matching the interpretation of the Technologist 80% of the time:
  - a. Describe Gram reaction and morphology.
  - b. Quantify bacteria and polymorphonuclear cells within +/-1 gradation of the technologist.
- 4. Demonstrate the ability to select isolated colonies from a culture plate, streak for isolation, and obtain isolated colonies.
- 5. Correlate Gram stain results with isolates on culture plates, to the satisfaction of the clinical instructor.
- 6. List the criteria for an acceptable sputum specimen.
- 7. Screen sputum smears for the quality of the specimen, to the satisfaction of the clinical instructor.
- 8. Recognize alpha  $(\Box)$ , beta  $(\Box)$  and gamma  $(\Box)$  hemolysis with 100% accuracy.
- 9. Distinguish between gram-positive and gram-negative organisms using Gram stain characteristics and/or growth on selective media with 100% accuracy.
- 10. Determine the required biochemical tests for a cost-effective identification of the unknown pathogens.

- 11. Inoculate all biochemical media and identification systems used in the laboratory, within a reasonable time limit as determined by the clinical instructor.
- 12. Determine a positive or negative reaction for each test to include (but not limited to or exclusive of) the following, matching the technologist's results:
  - a. Catalase

- g. Hippurate hydrolysis/CAMP
- b. Slide & tube coagulase
- h. Optochin/bile solubility
- c. Novobiocin susceptibility
- i. Commercial bacterial ID system(s)
- d. Bile esculin/6.5% NaCl
- j. Haemophilus ID & Neisseria ID systems
- e. PYR/bacitracin/SXT
- k. Oxidase

f. Spot indole

- 1. Streptococci grouping
- 13 Using the information obtained from Gram stain, isolation on select media, and biochemical testing demonstrates the ability to utilize flow charts and coded system to identify the following organisms with a 90% rate of success in identification.

E. coli	Neisseria gonorrhoeae
Klebsiella / Enterobacter / Serratia	N. meningitidis
Citrobacter spp.	Moraxella catarrhalis
Salmonella spp.	Haemophilus influenzae
Shigella spp.	Haemophilus parainfluenzae
Proteus / Providencia / Morganella	Campylobacter jejuni
Yersinia enterocolitica	Gardnerella vaginalis
Staphylococcus aureus	Clostridium perfringens
Staphylococcus saprophyticus	Bacteroides fragilis group
Staphylococcus-coagulase-negative	Fusobacterium nucleatum
Group D Streptococcus	Prevotella spp.
Enterococcus faecalis / faecium	Peptostreptococcus
viridans streptococci	Acinetobacter baumannii
Streptococcus pneumonia	Pseudomonas aeruginosa
Beta streptococci	Stenotrophomonas maltophilia
Gp A / Gp B / others	
Abiotrophia spp.(NV strept)	Vibrio spp.
Listeria monocytogenes	

- 14. Discuss the isolation and identification of the following organisms:
  - Mycoplasma/Ureaplasma
  - Nocardia asteroides
  - *Actinomyces* spp.
  - *Aeromonas* spp.
  - Burkholderia cepacia and other NFB
  - Pasteurella multocida

- *Legionella* spp.
- Propionibacterium

#### 15. Urine cultures:

List common uropathogens.

- a. Recognize urethral contaminants vs. potential pathogens.
- b. Differentiate lactose vs. non-lactose-fermenters with 100% accuracy.
- c. Quantify colony counts according to laboratory protocol, matching the instructor's counts.
- d. Using laboratory criteria, determine which colony counts/isolates required identification and susceptibility testing.
- e. Perform/observe appropriate identification and susceptibility tests on significant isolates with 90% accuracy.

## 16. Respiratory cultures:

- a. Recognize normal respiratory flora on a **minimum of 10 samples**, to the satisfaction of the clinical instructor.
- b. List the primary pathogens detected in throat vs. sputum cultures.
- c. Using laboratory criteria, determine which isolates are considered significant for identification and susceptibility tests.
- d. Rule out group A streptococci in throat cultures with 100% accuracy.
- e. Explain the principle of rapid group A streptococcal (GAS) antigen test.
- f. Perform or discuss the test procedure for rapid GAS antigen test.

#### 17. Genital cultures (vaginal, cervical, urethral, etc.):

- a. Recognize normal vaginal flora, i.e. lactobacilli.
- b. Evaluate specimens for the presence of potential pathogens (e.g. *Neisseria gonorrhoeae*, *Gardnerella vaginalis* and group B streptococci).
- c. Perform/observe presumptive identification procedures, confirmatory tests and susceptibility tests on suspected pathogens with 90% accuracy.

#### 18. **Stool cultures:**

- a. List the possible bacterial pathogens for which stool cultures are routinely examined.
- b. Describe the appearance of each enteric pathogen on selective/differential media used in the laboratory.
- c. Recognize suspicious colonies of possible enteric pathogens on selective media.
- d. Perform or discuss appropriate identification tests including serological confirmatory tests.
- e. State the selective media to isolate the following and describe their appearance on this medium:

■ Shigella spp. E. coli O:157 H:7 Vibrio spp.

• Salmonella spp. Yersinia enterocolitica

## Aeromonas hydrophila

- Campylobacter jejuni Plesiomonas spp.
- f. State the optimum temperature and atmosphere requirements for *C. jejuni* and *Y. enterocolitica*

#### 19. Blood cultures:

- a. Describe the media used for blood cultures and the principle of the blood culture detection system.
- b. After performing staining of suspicious or positive cultures, detect the presence/ absence of organisms in the smears to the satisfaction of the instructor.
- c. Using proper sterile techniques, subculture positive cultures to appropriate media, obtaining isolated colonies.
- d. Using laboratory protocol, perform/observe rapid identification testing, where applicable.

## 20. Wound/body fluid cultures:

- a. List normal flora and possible pathogens isolated from the site.
- b. Using laboratory criteria, determine which isolates are considered significant for identification and susceptibility tests.
- c. Perform/observe appropriate identification and susceptibility tests of isolated pathogens, with 90% accuracy.

#### 21. Anaerobic cultures:

- a. Compare and contrast the anaerobic jar and anaerobic chamber systems.
- b. List the types of clinical specimens that are acceptable/ unacceptable for anaerobic culture.
- c. List the media used for primary isolation of anaerobes and the purpose of each.
- d. Observe or isolate suspected anaerobic colonies.
- e. Perform/observe appropriate identification and susceptibility tests (if applicable) of isolated pathogens, with 90% accuracy.

#### 22. Susceptibility testing:

- a. Explain the choice of antibiotics in relation to the test organism and clinical source.
- b. Perform the Kirby-Bauer disk diffusion procedure, according to the procedure manual.
- c. Measure zone sizes, obtaining results within 1-2 mm of the technologist's results.
- d. Using CLSI charts, interpret and record results without error.
- e. Explain potential sources of error in the Kirby-Bauer procedure and appropriate corrective actions.
- f. Explain the principles of the MIC microdilution procedure and the E-test.
- g. Perform MICs and/or E-tests to the satisfaction of the clinical instructor.

- h. Interpret results of MICs, matching the technologist's results.
- i. Perform and interpret a test for beta-lactamase with 100% accuracy.
- j. Describe the procedures to identify VRE, MRSA, clindamycin-resistant *S. aureus* (D-test), penicillin-resistant *S. pneumoniae*, ESBL and KPC.
- k. Recognize "typical" susceptibility patterns of commonly isolated organisms.
- 1. Discuss the significance of susceptibility patterns (results) in VRE, MRSA, ESBL, KPC, penicillin-resistant *S. pneumoniae*, VISA, VRSA and multiply-resistant organisms (MDRs).
- m. Interpret algorithms for MDR organisms used for reporting purposes.

#### IV. MYCOBACTERIOLOGY

- 1. Describe or demonstrate the safety precautions to be taken when working with mycobacteriae.
- 2. List the specimens most likely to be received for culture of mycobacteriae and identify which specimens need digestion/decontamination.
- 3. List the media used in the isolation and cultivation of mycobacteriae.
- 4. Explain why the genus *Mycobacterium* is often referred to as "acid-fast bacilli" (AFB).
- 5. Observe, perform or discuss the Ziehl-Neelsen, Kinyoun, or fluorochrome acid-fast stain, where applicable.
- 6. Recognize AFB in clinical or QC stained slides, where applicable.
- 7. State the criteria and proper report format for numbers of acid-fast bacilli observed in stained smears.
- 8. Outline the method used to digest, decontaminate, concentrate, and culture specimens for mycobacteriae.
- 9. Observe the digestion and concentration procedure on culture specimens for mycobacteriae, if performed in lab.
- 10. State the optimal growth requirements (temperature and atmosphere) for *M. tuberculosis* and NTM (non-tuberculosis mycobacteriae).

#### V. MYCOLOGY

- 1. Describe or demonstrate the safety precautions to be taken when working with fungal isolates.
- 2. Explain the purpose of each medium used for the isolation of fungi from clinical specimens and the optimum temperature for incubation.

- 3. Recognize yeast vs. filamentous fungi on culture media.
- 4. Identify the presence of *Candida albicans* using germ tube test, cornmeal agar, CHROMagar, or equivalent rapid test with 100% accuracy.
- 5. Perform the yeast identification system used in the laboratory with 100% accuracy.
- 6. Describe the preparation OR set-up a slide culture for fungal identification.
- 7. Perform latex agglutination test for detection of cryptococcal antigen with 100% accuracy.
- 8. Prepare lacto-phenol cotton blue or lacto-fuchsin and calcofluor/KOH preps, to the satisfaction of the clinical instructor.
- 9. Using prepared slides, colony morphology on fungal media, CD-ROM and/or slides, identify the following molds with 90% success rate:
  - *Rhizopus* spp.
  - *Mucor* spp.
  - *Penicillium* spp.
  - Aspergillus fumigatus
  - Microsporum spp
  - *Trichophyton* spp.
  - Epidermophyton floccosum
  - Pneumocystis jiroveci
- 10. Describe the microscopic and macroscopic identifying features of the dimorphic fungi.

## VI. VIROLOGY

- 1. Discuss or observe specimen collection, handling and processing of viral specimens for direct detection and other viral assays.
- 2. Perform or discuss an RSV antigen detection assay to the satisfaction of the Clinical instructor.
- 3. Perform or discuss at least one additional immunoassay viral detection test to the satisfaction of the clinical instructor.
- 4. Perform or discuss viral culture techniques for the isolation and identification of some viruses.

## VII. MOLECULAR AND RAPID DIAGNOSTIC TESTING

- 1. Discuss the principles and procedures of molecular testing including GC/*Chlamydia and Mycobacterium*.
- 2. Discuss or perform EIA methods for *C. difficile* toxin detection.

# VIII. PARASITOLOGY (NOT PART OF ROTATION; Student Self-study)

- 1. State the purpose of each of these techniques used for O&P specimens:
  - a. Saline direct smear
  - b. Iodine direct smear
  - c. Trichrome stain
  - d. Concentration (formalin ethyl-acetate)
  - e. Cellophane tape prep
  - f. Modified acid-fast stain
- 2. If, available, perform the following techniques (if available) to the satisfaction of the clinical instructor:
  - a. Trichrome stain
  - b. Concentration (e.g. formalin ethyl-acetate)
- 3. Using reference slides and preserved specimens, identify these parasites:
  - Ascaris lumbricoides
  - Strongyloides stercoralis
  - Hookworm
  - Enterobius vermicularis
  - Hymenolepis nana
  - *Taenia* spp.
  - Entamoeba histolytica
  - Giardia lamblia
  - Entamoeba coli
  - Trichuris trichiura
  - Plasmodium spp.
- 4. In addition to the parasites listed in objective #3, identify the following parasites, using reference slides, CD-ROM and/or preserved specimens (where available):
  - Dientamoeba fragilis
  - *Diphyllobothrium latum*
  - Clonorchis sinensis
  - *Schistosoma* spp.
  - Toxoplasma gondii

#### MLS 411-CLINICAL PERFORMANCE OBJECTIVES IN URINALYSIS

Upon completion of the urinalysis rotation the student will be able to:

# I. Specimen Handling and Processing

- 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. Explain the importance of proper collection and transport of specimens.
- 3. List criteria for evaluating specimen quality and corrective actions to Resolve problems.

## II. Quality Assurance and Quality Control

- 1. Perform quality control analysis in the urinalysis laboratory.
- 2. Evaluate, with 100% accuracy, quality control results from a minimum of <u>10</u> days of testing.
- 3. Perform or discuss corrective action needed to be taken if quality control values are not within established limits.
- 4. Report or record quality control results according to the standard operating procedures of the laboratory with 100% accuracy.
- 5. List substances that will cause false negative and false positive results in a routine urinalysis.
- 6. Summarize the advantages and disadvantages of commonly used urine preservatives.
- 7. State the confidentiality policy of the facility during testing procedure and reporting in accordance with HIPAA guidelines.
- 8. Observe basic computer applications where relevant.
- 9. Report all divergent or discordant results between quantitative and microscopic data to the clinical instructor.
- 10. Recognize all critical values and report these findings to the clinical instructor.

## **III.** Technical Procedures

- 1. For a minimum of  $\underline{25}$  urine specimens with 95% accuracy:
  - a. Describe the physical appearance.
  - b. Perform specific gravity analysis using the refractometer and/or dipstick methods.
  - c. Perform chemical analysis of the urine specimens.
  - d. Interpret results obtained from chemical analysis.
  - e. Where applicable, confirm abnormal results with appropriate confirmatory tests for a minimum of <u>5</u> different abnormal urine specimens.
  - f. Interpret the confirmatory test results.
  - g. Perform microscopic analysis on urine specimens according to the standard operating procedure of the laboratory.
- 2. Given a specimen or kodachrome, identify normal and abnormal constituents in a microscopic analysis of urine specimens with 95% accuracy. These constituents include:
  - Erythrocytes
  - Leukocytes
  - Epithelial cells: squamous, transitional, renal
  - Bacteria
  - Yeast
  - Casts: hyaline, fine and coarse granular, rbc, wbc, waxy
  - Crystals: uric acid, calcium oxalate, triple phosphate, tyrosine, cystine, ammonium biurate
  - Oval fat bodies
  - Contaminants: fibers, talc, glass, etc.
- 3. Correlate the origin and significance of the chemical constituents usually found in urine by the multi-test reagent strip methodology to include:
  - pH
  - Protein
  - Glucose
  - Ketone
  - Bilirubin

- Blood
- Nitrite
- Urobilinogen
- Specific gravity

- 1. Explain the principle and methodology limitations of each test on the multitest reagent strip.
- 2. Discuss the significance of the confirmatory tests used in the chemical analysis of urine, i.e., ictotest, sulfosalicylic acid, clinitest, acetest.
- 3. Explain the principle and methodology limitations of each of the following confirmatory tests: ictotest, sulfosalicylic acid, clinitest, acetest.
- 4. Explain the principle and methodology limitations of refractometry for urine specific gravity.
- 5. State the reference (normal) values for all routine assays performed in the urinalysis laboratory.
- 6. With 95% accuracy, correlate quantitative data with microscopic data.
- 7. Correlate abnormal results with associated common disease states.
- 8. Explain the principles of bright field, phase contrast, and polarized microscopy.
- 9. Operate automated dipstick readers with 100% accuracy.
- 10. Explain the physiological role of the components of the urinary system.
- 11. For the following procedures, it is essential that the student receive hands-on experience and perform with 95% accuracy in whichever department the procedure is performed:
  - a. Cerebrospinal fluid analysis to include cell count, differential, chemistry
  - b. Fecal occult blood
  - c. Urine/serum pregnancy test
- 12. Recognize cells specific to each body fluid type to include histiocytes, mesothelial cells, malignant cells, macrophage with inclusions, crystals, yeast, bacteria and others.
- 13. Discuss or perform body fluid analysis on synovial, serous, and other fluids.
- 14. Interpret the results obtained from performing body fluid analysis on synovial, serous, and other fluids.

#### MLS 441-CLINICAL PERFORMANCE OBJECTIVES IN IMMUNOLOGY

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

# I. Specimen Handling and Processing

- 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 <u>3</u> immunology tests 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 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, postzone (and how that might impact patient test results).
  - c. Determine corrective action when prozone occurs.
  - 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 sensitivity and specificity.

## IV. <u>Immunology Assay Methodologies/Instruments</u>

- 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 nephelometer.
- 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. <u>Bacterial Serology: Non treponemal (VDRL, RPR) Treponemal (FTA-ABS), Streptozyme, Lyme Disease</u>

- 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 <u>10 RPR</u> screening tests.
  - g. Perform a minimum of  $\underline{2}$  RPR titers on previously reactive specimens, matching the technologist's results within  $\pm$  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  $\underline{2}$  specimens.
- j. Discuss or perform the screening and/or confirmatory western blot for Lyme Disease on a minimum of two (2) specimens.

# VI. <u>Viral Serology - Hepatitis A-C, EBV, HIV, Rubella, CMV</u>

- 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 screening test 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 a kodachrome or slide, identify the following ANA patterns: homogeneous, speckled, nucleolar, and centromere.
- 3. When given a kodachrome or slide, correlate the patterns with the following disease states: SLE, Sjorgens syndrome, Myasthenia gravis.
- 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.