Clinical Performance Objectives in MEDT 453
Clinical Practice in Chemistry
Department of Medical and Research Technology
University of Maryland School of Medicine

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

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I. Specimen Handling and Processing

1. Comply with the standard operating procedure (SOP) for specimen handling, distribution, and storage.

2. Implement the standard safety precautions for the clinical laboratory.

3. Check for correct identification/labeling of specimens.

4. Evaluate specimens for appropriate anticoagulant, collection time and site of collection.

5. Identify specimens that may be unsuitable for analysis due to inadequate volume, incorrect anticoagulant used, hemolysis, lipemia, icteric, clot and/ or air bubbles.

6. Explain corrective measures for unacceptable specimens.

7. Prepare a minimum of **20 specimens** for analysis by centrifugation and separation of cells from serum/plasma.

8. Dispose of waste according to laboratory protocol.

II. Quality Assurance, Quality Control and Regulatory issues

1. State the name of the quality control program and control material.

2. Prepare reagents, calibrators and control material within the acceptable QA limits *with 100% accuracy.*

3. Perform calibrations.

4. Perform routine maintenance checks.

5. Evaluate the validity of standardization/calibration of the instrument.

6. Document results of calibration, performance, maintenance checks, malfunctions and corrections *without error.*

7. Identify control results not within the accepted quality control limits *with 100% accuracy.*

8. Discuss appropriate actions for unacceptable control results.

9. Observe corrective documentation for unacceptable control values.

10. State possible sources of error, if results are not within limits (e.g. outside instrument limits).

11. Observe basic LIS computer applications, where relevant.

12. Describe various periodic maintenance procedures for the different instruments and maintenance sheets.

13. Comply with regulatory issues.

III. <u>Performance of Procedures</u>

1. Follow the procedure and safety precautions, *without error*, for analytical instrument and manual testing with respect to:
   a. Specimen preparation
   b. Control selection
   c. Intervals at which standards and controls are to be analyzed
   d. Identification and correct positioning of specimens
   e. Operation of the instrument

2. Pipet reagents and samples accurately.

3. Prepare dilutions with *100% accuracy.*

4. Describe the sample path or flow for one instrument.

5. Complete a minimum of 10 runs/assays *with acceptable results within the laboratory's timeframe specified for stat and/or routine turn around time.*

6. Operate at least one analyzer *with minimal supervision in accordance with laboratory protocol.*

7. Observe the sample path or flow in 2 instruments.

8. Discuss the theoretical principles for each analytical methodology.

9. Demonstrate the ability to organize workflow.

10. Recognize common malfunctions of the instrument.

11. Classify the instruments at the site according to the approach of automation (i.e., discrete and parallel analyzers)
12. Describe/ demonstrate basic trouble-shooting skills for common malfunctions.

IV. Interpretation and Reporting of Results

1. Recognize interfering substances for each procedure performed.

2. Identify patient values that are significantly different than normal (e.g. critical values, analytical errors) and bring these to the attention of the technologist immediately.

3. Determine need for repeat analysis on unacceptable reportable ranges.

4. Determine whether results fit the expected pattern with respect to previously obtained results on the same test or other test results on the same patient.

5. Evaluate a **minimum of 50 patient results** according to laboratory protocol for routine, STAT (including telephone results) and critical value results.

6. Perform and interpret **10 routine calculations** to include dilutions, anion gap, 24 hour urine, creatinine clearance, LDL and thyroid index *with 100% accuracy.*

V. For Immunology

1. State the specimen collection and handling requirements for each immunologic test.

2. Evaluate patient specimens for acceptability, using laboratory policy.

3. If patient specimens are determined to be unacceptable, state the resolution.

4. Prepare controls and reagents results within acceptable QA limits.

5. Using established criteria, determine whether or not available controls and reagents are acceptable for use according to lab protocol.

6. Evaluate quality control data for a **minimum of 3 different immunology assays** performed in the laboratory.

7. Discuss appropriate actions for unacceptable control results.

8. Recognize all critical values obtained during patient testing and report this immediately to the clinical instructor.

9. Demonstrate accurate pipetting technique *to the satisfaction of the clinical instructor.*

10. Perform/ observe the following assay methods:
    a. Immunodiffusion
    b. Direct and Indirect immunofluorescence (e.g. ANAs, FTA-Abs)
    c. EIA (e.g. HIV, Hepatitis, Lyme)

11. Perform/ observe on a minimum of 2 specimens:
    a. Streptozyme assay
    b. Screening or confirmatory testing for Lyme disease

12. Perform a **minimum of 5 screening tests for IM** *with 100% accuracy.*

13. **For RPR and FTA-ABS testing:**
    a. Perform **RPR QC/calibration techniques** (temperature, needle, rotator speed) according to laboratory protocol.
    b. Perform a **minimum of 10 RPR tests** *with 100% accuracy.*
    c. Interpret a **minimum of 10 RPR tests** *with 100% accuracy.*
    d. Perform a **minimum of 2 RPR titers** on previously reactive specimens, *matching the technologist's results within +/–1 dilution.*