

# MEDICAL LABORATORY SCIENTIST, MLS(ASCP) INTERNATIONAL MEDICAL LABORATORY SCIENTIST, MLS(ASCP<sup>i</sup>) EXAMINATION CONTENT GUIDELINE

## EXAMINATION MODEL

The MLS(ASCP) and MLS(ASCP<sup>i</sup>) certification examination is composed of 100 questions given in a 2 hour 30 minute time frame. All exam questions are multiple-choice with one best answer. The certification exam is administered using the format of computer adaptive testing (CAT).

With CAT, when a person answers a question correctly, the next test question has a slightly higher level of difficulty. The difficulty level of the questions presented to the examinee continues to increase until a question is answered incorrectly. Then a slightly easier question is presented. In this way, the test is tailored to the individual's ability level.

Each question in the test bank is calibrated for level of difficulty and is classified by content area. The content area aligns with the examination specific content outline. The examinee must answer enough questions correctly to achieve a measure above the pass point in order to successfully pass the certification examination. There is no set number of questions one must answer to pass, nor is there a set percentage one must achieve to pass. If at the end of the exam the examinee's score is above the pass point, then he or she passes the exam.

## EXAMINATION CONTENT AREAS

The MLS exam questions encompass different content areas within Medical Laboratory Science: Blood Banking, Urinalysis and Other Body Fluids, Chemistry, Hematology, Immunology, Microbiology, and Laboratory Operations. Each of these content areas comprise a specific percentage of the overall 100-question exam. The content areas and percentages are described below:

CONTENT AREA	DESCRIPTION	EXAM PERCENTAGE
<b>BLOOD BANKING</b>	Blood products, blood group systems, blood group immunology, physiology and pathophysiology, serologic and molecular testing, transfusion practice	<b>17 – 22%</b>
<b>URINALYSIS AND OTHER BODY FLUIDS</b>	Physical and chemical testing, microscopic analysis, physiology, disease states	<b>5 – 10%</b>
<b>CHEMISTRY</b>	Carbohydrates, lipids, heme derivatives, enzymes, proteins and other nitrogen-containing compounds, acid-base determinations (including blood gases), electrolytes, endocrinology, vitamins and nutrition, therapeutic drug monitoring, toxicology	<b>17 – 22%</b>
<b>HEMATOLOGY</b>	Physiology, disease states, laboratory testing, hemostasis (including physiology, disease states, and laboratory determinations)	<b>17 – 22%</b>
<b>IMMUNOLOGY</b>	Principles of immunology, diseases of the immune system, transplantation, infectious disease serology, serologic procedures, test results	<b>5 – 10%</b>
<b>MICROBIOLOGY</b>	Preanalytic procedures; analytic procedures for bacteriology; analytic procedures for mycobacteriology, virology, parasitology, and mycology; postanalytic procedures	<b>17 – 22%</b>
<b>LABORATORY OPERATIONS</b>	Quality assessment/troubleshooting, safety, laboratory mathematics, manual/automated methodology and instrumentation, basic management principles, education principles	<b>5 – 10%</b>

For a more specific overview of the MLS exam, please refer to the **CONTENT OUTLINE** starting on page 2.

# MEDICAL LABORATORY SCIENTIST, MLS(ASCP) INTERNATIONAL MEDICAL LABORATORY SCIENTIST, MLS(ASCP<sup>i</sup>) EXAMINATION CONTENT OUTLINE

---

Examination questions, which are related to the subtest areas outlined below, may be both theoretical and/or procedural. Theoretical questions measure skills necessary to apply knowledge, calculate results, and correlate patient results to disease states. Procedural questions measure skills necessary to perform laboratory techniques and follow quality assurance protocols. Additionally, regulatory questions are based on U.S. sources (e.g., AABB, FDA, CLIA).

**IMPORTANT NOTE ABOUT COVID-19:** FDA guidance for changes in donor eligibility during the COVID-19 pandemic are to ensure an adequate blood supply and only apply for the duration of the pandemic. Donor eligibility questions are based on pre-pandemic requirements and will not reflect temporary changes.

## **BLOOD BANKING**

(17 – 22% of total exam)

### **I. BLOOD PRODUCTS**

#### **A. Donors**

1. Qualification
2. Collection methods
3. Adverse reactions
4. Special donations (e.g., autologous)

#### **B. Processing**

1. Testing
2. Labeling

#### **C. Storage**

1. Anticoagulants/additives
2. Temperature requirements
3. Transportation
4. Properties of stored products
5. Expiration

#### **D. Blood Components**

1. Red blood cells
2. Cryoprecipitated AHF
3. Platelets
4. Plasma
5. Granulocytes
6. Leukocyte-reduced components
7. Frozen/deglycerolized red blood cells
8. Apheresis products
9. Fractionation products
10. Whole blood
11. Washed red blood cells
12. Irradiated components

#### **E. Blood Component Quality Control**

### **II. BLOOD GROUP SYSTEMS**

#### **A. Genetics**

1. Basic
2. Molecular
3. Inheritance of blood groups

#### **B. Biochemistry/Antigens**

1. ABO
2. Lewis
3. Rh
4. MNS
5. P1PK/Globoside(P)
6. Ii
7. Kell
8. Kidd
9. Duffy
10. Lutheran
11. Antigens of high prevalence
12. Antigens of low prevalence
13. HLA
14. Platelet-specific

#### **C. Role of Blood Groups in Transfusion**

1. Immunogenicity
2. Antigen prevalence

### **III. BLOOD GROUP IMMUNOLOGY**

#### **A. Immune Response**

1. Primary and secondary response
2. B and T cells, macrophages
3. Genetics

#### **B. Immunoglobulins**

1. Classes and subclasses
2. Structure
3. Biologic and physical properties

**C. Antigen-Antibody Interactions**

1. Principles
2. Testing
  - a. Principles
  - b. Methods

**D. Complement**

1. Classical and alternative pathway mechanisms
2. Biologic properties

**IV. PHYSIOLOGY AND PATHOPHYSIOLOGY**

**A. Physiology of Blood**

1. Circulation and blood volume
2. Composition and function of blood
  - a. Normal function
  - b. Abnormal physiology
3. Cell survival
4. Cell metabolism

**B. Hemostasis and Coagulation**

1. Coagulation factors and disorders
2. Platelet functions and disorders

**C. Hemolytic Disease of the Fetus and Newborn**

1. Pathophysiology
2. Detection
3. Treatment
4. Prevention

**D. Anemias**

1. Congenital and acquired
  - a. Pathophysiology
  - b. Detection
  - c. Treatment
2. Immune hemolytic anemias: warm, cold, drug-induced
  - a. Pathophysiology
  - b. Detection
  - c. Treatment

**E. Transplantation**

1. Solid organ
2. Hematopoietic progenitor cell (HPC)

**V. SEROLOGIC AND MOLECULAR TESTING**

**A. Routine Tests**

1. Blood grouping tests
2. Compatibility tests
  - a. Antibody detection
  - b. Crossmatch
3. Antibody identification/clinical significance
4. Direct antiglobulin testing

**B. Reagents**

1. Antiglobulin sera
2. Blood grouping sera
3. Reagent red cells

**C. Application of Special Tests and Reagents**

1. Enzymes
2. Enhancement media
3. Lectins
4. Adsorptions
5. Elutions
6. Titrations
7. Cell separations
8. ELISA
9. Molecular techniques
10. Neutralization/inhibition
11. Use of thiol reagents
12. Immunofluorescence
13. Solid phase
14. Column agglutination test
15. Chloroquine diphosphate
16. EDTA glycine-acid

**D. Leukocyte/Platelet Testing**

1. Cytotoxicity
2. Platelet testing

**E. Quality Assurance**

1. Blood samples
2. Reagents
3. Test procedures

**VI. TRANSFUSION PRACTICE**

**A. Indications for Transfusion**

**B. Component Therapy**

**C. Adverse Effects of Transfusion**

1. Immunologic reactions
2. Nonimmunologic reactions
3. Transfusion-transmitted diseases

**D. Apheresis and Extracorporeal Circulation**

**E. Blood Administration and Patient Blood Management**

## **URINALYSIS AND BODY FLUIDS**

(5 – 10% of total exam)

### **I. URINALYSIS**

#### **A. Physical**

1. Color and clarity
2. Specific gravity/osmolality

#### **B. Chemical**

1. Reagent strip
2. Confirmatory tests

#### **C. Microscopic**

1. Cells
2. Casts
3. Crystals
4. Microorganisms
5. Contaminants
6. Artifacts

#### **D. Renal Physiology**

#### **E. Disease States**

### **II. BODY FLUIDS (e.g., CSF, Amniotic, Synovial, Serous, Semen, Feces)**

#### **A. Physical**

#### **B. Chemical**

#### **C. Microscopic**

#### **D. Physiology**

#### **E. Disease States**

## **CHEMISTRY**

(17 – 22% of total exam)

### **I. GENERAL CHEMISTRY**

#### **A. Carbohydrates**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Physical and chemical properties
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
  - c. Tolerance testing
  - d. Glycated proteins
3. Test result interpretation
4. Disease state correlation

### **B. Lipids**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Physical and chemical properties
    - 1) Lipoproteins
    - 2) Phospholipids
    - 3) Triglycerides
    - 4) Cholesterol
    - 5) Apolipoproteins
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Test result interpretation
4. Disease state correlation

### **C. Heme Derivatives**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Physical and chemical properties
    - 1) Hemoglobin
    - 2) Bilirubin
    - 3) Urobilinogen
    - 4) Myoglobin
    - 5) Porphyrins
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Test result interpretation
4. Disease state correlation

### **II. PROTEINS AND ENZYMES**

#### **A. Enzymes**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Physical and chemical properties
    - 1) LD
    - 2) CK
    - 3) AST/ALT
    - 4) GGT
    - 5) Lipase

- 6) Amylase
- 7) Alkaline phosphatase
- 8) Angiotensin converting enzyme
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Test result interpretation
4. Disease state correlation

#### **B. Proteins and Other Nitrogen-Containing Compounds**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Physical and chemical properties
    - 1) Proteins
    - 2) Amino acids
    - 3) Urea
    - 4) Uric acid
    - 5) Creatinine
    - 6) Ammonia
    - 7) Tumor markers
    - 8) Cardiac markers
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
  - c. Clearances
3. Test result interpretation
4. Disease state correlation

### **III. ACID-BASE, BLOOD GASES AND ELECTROLYTES**

#### **A. Acid-Base Determinations (Including Blood Gases)**

1. Biochemical theory and physiology
  - a. Henderson-Hasselbach equation
  - b. pH and H<sup>+</sup> ion concentration
  - c. CO<sub>2</sub> and O<sub>2</sub> transport
  - d. Normal and abnormal states
2. Test procedures
  - a. Analytical principles

- b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Test result interpretation
4. Disease state correlation

#### **B. Electrolytes**

1. Biochemical theory and physiology
  - a. Sodium, potassium, chloride, CO<sub>2</sub>, bicarbonate
  - b. Calcium, magnesium, phosphorus, iron, TIBC
  - c. Trace elements
  - d. Normal and abnormal states
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Calculations (osmolality, anion gap)
4. Test result interpretation
5. Disease state correlation

### **IV. SPECIAL CHEMISTRY**

#### **A. Endocrinology**

1. Biochemical theory and physiology
  - a. Metabolic pathways
  - b. Normal and abnormal states
  - c. Mechanism of action
  - d. Physical and chemical properties
    - 1) Steroid hormones (e.g., cortisol, estrogen, hCG)
    - 2) Peptide hormones (e.g., insulin, prolactin)
    - 3) Thyroid hormones
    - 4) Catecholamines
2. Test procedures
  - a. Principles
    - 1) Fluorescence
    - 2) Immunoassay
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
  - c. Stimulation/suppression tests
3. Test result interpretation
4. Disease state correlation

## B. Vitamins and Nutrition

1. Biochemical theory and physiology
  - a. Metabolism and action
  - b. Normal and abnormal states
  - c. Properties
2. Test procedures
  - a. Principles
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
3. Test result interpretation
4. Disease state correlation

## C. Therapeutic Drug Monitoring

1. Pharmacokinetics
  - a. Therapeutic states
  - b. Toxic states
  - c. Metabolism and excretion
2. Chemical and physical properties
  - a. Aminoglycosides (e.g., gentamicin)
  - b. Cardioactive (e.g., digoxin)
  - c. Anticonvulsants (e.g., phenobarbital)
  - d. Antidepressants (e.g., lithium)
  - e. Immunosuppressants (e.g., tacrolimus)
3. Test procedures
  - a. Principles
    - 1) Immunoassay
  - b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
4. Test result interpretation
5. Disease state correlation

## D. Toxicology

1. Toxicokinetics
  - a. Toxic effects, signs and symptoms
  - b. Metabolism and excretion
2. Chemical and physical properties
  - a. Alcohols
  - b. Heavy metals (e.g., lead)
  - c. Analgesics (e.g., acetaminophen)
  - d. Drugs of abuse
3. Test procedures
  - a. Principles
    - 1) Immunoassay
    - 2) Enzymatic methods

- b. Special precautions, specimen collection and processing, troubleshooting, and interfering substances
4. Test result interpretation
5. Disease state correlation

## HEMATOLOGY

(17 – 22% of total exam)

### I. HEMATOLOGY PHYSIOLOGY (to include blood, body fluids, and bone marrow)

- A. Production
- B. Destruction
- C. Function

### II. HEMATOLOGY DISEASE STATES

#### A. Erythrocytes

1. Anemia
  - a. Microcytic
    - 1) Iron deficiency
    - 2) Thalassemia
    - 3) Sideroblastic
    - 4) Chronic inflammation
  - b. Normocytic
    - 1) Hereditary hemolytic
    - 2) Acquired hemolytic
    - 3) Hypoproliferative
    - 4) Acute hemorrhage
  - c. Macrocytic
    - 1) Megaloblastic
    - 2) Non-megaloblastic
  - d. Hemoglobinopathies
2. Erythrocytosis
  - a. Relative
  - b. Absolute

#### B. Leukocytes (WHO classification)

1. Benign leukocyte disorders
  - a. Myeloid
  - b. Lymphoid
2. Myeloid neoplasia
  - a. Acute leukemia
  - b. Myelodysplastic syndromes
  - c. Myeloproliferative neoplasms
3. Lymphoid neoplasia
  - a. Acute leukemia
  - b. Chronic leukemia/lymphoma
  - c. Plasma cell dyscrasias
4. Hereditary anomalies



### C. Platelets

1. Quantitative abnormalities
  - a. Thrombocytopenia
    - 1) Increased destruction (e.g., ITP, TTP, HIT)
    - 2) Decreased production
    - 3) Pseudothrombocytopenia
  - b. Thrombocytosis
2. Qualitative defects
  - a. von Willebrand disease
  - b. Bernard-Soulier syndrome
  - c. Glanzmann thrombasthenia

## III. HEMATOLOGY LABORATORY TESTING

### A. Cell Counts (to include blood and body fluids)

1. Manual
2. Automated
3. Reticulocytes
4. Spurious results

### B. Differentials and Morphology Evaluation (to include blood and body fluids)

### C. Hemoglobin

1. Quantitative
2. Qualitative
  - a. Electrophoresis
  - b. HPLC
  - c. Sickle solubility

### D. Hematocrit

### E. Indices

### F. Hemolytic Indicators (e.g., haptoglobin, LD)

### G. Special Stains

1. Esterase
2. Myeloperoxidase
3. Prussian blue
4. Kleihauer-Betke

### H. Other Studies

1. ESR
2. G-6-PD
3. Heinz body

### I. Flow Cytometry Immunophenotyping

1. Leukemia
2. Lymphoma
3. Lymphocyte subsets
4. PNH

### J. Molecular and Cytogenetic Testing

1. Recurring cytogenetic abnormalities (WHO classification)
2. *BCR/ABL1*
3. *JAK2*

## IV. HEMOSTASIS

### A. Physiology

1. Coagulation pathways
2. Fibrinolytic pathway
3. Vascular system

### B. Disease States

1. Coagulation factor deficiencies
  - a. Acquired
  - b. Hereditary
2. Inhibitors
3. Fibrinolytic system
4. Hypercoagulable states
5. DIC

### C. Laboratory Determinations

1. PT/INR
2. APTT
3. Fibrinogen
4. D-dimer
5. Thrombin time
6. Mixing studies
7. Platelet function (e.g., PFA)
8. Inhibitor assays
9. Factor assays
10. von Willebrand assays
11. Platelet aggregation
12. Thromboelastography
13. Hypercoagulability assessment
  - a. Assays (e.g., lupus anticoagulant, protein S, protein C, HIT studies)
  - b. Molecular (e.g., factor V Leiden, prothrombin 20210)
14. Anti-Xa
15. Direct thrombin inhibitors
16. Heparin neutralization

## **IMMUNOLOGY**

(5 – 10% of total exam)

### **I. PRINCIPLES OF IMMUNOLOGY**

#### **A. Immune System Physiology**

1. Primary and secondary response
2. B and T cells, macrophages
3. Genetics

#### **B. Immunoglobulins**

1. Classes and subclasses
2. Structure
3. Biologic and physical properties

#### **C. Antigen-Antibody Interactions**

1. Principles
2. Testing
  - a. Principles
  - b. Methods

#### **D. Complement**

1. Classical and alternative pathway mechanisms
2. Biologic properties

### **II. DISEASES OF THE IMMUNE SYSTEM**

#### **A. Autoimmunity**

1. Systemic (e.g., SLE)
2. Organ-specific (e.g., Graves disease)

#### **B. Hypersensitivity**

1. I, II, III, IV

#### **C. Immunoproliferative Diseases**

1. Monoclonal gammopathies (e.g., plasma cell myeloma, Waldenström macroglobulinemia)

#### **D. Immunodeficiency**

1. Hereditary (e.g., SCID)
2. Acquired (e.g., HIV)

### **III. TRANSPLANTATION**

- A. Graft-versus-host Disease
- B. HLA Typing
- C. Tumor Immunology

### **IV. INFECTIOUS DISEASE SEROLOGY**

- A. Clinical Significance and Epidemiology of Viral Pathogens (e.g., hepatitis [A, B, C], EBV, HIV, CMV, rubella, measles)
- B. Stages of Infection of *Treponema pallidum* and *Borrelia burgdorferi*
- C. Tuberculosis Infection (e.g., interferon-gamma release assay, PPD)

### **V. SEROLOGIC PROCEDURES**

- A. ANA
- B. Thyroid Antibodies
- C. Rheumatoid Factor
- D. Labeled Immunoassays (e.g., ELISA)
- E. Nontreponemal Syphilis Testing (e.g., RPR)
- F. Treponemal Syphilis Testing (e.g., MHATP)
- G. Cytokine Testing
- H. Immunofluorescence

### **VI. TEST RESULTS**

- A. Interpretation
- B. Confirmatory Testing
- C. Disease State Correlation

## **MICROBIOLOGY**

(17 – 22% of total exam)

### **I. PREANALYTIC PROCEDURES**

#### **A. Specimen Collection and Transport**

1. Patient identification and specimen labeling
2. Specimen collection
3. Specimen transport systems and conditions for all organisms

#### **B. Specimen Processing**

1. Specimen prioritization and rejection criteria
2. Biosafety cabinet and personal protective equipment
3. Specimen preparation methods and applications
4. Media
5. Inoculation of media
6. Incubation conditions (e.g., temperature, atmosphere, duration)
7. Preparation methods for slides used for stains

#### **C. Stains: Procedure, Principle, and Interpretation**

1. Gram
2. Acid-fast
3. Modified acid-fast
4. KOH and calcofluor-white
5. Trichrome
6. Giemsa
7. Acridine orange



## II. ANALYTIC PROCEDURES FOR BACTERIOLOGY

### A. Blood and Bone Marrow

1. Specimen sources (e.g., peripheral, intravenous catheters)
2. Continuous-monitoring systems
3. Rapid identification/resistance detection methods
4. Species comprising skin flora and clinical significance
5. Colony morphology and identification of major pathogens (e.g., *Staphylococcus aureus*, other *Staphylococcus* spp. including coagulase-negative staphylococci, beta-hemolytic streptococci, *Enterococcus* spp., *Candida* spp., *Streptococcus pneumoniae*, *Acinetobacter baumannii*, *Enterobacteriaceae*, *Pseudomonas* spp.)
6. Common agents of endocarditis
7. Agents of bone marrow infection (e.g., *Brucella* spp., *Salmonella* spp.)
8. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

### B. Cerebrospinal Fluid

1. Specimen sources (e.g., lumbar puncture, shunt, reservoir)
2. Colony morphology and identification of major pathogens associated with acute meningitis (e.g., *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Neisseria meningitidis*, *Escherichia coli*, *Listeria monocytogenes*, *Enterobacteriaceae*, *Staphylococcus aureus*, beta-hemolytic streptococci)
3. Common agents of shunt infections (e.g., other *Staphylococcus* spp. including coagulase-negative staphylococci, *Corynebacterium* spp., *Propionibacterium* spp., *Cutibacterium* spp.)
4. Correlation with other laboratory results (e.g., glucose, protein, cell count)
5. Direct detection and molecular methods
6. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

### C. Body Fluids from Normally Sterile Sites

1. Specimen sources (e.g., pleural, peritoneal, pericardial, vitreous and aqueous humor, synovial, amniotic)

2. Indigenous organisms associated with mucosal surfaces and skin
3. Colony morphology and identification of major pathogens (e.g., *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Neisseria* spp., *Escherichia coli*, *Listeria monocytogenes*, *Enterobacteriaceae*, *Staphylococcus aureus*, beta-hemolytic streptococci, *Enterococcus* spp., *Pseudomonas aeruginosa*, *Acinetobacter* spp., *Clostridium perfringens*, *Bacteroides fragilis* group)
4. Molecular methods
5. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

### D. Lower Respiratory

1. Specimen sources (e.g., sputum, endotracheal aspirate, bronchoalveolar lavage, bronchial wash, bronchial brush)
2. Significance of quantitative and semi-quantitative reporting of results
3. Species comprising oral flora colony and Gram stain morphology
4. Colony morphology and identification of major pathogens
5. Direct detection and molecular methods (e.g., *Streptococcus pyogenes*, *Bordetella pertussis*)
6. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

### E. Upper Respiratory

1. Specimen sources (e.g., throat, nasopharynx, middle ear, sinus)
2. Indigenous flora colony and Gram stain morphology
3. Colony morphology and identification of major pathogens
4. Direct detection and molecular methods (e.g., *Streptococcus pyogenes*, *Bordetella pertussis*)
5. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

## F. Gastrointestinal

1. Colony morphology and identification of major pathogens (e.g., *Salmonella* spp., *Shigella* spp., toxigenic *Escherichia coli*, *Campylobacter* spp., *Vibrio* spp., *Yersinia enterocolitica*, *Aeromonas* spp., *Plesiomonas shigelloides*)
2. Direct detection and molecular methods (e.g., *Clostridioides difficile*, Shiga toxin)
3. Serotyping of *Escherichia coli*, *Salmonella* spp., and *Shigella* spp.
4. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)
5. Detection methods for *Helicobacter pylori*

## G. Skin, Soft Tissue, and Bone

1. Specimen sources (e.g., wound, abscess, biopsy)
2. Indigenous flora colony and Gram stain morphology
3. Colony morphology and identification of major pathogens
4. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

## H. Genital Tract

1. Specimen sources (e.g., vaginal, cervical, urethral, endocervical)
2. Indigenous organisms colony and Gram stain morphology
3. Methods for detection of pathogens associated with vaginitis (e.g., *Trichomonas vaginalis*, *Candida* spp., bacterial vaginosis)
4. Culture and/or molecular detection (e.g., *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Streptococcus agalactiae*, and *Mycoplasma* spp.)
5. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

## I. Urine

1. Specimen sources (e.g., mid-stream clean-catch, catheterized, suprapubic, nephrostomy)
2. Colony morphology and identification of major urinary pathogens (e.g., *Enterobacteriaceae*, *Enterococcus* spp., *Streptococcus agalactiae*, *Candida* spp., *Staphylococcus saprophyticus*)

3. Correlation of colony counts with clinical significance
4. Correlation of culture with urinalysis results

## J. Identification Methods (Theory, Interpretation, and Application)

1. Colony morphology
2. Rapid tests used for presumptive identification (e.g., coagulase, catalase, oxidase, indole, PYR)
3. Conventional biochemical identification (e.g., X and V factors, *Neisseria* carbohydrate utilization)
4. Commercial kits
5. Automated methods
6. MALDI-TOF MS
7. Multiplex molecular methods
8. Sequencing (e.g., 16S)

## K. Antimicrobial Susceptibility Testing and Antibiotic Resistance

1. Method, theory, interpretation, and application
2. Phenotypic detection of resistance (e.g., beta-lactamase, ESBL, inducible clindamycin resistance, carbapenamases)
3. Mechanisms of action of major antibiotic classes
4. Detection of genetic determinants of resistance (e.g., *mecA*, *vanA*, *bla<sub>KPC</sub>*)
5. Intrinsic resistance patterns for common species

## L. MRSA/MSSA, VRE, ESBL/CRE Screening

1. Specimen sources
2. Culture methods
3. Molecular methods

## M. BSL-3 Pathogens and Select Agents (Bioterrorism)

1. Specimen sources (e.g., blood, sputum, tissue, lymph node)
2. Colony morphology and rapid tests used for presumptive identification (e.g., *Bacillus anthracis*, *Yersinia pestis*, *Brucella* spp., *Francisella tularensis*)
3. Role of regional laboratory and Laboratory Response Network
4. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

### III. ANALYTIC PROCEDURES FOR MYCOBACTERIOLOGY, VIROLOGY, PARASITOLOGY, AND MYCOLOGY

#### A. Mycobacteriology and *Nocardia* spp.

1. Specimen sources (e.g., lower respiratory, blood, soft tissue)
2. Major pathogens and disease states (e.g., etiology, epidemiology, transmission)
3. Acid-fast reaction, colony morphology, and growth characteristics
4. Identification methods (e.g., probes, sequencing, MALDI-TOF MS)
5. Direct detection by molecular methods
6. Antimicrobial therapy
7. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

#### B. Virology

1. Specimen sources
2. Major pathogens and disease states (e.g., etiology, epidemiology, transmission)
3. Direct detection of pathogens

#### C. Parasitology

1. Specimen sources (e.g., stool, respiratory, blood, tissue)
2. Major pathogens and disease states (e.g., etiology, epidemiology, transmission)
3. Microscopic and macroscopic identification
4. Direct and molecular detection

#### D. Mycology

1. Specimen sources
2. Major pathogens and disease states (e.g., etiology, epidemiology, transmission)
3. Colony morphology and growth characteristics of major pathogens (e.g., temperature, growth rate, length of incubation)
4. Microscopic identification of major pathogens
5. Direct and molecular detection
6. Other identification methods (e.g., biochemical, automated methods, MALDI-TOF MS)

### IV. POSTANALYTIC PROCEDURES

- A. Documentation Practices
- B. Urgent and Critical Value Reporting
- C. Result Review and Autoverification
- D. Issuing Corrected Reports
- E. Reporting to Infection Control/Prevention and Public Health

## LABORATORY OPERATIONS

(5 – 10% of total exam)

### I. QUALITY ASSESSMENT/TROUBLESHOOTING

- A. Preanalytical, Analytical, Postanalytical
- B. Quality Control
- C. Point-of-care Testing (POCT)
- D. Compliance
- E. Regulation (e.g., proficiency testing, competency assessment, accreditation standards)

### II. SAFETY

- A. Safety Programs and Practices
  1. Prevention of infection with bloodborne pathogens
  2. Use of personal protective equipment (PPE)
  3. Safe work practices
  4. Packaging and transportation of specimens and microorganisms
  5. Safety data sheets (SDS) for chemicals and reagents
- B. Emergency Procedures (e.g., needlesticks, splashes to mucous membranes, fire)

### III. LABORATORY MATHEMATICS

- A. Concentration, Volume, and Dilutions
- B. Molarity, Normality
- C. Standard Curves
- D. Mean, Median, Mode, and Confidence Intervals
- E. Sensitivity, Specificity, and Predictive Value

#### **IV. MANUAL/AUTOMATED METHODOLOGY AND INSTRUMENTATION**

- A.** Basic Laboratory Equipment
- B.** Spectrophotometry and Photometry
- C.** Mass Spectrometry
- D.** Osmometry
- E.** Electrophoresis
- F.** Chromatography
- G.** Electrochemistry
- H.** Fluorometry
- I.** Nephelometry
- J.** Flow Cytometry
- K.** Molecular Methods
- L.** Automated Microbiology Processors
- M.** Hematology Instrumentation

#### **V. BASIC MANAGEMENT PRINCIPLES**

#### **VI. EDUCATION PRINCIPLES**

Examples provided (as indicated by e.g.) are not limited to those listed.

All Board of Certification examinations use conventional and SI units for results and reference ranges.

**THE EXAMINEE IS EXPECTED TO KNOW THESE ADDITIONAL CALCULATIONS AND REFERENCE RANGES:**

**CALCULATIONS**

- % Transferrin saturation/UIBC/TIBC
- Unconjugated/indirect bilirubin
- LDL/Friedewald equation/non-HDL
- A/G ratio
- Timed urine calculations
- Creatinine clearance calculations
- Beer's law
- Corrected WBC counts when > 10 nRBCs present
- Manual hemocytometer counts
- Red blood cell indices (e.g., MCV, MCH, MCHC)
- Absolute cell counts given the relative values (e.g., WBCs, reticulocytes)

**REFERENCE RANGES (COMBINED MALE AND FEMALE)**

**CHEMISTRY REFERENCE RANGES**

	<u>Conventional Units</u>	<u>SI Units</u>
Sodium	136 – 145 mmol/L	136 – 145 mmol/L
Potassium	3.5 – 5.1 mmol/L	3.5 – 5.1 mmol/L
Chloride	98 – 107 mmol/L	98 – 107 mmol/L
Total CO <sub>2</sub>	22 – 33 mmol/L	22 – 33 mmol/L
Creatinine	0.8 – 1.2 mg/dL	71 – 106 μmol/L
Blood urea nitrogen (BUN)	6 – 20 mg/dL	2.1 – 7.1 mmol/L
Glucose (fasting)	74 – 100 mg/dL	4.1 – 5.6 mmol/L
Hemoglobin A <sub>1c</sub>	< 5.7%	< 39 mmol/mol
Haptoglobin	30 – 200 mg/dL	0.3 – 2.0 g/L
<b>Arterial blood gases</b>		
pH	7.35 – 7.45	7.35 – 7.45
pCO <sub>2</sub>	35 – 44 mmHg	4.7 – 5.9 kPa
pO <sub>2</sub>	> 80 mmHg	> 10.6 kPa
O <sub>2</sub> saturation	> 95%	> 95%
HCO <sub>3</sub> <sup>-</sup> (bicarbonate)	23 – 29 mmol/L	23 – 29 mmol/L

**HEMATOLOGY REFERENCE RANGES**

	<u>Conventional Units</u>	<u>SI Units</u>
RBC	4.00 – 6.00 x 10 <sup>6</sup> /μL	4.00 – 6.00 x 10 <sup>12</sup> /L
HGB	12.0 – 18.0 g/dL	120 – 180 g/L
HCT	35% – 50%	0.35 – 0.50 L/L
MCV	76 – 100 fL	76 – 100 fL
MCH	26 – 34 pg	26 – 34 pg
MCHC	32 – 36 g/dL	320 – 360 g/L

RDW	11.5 – 14.5%	0.115 – 0.145
Reticulocytes (absolute)	20 – 115 x 10 <sup>3</sup> /μL	20 – 115 x 10 <sup>9</sup> /L
Reticulocytes (relative)	0.5 – 2.5%	0.05 – 0.025
nRBCs	0 nRBC/100 WBC	0 nRBC/100 WBC
Platelets	150 – 450 x 10 <sup>3</sup> /μL	150 – 450 x 10 <sup>9</sup> /L
WBC (Total)	3.6 – 10.6 x 10 <sup>3</sup> /μL	3.6 – 10.6 x 10 <sup>9</sup> /L
Neutrophils (absolute)	1.7 – 7.5 x 10 <sup>3</sup> /μL	1.7 – 7.5 x 10 <sup>9</sup> /L
Neutrophils (relative)	50 – 70%	0.50 – 0.70
Lymphocytes (absolute)	1.0 – 3.2 x 10 <sup>3</sup> /μL	1.0 – 3.2 x 10 <sup>9</sup> /L
Lymphocytes (relative)	18 – 42%	0.18 – 0.42
Monocytes (absolute)	0.1 – 1.3 x 10 <sup>3</sup> /μL	0.1 – 1.3 x 10 <sup>9</sup> /L
Monocytes (relative)	2 – 11%	0.02 – 0.11
Eosinophils (absolute)	0 – 0.3 x 10 <sup>3</sup> /μL	0 – 0.3 x 10 <sup>9</sup> /L
Eosinophils (relative)	1 – 3%	0.01 – 0.03
Basophils (absolute)	0 – 0.2 x 10 <sup>3</sup> /μL	0 – 0.2 x 10 <sup>9</sup> /L
Basophils (relative)	0 – 2%	0.00 – 0.02

#### **BODY FLUID REFERENCE RANGES**

	<b><u>Conventional Units</u></b>	<b><u>SI Units</u></b>
<b><u>Cerebrospinal Fluid (CSF)</u></b>		
WBC and RBC	0 – 5/μL	0 – 5 x 10 <sup>6</sup> /L
Glucose	50 – 80 mg/dL	2.8 – 4.4 mmol/L
Protein	15 – 45 mg/dL	150 – 450 mg/L
<b><u>Seminal Fluid</u></b>		
Liquefaction	30 – 60 minutes	30 – 60 minutes
WBC	< 1 x 10 <sup>6</sup> /mL	< 1 x 10 <sup>9</sup> /L
Volume	2 – 5 mL	2 – 5 mL
pH	7.2 – 8.0	7.2 – 8.0
Motility	> 50% within 1 hour	> 50% within 1 hour
Sperm concentration	> 20 x 10 <sup>6</sup> /mL	> 20 x 10 <sup>9</sup> /L
Morphology	> 30% normal forms	> 30% normal forms
<b><u>Urine</u></b>		
Specific gravity	1.003 – 1.035	1.003 – 1.035
pH	4.5 – 8.0	4.5 – 8.0
Protein	< 10 mg/dL, trace, or negative	< 0.1 g/L, trace, or negative
Bilirubin	negative	negative
Blood	negative	negative
Glucose	≤ 15 mg/dL or negative	≤ 0.8 mmol/L or negative
Nitrite	negative	negative
Leukocyte esterase	negative	negative
Urobilinogen	< 1.0 EU	< 17.0 μmol/L



Ketones	< 5 mg/dL or negative	< 0.5 mmol/L or negative
Microscopic		
RBC	0 – 3/HPF	0 – 3/HPF
WBC	0 – 8/HPF	0 – 8/HPF
Casts	0 – 2 hyaline/LPF	0 – 2 hyaline/LPF
Epithelial cells	0 – 5/HPF	0 – 5/HPF

*All values on the MLS exam can be interpreted using the reference ranges above. These reference ranges will not be given on the exam. Other reference ranges will be provided as needed on the exam.*

**END OF CONTENT GUIDELINE**