

## 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, Serology 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 & 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, Hematology Laboratory Testing, Hemostasis	<b>17 – 22%</b>
<b>IMMUNOLOGY</b>	Principles of Immunology, Diseases of the Immune System, Transplantation, Infectious Disease Serology, Serologic and Molecular Procedures, Test Results	<b>5 – 10%</b>
<b>MICROBIOLOGY</b>	Preanalytic Procedures; Analytic Procedures for Bacteriology; Analytic Procedures for Mycology, Mycobacteriology, Parasitology, and Virology; Post-Analytic 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, etc.).

**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. Leukocyte-reduced components
6. Frozen/deglycerolized red blood cells
7. Apheresis products
8. Fractionation products
9. Whole blood
10. Washed red blood cells
11. Rejuvenated 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. Chemistry, Antigens**

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

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

1. Immunogenicity
2. Antigen frequency

### **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 cells (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
3. Granulocyte 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, and 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) Other 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) Other enzymes
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) Viral proteins
    - 9) Cardiac markers
    - 10) Other compounds
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) Other hormones
2. Test procedures
  - a. Principles
    - 1) Fluorescence
    - 2) Immunoassay
    - 3) Other methods
  - 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
    - 1) Vitamin D
    - 2) Vitamin B12/folate
    - 3) Other vitamins
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. Anti-convulsants (e.g., phenobarbital)
  - d. Anti-depressants (e.g., lithium)
  - e. Immunosuppressants (e.g., tacrolimus)
  - f. Other drugs
3. Test procedures
  - a. Principles
    - 1) Immunoassay
    - 2) Other methods
  - 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
  - e. Other toxins

3. Test procedures
  - a. Principles
    - 1) Immunoassay
    - 2) Other 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. PHYSIOLOGY (to include blood, body fluids, and bone marrow)**

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

### **II. 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. G6PD
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-ABL*
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., multiple 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 AND MOLECULAR PROCEDURES**

- A. ANA
- B. Thyroid Antibodies
- C. Rheumatoid Factor
- D. Direct Detection Methods for Pathogens
- E. Labeled Immunoassays (e.g., ELISA)
- F. Nontreponemal Syphilis Testing (e.g., RPR)
- G. Treponemal Syphilis Testing (e.g., MHATP)
- H. Cytokine Testing
- I. Target Amplification
- J. Nucleic Acid Sequencing
- K. Hybridization Techniques
- L. Other

### **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*, 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., coagulase-negative staphylococci, *Corynebacterium* spp., *Propionibacterium* spp.)
4. Correlation with other lab 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., *S. pneumoniae*, *H. influenzae*, *Neisseria* spp., *E. coli*, *Listeria monocytogenes*, *Enterobacteriaceae*, *S. aureus*, beta-hemolytic streptococci, *Enterococcus* spp., *Pseudomonas aeruginosa*, *Acinetobacter*, *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 *E. coli*, *Campylobacter* spp., *Vibrio* spp., *Yersinia enterocolitica*, *Aeromonas* spp., *Plesiomonas shigelloides*)
2. Direct detection and molecular methods (e.g., *Clostridium difficile*, Shiga toxin)
3. Serotyping of *E. coli*, *Salmonella*, *Shigella*

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*, *Candida*, bacterial vaginosis)
4. Culture and/or molecular detection (e.g., *N. gonorrhoeae*, *C. trachomatis*, *Streptococcus agalactiae*, and *Mycoplasma* spp.)
5. Organism pathogenicity (e.g., etiology, transmission, virulence mechanisms)

**I. Urine**

1. Specimen source (e.g., mid-stream clean catch, catheterized, suprapubic, nephrostomy)
2. Colony morphology and identification of major urinary pathogens (e.g., *Enterobacteriaceae*, *Enterococcus*, *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., TSI, decarboxylases, carbohydrate utilization, motility, urease, XV factors)
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, carbapenemases)
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 source (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 MYCOLOGY, MYCOBACTERIOLOGY, PARASITOLOGY, AND VIROLOGY**

**A. Mycobacteriology and Nocardia spp.**

1. Specimen source (e.g., lower respiratory, blood, soft tissue)
2. Acid-fast reaction, colony morphology and growth characteristics
3. Identification methods (e.g., probes, sequencing, MALDI-TOF MS)
4. Direct detection by molecular methods
5. Antimicrobial therapy
6. 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 source (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. POST-ANALYTIC 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. Pre-analytical, Analytical, Post-analytical
- 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. Safety data sheets (SDS) for chemicals and reagents
- B. Emergency Procedures (e.g., needlesticks, splashes to mucous membranes, fire)
- C. Packaging and Transportation of Specimens and Microorganisms

## **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. Microscopy
- B. Centrifugation
- C. Spectrophotometry and Photometry
- D. Mass Spectrometry
- E. Osmometry
- F. Electrophoresis
- G. Chromatography
- H. Electrochemistry
- I. Molecular Methods
- J. Other Methods

## **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.

You will need to bring a non-programmable calculator with log function to the examination.

**END OF CONTENT GUIDELINE**