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DIPLOMATE IN MEDICAL LABORATORY IMMUNOLOGY, DMLI(ASCP)

EXAMINATION CONTENT GUIDELINE

EXAMINATION MODEL

The DMLI(ASCP) certification examination is composed of 150 questions given in a 4-hour time frame. All exam questions are multiple-choice with one best answer.

Exam questions 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, CLSI, etc.).

EXAMINATION CONTENT AREAS

The DMLI exam questions encompass the following content areas within Immunology: Basic Immunologic Principles and Mechanisms; Immunologic Techniques; Immunodiagnosis and Clinical Correlations; and Clinical Laboratory Management and Operations. Each of these content areas comprises a specific percentage of the overall 150-question exam. The content areas and percentages are described below:

CONTENT AREAS	DESCRIPTION	EXAM PERCENTAGES
BASIC IMMUNOLOGIC PRINCIPLES AND MECHANISMS	Antigens and antibodies, immune system cells and tissues, cellular interaction and immune regulation, effects of immune mechanisms on host	**15%**
IMMUNOLOGIC TECHNIQUES	Antigen/antibody reaction assays, immunoassays, flow cytometry, electrophoresis techniques, molecular techniques	**15%**
IMMUNODIAGNOSIS AND CLINICAL CORRELATIONS	Infectious diseases, autoimmune diseases, immunodeficiency disorders (primary and secondary), allergic diseases, histocompatibility/immunogenetic and transplant immunology, tumor immunology/hematologic disorders, inflammation	**50%**
CLINICAL LABORATORY MANAGEMENT AND OPERATIONS	Quality control and quality assurance; test development, validation, verification, and implementation; instrument validation and implementation; safety programs and practices; laboratory administration	**20%**

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

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EXAMINATION CONTENT OUTLINE

I. BASIC IMMUNOLOGIC PRINCIPLES AND MECHANISMS (15% of exam)

A. Antigens and Antibodies

1. Antibody isotypes and subclasses
2. Antibody structure and function
3. Antigen-antibody interactions (e.g., affinity and avidity)
4. Diversity and immunogenicity

B. Immune System Cells and Tissues

1. Cell subpopulations (e.g., lymphocytes, monocytes, macrophages, neutrophils, eosinophils, basophils)
2. Cellular markers (e.g., CD proteins)
3. Development and differentiation and functional maturation
4. Role in immune response
5. Lymphoid system (e.g., lymph node, spleen, thymus, mucosal-associated lymphoid tissue, bone marrow)

C. Cellular Interaction and Immune Regulation

1. Cellular activation
2. Signal transduction
3. Mechanisms of cell death (e.g., pyroptosis, apoptosis, and necrosis)
4. Immunization and adjuvants
5. Major histocompatibility complex (MHC) restriction
6. Immunosuppressive and immunomodulatory drugs
7. T-regulatory cells
8. T-cell excision circles
9. Soluble mediators (e.g., cytokines, soluble receptors, reactive oxygen intermediates, interleukins, interferons, chemokines, growth factors)
10. Pattern recognition receptors (e.g., toll-like receptors [TLRs], NOD-like receptors [NLRs])
11. Killer-cell immunoglobulin-like receptors (KIR)
12. Cellular migration (e.g., adhesion molecules)

D. Effects of Immune Mechanisms on Host

1. Mechanisms of immune homeostasis
2. Microbial and tumor immunity
3. Autoimmunity
4. Transplantation immunity
5. Immunotherapy
6. Inflammation
7. Complement pathways and activation

II. IMMUNOLOGIC TECHNIQUES (15% of exam)

A. Antigen/Antibody Reaction Assays

1. Precipitation (e.g., radial, Ouchterlony)
2. Agglutination (e.g., latex, particle, hemagglutination, flocculation)
3. Nephelometry
4. Turbidimetry

B. Immunoassays

1. Enzyme immunoassays (EIA)
2. Immunoblotting
3. Chemiluminescence
4. Immunofluorescence
5. Multiplex liquid- and bead-based techniques
6. Solid-based arrays (e.g., single-cell immunoproteomics on a chip)
7. Enzyme-linked immunospot (ELISpot) assay
8. Plaque-reduction neutralizing antibody titer (PRNT) assay
9. Other

C. Flow Cytometry

1. Principles and techniques
2. Applications (e.g., immunophenotyping, functional analysis, rare event analysis)

D. Electrophoresis Techniques

1. Protein electrophoresis (e.g., gel, capillary)
2. Oligoclonal banding
3. Immunofixation
4. Free light chain analysis

E. Molecular Techniques

1. Nucleic acid amplification (e.g., polymerase chain reaction [PCR], PCR variations, transcription-mediated amplification [TMA])
2. Separation techniques (e.g., electrophoresis)
3. Nucleic acid sequencing (e.g., Sanger sequencing, pyrosequencing, next-generation sequencing [NGS])

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III. IMMUNODIAGNOSIS AND CLINICAL CORRELATIONS (50% of exam)

A. Infectious Diseases

1. Indications for testing
2. Test result interpretation
3. Diagnostic strategies
4. Test selection
   a. Serologic (e.g., bacterial, viral, mycotic, parasitic)
   b. Molecular (e.g., bacterial, viral, mycotic, parasitic)
   c. Cytokine testing (e.g., IGRA, CS1)
5. Appropriate timing and specimen for disease staging
6. Differential diagnosis/algorithms

B. Autoimmune Diseases

1. Indications for testing
2. Immunologic causes of autoimmune diseases (e.g., HLA associations) and disease categorization
3. Test result interpretation
   a. Systemic autoimmune diseases (e.g., ANA, ENA, anti-DNA, RF, anti-CCP, aPL)
   b. Organ-specific autoimmune diseases (e.g., kidney, endocrine, skin, cardiovascular, neuromuscular, gastrointestinal, pulmonary)
   c. Other indicators of autoimmunity (see III.G.)
4. Differential diagnosis/algorithms
5. Limitations of autoantibody tests including standardization and harmonization
6. Disease monitoring (e.g., immune therapy)

C. Immunodeficiency Disorders (Primary and Secondary)

1. Indications for testing
2. Monitoring and prognostic tests
3. Test result interpretation
   a. Assessment of cellular responses (e.g., neutrophil oxidative burst, lymphocyte antigen and mitogen proliferation, cytokine production)
   b. Immunophenotyping (e.g., lymphocyte subsets, leukocyte adhesion panel)
   c. Humoral (e.g., complement, immunoglobulins)
   d. Molecular testing (e.g., newborn screening, primary immunodeficiency [PID] genetic testing)
4. Differential diagnosis/algorithms

D. Allergic Diseases

1. Indications for testing
2. Test result interpretation
3. Allergen testing
   a. Total IgE
   b. Allergen-specific IgE
   c. Allergen component
   d. Cellular allergen-specific response (e.g., basophil function test)
4. Evaluation of therapy (e.g., allergen-specific IgG)

E. Histocompatibility/Immunogenetic and Transplant Immunology

1. Indications for testing
2. Test result interpretation
3. HLA typing for solid-organ transplants
4. HLA testing for hematopoietic cell transplants
5. Posttransplant monitoring (e.g., chimerism, donor-specific antibody testing)
6. Disease association (e.g., celiac disease, pharmacogenetics, platelet transfusion)

F. Tumor Immunology/Hematologic Disorders

1. Indications for testing
2. Test result interpretation
3. Hematologic testing (e.g., paroxysmal nocturnal hemoglobinuria testing, fetal hemoglobin, platelet analysis by flow cytometry, stem cell enumeration)
4. Cancer testing (e.g., tumor markers, paraneoplastic antibodies, leukemia/lymphoma panel [immunophenotyping or molecular methods], solid tumors)
5. Cancer immune monitoring (e.g., CAR T cells, immune checkpoint inhibitors)
6. Monitoring effects of therapy (e.g., minimal/measurable residual disease [flow cytometry or molecular methods])

G. Inflammation

1. Indications for testing
2. Test result interpretation
3. Systemic (e.g., CRP, ESR, cytokines)
4. Organ-specific (e.g., gastrointestinal [calprotectin, lactoferrin], pulmonary [elastase, alpha-1-antitrypsin], organ-specific cytokines)

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IV. CLINICAL LABORATORY MANAGEMENT AND OPERATIONS (20% of exam)

A. Laboratory Operations

1. Quality control and quality assurance (preanalytical, analytical, postanalytical)
2. Test development, validation, verification, and implementation (e.g., test performance characteristics)
3. Instrument validation and implementation (e.g., microscopy, flow cytometry, automated immunoassay systems)

B. Safety

1. Safety programs and practices (e.g., prevention of infection with bloodborne pathogens, personal protective equipment [PPE], chemical hygiene, sharps, splashes to mucous membranes, fire drills, radioactive safety)

C. Laboratory Administration

1. Financial (e.g., budgets, capital equipment acquisition, cost analysis, reimbursement, purchasing, inventory, billing and coding)
2. Service operations (e.g., customer service, facility management, information technology)
3. Personnel (e.g., staffing and productivity, performance standards, training and evaluation)
4. Quality management (e.g., continuous quality improvement, risk management/medical-legal issues)
5. Regulatory compliance and lab accreditation (e.g., CAP, CLIA, HIPAA, OSHA)

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.

END OF CONTENT GUIDELINE