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Preparing for the American Board of Pathology (ABPath) Primary Examination of Fundamental Knowledge and Skills

Clinical Pathology

Content Specifications

Overview:

Clinical Pathology Content Specifications

This guide outlines the content that may appear on an American Board of Pathology Primary Certification examination.

Guidance: Residents are expected to have a mastery of material designated as Core/Foundational and at least achieved competence for material designated as Advanced Resident. This document also includes content that would be covered in Fellow-level training (shaded in blue) for which Residents should be superficially familiar.

Key to Designations:

C = Core/Foundational Knowledge

AR = Advanced Resident

F = Fellow/Advanced Practitioner

The exam assesses the knowledge, judgment, skills, and abilities needed to identify particular entities, appropriately process specimens (i.e., work-up), and diagnose and/or characterize disease by methods used in clinical pathology, including molecular methods. Residents are also referred to the Molecular Genetic Pathology Content Specifications document for an in-depth outline of content related to Molecular Pathology, in addition to that presented here.

The specific diseases listed in this document are important for trainees to know, but it is not possible to create a fully comprehensive list of all the material needed for certification and effective practice. This document should be used as a guide.

Contents

Blood Banking/Transfusion Medicine

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	5. Treatment/Transfusion	AR
	6. Treatment/Pharmacologic	F
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	2. Autoantibodies	AR
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6. Babesiosis		F
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v.	Coagulation Factors, Coagulation Factor Inhibitors, and von Willebrand Factor (e.g., description, half-life)	AR
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vii.	C1 Inhibitor	F
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c. Intensive Care		C
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3. Risks and Adverse Effects		AR
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3. Risks and Adverse Effects		AR
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3.	Window Period and Risk of Transmission	C
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6.	Prevention	C
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3. Window Period and Risk of Transmission	F
4. Donor Testing and Counseling	F
5. Clinical Features	F
6. Prevention	F
7. Treatment	F
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3. Clinical Features	C
4. Prevention	C
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1. General Information and Epidemiology	AR
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e. Transfusion Transmission of Parasites	
i. Chagas Disease	
1. General Information and Epidemiology	AR
2. Transmission	AR
3. Donor Testing and Counseling	AR
4. Clinical Features	F
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ii. Malaria	
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2. Transmission	AR
3. Donor Testing and Counseling	AR
4. Clinical Features	F
5. Prevention	F
iii. Babesiosis	
1. General Information and Epidemiology	AR
2. Transmission	AR

3. Donor Testing and Counseling	AR
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5. Prevention	F
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4. Clinical Features	F
5. Prevention	F
f. Bacterial Contamination of Blood Products	AR
i. Red Blood Cells – Overview and Epidemiology	AR
ii. Allogeneic RBCs – Agents and Incidence	AR
iii. Autologous RBCs – Agents and Incidence	AR
iv. Plasma, Cryoprecipitate, and Derivatives – Agents and Incidence	AR
v. Platelets	AR
1. Sources of Contamination	AR
2. Agents and Incidence	AR
3. Clinical Features	AR
4. Treatment	AR
5. Prevention	AR
vi. Strategies to Reduce the Risk of Posttransfusion Sepsis	AR
1. Donor Screening	AR
2. Skin Preparation	AR
3. Diversion	AR
4. Apheresis versus Whole Blood-Derived Platelets	AR
5. Storage Time and Temperature	AR
6. Bacterial Detection	AR
7. Bacterial Elimination	AR
8. Syphilis	AR
g. Prion Diseases	F
i. General Information and Epidemiology	F
ii. Transmission	F
iii. Clinical Features	F
iv. Risk Management – Donor Selection	F
v. Blood Component Processing	F
vi. Plasma Derivative Manufacture	F
vii. Cellular, Tissue, and Organ Transplantation	F
h. Pathogen Inactivation	
i. Overview and Description	AR
ii. Plasma	
1. Psoralen Ultraviolet Light Treatment	C
2. Solvent/Detergent Treatment	AR
3. Methylene Blue Light Treatment	AR
4. Riboflavin Light Treatment	AR

iii. Platelets
1. Psoralen Ultraviolet Light Treatment C
2. Riboflavin Light Treatment AR
3. Thionine Light Treatment AR
iv. Red Cells F
1. Alkylating Agents F
2. Photosensitizers F
3. Riboflavin Light Treatment F
v. Emerging Technologies F

9. Blood Donors and Blood Collection

a. Recruitment and Screening of Donors and the Collection, Processing and Testing of Blood
i. Organization of Blood Services
1. United States C
2. Outside the United States F
ii. Blood Donor Recruitment AR
iii. Collection Process
1. Donor Evaluation AR
a. Consent AR
b. History & Physical Examination AR
c. Laboratory Testing AR
d. Deferral Criteria AR
2. Blood Collection AR
a. Whole Blood AR
b. Component Separation AR
c. Leukocyte Reduction AR
d. Automated Collection AR
3. Blood Component Testing AR
a. ABO/Rh AR
b. Antibody Screening AR
c. Infectious Disease AR
4. Distribution AR
5. Source Plasma AR
iv. Blood Donor Adverse Events
1. Donor Reactions AR
a. Categories AR
b. Incidence AR
c. Clinical Features AR
d. Risk Factors AR
e. Treatment AR
f. Prevention AR
2. Phlebotomy-Related AR

a. Categories	AR
b. Incidence	AR
c. Clinical Features	AR
d. Risk Factors	AR
e. Treatment	AR
f. Prevention	AR
3. Long-Term Effects of Donation	F
a. Iron	F
b. Platelets	F
c. Plasma Proteins	F

10. Surgery Patients

a. Alternatives to Transfusion: Perioperative Blood Management	AR
i. Preoperative	AR
1. Autologous Blood Donation	AR
2. Anemia Optimization	AR
a. Iron	AR
b. Erythropoietin	AR
ii. Intraoperative/Postoperative	AR
1. Acute Normovolemic Hemodilution	AR
2. Intraoperative Autologous Blood Recovery and Reinfusion (Cell Salvage)	AR
3. Postoperative Autologous Blood Recovery and Reinfusion	AR
b. Hemostasis for Surgery/Invasive Procedures	
i. Preprocedure Blood Components	
1. Common Laboratory Tests of Hemostasis and Their Relationship with Procedure-Related Bleeding	C
2. Procedure-Related Bleeding	
a. Central Venous Catheter	AR
b. Liver Biopsy	AR
c. Thoracentesis and Paracentesis	AR
d. Gastrointestinal Endoscopy and Biopsy	AR
e. Procedures on Upper Airway, Bronchoscopy, and Transbronchial Lung Biopsy	AR
f. Renal Biopsy	AR
g. Epidural Anesthesia, Lumbar Puncture, and Neurosurgical Procedures	AR
h. Angiography	AR
ii. Treatment of Bleeding	F
1. Local	F
a. Physical – Sutures, Electrocautery, Compression, Direct Packing, etc.	F
b. Topical Agents	F

c. Topical Sealants	F
d. Topical Thrombin	F
e. Topical Antifibrinolytics	F
2. Generalized	F
a. Skin and Membrane	F
b. Purpura and Soft Tissue	F
c. Small Vessel Bleeding During Surgery	F
d. DDAVP	F
c. Transfusion Therapy for Trauma and Burn Patients	
i. Shock	
1. General Information and Definition	C
2. Hemorrhagic Shock and Classification	C
a. Acidosis	C
b. Hypothermia	C
c. Coagulopathy	C
3. Trauma Patient	
a. Initial Resuscitation	
a. Damage Control	C
b. Blood Component Therapy	C
c. Hemostatic Agents	AR
d. Pharmacologic Agents	AR
b. Intraoperative	
a. Blood Component Therapy	C
b. Damage Control	AR
c. Temperature	AR
d. Autotransfusion	AR
e. Solid Organ Injury	AR
f. Hemostatic Agents	AR
g. Pharmacologic Agents	AR
c. Recovery Phase	C
a. Blood Component Therapy	C
d. Massive Transfusion	C
a. Definition	C
b. Blood Component Therapy	C
c. Complications	C
4. Patients with Thermal Injuries (Burns)	F
a. Initial Resuscitations	F
a. Fluid Therapy	F
1. Colloid	F
2. Crystalloid	F
b. Transfusion Therapy	F
c. Hemostatic Agents	F
d. Pharmacologic Agents	F
d. Transfusion Therapy in Solid Organ Transplantation	

i. Organ Procurement and Transplants		F
ii. Immunologic Barriers – ABO and HLA		AR
	a. Across Immunologic Barriers	AR
	b. Organ Selection	AR
	c. Plasma Exchange	F
	d. Pharmacologic Agents	F
iii. Immunohematology		AR
	a. Patient Alloantibodies	AR
	b. Passenger Lymphocyte Antibodies	AR
iv. Transfusion Therapy		AR
	a. Liver	AR
	b. Heart	AR
	c. Lung	AR
	d. Kidney	AR
	e. Pancreas	AR
	f. Other	AR
v. Special Needs		AR
	a. CMV Low Risk	AR
	b. Leukocyte Reduction	AR
	c. Irradiation	AR

11. Biovigilance and Transfusion-Related Immunomodulation

a. Biovigilance/Hemovigilance	F
i. Requirements for Effective Program	F
ii. Scope	F
1. Reporting Criteria	F
a. Adverse Reactions	F
b. Adverse Incidents	F
c. Near Misses	F
2. Biovigilance	F
a. Passive Reporting versus Active Surveillance	F
b. Traceability	F
3. Blood Donors	F
4. Transfusion Recipients	F

12. Platelets

a. Platelet Production (Thrombopoiesis)	C
i. Megakaryocyte Development, Maturation, and Differentiation	C
ii. Thrombopoietic/Megakaryocyte/Hematopoietic Growth Factors	C
iii. Genetic and Cellular Regulation of Thrombopoiesis	C
iv. Platelet Production, Shedding, and Release	C
b. Platelets and Hemostasis	C
i. Normal Platelet Plug and Clot Formation	C

ii. Genetic/Congenital Platelet Disorders	C
iii. Acquired Platelet Disorders	C
c. Platelet Transfusions	
i. Collection and Storage of Platelet Preparations/Concentrates	C
ii. Clinical Platelet Transfusions (Indications, Dose, and Schedule)	C
iii. Alternatives to Platelet Transfusions (Thrombopoietic & Pharmacologic Agents)	AR
d. Platelet Immunity	AR
i. Platelet Antigens (ABO, HLA, Platelet Specific)	AR
ii. Disorders of Platelet Alloimmunization	AR
iii. Platelet Autoimmunity	AR
e. Platelets in the Bloodstream	AR
i. Platelet Circulation, Distribution, and Destruction	AR
ii. Platelet Survival Kinetics in Health and Disease	AR

13. Neutrophils

a. Neutrophil/Granulocyte Transfusions – Primary Clinical Issues	AR
i. Neutrophil Collection, Storage, and Transfusion	AR
ii. Alternatives to Neutrophil Transfusions (Myelopoietic Factors)	AR

14. Intravascular Cell Kinetics — **F**

a. Concepts of Post-Transfusion Recovery and Tracking Labeled/Tracer Cells	F

15. Obstetric and Pediatric Patients

a. Hemolytic Disease of the Fetus and Newborn	
i. ABO Incompatibility	C
ii. Rh(D) and Other Fetal-Maternal RBC Incompatibilities	C
iii. Management	AR
1. Diagnostic and Surveillance Tests	AR
2. Fetal and Neonatal Transfusions, Phototherapy, IVIG, etc	AR
b. Obstetric Transfusion Practices	AR
i. Maternal Hematologic Disorders During Pregnancy	AR
ii. Maternal Hemorrhagic and Transfusions During Pregnancy	AR
iii. Fetal (Intrauterine) Transfusions	AR
c. Congenital Disorders of Clotting and Anticoagulant Protein	
i. Developmental Physiology of Plasma Proteins	C
ii. Hemophilia A, B, and von Willebrand Disease	
1. Pathophysiology and Treatment	C
2. DDAVP	C
3. Congenital Disorders of Non-Hemophilia Clotting Proteins	F
4. Congenital Disorders of Anticoagulant/Prothrombotic Proteins	F
d. Congenital Hemoglobinopathies and Hemolytic Anemias	
i. Sickle Cell Disease (Pathophysiology and Treatment)	C

ii. Non-Sickle Cell Hemoglobinopathies	C
iii. Thalassemias (Pathophysiology and Treatment)	C
iv. Congenital Red Cell Membrane and Enzyme Defects	AR
e. Neonatal Transfusions	
i. Anemia of Prematurity (Pathophysiology and Treatment)	C
ii. Thrombocytopenia of Prematurity (Pathophysiology and Treatment)	C
iii. Neonatal Blood Banking Practices (Dedicated Units, WBC-Reduction, Irradiation, etc.)	AR
iv. Neonatal/Infant Plasma, Cryoprecipitate, and Neutrophil Transfusions	AR

16. Hematopoietic Progenitor Cell (HPC) Transplantation

a. Biology of Marrow Transplantation	
i. Autologous	AR
ii. Allogeneic/Syngeneic	AR
iii. Indications, Methods, Results, and Adverse Effects	F
b. Biology of HPC and HPC Transplantation	
i. HLA Typing for HPC Transplantation	AR
ii. HPC Biology	F
iii. Identification and Measurement of HPC	F
iv. Allogeneic/Syngeneic Donor Selection, Quantification, Eligibility	F
v. Processing Requirements for HPC	F
1. General	F
2. Patient-Specific	F
vi. Regulatory, Compliance, and Accreditation	F
c. HPC Sources and Collection	AR
i. HPC Apheresis – Characteristics and Adverse Effects	AR
1. Biology of Stem Cell Mobilization	AR
2. Apheresis Consideration	
a. Techniques, Vascular Access, Donor Management, and Adverse Events (Allogeneic vs. Autologous)	AR
3. Mobilization Regimens	
a. Indications, Dose, Schedule, Efficacy, and Adverse Effects	F
Chemotherapy	F
Growth Factors – G-CSF, GM-CSF	F
Adhesion Blockers-Plerixafor	F
b. Scheduling Mobilization and Apheresis Collection	F
c. Monitoring Mobilization and HPC Collection	F
d. Collection of Lymphocytes for Infusion (Donor Lymphocyte Infusion [DLI])	F
4. Scheduling Mobilization and Apheresis Collection	F
ii. HPC-Marrow	F
1. Methods of Harvesting	F

2. Characteristics	F
3. Adverse Effects	F
iii. HPC Cord Blood	
1. Characteristics and Methods	F
a. Cord Blood Banking	
Donor Eligibility, Collection Methods, Processing,	
Testing, and Cryopreservation	F
b. Cord Blood Characteristics	F
c. Donor Selection for Transplant	
(Related and Unrelated)	F
iv. Selection of Appropriate HPC Source for a Given Patient	F
d. HPC Processing – Goals, Guidelines, and Methods (Preparation for Infusion)	F
i. HPC for Autologous Transplants	F
ii. HPC for Allogeneic Transplants	F
1. Indications for Plasma, RBC Reduction	F
iii. Preparation for Cells for Donor Lymphocyte Infusion	F
iv. Cord Blood	F
v. Processing of Other CT Products	
(e.g., Antigen-Directed T-cells, Marrow Stromal Cells)	F
e. HPC Storage and Preservation	F
i. Liquid Storage and Transport	
-Anticoagulant, Time, Temperature, Preservative, Cell Concentration	F
ii. Rationale for Cryopreservation	F
iii. Cryopreservation Theory and Practice	F
1. Cryoprotectants	F
2. Cryopreservation Techniques	
-Controlled Rate, “Dump Freeze”	F
3. Storage -Mechanical and Liquid Nitrogen (Vapor vs. Liquid)	F
f. Management of RBC Antigen Incompatibility in Allogeneic Transplantation	
i. Patient Transfusion Management	AR
1. Major or Minor ABO Incompatibility	AR
a. Immediate vs. Delayed Hemolysis	AR
2. Passenger Lymphocyte Syndrome (PLS)	AR
a. Cause, Diagnosis, Course, Therapy, Prevention	AR
ii. Graft Management	F
-Depletion of RBC (Major), Plasma (Minor)	F
g. HPC Assessment – Pre- and Post-Processing and Post Thaw	F
i. Cell Counts and Methods	F
ii. HPC Measurement and Enumeration	F
1. Flow Cytometry	F
2. Non-Flow Methods	F
iii. HPC Viability Assessment Techniques	F
iv. HPC Cell Culture Assays	F
v. HPC Functional and Differentiation Assays	F

vi.	HPC Microbial Assessment	F
	1. Gram Stain and Cultures	F
h.	Cell Selection Methods and Applications	F
i.	Positive and Negative Selection	F
	1. Techniques, Results, Indications	F
ii.	CD34 Cells and Others (e.g., Treg)	F
iii.	Tumor Purging and T-cell Depletion	F
i.	HPC and CTP Thawing and Post-Thaw Processing	
i.	(Apheresis, Marrow, Cord Blood, etc.)	F
ii.	Direct HPC Infusion vs. Pre-Infusion Cell Washing	F
iii.	Special Considerations for Preparation of Cord Blood HPC for Infusion	F
j.	HPC and CTP Infusion	F
i.	General Guidelines	F
	1. Filters, No Irradiation, Infusion Rate DMOS Limits, Infusion Pumps	F
ii.	Adverse Effects and Infusion Reactions	
	1. Incidence, Causes, Diagnosis, and Management	F
iii.	Management and Infusion of Contaminated Products	F
k.	Engraftment	
i.	Definition, Chimerism, Relationship to CD34+ Cell Doses	F
ii.	Rates – Autologous vs. Allogeneic, Related vs. MUD, HPC Source, Conditioning	F
iii.	Engraftment Failure – Causes and Management	F
iv.	Immune Reconstitution Post-Transplant	F
v.	Donor Lymphocyte Infusion – Rationale, Efficacy	F
l.	HPC Laboratory Quality Assurance and Accreditation	F
i.	AABB, FACT, CAP, NMDP	F
ii.	Regulatory Considerations	F
	Federal GMP, GTP, State Supplies, Laboratory Development, Deviations, Non-Conforming HPC and CTP	F
m.	Laboratory Administration	
i.	Staff Hiring and Training	F
ii.	Facilities	F
iii.	Equipment and Supplies	F
iv.	Laboratory Development	F
v.	Deviations, Non-Conforming HPC and CTP	F
n.	Experimental Cell Therapies	
i.	Institutional vs. Commercially Sponsored	F
ii.	Types (e.g., Marrow Stromal, Adoptive Therapy with T-cells, Genetically-Modified Cells)	F
iii.	Special Requirements for Processing (Clean Room, etc.)	F
iv.	Regulatory Considerations	F

17. Blood Bank/Transfusion Medicine-Specific Administration and Laboratory Management

a. Current Legal Issues	
i. Blood Transfusion Injury Claims	
1. Informed Consent	C
2. Blood Shield Laws	F
3. Negligence	F
4. Standard of Care	F
5. Causation	F
ii. HIPAA Privacy Rule	C
iii. Donor Injury	F
iv. Cord Blood	F
v. Tissue Banking	F
b. Current Good Manufacturing Practice	
i. General Overview	C
ii. Licensing Products and Establishments	AR
iii. Recalls and FDA Enforcement Activities	AR
iv. Safety Initiatives	AR
v. Enforcement Options	AR
vi. Rationale	AR
1. Standard Operating Procedures	AR
2. Record Keeping	AR
3. Personnel and Training	AR
4. Calibration	AR
5. Validation	AR
6. Labeling	AR
7. Error Management	AR
8. Quality Control Unit and Internal Audits	AR
9. Facilities and Equipment	AR
10. Process and Production Controls	AR
vii. Information Management	AR
viii. Common Violations	AR
c. Hospital Transfusion Services, Transfusion Committee, and Quality Assurance	
i. Role of the Medical Director	AR
1. Administrative	AR
2. Clinical	AR
3. Education	AR
ii. Quality Assurance	AR
1. Process Control	AR
2. Error Management	AR
3. Improving Transfusion Practice	AR
iii. Regulatory and Accreditation Requirements	AR
1. Food and Drug Administration	AR
2. AABB	AR

3. Joint Commission		AR
4. College of American Pathologists		AR
iv. Transfusion Committee		AR
1. Membership		AR
2. Functions		AR
3. Oversight of Transfusion Policies, Procedures and Guidelines		AR
4. Education		AR
v. Other Administrative Issues		AR
d. Transplant Organizations and Networks in the Regulation of Cellular and Tissue Therapy Programs		
i. Hematopoietic Progenitor Cells		F
1. Sources		F
2. Indications		F
3. HLA Matching		F
4. Donor Registries and Networks, Outcomes Registries, Professional Associations and Networks		F
5. Accreditation Organizations		F
ii. Other Cellular Therapies		F
1. Organizational Aspects		F
2. Accreditation and Regulation		F
iii. Tissue Banks		F
1. Organizational Aspects		F
2. Accreditation and Regulation		F

Chemical Pathology

1. Analytical Techniques and Safety

a. Concept of Solute and Solvent		
i. Expressing Concentrations of Solutions		C
b. Units of Measurement		
i. International Units, Decimal Multiples, and Submultiples of SI units		C
ii. Problem Areas in the Use of SI Units		C
iii. Standardized Reporting of Test Results		C
c. Safety		C
d. Basic Measurement Techniques and Procedures		
i. Centrifugation		C
ii. Controlling Hydrogen Ion Concentration (Buffer Solution)		C
iii. Procedures for Processing Solutions (Dilution, Evaporation, Filtration)		AR
iv. Viscosity		AR
v. Extraction		F
vi. Gravimetry		F
vii. Measurement of Radioactivity		F

e.	Interference with Testing, General	AR
f.	Chemicals	
i.	Reagent Grade and Analytical Reagent Grade Water	AR
ii.	Ultrapure Reagents	F
g.	Reference Materials (Primary, Secondary, Standard, Certified)	F

2. Specimen Collection and Processing

a.	Patient Preparation	C
b.	Handling of Specimens for Testing	C
i.	Maintenance of Specimen Identification	C
ii.	Preservation of Specimens in Transit	C
iii.	Separation and Storage of Specimens	C
iv.	Transport of Specimens	C
c.	Specimens	
i.	Blood	
1.	Venipuncture (Prolonged Occlusions; Order of Draw)	C
2.	Additives (EDTA, Heparin, Citrate, Fluoride, Oxalate, ACD, Gel)	C
3.	Infant (Heel Stick, Small Needles)	C
4.	Hemolysis	C
ii.	Urine (Timed, Random, Preservatives)	C
iii.	Cerebrospinal Fluid	C
iv.	Pleural, Pericardial, and Ascitic Fluids	C
d.	Feces (Timed, Random)	AR
e.	Synovial Fluid	AR
f.	Amniotic Fluid (Amniocentesis)	AR
g.	Saliva	AR
h.	Solid Tissue	F
i.	Hair and Finger Nails	F

3. Optical Techniques

a.	Nature of Light	C
b.	Spectrophotometry (Beer's Law, Wavelengths, Calibration, Performance Checks)	C
c.	Fluorometry	AR
d.	Chemiluminescence, Bioluminescence, Electrochemiluminescence	AR
e.	Nephelometry and Turbidimetry	AR
f.	Atomic Absorption Spectrophotometry	F

4. Electrochemistry and Chemical Sensors

a.	Potentiometry and Ion-Selective Electrodes	AR
b.	Voltammetry/Amperometry	AR

c.	Conductometry	F
d.	Coulometry	F
e.	Optical Chemical Sensors	F
f.	Biosensors	F

5. Electrophoresis

a.	Theory of Electrophoresis	C
b.	Conventional Electrophoresis (Slab Gel, IEF, 2-D)	C
c.	Capillary Electrophoresis	C

6. Chromatography

a.	Separation Mechanisms and Concepts (Retention Factor, Efficiency)	C
i.	Ion-Exchange Chromatography	AR
ii.	Partition Chromatography	AR
iii.	Adsorption Chromatography	AR
iv.	Affinity Chromatography	AR
v.	Size-Exclusion Chromatography	AR
b.	Column Chromatography	AR
i.	Gas Chromatography	AR
ii.	Liquid Chromatography	AR
c.	Qualitative and Quantitative Analyses in Chromatography	AR
i.	Analyte Identification	AR
ii.	Analyte Quantification	AR

7. Mass Spectrometry

a.	Basic Concepts and Definitions	AR
b.	Clinical Applications	
i.	Gas Chromatography-Mass Spectrometry	AR
ii.	Liquid Chromatography	AR
iii.	MALDI-TOF Mass Spectrometry	AR
iv.	SELDI Mass Spectrometry	F
v.	ICP Mass Spectrometry	F
vi.	TOF Mass Spectrometry	F
c.	Instrumentation	
i.	Ion Source	F
ii.	Vacuum System	F
iii.	Mass Analyzers, Ion Detectors, and Tandem Mass Spectrometers	F
d.	Proteomics	F
e.	Analytical Problem of Ion Suppression	F

8. Enzyme and Rate Analyses

a. Basic Principles of Enzymology	C
b. Analytical Enzymology	
i. Measurement of Reaction Rates	AR
ii. Measurement of Enzyme Mass Concentration	AR
iii. Enzymes as Analytical Reagents	AR
iv. Measurement of Isoenzymes and Isoforms	AR
v. Units for Expressing Enzyme Activity	F
vi. Measurement of Substrates	F
vii. Optimization, Standardization, and Quality Control of Enzymes	F
c. Enzyme Kinetics	
i. The Enzyme-Substrate Complex	F
ii. Factors Governing the Rate of Enzyme-Catalyzed Reactions (Michaelis-Menton, Temperature, Substrate Concentration, pH, Inhibitor)	F

9. Principles of Immunochemical Techniques

a. Basic Concepts	
i. General Characteristics of Antigen-Antibody Reaction	C
ii. Characteristics of Antibodies (Polyclonal, Monoclonal)	C
iii. Characteristics of Antigens and Immunogens	AR
b. Overview of General Principles of Immunoassay	
i. Classes of Immunoassay	C
ii. Competitive Immunoassays	C
iii. Noncompetitive Immunoassay (Sandwich, ELISA)	C
iv. Interferences in Immunoassays (HAMA)	C
v. High-Dose Hook Effect	C
c. Antigen Antibody Binding	
i. Antigen Excess	C
ii. Binding Forces	F
iii. Reaction Mechanism	F
iv. Kinetics of Antigen-Antibody Reaction	F
v. Factors Influencing Binding (Ionic Strength, Polymer Effect)	F
d. Qualitative Methods	
i. Immunofixation Electrophoresis (IFE)	C
ii. Western Blotting	AR
iii. Dot Blotting	AR
iv. Principle of Precipitin Reaction	F
e. Quantitative Methods	
i. Turbidimetric and Nephelometric Assay	C
ii. Particle Immunoassay	
1. Latex Turbidimetric Assay	C
2. Latex Agglutination	AR
3. Hemagglutination	F

4. Gelatin Particle Agglutination	F
f. Enzyme Immunoassays	
i. Heterogeneous Immunoassays	C
1. Enzyme Immunoassays	AR
2. Fluorescent Immunoassays	AR
3. Chemiluminescent Immunoassays	AR
ii. Homogeneous Immunoassays (e.g., EMIT, CEDIA)	C
g. Simultaneous Multiple Immunoassays (e.g., Flow Cytometry, Luminex)	AR

10. Point-of-Care Testing

a. Analytical and Technological Considerations	
i. Requirements and Design	C
ii. POCT Applications & Assays	C
1. Drugs of Abuse	C
2. Urinalysis	C
3. Glucose Strips and Meters	C
4. Hematology & Coagulation	C
5. Infectious Disease	C
6. Pregnancy Test	C
7. Blood Gases, Electrolytes, Other	C
8. Transcutaneous Bilirubin	F
b. Implementation Considerations for POCT	AR

11. Peptides and Proteins

a. Interpretation of Protein Electrophoresis & Immunofixation	
i. Serum, Non-Monoclonal Gammopathy	
1. Hepatic Cirrhosis	C
2. Bisalbumin	C
3. Acute Phase Reaction	C
4. Chronic Inflammation	C
5. Alpha-1-Antitrypsin	C
6. Fibrinogen	C
7. Hypogammaglobulinemia	C
8. Nephrotic Syndrome	C
9. Hemolysis	AR
10. Radio Contrast Dyes	F
11. IgG4	F
ii. Serum, Monoclonal Gammopathy (Myeloma, MGUS, Waldenström)	
1. IgG, IgA Paraproteins	C
2. IgM Paraproteins	C
3. IgD, IgE Paraproteins	C

	4. Kappa & Lambda Light Chains	C
	5. Cryoglobulins	C
	6. Therapeutic Antibodies	C
iii.	Urine, Non-Monoclonal Gammopathy	C
iv.	Urine, Monoclonal Gammopathy	C
	1. Intact Immunoglobulin	C
	2. Light Chain (Bence Jones)	C
v.	Light Chains, Serum	
vi.	CSF Electrophoresis	AR
	1. Beta-Transferrin in CSF	AR
	2. CSF Findings in Multiple Sclerosis (Oligoclonal immunoglobulin bands in CSF, Albumin, IgG)	AR

12. Enzymes

a.	Muscle Enzymes	
i.	Creatine Kinase	C
ii.	Aldolase	F
b.	Liver Enzymes	
i.	Aminotransferases	C
ii.	Alkaline Phosphatase	C
iii.	Gamma-Glutamyl Transferase	C
c.	Pancreatic Enzymes	
i.	Amylase	C
ii.	Lipase	C
iii.	Trypsin	F
d.	Red Cell Enzymes	
i.	Hexose Monophosphate Pathway (G6PD)	AR
ii.	The Embden-Meyerhof Pathway (Pyruvate Kinase)	F
e.	Bone Enzymes	
i.	Alkaline Phosphatase (Bone Isoform)	F
ii.	Acid Phosphatase	F
f.	Other Enzymes	
i.	Lactate Dehydrogenase	C
ii.	Cholinesterase	AR

13. Tumor Markers

a.	Clinical Utility of Tumor Markers	
i.	Distribution of Tumor Marker Values	C
ii.	Disease Management using Tumor Markers	C
b.	Individual Tumor Markers	
i.	Prostate-Specific Antigen	C
ii.	Alpha Fetoprotein	C

iii.	Beta-2-Microglobulin	C
iv.	Carcinoembryonic Antigen	C
v.	CA 15-3	C
vi.	CA 125	C
vii.	CA 19-9	C
viii.	Thyroglobulin and Antibodies	C
ix.	Calcitonin	AR
x.	S-100 Proteins	F
xi.	Chromogranins	F
xii.	Neuron-Specific Enolase	F

14. Carbohydrates

a.	Chemistry of Carbohydrates, including Disaccharides, Polysaccharides, and Glycoproteins	C
b.	Metabolism of Carbohydrates	
i.	Digestion and Absorption of Carbohydrates	AR
ii.	Intermediary Metabolism of Carbohydrates	AR
iii.	Regulation of Blood Glucose Concentration	AR
c.	Determination of Glucose	
i.	Specimen Collection and Storage for Glucose	C
ii.	Glucose Methods	C
iii.	Glucose Reference Intervals	C
iv.	Measurement of Glucose in Urine	C
v.	Self-Monitoring of Blood Glucose	F
vi.	Minimally Invasive Monitoring of Blood Glucose	F
d.	Diabetes Mellitus	
i.	Classification of Diabetes Mellitus	C
ii.	Pathogenesis of Type 1 Diabetes Mellitus	C
iii.	Pathogenesis of Type 2 Diabetes Mellitus	C
iv.	Diagnosis of Diabetes Mellitus	C
v.	Chronic Complications of Diabetes Mellitus	C
vi.	Role of the Clinical Laboratory in Diabetes Mellitus	C
e.	Glycated Proteins	
i.	Glycated Hemoglobin	C
ii.	Glycated Fructosamine and Glycated Albumin	F
f.	Ketone Bodies	
i.	Clinical Significance of Ketone Bodies	C
ii.	Determination of Ketone Bodies	C
g.	Hypoglycemia	
i.	Insulin, C-Peptide	C
ii.	Hypoglycemia in Neonates and Infants	AR
iii.	Fasting Hypoglycemia in Adults	AR
iv.	Postprandial Hypoglycemia	AR

v.	Hypoglycemia in Diabetes Mellitus	AR
h.	Lactate	
i.	Urinary Albumin	
i.	Clinical Significance of Urinary Albumin	C
ii.	Methods of Measuring Urinary Albumin	C
j.	Autoantibodies of Diabetes Mellitus	F
i.	Islet Cell Autoantibodies	F
ii.	Insulin Autoantibodies	F
iii.	Glutamic Acid Decarboxylase Autoantibodies	F
k.	Glycogen Storage Disease	F

15. Lipids, Lipoproteins and Apolipoproteins

a.	Cholesterol, HDL Cholesterol, LDL cholesterol, and Triglycerides	C
b.	Apolipoprotein B	AR
c.	Lipoprotein A	AR
d.	Apolipoprotein A and E	F

16. Electrolytes and Blood Gases

a.	Electrolytes	
i.	Specimen for Electrolyte Determinations	C
ii.	Sodium	
	(Hypo-(e.g., SIADH) and Hypernatremia (e.g., Dehydration)	C
iii.	Potassium	C
iv.	Electrolyte Exclusion Effect	C
v.	Chloride	C
vi.	Bicarbonate	C
vii.	Anion Gap	C
b.	Plasma and Urine Osmolality	C
c.	Blood Gases and pH	
i.	Preanalytical Issues	C
ii.	Cooximetry	C
iii.	Determination of pCO_2, pO_2, and pH	C
iv.	Temperature Correction of Measured pCO_2, pO_2, and pH	F
d.	Sweat Testing	
i.	Qualitative Screening Tests	F
ii.	Quantitative Confirmatory Tests	F
iii.	Reference Intervals for Sweat Chloride	F
iv.	Sweat Stimulation and Collection	F
v.	Sources of Error in Sweat Testing	F
vi.	Sweat Testing Quality Assurance	F

17. Hormones

a.	Hormone Classification	
i.	Polypeptide or Protein Hormones	AR
ii.	Steroid Hormones	AR
iii.	Amino Acid-Related Hormones	AR

18. Catecholamines and Serotonin

a.	Clinical Applications	
i.	Pheochromocytoma	AR
ii.	Neuroblastoma	AR
iii.	Carcinoid	AR
iv.	Dysautonomias and Genetic Disorders	F

19. Vitamins and Trace Elements

a.	Individual Vitamins	
i.	Vitamin B12, Cyanocobalamin	C
ii.	Folic Acid	C
iii.	Vitamin B1, Thiamine	AR
iv.	Vitamin B2, Riboflavin	AR
v.	Vitamin B6, Pyridoxine, Pyridoxamine, and Pyridoxal	AR
vi.	Vitamin A	F
vii.	Vitamin E	F
viii.	Vitamin C, Ascorbic Acid	F
ix.	Biotin	F
x.	Niacin and Niacinamide	F
b.	Nutritional Trace Elements	
i.	Laboratory Assessment of Nutritional Trace Element Status	F
ii.	Individual Nutritional Trace Element (e.g., Cobalt, Copper, Zinc, Manganese, Molybdenum, Iodine, Bromine, and Selenium)	F
c.	Iron, Transferrin, Hemochromatosis, Ferratin, and Hemoglobin	C
d.	Hemoglobinopathy Variants and Thalassemias	
i.	HPLC	C
ii.	Capillary Electrophoresis	C
iii.	Alkaline & Acid Electrophoresis	AR
iv.	Isoelectric Focusing	F
v.	Other Hemoglobinopathy Analysis	F

20. Porphyrins and Disorders of Porphyrin Metabolism

a.	Abnormalities of Porphyrin Metabolism	
i.	The Porphyrias	

1. Acute Intermediate Porphyria		C
2. Porphyria Cutanea Tarda		C
3. Other Inherited Porphyrias		F
ii. Abnormalities of Porphyrin Metabolism Not Caused by Porphyria		F
iii. Pseudoporphyria		F
b. Laboratory Diagnosis of Porphyria		
i. Patients with Symptoms of Porphyria		C
ii. Relatives of Patients with Porphyria		F
c. Porphyrin Chemistry		
i. Structure and Nomenclature, Chelation of Metals		F
ii. Spectral Properties and Solubility		F
d. Heme Biosynthesis		
i. Enzymes of Heme Biosynthesis		F
e. Excretion of Heme Precursors		F
f. Regulation of Heme Biosynthesis		F
g. Analytical Methods		
i. Methods of Metabolites		F
ii. Methods of Blood Porphyrins		F
iii. Analysis of Plasma Porphyrins		F
iv. Enzyme Measurements		F

21. Therapeutic Drugs and Their Management

a. Definitions and Basic Concepts	
i. Mechanism of Action	AR
ii. Pharmacokinetics	AR
iii. Drug Disposition	AR
iv. Clinical Utility	AR
v. Analytical Techniques	AR
vi. Pharmacogenetics	AR
b. Specific Drug Groups	
i. Antiepileptic Drugs	C
ii. Antibiotics	C
iii. Immunosuppressants	C
iv. Cardioactive Drugs	AR
v. Bronchodilators	AR
vi. Antiretrovirals	AR
vii. Antipsychotic Drugs	AR
viii. Antimetabolites	AR

22. Clinical Toxicology

a. Screening Procedures for Detection of Drugs (General)	C
i. Immunoassay	AR

ii.	High-Performance Liquid Chromatography	AR
iii.	Gas Chromatography	F
b.	Pharmacology and Analysis of Specific Drugs and Toxic Agents	
i.	Alcohols	C
ii.	Analgesics (Non-Prescription)	C
iii.	Ethylene Glycol	C
iv.	Drugs of Abuse	C
v.	Cyanide	F

23. Toxic Metals

a.	Specific Metals	
i.	Iron	C
ii.	Lead	C
iii.	Arsenic	AR
iv.	Copper, Ceruloplasmin, Wilson Disease	AR
v.	Mercury	AR
vi.	Aluminum	F
vii.	Antimony	F
viii.	Beryllium	F
ix.	Cadmium	F
x.	Chromium	F
xi.	Cobalt	F
xii.	Manganese	F
xiii.	Nickel	F
xiv.	Platinum	F
xv.	Selenium	F
xvi.	Silicon	F
xvii.	Silver	F
xviii.	Thallium	F
b.	Occupational Monitoring	AR

24. Cardiac Function

a.	Cardiac Disease	
i.	Congestive Heart Failure	C
ii.	Acute Coronary Syndromes	C
b.	Cardiac Biomarkers, Analytic Measurement, and Clinical Utility	
i.	Cardiac Troponin I and T	C
ii.	Brain Natriuretic Peptide and NT-proBNP	C
iii.	C-Reactive Protein	C
iv.	Myoglobin	AR
v.	Homocysteine	F

25. Kidney Disease

a. Kidney Function and Physiology	
i. Endocrine Function	C
ii. Glomerular Filtration	C
b. Diseases of the Kidney	
i. Chronic Kidney Disease	C
ii. End-Stage Renal Disease	C
iii. Diabetic Nephropathy	C
iv. Glomerular Diseases	C
v. Acute Kidney Injury	C
vi. Polycystic Kidney Disease	C
vii. Renal Calculi	C
viii. Tubular Diseases	AR
c. Kidney Function Tests	
i. Creatinine	C
ii. Urea	C
iii. Uric Acid	C
iv. Cystatin C	C
v. Urinary Osmolality (Assessment of Renal Concentrating Ability)	AR
vi. Screening for Kidney Disease	C
1. Urinalysis	C
2. Microscopic Examination of Urine	C
vii. Proteinuria (Quantitative Assessment of Glomerular Permeability)	C
1. Clinical Significance of Proteinuria	C
2. Specimen Collection for Total Protein and Albumin Measurement	C
3. Measurement of Urine Total Protein	C
viii. Estimation of Glomerular Filtration Rate (GFR) (Assessment of Kidney Function)	
1. The Concept of Clearance	C
2. Markers Used for GFR	C
3. GFR at the Extremes of Age	C

26. Physiology & Disorders of Water, Electrolyte, and Acid-Base Metabolism

a. Water and Electrolytes-Composition of Body Fluids	C
b. Acid-Base Disorders	C
i. Metabolic Acidosis (Primary Bicarbonate Deficit)	C
ii. Metabolic Alkalosis (Primary Bicarbonate Excess)	C
iii. Respiratory Acidosis	C
iv. Respiratory Alkalosis	C

27. Liver Disease

a. Diseases of the Liver	
i. Disorders of Bilirubin Metabolism	C
ii. Hepatic Viral Infections	C
1. Acute Viral Hepatitis	C
2. Chronic Viral Hepatitis	C
iii. Autoimmune Hepatitis	C
iv. Alcoholic Liver Disease	C
v. Hyperbilirubinemia of the Newborn	C
vi. Fatty Liver Disease	AR
vii. Cholestatic Liver Disease	
1. Obstruction	AR
2. Primary Biliary Cirrhosis	F
3. Primary Sclerosing Cholangitis	F
viii. Cirrhosis/Fibrosis	F
b. Diagnostic Liver Tests	
i. Hepatic Enzymes	C
ii. Albumin	C
iii. Prothrombin Time	C
iv. Bilirubin	C
v. Antinuclear Autoantibodies	AR
vi. Antimitochondrial Autoantibodies	AR
vii. Smooth Muscle Autoantibodies	F
viii. Liver-Kidney Microsomal Autoantibodies	F

28. Gastric, Pancreatic, and Intestinal Function

a. Intestinal Disorders and Their Laboratory Investigation	
i. Celiac Disease (Celiac Sprue, Gluten-Sensitive Enteropathy)	AR
1. IgA and IgG anti-tissue transglutaminase (anti-tTG)	AR
2. IgG and IgA anti-deamidated gliadin	AR
ii. Ulcerative Colitis and Crohn Disease	AR
1. Anti-Saccharomyces cerevisiae (ASCA)	AR
2. Calprotectin	AR
iii. Disaccharidase Deficiencies	F
iv. Bacterial Overgrowth	F
b. Pancreatic Insufficiency	AR
c. Investigation of Maldigestion/Malabsorption	
i. Evaluation of Fat Absorption	
1. Fecal Pancreatic Elastase	AR
2. Fecal Fat	F
d. Investigation of Chronic Diarrhea (General Considerations)	
i. Laxative Abuse	F

ii.	Fecal Osmotic (Osmolal) Gap	F
e.	Gastrointestinal Regulatory Peptides	
i.	Gastrin	F
ii.	Vasoactive Intestinal Polypeptide	F
iii.	Glucose-Dependent Insulinotropic Peptide (GIP, Gastric Inhibitory Polypeptide)	F

29. Mineral and Bone Metabolism

a.	Overview of Bone and Mineral Calcium	
i.	Biochemistry, Physiology, and Clinical Significance of Calcium	C
ii.	Measurement of Calcium	C
iii.	Patient Preparation and Sources of Preanalytical Error for Total and Free Calcium Measurements	AR
iv.	Interpretation of Total and Free Calcium Results	AR
v.	Urinary Calcium	F
b.	Magnesium	
i.	Biochemistry, Physiology, and Clinical Significance of Magnesium	C
ii.	Measurement of Total Magnesium	C
c.	Hormones Regulating Mineral Metabolism	
i.	Parathyroid Hormone	C
ii.	Vitamin D and its Metabolites	C
iii.	Parathyroid Hormone-Related Protein	F
d.	Phosphate	
i.	Measurement of Phosphate	AR
e.	Biochemical Markers of Bone Turnover	
i.	Markers of Bone Resorption	AR
ii.	Markers of Bone Formation	AR

30. Pituitary Function

a.	Prolactin	C
b.	Corticotropin (Adrenocorticotropin) and Related Peptides	C
c.	Gonadotropins (Follicle-Stimulating Hormone and Luteinizing Hormone)	C
d.	Thyrotropin	C
e.	Growth Hormone and Insulin-Like Growth Factors	AR
f.	Arginine Vasopressin	AR
g.	Oxytocin	AR

31. The Adrenal Cortex

a.	Adrenocortical Steroids	
i.	General Biochemistry and Metabolism of Adrenocortical Steroids	C
ii.	The Hypothalamic-Pituitary-Adrenal Cortical Axis	C

	iii. Regulation of Adrenal Hormones	C
b.	Pre-Analytical Testing Issues	
	i. Hypofunction of the Adrenal Cortex	AR
	ii. Hyperfunction of the Adrenal Cortex	AR
c.	Disorders of the Adrenal Cortex	
	i. Choice of Specimen (e.g., plasma, saliva)	C
	ii. Time of Day	C

32. Thyroid

a.	Thyroid Hormones	
	i. Chemistry, Biological Function, & Biochemistry of Thyroid Hormones	C
	ii. Metabolism and Physiology of Thyroid Hormones	C
b.	Thyroid Dysfunction	
	i. Hypothyroidism (e.g., Hashimoto Thyroiditis)	C
	ii. Hyperthyroidism (Graves Disease)	C
	iii. Non-Thyroidal Illnesses affecting Thyroid Function	C
c.	Thyroid Hormones and Binding Proteins	
	i. Thyroid-Stimulating Hormone	C
	ii. Thyroxine (T4)	C
	iii. Triiodothyronine (T3)	C
	iv. Free Thyroid Hormones	C
	v. Thyroglobulin	C
	vi. Anti-Thyroid Peroxidase Autoantibodies	C
	vii. Anti-Thyroglobulin Autoantibodies	C
	viii. Anti-Thyroid-Stimulating Hormone Receptor Autoantibodies	C
	ix. Reverse Triiodothyronine (rT3)	F
	x. Thyroxine-Binding Globulin	F

33. Reproductive Related Disorder

a.	Male Reproductive Biology	
	i. Male Reproductive Development and Abnormalities	AR
b.	Female Reproductive Biology	
	i. Female Reproductive Development	C
	ii. Female Reproductive Abnormalities	C
	iii. Normal Menstrual Cycle	C
	iv. Ovulation	C
	v. Irregular Menses	AR
c.	Reproductive Tests	
	i. Total Testosterone	C
	ii. Free and Weakly Bound Testosterone	C
	iii. Estrogens (e.g., Estradiol, Estrone, Estriol)	C
	iv. Progesterone	C
	v. Dehydroepiandrosterone Sulfate (DHEAS)	AR

vi.	Testosterone Precursors and Metabolites	F
vii.	Anabolic Steroids	F

34. Clinical Chemistry of Pregnancy

a.	Human Pregnancy	
i.	Maternal Adaptation to Pregnancy	AR
b.	Maternal and Fetal Health Assessment	
i.	Detection and Dating of Pregnancy	C
c.	Complications of Pregnancy	
i.	Trophoblastic Disease	C
ii.	Abnormal Pregnancies	
	(e.g., Preeclampsia, Ectopic, HELLP syndrome, Thyroid Disorders)	AR
iii.	Preterm Delivery	AR
d.	Maternal Serum Screening for Fetal Defects	
i.	Clinical Application or Prenatal Screening	AR
e.	Laboratory Tests	
i.	Chorionic Gonadotropin	C
ii.	Cell-Free Fetal DNA for Aneuploidy	C
iii.	Alpha Fetoprotein	AR
iv.	Unconjugated Estriol	AR
v.	Dimeric Inhibit A	AR
vi.	Placental Plasma Protein A	AR
vii.	Fetal Fibronectin	AR
viii.	Amniotic Fluid Bilirubin	F

35. Inborn Errors of Amino Acid, Organic Acid, and Fatty Acid Metabolism

a.	Biochemical Diagnosis	
i.	Newborn Screening	C
ii.	Evaluation of Symptomatic Patients	AR
iii.	Prenatal Diagnosis	F
iv.	Postmortem Screening	F
b.	Disorders of Amino Acid Metabolism	
i.	Classic Phenylketonuria and Other Hyperphenylalaninemias	F
ii.	Tyrosinemia Type 1	F
iii.	Homocystinuria	F
iv.	Maple Syrup Urine Disease	F
v.	Urea Cycle Defects	F
vi.	Nonketotic Hyperglycemia	F
c.	Disorders of Organic Acid Metabolism	
i.	Disorders of Propionate Metabolism	F
ii.	Isovaleric Acidemia	F
iii.	Glutaric Acidemia Type I	F

iv.	Ethylmalonic Encephalopathy	F
d.	Disorders of Fatty Acid Oxidation	
i.	Very Long-Chain Acyl-CoA Dehydrogenase Deficiency	F
ii.	Trifunctional Protein and Long-Chain 3-Hydroxy Acyl-CoA Dehydrogenase Deficiencies	F
iii.	Medium-Chain Acyl-CoA Dehydrogenase Deficiency	F
iv.	Short-Chain Acyl-CoA Dehydrogenase Deficiency	F
e.	Disorders of Carbohydrates	
i.	Galactosemia	F

36. Laboratory Evaluation of Immunoglobulin Function and Humoral Immunity

a.	Immunoglobulins	
i.	Immunoglobulin M, IgM	C
ii.	Immunoglobulin G, IgG	C
1.	IgG Subclasses	AR
iii.	Immunoglobulin A, IgA	C
iv.	Free Light Chains, Serum	C
v.	Immunoglobulin D, IgD	AR
vi.	Immunoglobulin E, IgE	AR
b.	Allergic Diseases	AR
c.	Infectious Diseases	
i.	Hepatitis A, B, and C	C
ii.	HIV	C
iii.	Syphilis	C
iv.	EBV	C
v.	Sepsis Evaluation (e.g., Lactate, Procalcitonin)	C
vi.	Lyme Disease	AR
vii.	Toxoplasma	AR
viii.	MMR	AR
ix.	SARS-CoV-2	AR
x.	HSV	AR
xi.	Tuberculosis (Interferon Gamma Release Assays)	AR
xii.	HTLV I/II	F
xiii.	CMV	F
xiv.	*Bartonella*	F
xv.	*Coxiella*	F

37. Mediators of Inflammation: Complement, Cytokines, and Adhesion Molecules

a.	Structure and Function of the Complement System	
i.	The Classical Pathway	AR
ii.	The Alternative Pathway	AR
iii.	The Mannan-Binding Lectin Pathway	F

iv.	Terminal Complement Components	F
v.	Anaphylatoxins	F
vi.	Regulation of Complement Activation	F
vii.	Complement Genetics	F
viii.	Complement and Acquired Immunity	F
b.	Complement in Disease States	
i.	Rheumatologic Diseases	AR
ii.	Hereditary Angioedema	AR
iii.	Infectious Diseases	AR
iv.	Renal Diseases	AR
v.	Hematologic Diseases	AR
c.	Assays of Complement	
i.	Functional Assays	AR
ii.	Antigenic Assays	AR
d.	Cytokines	
i.	General Information	AR
ii.	Interleukin-6	F

38. Immunodeficiency Disorders (e.g., Neutrophil Oxidative Burst Activity) **F**

39. Rheumatological Diseases

a.	Anti-Nuclear Antibody Methods and Interpretations	
i.	ANA by Indirect Immunofluorescence	C
ii.	ANA by EIA	C
iii.	ANA by Multiplex Bead Assays	C
b.	Specific Autoantibodies in Diseases	
i.	Systemic Lupus Erythematosus	C
ii.	Sjögren Syndrome	AR
iii.	Rheumatoid Arthritis (e.g., Rheumatoid Factor, Anti-CCP)	AR
iv.	Polymyositis and Dermatomyositis (Anti-Jo-1)	AR
v.	Antiphospholipid Syndrome (e.g., B2GP1, Cardiolipin, PS/PT)	AR
vi.	Mixed Connective Tissue Disease	AR

40. Vasculitis

a.	Antineutrophil Cytoplasmic Antibody	C
i.	c-ANCA (PR3)	C
ii.	p-ANCA (Myeloperoxidase)	C
b.	Polyarteritis Nodosa	AR
c.	Churg-Strauss Syndrome	AR
d.	Microscopic Polyangiitis	AR
e.	Granulomatosis with Polyangiitis	AR

41. Neurological Autoimmunity

- a. Myasthenia Gravis (e.g., ACHR) — C
- b. Multiple Sclerosis
  - i. Myelin Basic Protein — AR
  - ii. Oligoclonal Bands on CSF IEF — AR
  - iii. CSF IgG Synthesis Rate — F

42. Chemical Pathology-Specific Administration and Laboratory Management

- a. Administration and Laboratory Management in Clinical Chemistry — C
  - I. Laboratory Management — F
  - II. Rules and Regulations — F
  - III. Laboratory Inspections — F
  - IV. QA/QC Issues — F
- b. Automation in the Clinical Laboratory — C
- c. Implementation and Management Considerations for POCT
  - i. General Considerations — C
  - ii. Informatics and POCT — AR

Hematopathology for Clinical Pathology

This section is directed toward AP/CP residents. AP-only candidates (i.e., AP single certificate) are expected to focus less on Clinical Pathology components, while CP-only candidates (i.e., CP single certificate) will focus less on tissue-based diagnostics.

1. Testing in Hematology and Hematopathology

- a. General Hematology Testing and Hematology Instruments
  - i. General Consideration — C
  - ii. RBC Analysis — C
  - iii. WBC Analysis — C
  - iv. Platelet Analysis — C
- b. Hemoglobinopathy Analysis
  - i. Alkaline & Acid Electrophoresis — AR
  - ii. High Performance Liquid Chromatography (HPLC) — AR
  - iii. Capillary Electrophoresis — AR
  - iv. Isoelectric Focusing — AR
  - v. Advance Hemoglobinopathy Analysis — F
- c. Morphologic Methods
  - i. Staining Methods
    1. Romanovsky Type Stains — C

	2. Routine and Special Histologic Stains	C
	3. Cytochemical and Advanced Hematology Stains	F
ii.	Peripheral Blood Smear Review	C
iii.	Fluid Review	C
iv.	Bone Marrow Review	C
v.	Review of Other Tissues in Hematopathology	C
d.	Hemostasis and Thrombosis Testing	
i.	Specimen Collection and Processing	C
ii.	Coagulation and Fibrinolysis	AR
iii.	Platelet Testing, including von Willebrand Disease	AR
iv.	Thrombophilia Testing	AR
e.	Immunohistochemistry	
i.	Basic Methods	AR
ii.	Pitfalls	AR
f.	Flow Cytometry	
i.	Basic Methodology	C
ii.	PNH & Other Non-Neoplastic Disease Testing	C
iii.	Lymphoid Testing	C
iv.	Myeloid Testing	C
v.	Advanced Flow Cytometry	F
g.	Cytogenetic Testing	
i.	Classical	AR
ii.	FISH	AR
iii.	Other Cytogenetic Techniques (e.g., aCGH, SNP)	AR
h.	Molecular Testing	
i.	Clonality/Lineage	AR
ii.	Translocations/Mutations	AR
iii.	Other Molecular Assays (e.g., Gene Expression Arrays)	AR
iv.	Coagulation-Related Molecular Testing	AR

2. Normal Anatomy, Histology, Hematopoiesis and Hemostasis

a.	Erythrocytes (RBCs)	C
b.	Leucocytes (WBCs)	C
i.	Myeloid	C
	1. Granulocytes	C
	2. Monocytes/Dendritic Cells	C
	3. Eosinophils/Basophils/Mast Cells	C
	4. Other Myeloid Cells	C
ii.	Lymphoid	C
	1. B-Cells	C
	2. T-Cells	C
	3. NK-Cells	C
	4. Other Lymphoid Cells	C
c.	Plasma Cells	C
d.	Normal Hemostasis & Thrombosis	C
i.	Platelets & Megakaryocytes	C
ii.	Coagulation and Fibrinolysis	C

e. General Hematopoiesis		C
f. Peripheral Blood		C
g. Bone Marrow		C
h. Lymph Nodes		C
i. Spleen		C
j. Thymus		C
k. Other Lymphoid Tissues (e.g., Tonsils)		C
l. Pediatric Issues, Including Fetal Hematopoiesis		AR

3. Non-Neoplastic Disorders of Erythrocytes

a. Anemias		
	i. Iron Deficiency and Related Disorders	C
	ii. Sideroblastic Anemias	
	1. Acquired	AR
	2. Inherited	F
	iii. Erythrocyte Membrane Disorders	
	1. Hereditary Spherocytosis	AR
	2. Hereditary Elliptocytosis	AR
	3. Other Erythrocyte Membrane Disorders (e.g., Spur Cell)	AR
	iv. Erythrocyte Enzyme Disorders	
	1. G6PD	AR
	2. Pyruvate Kinase Deficiency	AR
	3. Other Erythrocyte Enzyme Disorders	AR
	v. Other Hemolytic Anemias	
	1. Immune	C
	2. Non-Immune (e.g., Thermal Injury)	C
	3. Microangiopathic Hemolytic Anemia	C
	vi. Megaloblastic Anemias	C
	vii. Aplastic Anemias	C
	viii. Anemia Related to Chronic Disease & Other Disorders	C
	ix. Congenital Dyserythropoietic Anemia	F
	x. Hemoglobinopathies	
	1. Hb S and Related Disorders	C
	2. Hb C Disorders	AR
	3. Hb E Disorders	AR
	4. Other Hemoglobinopathies	F
	xi. Thalassemias	C
	xii. PNH	C
	xiii. Porphyrias	AR
	xiv. Other Causes of Anemia	
	1. Lead Poisoning	AR
	2. Diamond-Blackfan Anemia	F
b. Erythrocytosis		AR
c. Cold Agglutinin Disease		AR
d. Advanced Erythrocyte Abnormalities		AR

4. Non-Neoplastic Disorders of Leucocytes

a. Inherited Disorders with Morphologic Correlates	
i. Pelger-Huet Anomaly	C
ii. Alder-Reilly Anomaly	AR
iii. Chediak-Higashi Syndrome	AR
b. Neutrophils – Quantitative & Qualitative Aspects	C
c. Monocytes – Quantitative & Qualitative Aspects	C
d. Histiocytic Disorders	
i. HLH/Macrophage Activation Disorders/Hemophagocytic Disorders	C
ii. Storage Disorders	AR
iii. Other Histocytic Disorders (e.g., Prosthetic Associated Histiocyte Proliferation)	F
e. Plasmacytoid Dendritic Cells	F
f. Lymphocytes – Including Quantitative Aspects	C
g. Eosinophils and Basophils	C
h. Plasma Cells	C

5. Multilineage Benign Hematopoietic Disorders

a. Inherited Disorders (e.g., May-Hegglin Anomaly)	AR
b. Other Benign Hematopoietic Disorders	F

6. Infections with Manifestation in the Peripheral Blood

a. Erythrocyte & Plasma Infections	
i. Malaria	C
ii. Babesia	C
iii. Other Erythrocyte & Plasma Infections	AR
b. Leucocyte Infections	
i. Infectious Mononucleosis	C
ii. Anaplasma & Ehrlichia	AR
iii. Other Infections of Leucocytes (e.g., Fungi including *Histoplasma*, Pertussis)	AR

7. Benign Hematologic Disorders of the Bone Marrow Not Otherwise Classified

a. Infectious Disorders (e.g., Parvovirus)	C
b. Therapy Related Effects	AR
c. Bone Abnormalities	
i. Paget Disease	AR
ii. Renal Osteodystrophy	AR
d. Other Benign Disorders of Bone Marrow	F

8. Benign Disorders of the Lymphoid Tissues

a. Lymph Node	
i. Dermatopathic Lymphadenopathy	C
ii. Cat Scratch Disease	AR
iii. Toxoplasmosis	AR

iv.	Infectious Mononucleosis	AR
v.	Other Infectious Disorders	AR
vi.	Kikuchi-Fujimoto Disease (i.e., Histiocytic Necrotizing Lymphadenitis)	AR
vii.	Rosai-Dorfman Disease	AR
viii.	Castleman Disease	AR
ix.	Autoimmune Disorders	AR
x.	Non-Lymphoid Inclusions (e.g., Mesothelial)	AR
xi.	Syphilis	F
xii.	Drug-Related (e.g., Phenytoin)	F
xiii.	Other Benign Disorders of the Lymph Nodes	F
b. Spleen		
i.	Lymphoid Hyperplasias	AR
ii.	Splenic Cysts & Other Non-Neoplastic Proliferations (e.g., Hamartomas)	AR
c. Thymus		
i.	Thymic Hyperplasia	AR
ii.	Other Benign Thymus Disorders (e.g., Thymoma)	AR
d. Extranodal Lymphoid Tissue		AR

9. Fluid Specimens

a. CSF		C
b. Other Body Fluids		C

10. Immunodeficiency Disorders

a. Primary Immunodeficiencies		F
b. Secondary Immunodeficiencies		
i.	Viral-Associated	F
ii.	Iatrogenic	F
c. Immunodeficiency-Associated Lymphoproliferative Disorders		
i.	HIV-Associated	AR
ii.	PTLD	AR
iii.	Other Iatrogenic Lymphoproliferative Disorders	F

11. Hemostasis and Thrombosis

a. Coagulation and Fibrinolytic Disorders		
i.	Factor Deficiency or Functional Abnormalities	C
ii.	Factor Inhibitors	AR
iii.	Fibrinolysis	AR
b. Platelet Disorders and von Willebrand Disease		
i.	Qualitative Issues with Normal Platelet Counts	C
ii.	Thrombocytosis	C
iii.	Thrombocytopenia	
1.	Immune	C
2.	Inherited	AR
3.	Other Causes of Thrombocytopenia	AR
iv.	von Willebrand Disease	C
v.	Abnormal Platelet Morphology, Not Otherwise Specified	AR
c. Thrombophilic Disorders		

i.	Heparin Induced Thrombocytopenia	C
ii.	TTP/HUS	C
iii.	DIC	C
iv.	Laboratory Diagnosis of Thrombosis and Thrombophilia	AR
v.	Fibrinolytic Thrombotic Disorders	AR
vi.	Antiphospholipid Antibody Syndrome	AR
d. Antiplatelet and Anticoagulant Drugs		
i.	Warfarin and Warfarin Monitoring	C
ii.	Heparin and Heparinoid Monitoring	C
iii.	Direct Thrombin and Factor Xa Inhibitor Monitoring	AR
iv.	Antiplatelet Agent Monitoring	AR

12. Myeloid Neoplasms

a. Myeloproliferative Neoplasms		
i.	CML (BCR-ABL1+)	C
ii.	Polycythemia Vera	AR
iii.	Primary Myelofibrosis	AR
iv.	Essential Thrombocythemia	AR
v.	Chronic Eosinophilic Leukemia, Not Otherwise Specified	AR
vi.	Mastocytosis	AR
vii.	Other Myeloproliferative Neoplasms (e.g., CNL)	F
b. Myeloid & Lymphoid Neoplasms with Eosinophilia and Gene Rearrangements		
i.	PDFGRA	AR
ii.	PDFGRB	AR
iii.	FGFR1	AR
iv.	PCM1-JAK2	AR
c. Myelodysplastic/Myeloproliferative Neoplasms		
i.	CMML	C
ii.	Other MDS/MPN Disorders	AR
1.	Atypical CML	AR
2.	BCR-ABL1	AR
iii.	Juvenile Myelomonocytic Leukemia	
d. Myelodysplastic Syndromes		AR
e. AML and Related Precursor Neoplasms		
i.	AML with Recurrent Genetic Abnormalities	
1.	AML with t(8;21)	AR
2.	AML with inv(16) or t(16;16)	AR
3.	APL with t(15;17)	C
4.	AML with t(9;11)	F
5.	Other AML with Recurrent Genetic Abnormalities	F
ii.	AML with Myelodysplasia-Related Changes	AR
iii.	Therapy-Related Myeloid Neoplasms	AR
iv.	AML, Not Otherwise Specified	
1.	Acute Monoblastic/Monocytic Leukemia	AR
2.	Acute Erythroid Leukemia	F
3.	Acute Megakaryoblastic Leukemia	F
4.	Other AML, Not Otherwise Specified	F

v.	Myeloid Sarcoma	AR
vi.	Myeloid Proliferations with Germline Predisposition	F
1.	Myeloid Proliferations with Down Syndrome	AR
vii.	Blastic Plasmacytoid Dendritic Cell Neoplasm	AR
viii.	Other Myeloid Proliferations with Germline Predisposition	F
13. Acute Leukemias of Ambiguous Lineage		F
14. Lymphoid Neoplasms		
a.	B Lymphoblastic Leukemia/Lymphoma	
i.	B Lymphoblastic Leukemia/Lymphoma, Not Otherwise Specified	AR
1.	B Lymphoblastic Leukemia/Lymphoma with Recurrent Genetic Abnormalities	AR
ii.	Other B Lymphoblastic Leukemias & Lymphomas	F
b.	T Lymphoblastic Leukemia/Lymphoma	C
c.	Mature B-cell Neoplasms	
i.	CLL/SLL including Monoclonal B-cell Lymphocytosis	C
ii.	MALT Lymphoma	C
iii.	Follicular Lymphoma	C
iv.	Mantle cell Lymphoma	C
v.	Large cell Lymphomas	
1.	Diffuse Large B-cell Lymphoma, Not Otherwise Specified	C
2.	Primary Mediastinal Large B-cell Lymphoma	AR
3.	Other Large B-cell Lymphomas	F
vi.	Burkitt Lymphoma	C
vii.	Splenic Marginal Zone Lymphoma (SMZL)	AR
viii.	Hairy Cell Leukemia (HCL)	AR
ix.	Lymphoplasmacytic Lymphoma (LPL)	AR
x.	Nodal Marginal Zone Lymphoma (MZL)	AR
xi.	In situ Lymphoid Neoplasia	F
d.	Mature T- and NK-cell Neoplasms	
i.	T-cell and NK-cell LGL	C
ii.	Extranodal NK/T-cell Lymphoma, Nasal Type	C
iii.	Anaplastic Large Cell Lymphoma (ALK + and ALK -)	C
iv.	T-cell PLL	AR
v.	Adult T-cell Leukemia/Lymphoma	AR
vi.	Hepatosplenic T-cell Lymphoma	AR
vii.	Mycosis Fungoides & Sézary Syndrome	AR
viii.	PTCL, Not Otherwise Specified	AR
ix.	Angioimmunoblastic T-cell Lymphoma	AR
x.	Enteropathy-Associated T-cell Lymphoma and Other Intestinal T-cell Lymphomas	F
xi.	CD30+ Cutaneous Lymphoproliferative Disorders	F
xii.	Other Cutaneous T-cell Lymphomas	F
xiii.	Other Mature T- and NK-cell Neoplasms	F
e.	Hodgkin Lymphoma	
i.	Nodular Lymphocyte Predominant	C

ii.	Classic	C

15. Plasma Cell Neoplasms, Paraprotein Disorders, & Amyloidosis

a.	Plasma cell Myeloma, Monoclonal Gammopathy of Unknown Significance (MGUS)	C
b.	Amyloidosis	C
c.	Cryoglobulinemia	AR
d.	POEMS (Polyneuropathy, Organomegaly, Endocrinopathy/Edema, Monoclonal Protein, and Skin Changes)	AR

16. Histiocytic/Dendritic Cell Neoplasms

a.	Landerhans cell Histiocytosis/Sarcoma	AR
b.	Follicular Dendritic Cell Sarcoma	F
c.	Histiocytic Sarcoma	F
d.	Other Histiocytic/Dendritic Neoplasms	F

17. Metastatic Neoplasms

a.	Metastases to the Bone Marrow	C
b.	Metastases to the Lymph Nodes	C
c.	Metastases to Other Lymphoid Tissue	C

18. Hematology & Hematopathology-Specific Administration & Laboratory Management

a.	Hematology & Hematopathology Laboratory Management	F
b.	Rules and Regulations	F
c.	Laboratory Inspections	F
d.	QA/QC Issue	F
e.	Other Administration/Laboratory Management Issues	F

Medical Microbiology

1. Bacteria, including Mycobacteria, *Nocardia,* and other Aerobic Actinomycetes

a.	Optimal Collection Methods	
i.	Lower Respiratory Tract Culture	AR
ii.	Sinus Culture	AR
iii.	Urine Culture	AR
iv.	Superficial Wound Culture	AR
v.	Deep Wound Culture	AR
vi.	Stool Culture	AR
vii.	Blood Culture	AR
viii.	Tissue Culture	AR
ix.	Cerebrospinal Fluid Culture	AR

x.	Normally Sterile Fluid Culture	AR
xi.	Genital Cultures	AR
xii.	Anaerobic Cultures	AR
b.	Principles of Specimen Collection, Transport and Processing	
i.	Principles Regarding the Appropriate Use of Swabs for Bacterial Culture	AR
ii.	Principles Regarding the Volume of Specimen Required	AR
iii.	Principles Regarding the Use of Broth Enrichment	AR
iv.	Principles Regarding the Cultivation of Fastidious Microorganisms	AR
v.	Principles Regarding the Maintenance of the Specimen during Transport	AR
c.	Safety Issues Regarding the Processing of Specimens for Bacteria	AR
d.	Specimen Rejection Criteria	
i.	Specimen Rejection Criteria for Respiratory Tract Specimens	AR
ii.	Specimen Rejection Criteria for Stool Specimens	AR
iii.	Specimen Rejection Criteria for Transportation Delay and Specimen Integrity Issues	AR
e.	Media	
i.	*Campylobacter* Selective Agar	AR
ii.	Cefsulodin-Irgasan Novobiocin (CIN) Agar	AR
iii.	Charcoal Yeast Extract (CYE) Agar	AR
iv.	Chocolate Agar	AR
v.	Colistin-Nalidixic Acid (CNA) Blood Agar	AR
vi.	Hektoen-Enteric (HE) Agar	AR
vii.	MacConkey Agar	AR
viii.	Sheep Blood Agar	AR
ix.	Thayer Martin Agar	AR
x.	Media Selection for:	
1.	Lower Respiratory Tract Cultures	AR
2.	Sinus Culture	AR
3.	Urine Culture	AR
4.	Superficial Would Culture	AR
5.	Deep Wound Culture	AR
6.	Stool Culture	AR
7.	Tissue Culture	AR
8.	Cerebrospinal Fluid Culture	AR
9.	Normally Sterile Fluid Culture	AR
10.	Genital Cultures	AR
xi.	Regan-Lowe Agar	F
xii.	Anaerobic Media	F
xiii.	Other Bacteriologic Media	F
f.	Stains and Direct Examination	
i.	Gram stain	AR
ii.	Artifacts (e.g., crystals)	AR

iii.	Dark Field Examination	F
g.	Identification Methods and Instrumentation	
i.	Culture	AR
ii.	Automated Blood Culture Instrumentation	AR
iii.	Automated Bacterial Identification Systems	AR
iv.	Manual and Automated Bacterial Susceptibility Testing	AR
v.	Mass Spectrometry (MALDI TOF)	AR
vi.	Targeted Molecular Assays (e.g., PCR)	AR
vii.	Sequence-Based Identification	AR
h.	Key Tests in Bacteriology	
i.	Beta-lactamase Test	AR
ii.	Bile Solubility	AR
iii.	Catalase Test	AR
iv.	CLO/Urea Breath Test	AR
v.	Coagulase Test	AR
vi.	Optochin Susceptibility	AR
vii.	Oxidase Test	AR
viii.	PYR Test	AR
ix.	Urease Test	AR
x.	Motility	AR
xi.	Indole	AR
xii.	Bacitracin Susceptibility	F
xiii.	Beta-galactosidase Test	F
xiv.	Bile-Esculin Test	F
xv.	CAMP Test	F
xvi.	Esculin Hydrolysis Test	F
xvii.	Hippurate Hydrolysis Test	F
xviii.	Nitrate/Nitrate Reduction Test	F
xix.	Salt Tolerance	F
xx.	TSI/KIA Slant	F
xxi.	Other Key Tests in Bacteriology	F
i.	Antibacterial Susceptibility Testing	
i.	CLSI Standards	AR
ii.	Broth Microdilution	AR
iii.	Kirby-Bauer	AR
iv.	E-Test	AR
v.	Molecular AST Testing	AR
vi.	Interpretation/Reporting AST	AR
j.	Mechanisms of Antimicrobial Resistance	
i.	Beta-Lactamases	AR
ii.	Carbapenemases	AR
iii.	Extended-Spectrum Beta Lactamases	AR
iv.	Inducible Clindamycin Resistance	AR
v.	*mecA* Associated Resistance	AR

vi. *vanA* and *vanB* Associated Resistance	AR
vii. AMP C Resistance	AR
k. Serologic and Antigenic Tests for Bacteria	AR
l. Molecular Diagnostics for Bacteria	AR
m. Quality Control and Infection Prevention Regarding Bacteria	AR
n. Aerobic Bacteria	
i. Gram Positive Aerobic Bacteria	
1. *Abiotrophia* spp.	AR
2. *Aerococcus* spp.	AR
3. *Arcanobacterium* spp.	AR
4. *Bacillus anthracis*	AR
5. *Bacillus cereus*	AR
6. *Corynebacterium diphtheriae*	AR
7. *Enterococcus faecium*	AR
8. *Enterococcus faecalis*	AR
9. *Erysipelothrix rhusiopathiae*	AR
10. *Gardnerella vaginalis*	AR
11. *Granulicatella* spp.	AR
12. *Lactobacillus* spp.	AR
13. *Leuconostoc* spp.	AR
14. *Listeria monocytogenes*	AR
15. *Pediococcus* spp.	AR
16. *Staphylococcus aureus* complex	AR
17. *Staphylococcus epidermidis*	AR
18. *Staphylococcus saprophyticus*	AR
19. *Staphylococcus lugdunensis*	AR
20. *Streptococcus pneumoniae*	AR
21. *Streptococcus pyogenes*	AR
22. *Streptococcus agalactiae*	AR
23. *Streptococcus bovis* Group	AR
24. *Streptococcus anginosus* Group	AR
25. *Actinomadura* spp.	F
26. *Bacillus* spp.	F
27. *Corynebacterium* spp.	F
28. *Enterococcus* spp.	F
29. *Facklamia* spp.	F
30. *Gemella* spp.	F
31. *Kocuria* spp.	F
32. *Lactococcus* spp.	F
33. *Microbacterium* spp.	F
34. *Micrococcus* spp.	F
35. *Paracoccus* spp.	F
36. *Rothia* spp.	F
37. Other *Staphylococcus* spp.	F

38. *Stomatococcus* spp.	F
39. *Streptococcus mitis* Group	F
40. *Streptococcus mutans* Group	F
41. *Streptococcus salivarius* Group	F
42. Other *Streptococcus* spp.	F
ii. Gram Negative Aerobic Bacteria	
1. *Acinetobacter baumannii* complex	AR
2. *Aeromonas* spp.	AR
3. *Aggregatibacter* spp.	AR
4. *Bartonella* spp.	AR
5. *Bordetella pertussis*	AR
6. *Brucella* spp.	AR
7. *Burkholderia pseudomallei*	AR
8. *Burkholderia cepacia* complex	AR
9. *Campylobacter jejuni*	AR
10. *Capnocytophaga* spp.	AR
11. *Cardiobacterium* spp.	AR
12. *Citrobacter* spp.	AR
13. *Eikenella* spp.	AR
14. *Elizabethkingia* spp.	AR
15. *Enterobacter* spp.	AR
16. *Escherichia coli*	AR
17. *Francisella tularensis*	AR
18. *Haemophilus influenzae*	AR
19. *Haemophilus parainfluenzae*	AR
20. *Haemophilus ducreyi*	AR
21. *Helicobacter pylori*	AR
22. *Kingella kingae*	AR
23. *Klebsiella* spp.	AR
24. *Legionella pneumophila*	AR
25. *Moraxella catarrhalis*	AR
26. *Neisseria meningitidis*	AR
27. *Neisseria gonorrhoeae*	AR
28. *Pasteurella multocida*	AR
29. *Proteus* spp. `	AR
30. *Providencia* spp.	AR
31. *Pseudomonas aeruginosa*	AR
32. *Salmonella* Non-Typhi	AR
33. *Salmonella* Typhi and ParaTyphi	AR
34. *Serratia marcescens*	AR
35. *Shigella* spp.	AR
36. *Stenotrophomonas maltophilia*	AR
37. *Streptobacillus moniliformis*	AR
38. *Vibrio cholerae*	AR

39. *Vibrio vulnificus*	AR
40. *Vibrio parahaemolyticus*	AR
41. *Yersinia pestis*	AR
42. *Yersinia enterocolitica*	AR
43. *Achromobacter* spp.	F
44. Other *Acinetobacter* spp.	F
45. *Actinobacillus* spp.	F
46. *Alcaligenes* spp.	F
47. *Bordetella parapertussis*	F
48. *Bordetella bronchiseptica*	F
49. Other *Bordetella* spp.	F
50. *Burkholderia mallei*	F
51. Other *Burkholderia* spp.	F
52. *Campylobacter coli*	F
53. *Campylobacter fetus*	F
54. Other *Campylobacter* spp.	F
55. *Chryseobacterium* spp.	F
56. *Comamonas* spp.	F
57. *Cronobacter* spp.	F
58. *Edwardsiella* spp.	F
59. Other *Haemophilus* spp.	F
60. Other *Legionella* spp.	F
61. *Methylobacterium* spp.	F
62. Other *Moraxella* spp.	F
63. *Morganella* spp.	F
64. Other *Neisseria* spp.	F
65. *Pantoea* spp.	F
66. *Plesiomonas* spp.	F
67. Other *Pseudomonas* spp.	F
68. *Roseomonas* spp.	F
69. *Sphingomonas* spp.	F
70. Other *Vibrio* spp.	F
71. Other *Yersinia* spp.	F
o. Procedures for the Isolation and Cultivation of Anaerobic Bacteria	F
p. Anaerobic Bacteria	
i. *Actinomyces* and Related Taxa	AR
ii. *Bacteroides fragilis* Group	AR
iii. *Clostridium botulinum*	AR
iv. *Clostridium perfringens*	AR
v. *Clostridium septicum*	AR
vi. *Clostridium tetani*	AR
vii. *Clostridioides difficile*	AR
viii. *Cutibacterium acnes*	AR
ix. *Fusobacterium nucleatum*	AR

x.	*Fusobacterium necrophorum*	AR
xi.	*Anaerococcus* spp.	F
xii.	Other *Bacteroides* spp.	F
xiii.	*Bifidobacterium* spp.	F
xiv.	Other *Clostridium* spp.	F
xv.	*Desulfovibrio* spp.	F
xvi.	*Eubacterium* spp.	F
xvii.	*Eggerthella* spp.	F
xviii.	*Fingoldia magna*	F
xix.	Other *Fusobacterium* spp.	F
xx.	*Leptotrichia* spp.	F
xxi.	*Mobiluncus* spp.	F
xxii.	*Peptostreptococcus* spp.	F
xxiii.	*Porphyromonas* spp.	F
xxiv.	*Prevotella* spp.	F
xxv.	*Veillonella* spp.	F
q. Mycoplasma and Ureaplasma		
i.	*Mycoplasma genitalium*	AR
ii.	*Mycoplasma pneumoniae*	AR
iii.	*Mycoplasma hominis*	F
iv.	Other *Mycoplasma* spp.	F
v.	*Ureaplasma* spp.	F
r. Spirochetes		
i.	*Borrelia burgdorferi*	AR
ii.	*Leptospira* spp.	AR
iii.	*Treponema pallidum*	AR
iv.	Other *Borrelia* and *Borreliella* spp.	F
v.	*Brachyspira* spp.	F
1.	*Spirillum minus*	F
vi.	Other *Treponema* species	F
s. Intracellular Bacteria		
i.	*Anaplasma phagocytophilum*	AR
ii.	*Chlamydia trachomatis*	AR
iii.	*Chlamydia pneumoniae*	AR
iv.	*Coxiella burnetti*	AR
v.	*Ehrlichia* spp.	AR
vi.	*Rickettsia rickettsii*	AR
vii.	*Chlamydia psittaci*	F
viii.	*Orientia tsutsugamushi*	F
ix.	Other *Rickettsia* spp.	F
t. Mycobacteria, *Nocardia,* and Other Aerobic Actinomycetes		
i.	Structure and Biology	AR
ii.	Taxonomy, Runyon Classification, & Nomenclature	AR
iii.	Specimen Collection, Handling, and Processing	

1.	Optimal Methods for Lower Respiratory Tract Specimen Collection for Mycobacteria	AR
2.	Specimens for Mycobacteria	AR
3.	Decontamination	AR
4.	The Use of PANTA	F
iv. Media		
1.	Principles Regarding the Use of Broth and Solid Media	AR
v. Stains and Direct Examination		
1.	Acid Fast Stain & Modified Acid Fast Stain	AR
2.	Ziehl-Neelsen & Kinyoun Methods	AR
3.	Fluorochrome Staining	AR
vi. Identification Methods and Instrumentation		F
vii. Empiric Therapy for Mycobacterial Infections		AR
viii. Antimycobacterial and Nocardial Agents		F
1.	Carbapenems and Related Agents	F
2.	Ethambutol and Related Agents	F
3.	Isoniazid and Related Agents	F
4.	Kanamycin and Related Agents	F
5.	Pyrazinamide and Related Agents	F
6.	Quinolones and Related Agents	F
7.	Rifampin and Related Agents	F
8.	Streptomycin and Related Agents	F
9.	Trimethoprim-Sulfamethoxazole	F
10.	Clarithromycin and Related Agents	F
ix. Susceptibility Testing		F
1.	Proportion Method	F
2.	Broth Dilution	F
3.	Molecular Susceptibility Testing	F
x. Mechanisms of Resistance		F
xi. Skin, Serologic Assays, & Host Response for Mycobacteria and Related Organisms		AR
xii. Molecular Diagnostics for Mycobacteria and Related Organisms		AR
xiii. Miscellaneous Topics & Subjects Regarding Mycobacteria and Related Organisms		F
xiv. Mycobacteria, *Nocardia,* and Aerobic Actinomycetes		
1. *Mycobacterium* spp.		
a)	*M. tuberculosis* complex	AR
b)	*M. bovis*	AR
c)	*M. bovis* BCG	AR
d)	*M. avium* complex	AR
e)	*M. intracellulare*	AR
f)	*M. gordonae*	AR
g)	*M. haemophilum*	AR
h)	*M. marinum*	AR

i) *M. xenopi*	AR
j) *M. fortuitum*	AR
k) *M. abscessus*	AR
l) *M. chelonae*	AR
m) *M. leprae*	AR
n) Other *Mycobacterium* spp.	F
2. *Nocardia* and Other Aerobic Actinomycetes	
a) *Nocardia* spp.	AR
b) *Rhodococcus equi*	AR
c) *Tropheryma whipplei*	AR
d) *Gordonia* spp.	F
e) *Streptomyces* and Other Aerobic Actinomycetes	F
f) *Tsukamurella* spp.	F

2. Fungi

a. Structure and Biology	AR
b. Specimen Collection, Transport, and Processing	AR
c. Media	AR
d. Stains and Direct Examination	
i. Gram Stain Appearance	AR
ii. KOH	AR
iii. KOH-Calcofluor White	AR
iv. Wet Mount	AR
v. Mucicarmine	AR
vi. Lactophenol Cotton Blue	AR
vii. India Ink	F
viii. Other Fungal Stains	F
e. Identification Methods and Instrumentation	
i. Automated Blood Culture Instrumentation for Yeasts	AR
ii. Automated and Manual Identification Systems for Yeasts	AR
iii. Automated Susceptibility Testing for Yeasts	AR
iv. Mass Spectrometry	AR
v. Molecular Identification (e.g., Sequence-Based Identification)	AR
f. Antifungal Agents, Susceptibility Testing and Mechanisms of Resistance	F
g. Serologic and Antigenic Tests for Fungi	AR
h. Molecular Diagnostics for Fungi	AR
i. Advanced Topics in Medical Mycology	F
j. Specific Fungi	
i. Yeast and Yeast-Like Fungi	
1. *Candida albicans*	AR
2. *Candida dubliniensis*	AR
3. *Candida auris*	AR
4. *Candida glabrata* (i.e., *Nakaseomyces glabrata*)	AR

5. *Candida krusei* (i.e., *Pichia kudriavzevii*)	AR
6. *Candida tropicalis*	AR
7. *Candida parapsilosis*	AR
8. *Candida lusitaniae* (i.e., *Clavispora lusitaniae*)	AR
9. *Candida guilliermondii* (i.e., *Meyerosyma guilliermondii*)	AR
10. *Cryptococcus neoformans*	AR
11. *Cryptococcus gattii*	AR
12. *Malassezia furfur*	AR
13. *Pneumocystis jirovecii*	AR
14. *Prototheca* spp.	AR
15. *Trichosporon asahii*	AR
16. Other *Candida* spp.	F
17. Other *Cryptococcus* spp.	F
18. *Malassezia pachydermatis*	F
19. *Rhodotorula mucilaginosa*	F
20. *Rhodotorula glutinis*	F
21. *Rhodotorula minuta*	F
22. Other *Rhodotorula* spp.	F
23. *Saccharomyces cervisiae*	F
24. Other *Saccharomyces* spp.	F
25. *Sporobolomyces* spp.	F
26. *Trichosporon cutaneum*	F
27. *Trichosporon inkin*	F
28. Other *Trichosporon* spp.	F
29. *Ustilago* spp.	F
ii. Hyaline Septate Molds	
1. *Aspergillus fumigatus*	AR
2. *Aspergillus flavus*	AR
3. *Aspergillus terreus*	AR
4. *Aspergillus niger*	AR
5. *Aspergillus nidulans*	AR
6. *Epidermophyton* spp.	AR
7. *Fusarium solani* complex	AR
8. *Microsporum canis*	AR
9. *Microsporum gypseum* (i.e., *Nannizzia gypseum*)	AR
10. *Paecilomyces* spp.	AR
11. *Penicillum* spp.	AR
12. *Scedosporium apiospermum* complex	AR
13. *Scedosporium boydii* complex (i.e. *Pseudallescheria boydii*)	AR
14. *Trichophyton rubrum*	AR
15. *Trichophyton mentagrophytes*	AR
16. *Trichophyton tonsurans*	AR
17. *Acremonium* spp.	F
18. Other *Aspergillus* spp.	F

19. *Beauveria* spp.	F
20. *Fusarium* spp.	F
21. *Geotrichum candidum*	F
22. *Geotrichum capitatum* (i.e., *Magnusiomyces capitatus*)	F
23. *Geotrichum clavatum* (i.e., *Magnusiomyces clavtus*)	F
24. Other *Geotricum* spp.	F
25. *Malbranchea* spp.	F
26. *Microsporum audouinii*	F
27. Other *Microsporum* spp.	F
28. *Scopulariopsis* spp.	F
29. *Sepedonium* spp.	F
30. *Trichoderma* spp.	F
31. Other *Trichophyton* spp.	F
32. *Trichophyton verrucosum*	F
iii. Dimorphic Fungi	
1. *Blastomyces* spp.	AR
2. *Coccidioides* spp.	AR
3. *Histoplasma capsulatum*	AR
4. *Penicillium talaromyces* (i.e., *Talaromyces marneffei*)	AR
5. *Sporothrix schenckii* complex	AR
6. Other *Histoplasma* spp.	F
iv. Mucoraceous Fungi	
1. *Lichtheimia corymbifera* complex	AR
2. *Mucor* spp.	AR
3. *Rhizomucor* spp.	AR
4. *Rhizopus* spp.	AR
5. *Apophysomyces elegans*	F
6. *Basidiobolus ranarum*	F
7. *Basidiobolus* spp.	F
8. *Cokeromyces* spp.	F
9. *Conidiobolus coronatus*	F
10. *Conidiobolus* spp.	F
11. *Cunninghamella* spp.	F
12. *Saksenaea* spp.	F
13. *Syncephalastrum* spp.	F
v. Dematiaceous Fungi	
1. *Alternaria* spp.	AR
2. *Bipolaris* spp.	AR
3. *Cladosporium* spp.	AR
4. *Cladophialophora* spp.	AR
5. *Curvularia* spp.	AR
6. *Fonsecaea* spp.	AR
7. *Phialophora* spp.	AR
8. *Chaetomium* spp.	F

9. *Exophiala* spp.	F
10. *Exserohilum* spp.	F
11. *Piedra* spp.	F
12. *Lomentaspora prolificans* (i.e., *Scedosporium* prolificans)	F
13. *Stachybotrys* spp.	F
vi. Microsporidia	AR
vii. Rhinosporidium	AR

3. Viruses and Prions

a. Structure and Biology	AR
b. Taxonomy, Classification, and Nomenclature	AR
c. Specimen Collection, Transport, and Processing	AR
d. Identification Methods and Instrumentation	AR
e. Serologic, Immunologic, and Antigenic Assays for Viruses	AR
f. Molecular Diagnostics for Viruses	AR
g. Prevention and Treatment of Viral Diseases	AR
h. Quality Control and Infection Prevention with Respect to Viruses	AR
i. Miscellaneous Topics with Respect to Viruses	F
j. Specific Viruses	
i. Adenovirus	AR
ii. Hanta Virus (i.e., Sin Nombre)	AR
iii. Seasonal Coronaviruses	AR
iv. SARS-CoV-2	AR
v. Rhinovirus	AR
vi. Polio Virus	AR
vii. Coxsackie Virus	AR
viii. Enterovirus D-68	AR
ix. Parechovirus	AR
x. Ebola Virus	AR
xi. Hepatitis C Virus	AR
xii. Yellow Fever Virus	AR
xiii. Dengue Virus	AR
xiv. Zika Virus	AR
xv. West Nile Virus	AR
xvi. Herpesviridae	
1. HSV	AR
2. VZV	AR
3. EBV	AR
4. CMV	AR
5. HHV6	AR
6. HHV8	AR
7. HHV7	F
xvii. Hepatitis B Virus	AR

xviii.	Hepatitis D Virus	AR
xix.	Rabies Virus	AR
xx.	Influenza A Virus	AR
xxi.	Influenza B Virus	AR
xxii.	Human Papilloma Viruses	AR
xxiii.	Paramyxoviruses	
	1. Parainfluenza Virus	AR
	2. Mumps	AR
	3. Measles	AR
	4. RSV	AR
	5. hMPV	AR
	6. Hendra	F
	7. Nipah	F
xxiv.	Parvovirus B19	AR
xxv.	Hepatitis A Virus	AR
xxvi.	Polyoma Viruses	
	1. BK Virus	AR
	2. JC Virus	AR
	3. Merkel Cell Polyoma Virus	F
xxvii.	Variola Viruses	
	1. Variola Major	AR
	2. Mpox Virus	AR
	3. Molluscum Contagiosum	AR
	4. Vaccinia Virus	F
xxviii.	Retroviruses	
	1. HIV	AR
	2. HTLV	AR
xxix.	Rhinovirus	AR
xxx.	Rotavirus	AR
xxxi.	Lassa Virus	F
xxxii.	Lymphocytic Choriomeningitis Virus	F
xxxiii.	Astroviruses	F
xxxiv.	Bocavirus	F
xxxv.	Rift Valley Fever Virus	F
xxxvi.	SARS-CoV-1	F
xxxvii.	Middle Eastern Respiratory Syndrome Coronavirus (MERS)	F
xxxviii.	Enterovirus	F
xxxix.	Marburg Virus	F
xl.	St. Louis Virus	F
xli.	Chikungunya Virus	F
xlii.	Japanese Encephalitis Virus	F
xliii.	Powassan Virus	F
xliv.	Less Common Influenza Variants	F
xlv.	Hepatitis E Virus	F

xlvi.	Colorado Tick Fever Virus	F
xlvii.	Sapovirus	F
xlviii.	Eastern Equine Encephalitis Virus	F
xlix.	Western Equine Encephalitis Virus	F
l.	California Serogroup Viruses	F
li.	Heartland Virus	F

k. Human Prion Diseases — AR

4. Parasites

a. Structure and Biology	AR
b. Specimen Collection, Transport, and Processing	AR
c. Stains and Direct Examination	AR
d. Identification Methods and Instrumentation	AR
e. Geographic Distribution	AR
f. Antiparasitic Agents, Susceptibility Testing, and Mechanisms	
i. Albendazole, Thiabendazole, and Related Agents	F
ii. Amphotericin B	F
iii. Bithionol	F
iv. Chloroquine and Related Agents	F
v. Clindamycin plus Quinine	F
vi. Diethylcarbamazine and Related Agents	F
vii. Ivermectin and Related Agents	F
viii. Nitaxoxanide	F
ix. Pentavalen Antimonials and Related Agents	F
x. Primaquine and Related Agents	F
xi. Praziquantel	F
xii. Quinidine and Related Agents	F
xiii. Trimethoprim-Sulfamethoxazole	F
g. Specific Parasites	
i. Protozoa	
1. Intestinal	
a) *Blastocystis hominis*	AR
b) *Cryptosporidium* spp.	AR
c) *Cyclospora* sp.	AR
d) *Cystoisospora* sp.	AR
e) *Entamoeba histolytica*	AR
f) *Entamoeba dispar*	AR
g) *Entamoeba coli*	AR
h) *Giardia* spp.	AR
i) *Leishmania* spp.	AR
j) *Trichomonas vaginalis*	AR
k) *Chilomastix* sp.	F
l) *Dientamoeba* sp.	AR
m) *Endolimax* sp.	F

n) Other *Entamoeba* spp.	F
o) *Iodamoeba* sp.	F
p) *Pentatrichomonas* sp.	F
2. Blood and Tissue	
a) *Acanthamoeba* spp.	AR
b) *Babesia* spp.	AR
c) *Leishmania* spp.	AR
d) *Naegleria fowleri*	AR
e) *Plasmodium*	
i. *Plasmodium falciparum*	AR
ii. *Plasmodium vivax*	AR
iii. *Plasmodium ovale*	AR
iv. *Plasmodium malariae*	AR
v. *Plasmodium knowlesi*	F
f) *Toxoplasma gondii*	AR
g) *Trypanosoma brucei*	AR
h) *Trypanosoma krusei*	AR
i) *Balamuthia* sp.	F
j) *Sarcocystis* spp.	F
k) *Sarcina* spp.	F
ii. Nematodes (Round Worms)	
1. *Ascaris* spp.	AR
2. *Enterobius* sp.	AR
3. Filarial Nematodes	F
4. Hookworms and Cutaneous Larva Migrans	AR
5. *Strongyloides* spp.	AR
6. *Trichuris* spp.	AR
7. Anisakids	F
8. *Baylisascaris* sp.	F
9. *Brugia* spp.	F
10. *Capillaria* spp.	F
11. *Dracunculus* sp.	F
12. *Gnathostoma* spp.	F
13. *Parastrongylus* sp. (i.e., *Angiostrongylus*)	F
14. *Toxocara* sp. and Visceral Larva Migrans	F
15. *Trichinella* spp.	F
16. *Trichostrongylus* sp.	F
iii. Trematodes	
1. *Schistosoma* spp.	AR
2. *Clonorchis* sp.	F
3. *Dirofilaria* spp.	F
4. *Echinostoma* sp.	F
5. *Fasciola* spp.	F
6. *Fasciolopsis* spp.	F

	7. *Paragonimiasis* spp.	F
iv.	Cestodes	
	1. *Dibothriocephalus latus* (i.e., *Diphyllobothrium latum*)	AR
	2. *Echinococcus* spp.	AR
	3. *Taenia saginata*	AR
	4. *Taenix solium* including Cysticercosis	AR
	5. *Dipylidium* sp.	F
	6. *Hymenolepsis* spp.	F
	7. *Sparganum* spp.	F
v.	Less Common Parasites	F
vi.	Insects, Arthropods, and Arachnids	F

5. Microbiology Laboratory Management

a.	Safety/Biosafety	C
b.	Microbiology Laboratory Management	F
c.	Rules and Regulations	F
d.	Laboratory Inspections	F
e.	QA/QC Issues	F
f.	Other Administration/Laboratory Management Issues	F

Management and Informatics

1. Quality Management

a.	Preanalytic Risks and Risk Mitigation	C
b.	Analytic Risks and Risk Mitigation	
i.	Ongoing Quality Control	C
ii.	Verification and Validation	AR
c.	Postanalytic Risk and Risk Mitigation	
i.	Communication (e.g., Laboratory Reports, Critical Values)	C
ii.	Interpretation	
1.	Reference Range Determination	C
2.	Test Performance Characteristics (e.g., Sensitivity, Specificity, PPV, NPV, etc.)	C
3.	Advanced Interpretations	AR
d.	Oversight of Quality	
i.	Guidelines	C
ii.	Test Utilization / Laboratory Stewardship	C
iii.	Quality Assurance, Management, and Improvement	AR
iv.	Process and Workflow Management	AR
v.	Management of Non-Conformances, Exceptions, and Incidents	AR

vi. Change Control		F

2. Safety

a. Patient Safety

i. Risk Classification		
1. Preanalytic Hazards		
a. Identification Error		C
b. Ordering Error		C
2. Analytic Hazards		
a. Interference		C
b. Interpretive Error		C
3. Postanalytic Hazards		
a. Communication Failure		C
ii. Risk Monitoring		
1. Sentinal Events		AR
2. Near Misses		AR
iii. Risk Mitigation Measures		
1. Failure Mode and Effects Analysis		AR
2. Root Cause Analysis		AR
3. Human Factors / LEAN Design		F

b. Employee and Environmental Safety

i. Risk Classification		
1. Ionizing Radiation Hazard		C
2. Biological Hazard		C
3. Electrical Hazards		C
4. Fire		C
5. Workplace Violence		C
6. Physical Hazards		C
7. Chemical Hazards (MSDS)		C
8. Other Risks to Employees and Environments		C
9. Automotive Accidents (e.g., Specimen Transport Drivers)		F
ii. Risk Monitoring		AR
iii. Risk Mitigation Measures		AR

c. Disaster Management — F

3. Human Resources

a. Employees

i. Job Descriptions		F
ii. Hiring and Termination		F
iii. Initial Orientation and Training		F
iv. Ongoing Education and Training		F
v. Competency and Performance Assessment		F

vi. Other Employees (e.g., HR, Employees)	F
b. Independent Contractors	F

4. Customers

a. Types of Customers	F
b. Customer Satisfaction	F
c. Marketing	F
d. Communication with Customers	F

5. Suppliers

a. Supplier Qualifications	F
b. Types of Supplies	F
vii. Analytical Equipment	F
viii. Kits, Reagents, and Consumables	F
ix. Blood and Blood Products	F
x. Management of Supplies	F
c. Supplier Agreements	F
d. Inventory Management	F
e. Recalls	F

6. Finance

a. Accounting and Financial Statements	AR
b. Management of Expenses	F
xi. Management of Unit Costs	F
xii. Utilization / Demand Management	F
c. Management of Revenue	
xiii. Coding, Billing, and Revenue Cycle	AR
xiv. Payment Models	F
1. Individual Service Based (i.e., Fee for Service)	F
2. Episode Based	F
3. Capitated / ACO	F
xv. Major Payors	F
1. Federal Government	F
2. State Government	F
3. Private Insurers	F
4. Individuals	F
d. Management of Capital	F

7. Business Strategy

a. Long Term Strategic Planning	F
b. Business Contracting and Negotiating	F
c. Business Models	F

8. Laws and Regulations

a. Laboratories and Testing

i. CLIA	C
ii. CAP	C
iii. Proficiency Testing (PT)	C
iv. FDA Testing Regulations	C
v. Regulation of Laboratory Financial Practices	AR
vi. Public Health Reporting	AR
vii. Joint Commission	AR
viii. ISO 15189	F
b. Physician Relations (e.g., Specific Laws [i.e., Stark, Anti-Kickback])	AR
c. Environmental and Worker Safety (e.g., OSHA)	C
d. Regulation of Information and Information Management (e.g., HIPAA)	C
e. Tort Law (e.g., Malpractice)	C
f. Employment Law	F
g. Law Pertaining to Charitable (i.e., Non-Profit) Organizations	F
h. Other Bodies of Law and Regulation (e.g., HPDB, OIG)	F

9. Professionalism and Ethics

a. Medical Profession – Professionalism	
i. Autonomy	C
ii. Beneficence	C
iii. Integrity	C
iv. Non-Malfeasance	C
v. Conflict of Interest	C
vi. Informed Consent	C
vii. Confidentiality	C
viii. Justice	C
b. Other Ethical Systems	
i. Biomedical Ethics	
1. Patient Care	C
2. IRB / Research / Belmont Report	C

10. Informatics

a. The Nature of Information	
i. Tracking (e.g., Barcoding)	C
ii. Coding (e.g., SNOMED, ICD10, CPT)	AR
iii. Types of Data	AR
iv. Data Architecture and Management (i.e. Databases)	F
b. Electronic Information Systems	
i. Types of Systems	
3. Laboratory Information Systems (LIS)	
a. Use of, Search Functions, Various Systems/Modules	C
b. Middleware, Data Integrity, Result Reporting	AR
4. Other Information Systems (e.g., EMR)	

c. Use and Search Functions	C
d. Dashboard Generation and Data Mining	F
ii. Systems Regulations (e.g., HIPAA)	C
iii. Computer Basics (e.g., Hardware, Software)	C
iv. System Operations (i.e., Selection, Verification/Validation, Implementation)	AR
v. Qualities of Information Systems	
1. Interoperability (i.e., Standards and Interfaces)	F
2. Security, Integrity, Privacy, and Confidentiality	F
c. Digital Imaging	
i. Digital Pathology / Whole Slide Imaging	C
1. Basic Use and Z Stacking	C
2. Legality of Restrictions	C
3. AI, Algorithms, and Data Structure	F
4. Compression and Decompression Data Integrity	F
5. Database and Image File Types	F
d. Project Management	
i. Tools, Critical Path, Interaction of Sub-Projects	AR
e. Document Control, including Job Aids (i.e., Control of Laboratory Policies, Procedures, and Directives)	AR
f. Inferences from Information	
i. Statistical Testing	
6. Sensitivity	C
7. Specificity	C
8. Positive Predictive Value	C
9. Negative Predictive Value	C
10. P values	C
11. Standard Deviation	C
ii. Decision Models	
12. Computer Algorithms	C
13. Disease-Specific Testing Algorithms	C
14. Clinical Decision Support Tools	C
iii. Big Data	C