LB
Diagnostics & Clinical Laboratory

Clinical Laboratory Procedures Manual

Laboratory Workflow and Procedures Guide

Services:

- Bloodtyping and Cross Matching
- Routine Screening and Genetic Tests
- Microbial Pathogen Screening

To save life, to bring truth.

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Introduction

The General Clinical Laboratory Procedures Manual serves as a comprehensive guide for all laboratory staff, outlining the essential policies, procedures, and protocols necessary to ensure accurate, efficient, and safe diagnostic testing. This manual is designed to maintain the highest standards of quality, regulatory compliance, and patient care.

Purpose of the Manual

The primary goal of this manual is to provide a centralized resource for clinical laboratory operations, ensuring consistent and standardized practices across all sections, including Hematology, Clinical Chemistry, Immunology and Serology, Clinical Microscopy, and Microbiology. It aims to:

- Support accurate and timely diagnosis through well-defined testing protocols.
- Enhance patient safety by minimizing errors in specimen handling, analysis, and reporting.
- Serve as a training and reference document for laboratory personnel.

Scope of Services

The clinical laboratory is equipped to perform a broad spectrum of diagnostic tests to meet the needs of patients and healthcare providers. These services support:

- Emergency, inpatient, and outpatient care.
- Long-term health monitoring and chronic disease management.
- Specialized testing for infectious diseases, autoimmune conditions, and metabolic disorders.

Regulatory Compliance and Accreditation

The laboratory adheres to rigorous regulatory standards set by organizations such as:

- Philippine Council for Quality Assurance in Clinical Laboratories (PCQACL).
- Asia Association of Medical Laboratory Scientists (AAMLS).
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- Other relevant national and international bodies.

These accreditations underscore the laboratory’s commitment to maintaining quality, safety, and reliability in all aspects of its operations.

Quality Assurance and Quality Control (QA/QC)

Quality is the cornerstone of laboratory operations. This manual integrates QA/QC measures to ensure that:

- Testing procedures yield accurate and reproducible results.

- Equipment calibration and maintenance schedules are rigorously followed.
- Proficiency testing and staff competency evaluations are conducted regularly.

User Guidelines

- **For Laboratory Personnel:** This manual serves as a step-by-step reference for daily operations, including specimen handling, test execution, and result reporting.
- **For Healthcare Providers:** It offers insight into laboratory capabilities and processes, ensuring better collaboration and optimized patient care.

Commitment to Excellence

The laboratory is dedicated to using state-of-the-art technology, employing highly skilled professionals, and fostering a culture of continuous improvement to meet the evolving needs of patients and healthcare providers.

Hematology

The Hematology section of the clinical laboratory is dedicated to the study and analysis of blood and its components, including red blood cells (RBCs), white blood cells (WBCs), platelets, hemoglobin, and coagulation factors. This section provides vital diagnostic information to support the management of various conditions, including anemia, infections, bleeding disorders, and hematologic malignancies.

1. General Information

The Hematology department performs both routine and specialized tests using state-of-the-art equipment and methodologies. Tests in this section support:

- Diagnosis of hematologic disorders.
- Monitoring of chronic conditions such as anemia and thrombocytopenia.
- Preoperative screening to assess bleeding risks.
- Emergency evaluation of critical hematologic conditions.

2. Specimen Collection

Proper specimen collection is crucial for accurate hematologic testing.

2.1 Types of Specimens

- **Whole Blood:** Used for most routine hematology tests, including Complete Blood Count (CBC) and coagulation profiles.
- **Bone Marrow Aspirates:** Collected for diagnosing hematologic malignancies and marrow disorders.

2.2 Collection Procedures

- **Venipuncture:** The primary method for collecting blood.
- **Capillary Sampling:** Used in specific situations such as neonatal testing or difficult venous access.
- **Anticoagulants:**
    - EDTA (Lavender top) for routine hematology tests (e.g., CBC, Differential).
    - Sodium citrate (Blue top) for coagulation studies.

2.3 Handling and Transport

- Blood samples must be gently inverted 8–10 times to mix with the anticoagulant and prevent clotting.
- Samples should be transported at room temperature and processed promptly to avoid hemolysis or cellular degradation.

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3. Testing Procedures

Hematology testing includes both automated and manual methodologies to ensure precise results.

3.1 Routine Tests

- **Complete Blood Count (CBC):** Includes RBC count, WBC count, platelet count, hemoglobin, hematocrit, and RBC indices.
- **Differential Count:** Identifies and quantifies WBC subtypes (e.g., neutrophils, lymphocytes).
- **Erythrocyte Sedimentation Rate (ESR):** Assesses inflammation or infection.

3.2 Coagulation Studies

- **Prothrombin Time (PT):** Measures clotting efficiency and evaluates warfarin therapy.
- **Activated Partial Thromboplastin Time (aPTT):** Assesses intrinsic coagulation pathways.
- **Fibrinogen and D-Dimer Tests:** Used for detecting clotting disorders such as Disseminated Intravascular Coagulation (DIC).

3.3 Specialized Tests

- **Reticulocyte Count:** Evaluates bone marrow function and RBC production.
- **Peripheral Blood Smear Examination:** Detects abnormal cell morphology.
- **Flow Cytometry:** Used for immunophenotyping in hematologic malignancies.

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4. Reference Ranges

Reference ranges vary by age, gender, and laboratory protocols. Example ranges:

Test	Adult Reference Range	Pediatric Reference Range
Hemoglobin	13.5–17.5 g/dL (male); 12–15.5 g/dL (female)	11.5–14.5 g/dL
Hematocrit	41–53% (male); 36–46% (female)	35–45%
Platelet Count	150,000–450,000/µL	150,000–450,000/µL
WBC Count	4,000–10,000/µL	5,000–15,000/µL
Reticulocyte Count	0.5–2.5%	1.0–4.5%

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5. Reporting Results

- **Critical Values:** Immediate notification of healthcare providers for critical results such as extremely low hemoglobin or platelet levels.

- **Turnaround Time (TAT):** Routine tests reported within 2–4 hours; STAT tests within 1 hour.
- **Documentation:** All results are recorded in the laboratory information system (LIS) and reviewed by qualified personnel before release.

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6. Equipment and Maintenance

Hematology relies on precise instruments to ensure reliable results.

- Automated Hematology Analyzers: Perform CBC and differential counts.
- Coagulation Analyzers: Measure clotting parameters like PT and aPTT.
- Microscopes: Used for manual differential counts and morphology studies.

Maintenance Protocols

- Daily calibration and quality control (QC) checks.
- Scheduled preventive maintenance as per manufacturer recommendations.
- Documentation of maintenance activities for audit purposes.

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7. Safety Measures

- Proper disposal of biohazardous materials (e.g., sharps, blood samples).
- Adherence to personal protective equipment (PPE) guidelines.
- Routine decontamination of work surfaces.

Clinical Chemistry

The Clinical Chemistry section focuses on the quantitative analysis of biochemical substances in bodily fluids, primarily blood and urine. These tests provide vital information for diagnosing and monitoring diseases, evaluating organ function, and guiding treatment decisions.

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1. General Information

The Clinical Chemistry department is equipped to perform routine and specialized tests using automated and manual methods. Tests encompass areas such as metabolic, renal, hepatic, and endocrine functions. The goals include:

- Ensuring timely and accurate test results.
- Supporting emergency, inpatient, and outpatient care.
- Maintaining high standards of quality control and compliance with regulatory guidelines.

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2. Specimen Collection and Handling

Proper specimen collection, labeling, and handling are critical to the accuracy of clinical chemistry results.

2.1 Specimen Types

- **Blood (Serum/Plasma):** Most chemistry tests require serum or plasma.
- **Urine:** Collected for metabolic studies, renal function, and 24-hour analysis.
- **Other Body Fluids:** Includes cerebrospinal fluid (CSF) and peritoneal fluid for specific tests.

2.2 Collection Protocols

- **Fasting Requirements:** Many tests (e.g., lipid profile, glucose) require an 8–12 hour fasting period.
- **Anticoagulants:**
    - Lithium heparin (Green top) for plasma-based assays.
    - No anticoagulant (Red or Gold top) for serum tests.
- **Special Handling:**
    - Protect light-sensitive samples (e.g., bilirubin) using amber tubes or foil.
    - Keep chilled samples (e.g., ammonia) on ice during transport.

2.3 Labeling and Transport

- Proper labeling includes the patient's full name, unique identifier, date, and time of collection.
- Specimens should be transported promptly to maintain integrity.

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3. Testing Procedures

Clinical Chemistry tests are divided into routine and specialized categories.

3.1 Routine Tests

- **Basic Metabolic Panel (BMP):** Includes glucose, electrolytes (sodium, potassium, chloride), BUN, creatinine, and CO2.
- **Comprehensive Metabolic Panel (CMP):** Adds liver enzymes (ALT, AST, ALP) and total protein/albumin to the BMP.
- **Lipid Profile:** Measures cholesterol, HDL, LDL, and triglycerides.

3.2 Specialized Tests

- **Endocrine Panel:** Thyroid hormones (TSH, T3, T4), cortisol, and insulin.
- **Toxicology:** Detection of drugs (therapeutic or toxic levels).
- **Enzyme Panels:** CK-MB, troponin for cardiac events; amylase and lipase for pancreatic function.
- **Renal Function Panel:** Includes urine microalbumin and creatinine clearance.

3.3 STAT Testing

- Critical analytes such as glucose, electrolytes, troponin, and ammonia are available on a STAT basis, with results reported within 1 hour.

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4. Reference Ranges

Reference ranges vary depending on the test, patient age, and gender. Below are examples:

Test	Adult Range	Pediatric Range
Glucose (fasting)	70–99 mg/dL	60–100 mg/dL
Sodium	135–145 mmol/L	135–145 mmol/L
Potassium	3.5–5.0 mmol/L	3.5–5.5 mmol/L
Total Bilirubin	0.1–1.2 mg/dL	0.1–1.0 mg/dL
Creatinine	0.6–1.3 mg/dL	0.3–1.0 mg/dL
ALT (SGPT)	7–56 U/L	10–40 U/L

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5. Equipment and Calibration

5.1 Automated Analyzers

- Chemistry analyzers capable of performing high-throughput testing with minimal manual intervention.
- Specific analyzers include those for electrolytes, immunoassays, and toxicology.

5.2 Calibration and Quality Control (QC)

- Daily calibration checks with certified standards.
- Routine use of control samples to verify accuracy and precision.
- Preventive maintenance schedules followed as per manufacturer guidelines.

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6. Reporting Results

6.1 Normal Reporting

- Routine test results are reported within 2–4 hours.
- Tests requiring complex analysis may take longer depending on in-house or reference laboratory processing.

6.2 STAT Reporting

- STAT results are processed and reported within 1 hour.
- Critical values (e.g., high potassium or troponin) are immediately communicated to the requesting provider.

6.3 Error Correction

- Erroneous results are flagged, corrected, and promptly communicated to the provider. Documentation includes root cause analysis and corrective actions.

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7. Safety and Waste Management

- **PPE Use:** Mandatory gloves, lab coats, and eye protection when handling specimens.
- **Biohazard Disposal:** All waste materials (e.g., tubes, pipettes) are disposed of in appropriate biohazard containers.
- **Spill Management:** Immediate cleanup using disinfectants and adherence to safety protocols.

8. Specialized Areas

8.1 Therapeutic Drug Monitoring (TDM)

- Monitors the levels of drugs such as digoxin, theophylline, and phenytoin to optimize therapy and avoid toxicity.

8.2 Toxicology Testing

- Screens for and quantifies substances in cases of overdose or poisoning.

8.3 Endocrinology Testing

- Measures hormone levels to assess conditions like hypothyroidism or adrenal insufficiency.

Immunology and Serology

The Immunology and Serology section focuses on detecting immune responses and the presence of specific antibodies or antigens in the blood and other bodily fluids. These tests are crucial for diagnosing infections, autoimmune disorders, allergies, and monitoring immune status.

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1. General Information

The Immunology and Serology department utilizes a variety of methods to assess immune system function and detect specific markers of disease. Key objectives include:

- Identifying infectious agents through antigen or antibody detection.
- Diagnosing autoimmune and hypersensitivity disorders.
- Supporting transfusion and transplantation services through compatibility testing.

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2. Specimen Collection and Handling

Proper specimen management is essential for reliable immunological and serological results.

2.1 Specimen Types

- **Serum:** The primary specimen for most serological tests.
- **Plasma:** May be used for specific assays requiring anticoagulants.
- **Other Fluids:** CSF or synovial fluid for specialized antibody testing.

2.2 Collection Protocols

- **Tube Selection:**
  - Red top tubes (no anticoagulant) for serum tests.
  - Lavender or yellow top tubes (with EDTA or ACD) for specific immunological tests.
- **Patient Preparation:**
  - No fasting is generally required unless specified for a particular test (e.g., complement assays).
- **Special Handling:**
  - Store and transport specimens at 2–8°C unless otherwise stated (e.g., cryoglobulins require warm collection and transport).

2.3 Labeling and Transport

- Ensure correct labeling, including the patient’s full name, ID, and collection time.

- Transport specimens promptly to maintain antigen and antibody stability.

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3. Testing Procedures

The Immunology and Serology department offers a wide range of tests divided into infectious disease markers, autoimmune assays, and hypersensitivity evaluations.

3.1 Infectious Disease Testing

- **HIV Antibody/Antigen (HIV 1/2):** Detects antibodies to HIV and the p24 antigen.
- **Hepatitis Panel:** Tests for hepatitis A, B, and C markers (e.g., HBsAg, anti-HCV).
- **Syphilis Testing (RPR, TP-PA):** Identifies syphilis antibodies.
- **TORCH Panel:** Detects infections affecting pregnancies (Toxoplasmosis, Rubella, CMV, Herpes).

3.2 Autoimmune Disease Testing

- **Rheumatoid Factor (RF):** Detects antibodies associated with rheumatoid arthritis.
- **Antinuclear Antibody (ANA):** Screens for autoimmune diseases such as lupus.
- **Anti-dsDNA and Anti-Smith (Sm):** Specific markers for systemic lupus erythematosus (SLE).
- **Anti-CCP (Cyclic Citrullinated Peptide):** Confirms rheumatoid arthritis.

3.3 Hypersensitivity and Allergy Testing

- **Immunoglobulin E (IgE):** Measures total and allergen-specific IgE levels.
- **Allergen Panels:** Detects sensitivity to food, environmental, or drug allergens.

3.4 Specialized Immunological Assays

- **Complement Testing (C3, C4):** Evaluates complement pathway activity.
- **Cryoglobulin Studies:** Diagnoses conditions such as cryoglobulinemia.
- **Flow Cytometry:** Measures immune cell populations and markers.

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4. Reference Ranges

Reference ranges for immunological and serological tests may vary depending on the assay and laboratory protocol. Below are examples of typical ranges:

Test	Reference Range
Rheumatoid Factor (RF)	<14 IU/mL

C3 (Complement Component 3)	88–206 mg/dL
C4 (Complement Component 4)	16–47 mg/dL
Total IgE	<100 IU/mL (varies by age)
ANA Titer	<1:40 (negative)
HIV Antigen/Antibody Combo	Non-reactive

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5. Equipment and Techniques

5.1 Equipment

- **ELISA Readers:** For enzyme-linked immunosorbent assays.
- **Immunofluorescence Microscopes:** For ANA and other immunofluorescence assays.
- **Flow Cytometers:** For advanced immunophenotyping.

5.2 Techniques

- **Agglutination Tests:** Used for RF and rapid syphilis tests.
- **Immunodiffusion:** Detects specific antigens or antibodies in gels.
- **Enzyme Immunoassays (EIA):** Detect and quantify antigens or antibodies.
- **Western Blotting:** Confirms serological results for diseases such as HIV.

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6. Reporting Results

6.1 Turnaround Times (TAT)

- Routine tests: 24–48 hours.
- STAT tests: Within 1–2 hours.

6.2 Critical Values

- Positive tests for highly infectious diseases (e.g., HIV, Hepatitis) must be immediately communicated to the provider.
- Strongly positive autoimmune markers with potential critical impact (e.g., high anti-dsDNA levels) must also be flagged.

6.3 Documentation

- Results are recorded in the Laboratory Information System (LIS) and cross-checked for accuracy.
- Reports include a detailed interpretation for complex immunological assays.

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7. Quality Control and Assurance

- **Daily Controls:** Positive and negative controls run with each batch of tests.
- **Proficiency Testing:** Participation in external programs to validate accuracy.
- **Calibration and Maintenance:** Routine checks and adjustments for all immunology equipment.

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8. Safety Measures

- Use of biosafety cabinets for handling infectious samples.
- Disposal of biohazardous materials in appropriate containers.
- Staff training on handling potentially infectious agents.

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9. Specialized Services

- **Transfusion Compatibility Testing:** Crossmatching and antibody screening.
- **Immune Status Monitoring:** Evaluating response to vaccination (e.g., anti-HBs for Hepatitis B).
- **Allergy Testing Services:** Comprehensive allergen testing panels tailored to patient needs.

Clinical Microscopy

The Clinical Microscopy section specializes in the analysis of body fluids, including urine, stool, and other excretions or secretions, to identify physical, chemical, and microscopic characteristics that aid in the diagnosis of various medical conditions.

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1. General Information

Clinical microscopy plays a vital role in diagnosing urinary tract infections, kidney diseases, parasitic infections, and other disorders. This section provides rapid and reliable results for:

- Routine urinalysis.
- Microscopic analysis of urine sediments.
- Stool analysis for parasites, blood, and fat.
- Examination of other body fluids (e.g., CSF, synovial, pleural).

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2. Specimen Collection and Handling

Proper specimen collection is crucial to ensure the accuracy of microscopy results.

2.1 Types of Specimens

- **Urine:** Clean-catch midstream samples, 24-hour collections, or catheterized specimens.
- **Stool:** Fresh samples for ova and parasites, occult blood, or fat analysis.
- **Other Body Fluids:** Cerebrospinal, pleural, synovial, peritoneal, or aspirates from specific sites.

2.2 Collection Protocols

- **Urine Samples:**
  - Clean-catch midstream method for routine urinalysis.
  - Use sterile containers for culture and sensitivity testing.
  - Collect 24-hour urine in appropriate preservative containers, if required.
- **Stool Samples:**
  - Collect in a clean, dry container without contamination from urine or toilet water.
  - Use special preservative vials for ova and parasite testing.
- **Other Body Fluids:**
  - Collect aseptically in sterile containers.
  - Transport immediately to the laboratory to avoid cellular degradation.

2.3 Transport and Storage

- Urine: Process within 2 hours or refrigerate at 2–8°C.
- Stool: Transport fresh samples promptly or refrigerate for short-term storage.
- Other Fluids: Keep at room temperature unless otherwise specified.

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3. Testing Procedures

3.1 Urinalysis

- **Physical Examination:**
  - **Color and Appearance:** Assess for clarity, turbidity, or abnormal color.
  - **Specific Gravity:** Evaluate renal concentrating ability.
- **Chemical Examination:**
  - Dipstick testing for pH, protein, glucose, ketones, blood, bilirubin, urobilinogen, nitrites, and leukocyte esterase.
- **Microscopic Examination:**
  - Centrifuged urine sediment examined for RBCs, WBCs, epithelial cells, casts, crystals, and microorganisms.

3.2 Stool Analysis

- **Microscopic Examination:**
  - Identification of ova, parasites, and trophozoites using saline and iodine wet mounts.
  - Detection of fat globules in cases of malabsorption.
- **Chemical Testing:**
  - Occult blood testing for gastrointestinal bleeding.
  - Reducing substances for carbohydrate malabsorption.

3.3 Other Body Fluids

- **Cell Counts:** Performed manually or using automated systems to count WBCs and RBCs.
- **Microscopic Examination:** Detects malignant cells, crystals, or microorganisms.
- **Gram Stains:** Performed to identify bacterial presence.

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4. Reference Ranges

Below are general reference ranges for common microscopy tests:

Test	Normal Range

Urine Specific Gravity	1.005–1.030
Urine pH	4.5–8.0
RBCs (urine sediment)	0–2/HPF
WBCs (urine sediment)	0–5/HPF
Casts (urine sediment)	0–2 hyaline/LPF
Ova and Parasites (stool)	None detected
WBCs (CSF)	0–5/mm³
RBCs (CSF)	None detected

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5. Reporting Results

5.1 Turnaround Time (TAT)

- Routine urinalysis: 1–2 hours.
- Stool microscopy: 2–4 hours.
- CSF analysis: STAT processing within 1 hour.

5.2 Critical Values

- Presence of significant RBCs, WBCs, or casts in urine.
- Positive stool occult blood or ova/parasites.
- Elevated WBCs or pathogens in CSF or other fluids.

5.3 Documentation

- All results entered into the Laboratory Information System (LIS) with interpretations for abnormal findings.

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6. Equipment and Techniques

6.1 Equipment

- **Centrifuges:** Used for concentrating urine and other body fluids.
- **Microscopes:** Brightfield microscopes for detailed analysis of sediments and slides.
- **Refractometers:** For specific gravity measurements.

6.2 Techniques

- **Wet Mounts:** For detecting motile organisms in stool or vaginal samples.
- **Gram Stains:** For identifying bacterial morphology.
- **Polarized Light Microscopy:** Used for detecting crystals, such as urate or cholesterol.

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7. Quality Control (QC)

- Daily calibration and maintenance of equipment (e.g., centrifuges, microscopes).
- Use of control samples to validate reagent strips and stains.
- Documentation of QC results and corrective actions.

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8. Safety Measures

- Use personal protective equipment (PPE) when handling specimens.
- Dispose of biohazardous materials, including used slides and urine containers, in designated waste bins.
- Disinfect work areas after processing infectious specimens.

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9. Specialized Services

- **Urine Cytology:** Identifies malignant cells in urine for bladder cancer screening.
- **Seminal Fluid Analysis:** Assesses fertility or post-vasectomy status.
- **Body Fluid Differentiation:** Distinguishes transudates from exudates in pleural or peritoneal effusions.

Clinical Microbiology

The Clinical Microbiology section is dedicated to identifying infectious agents, including bacteria, fungi, viruses, and parasites, to guide effective treatment decisions. This section plays a critical role in diagnosing infections, determining antimicrobial susceptibility, and monitoring disease outbreaks.

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1. General Information

The Clinical Microbiology department supports the diagnosis and management of infectious diseases through:

- Isolation and identification of pathogens.
- Determination of antimicrobial resistance and susceptibility.
- Coordination with infection control for outbreak management.
- Providing guidance on appropriate specimen collection and testing methods.

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2. Specimen Collection and Handling

Proper specimen collection, transport, and processing are essential for the accurate detection of infectious agents.

2.1 Specimen Types

- **Blood:** For blood cultures to identify systemic infections.
- **Urine:** For diagnosing urinary tract infections (UTIs).
- **Respiratory Samples:** Includes sputum, throat swabs, and nasopharyngeal aspirates.
- **Stool:** For detecting gastrointestinal pathogens such as bacteria, parasites, and viruses.
- **Wound Swabs:** For identifying infections in surgical sites or open wounds.
- **Other Body Fluids:** Includes CSF, synovial, and pleural fluids for specialized culture and testing.

2.2 Collection Protocols

- Use sterile containers and aseptic techniques to prevent contamination.
- Collect specimens before initiating antimicrobial therapy whenever possible.
- Follow specific protocols for sample types (e.g., anaerobic transport media for anaerobic cultures).

2.3 Transport and Storage

- Transport specimens to the laboratory promptly to preserve viability.
- Use appropriate transport media for specialized testing (e.g., Cary-Blair for stool samples).
- Refrigerate or store at room temperature as recommended for each specimen type.

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3. Testing Procedures

3.1 Bacterial Culture and Identification

- **Blood Cultures:** Automated systems to detect bacteremia or fungemia.
- **Urine Cultures:** Quantitative colony counts to diagnose UTIs.
- **Throat Swabs:** Group A Streptococcus detection using rapid antigen testing or culture.
- **Wound Cultures:** Identification of pathogens in pus or tissue samples.

3.2 Antimicrobial Susceptibility Testing (AST)

- Performed using standardized methods (e.g., Kirby-Bauer disk diffusion, MIC determination).
- Results reported as susceptible, intermediate, or resistant to guide therapy.

3.3 Parasitology

- Direct wet mount and stained smear examinations for ova and parasites in stool.
- Specialized tests for blood parasites (e.g., malaria, trypanosomes).

3.4 Mycology

- Culture and microscopy for identifying fungi in clinical samples.
- Direct examination using KOH prep or calcofluor white staining.

3.5 Virology

- Molecular methods such as PCR for detecting viral DNA/RNA.
- Immunoassays for detecting viral antigens (e.g., influenza, RSV).

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4. Reference Ranges

There are no standard reference ranges for microbiology, as results depend on pathogen isolation and susceptibility patterns. Reports include:

- Identification of the organism (e.g., Staphylococcus aureus).

- Colony count thresholds (e.g., significant growth >100,000 CFU/mL in urine).
- Antimicrobial susceptibility results.

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5. Reporting Results

5.1 Turnaround Times (TAT)

- Preliminary reports for cultures: 24–48 hours.
- Final reports: 48–72 hours for most bacterial cultures; longer for fungi or mycobacteria.
- STAT testing (e.g., Gram stain): Within 1 hour.

5.2 Critical Values

- Positive blood cultures.
- Pathogenic organisms in sterile body fluids (e.g., CSF).
- Multidrug-resistant organisms (e.g., MRSA, ESBL-producing bacteria).

5.3 Documentation

- Results are entered into the Laboratory Information System (LIS) and flagged for review.
- Critical results are immediately communicated to the requesting provider.

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6. Equipment and Techniques

6.1 Equipment

- **Automated Blood Culture Systems:** For rapid detection of microbial growth.
- **Microscopes:** Used for Gram stains, wet mounts, and KOH preparations.
- **Molecular Platforms:** PCR systems for rapid pathogen identification.
- **Culture Media:** Specialized media for routine and selective growth (e.g., MacConkey, Chocolate Agar).

6.2 Techniques

- **Staining Methods:**
  - Gram staining for bacterial classification.
  - Acid-fast staining for mycobacteria.
- **Molecular Diagnostics:**
  - PCR for identifying genetic material of pathogens.
- **Serological Testing:**
  - Antibody detection for certain pathogens (e.g., syphilis, Lyme disease).

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7. Quality Control (QC)

- Routine use of control strains for verifying culture media and test methods.
- Calibration and maintenance of equipment, including microscopes and PCR machines.
- Proficiency testing to ensure laboratory accuracy and reliability.

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8. Safety Measures

- Handle infectious specimens in a biosafety cabinet where appropriate.
- Use personal protective equipment (PPE) at all times.
- Follow strict protocols for the disposal of biohazardous waste.

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9. Specialized Services

- **Tuberculosis (TB) Testing:** Acid-fast bacilli (AFB) staining and culture.
- **Sexually Transmitted Infection (STI) Testing:** Includes cultures and molecular diagnostics for gonorrhea and chlamydia.
- **Outbreak Investigations:** Collaboration with infection control for organism typing and resistance pattern analysis.
- **Resistance Surveillance:** Monitoring local patterns of antimicrobial resistance to guide empiric therapy.

Histopathology and Cytology

The Histopathology and Cytology section is dedicated to the preparation, examination, and interpretation of tissue and cellular samples for the diagnosis of diseases, including cancers, inflammatory conditions, and infections. This section provides critical diagnostic services to clinicians, aiding in patient management and treatment planning.

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1. General Information

Histopathology focuses on the microscopic examination of tissues, while Cytology deals with the study of individual cells and small cell clusters. Key objectives of this section include:

- Accurate diagnosis of neoplastic, inflammatory, and infectious conditions.
- Examination of tissue architecture and cellular morphology.
- Specialized studies for detecting biomarkers and molecular features of disease.

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2. Specimen Collection and Handling

Proper handling of tissue and cytology specimens is essential to preserve their integrity and ensure diagnostic accuracy.

2.1 Types of Specimens

- **Histopathology Specimens:** Biopsy samples, surgical excisions, and autopsy tissues.
- **Cytology Specimens:** Pap smears, body fluids (e.g., pleural, peritoneal), and fine-needle aspiration (FNA) samples.

2.2 Collection Protocols

- **Histopathology:**
  - Place specimens immediately in 10% neutral buffered formalin unless special studies (e.g., frozen sections) are required.
  - Ensure proper orientation of large specimens for accurate sectioning.
- **Cytology:**
  - For Pap smears, use a brush or spatula to collect cervical cells and transfer onto slides or into liquid-based media.
  - Collect body fluids in sterile containers, and if delay in processing is expected, refrigerate the specimen.

2.3 Labeling and Transport

- Ensure accurate labeling with patient identification, site of origin, and clinical history.
- Transport specimens promptly to maintain cellular and tissue integrity.

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3. Tissue and Cytology Processing

3.1 Histopathology Processing

- **Gross Examination:** Tissue samples are described, measured, and dissected for optimal sectioning.
- **Tissue Embedding:** Samples are processed and embedded in paraffin blocks for sectioning.
- **Sectioning and Staining:** Thin sections are cut using a microtome and stained with Hematoxylin and Eosin (H&E). Special stains or immunohistochemistry may be performed based on clinical indications.

3.2 Cytology Processing

- **Smears and Liquid-Based Preparations:** Slides are prepared from collected material and fixed with appropriate agents.
- **Staining:**
  - Pap stain for gynecological cytology.
  - Diff-Quik or Giemsa stain for FNA specimens.
- **Microscopic Evaluation:** Cells are examined for abnormalities in morphology and staining characteristics.

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4. Specialized Studies

4.1 Immunohistochemistry (IHC)

- Detects specific antigens in tissues using labeled antibodies.
- Applications include subclassification of cancers (e.g., HER2 in breast cancer) and identification of infectious agents.

4.2 Molecular Pathology

- Techniques such as in situ hybridization (ISH) and PCR are used for identifying genetic abnormalities or pathogens.

4.3 Frozen Section Analysis

- Performed intraoperatively for rapid diagnosis.
- Tissue is frozen, sectioned, and stained for immediate microscopic examination.

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5. Reporting and Interpretation

5.1 Histopathology Reports

- Includes gross and microscopic descriptions, final diagnosis, and relevant observations such as tumor grading or margins.

5.2 Cytology Reports

- Provides a detailed description of cellular findings and diagnostic interpretation.
- Classification systems such as The Bethesda System for cervical cytology are used.

5.3 Turnaround Times (TAT)

- Routine histopathology: 3–5 working days.
- Frozen sections: Within 30 minutes during surgical procedures.
- Cytology: 1–2 working days for routine cases.

5.4 Critical Results

- Positive malignancy findings.
- Unexpected infectious agents (e.g., acid-fast bacilli, fungal organisms).
- Immediate communication of results for intraoperative consultations.

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6. Equipment and Techniques

6.1 Histopathology Equipment

- **Tissue Processors:** For dehydration and paraffin embedding.
- **Microtomes:** For cutting thin tissue sections.
- **Automated Stainers:** For routine and special staining.

6.2 Cytology Equipment

- **Centrifuges:** For concentrating cells in fluid specimens.
- **Microscopes:** For detailed examination of cellular morphology.

- **Liquid-Based Cytology (LBC) Systems:** For improving sample quality in gynecological and non-gynecological cytology.

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7. Quality Control (QC)

- Daily calibration of microtomes and staining equipment.
- Routine monitoring of staining quality with control slides.
- Documentation of QC activities in compliance with accreditation standards.

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8. Safety Measures

- Use of personal protective equipment (PPE) when handling potentially infectious specimens.
- Disposal of tissue and cytology waste in biohazard containers.
- Ventilated grossing stations to minimize exposure to formalin fumes.

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9. Specialized Services

- **Breast Biopsy Analysis:** Includes hormone receptor and HER2 status testing.
- **Bone Marrow Biopsies:** Evaluates hematologic malignancies and marrow disorders.
- **Cytogenetic Studies:** Detect chromosomal abnormalities in prenatal, oncology, or hematology cases.
- **Fine-Needle Aspiration (FNA) Services:** Rapid on-site evaluation for adequacy during aspirates.

Appendices

1. Glossary of Terms

The glossary provides definitions for common terms and abbreviations used throughout this manual to ensure clarity and consistency. It is particularly useful for new staff or those unfamiliar with laboratory terminology.

- **CBC (Complete Blood Count):** A blood test used to evaluate overall health and detect a variety of disorders, such as anemia, infection, and many other diseases.
- **MIC (Minimum Inhibitory Concentration):** The lowest concentration of an antimicrobial that will inhibit the visible growth of a microorganism.
- **SOP (Standard Operating Procedure):** A set of step-by-step instructions compiled by an organization to help workers carry out routine operations.
- **TAT (Turnaround Time):** The total time taken from the receipt of a specimen in the laboratory to the final report of test results.
- **FNA (Fine Needle Aspiration):** A diagnostic procedure used to investigate lumps or masses. A thin, hollow needle is used to remove a small sample of tissue for examination under a microscope.
- **IHC (Immunohistochemistry):** A laboratory technique used to visualize the expression of specific proteins in tissue sections using labeled antibodies.

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2. Reference Charts and Tables

The following reference charts provide essential information for quick decision-making:

Specimen Collection Requirements

Test Name	Specimen Type	Collection Container	Volume Required	Special Instructions
Complete Blood Count (CBC)	Blood (Venous)	Lavender-top EDTA tube	3–5 mL	Mix thoroughly; avoid hemolysis.
Urine Culture	Urine	Sterile urine container	10–15 mL	Midstream clean catch method.
Sputum Culture	Sputum	Sterile container	5–10 mL	Collect early morning sample.
Stool for Ova and Parasites	Stool	Plastic stool container	10–15 g	Transport within 1–2 hours of collection.
Blood Culture	Blood (Venous)	Blood culture bottle	5–10 mL	Collect before starting antibiotics.

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3. Test Menu

This section provides a comprehensive list of all available tests in the laboratory, categorized by department.

Hematology Tests:

- Complete Blood Count (CBC)
- Hemoglobin Electrophoresis
- Reticulocyte Count
- Platelet Function Tests
- Coagulation Studies (PT, PTT, INR)
- Bone Marrow Aspiration

Clinical Chemistry Tests:

- Basic Metabolic Panel (BMP)
- Comprehensive Metabolic Panel (CMP)
- Lipid Profile
- Liver Function Tests (LFT)
- Kidney Function Tests (BUN, Creatinine)
- Endocrine Panels (Thyroid, Adrenal)
- Therapeutic Drug Monitoring (Digoxin, Theophylline)

Microbiology Tests:

- Blood Cultures
- Urine Cultures
- Respiratory Cultures (Sputum, Throat Swab)
- Stool Cultures
- Ova and Parasite Testing
- Gram Staining

Immunology and Serology Tests:

- HIV Antibody/Antigen Testing
- Hepatitis B and C Panels
- ANA (Antinuclear Antibody) Test
- Rheumatoid Factor (RF)
- Immunoglobulin E (IgE)
- Syphilis Testing (RPR, TP-PA)

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4. Quality Control (QC) Logs and Forms

The QC section ensures that laboratory equipment and processes remain within acceptable operational standards. Below are sample templates for maintaining QC:

Daily QC Log:

Date	Instrument	QC Check	Result
2024-11-26	CBC Analyzer	Calibration	Passed
2024-11-26	Chemistry Analyzer	QC Sample Control	Passed
2024-11-26	Microscope	Cleaning Verification	Cleaned

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5. Safety Guidelines and Emergency Procedures

Laboratory safety is paramount. The following guidelines outline safety protocols for handling specimens, chemicals, and biological materials:

Personal Protective Equipment (PPE):

- Always wear lab coats, gloves, and safety goggles when handling biological samples or chemicals.
- Wear face shields when working with hazardous chemicals or infectious specimens.

Emergency Procedures:

- **Chemical Spill:** Immediately notify the supervisor, evacuate the area if needed, and clean with appropriate absorbent materials.
- **Needle Stick Injury:** Immediately wash the affected area with soap and water, report the incident, and follow the exposure protocol.
- **Fire or Explosion:** Evacuate the lab, activate the fire alarm, and call the fire department.

First-Aid Kits:

- Located in the laboratory's emergency area and equipped with gloves, eye wash, bandages, and antiseptic wipes.

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6. Regulatory Guidelines

This section summarizes the primary regulations that govern laboratory operations:

- **CLIA (Clinical Laboratory Improvement Amendments):** Ensures quality testing in laboratory medicine.
- **PCQACL (Philippine Council for Quality Assurance in Clinical Laboratories):** Sets standards for laboratory practices and offers accreditation programs.
- **OSHA (Occupational Safety and Health Administration):** Requires safety protocols and protective measures for laboratory staff.
- **JCAHO (Joint Commission on Accreditation of Healthcare Organizations):** Ensures laboratory services meet clinical care standards.

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7. Specimen Rejection Criteria

Specimens that fail to meet certain criteria will be rejected and may require recollection. The following are common rejection reasons:

- **Hemolyzed Samples:** Blood samples that appear red and watery due to improper collection or storage.
- **Insufficient Volume:** Specimens that are insufficient to perform the required tests.
- **Incorrect Labeling:** Samples without proper patient identification or collection information.
- **Improper Storage:** Specimens that have not been transported or stored under required conditions (e.g., refrigerated when necessary).

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8. Critical Values Notification Protocol

When a critical value is identified, immediate notification is essential for patient safety. The protocol is as follows:

- **Step 1:** Laboratory staff identifies the critical value (e.g., abnormal potassium, low hemoglobin).
- **Step 2:** Results are flagged as "Critical" in the laboratory information system (LIS).
- **Step 3:** The laboratory staff contacts the attending healthcare provider immediately by phone and follows up with a written report.
- **Step 4:** The laboratory documents all communication regarding the critical result.

Review and Revision Policy

This manual is reviewed annually or whenever significant changes in laboratory procedures or regulations occur. The review process is managed by the Laboratory Quality Assurance team.

Last Review Date: November 2024
Next Review Date: November 2025
Reviewed by: Dr. Ellah Iracielli Teves, MD

Process for Updates:

- Department heads submit proposed changes to the QA team.
- The manual is updated, and changes are documented with version control.
- Updates are reviewed and approved by the Laboratory Director.

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Approval

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