NATURE OF THE CLINCAL LABORATORY

Principles of Medical Laboratory Science 1

Learning Outcomes

1. Discuss the different sections of the laboratory and the tests done in each section.
2. Compare and contrast the different types of clinical laboratories.
3. Identify the salient points of the laws governing the establishment, operation, and maintenance of clinical laboratories in the Philippines.
4. Discuss the importance of quality assurance in the clinical laboratory.

Topic Outline

I. The Clinical Laboratory
II. Laws on the Operation, Maintenance, and Registration of Clinical Laboratories in the Philippines
III. Sections of the Clinical Laboratory
IV. Laboratory Testing Cycle
V. Laboratory Information System
VI. Quality Assurance in the Laboratory

I. The Clinical Laboratory

The Clinical Laboratory

- Place where specimen collected from individuals are processed, analyzed, preserved, and properly disposed.
- Provide accurate and reliable information to doctors for the diagnosis, prognosis, treatment, and disease management

The Clinical Laboratory

- A medical technologist / laboratory scientist plays a significant role in the performance of lab testing and ensuring reliability of results.
- In the past, assays performed in the lab are manual, taxing, labor-intensive, and time-consuming.

TAT = Turnaround Time

- In the future: there will be more changes in the clinical laboratory (shifting demographics, emergence of new and re-emergence of infectious and NCDs, demand for a more efficient and effective workflow, and new government institutional policies.)

II. Laws on the Operation, Maintenance, and Registration of Clinical Laboratories in the Philippines

Republic Act 4688

- **Approved:** June 18 1966
- Clinical Laboratory Act of 1966
- Composed of 8 sections
- An act regulating the operation and maintenance of clinical laboratories and requiring the registration of the same with the department of health, providing penalty for the violation thereof, and for other purposes

Republic Act 4688

Purpose:

- Regulate the operations of clinical laboratories in the Philippines
- To set standards that will ensure accurate and reliable laboratory results
- To protect patients and the public

Administrative Order No. 2021-0037

Objective : These rules and regulations shall serve as the new guidelines in the licensing of diagnostic clinical laboratories in the Philippines which shall ensure accountability of the laboratory on generation of accurate, precise and reliable laboratory results in a timely manner through continuous compliance.

aligned with the objective of Universal Health Care Act which is to ensure that diagnostic results are accurate, reliable, and affordable

Secretary of Health: Francisco Duque III

Current Secretary of Health:

Classification of Clinical Laboratories

Classification	Types
By Ownership	• Government • Private
By Character	• Institution-based • Non-institution based
By Function	• Clinical pathology • Anatomic pathology • Molecular pathology
By Service Capability	• Primary • Secondary • Tertiary • Limited

According to Function

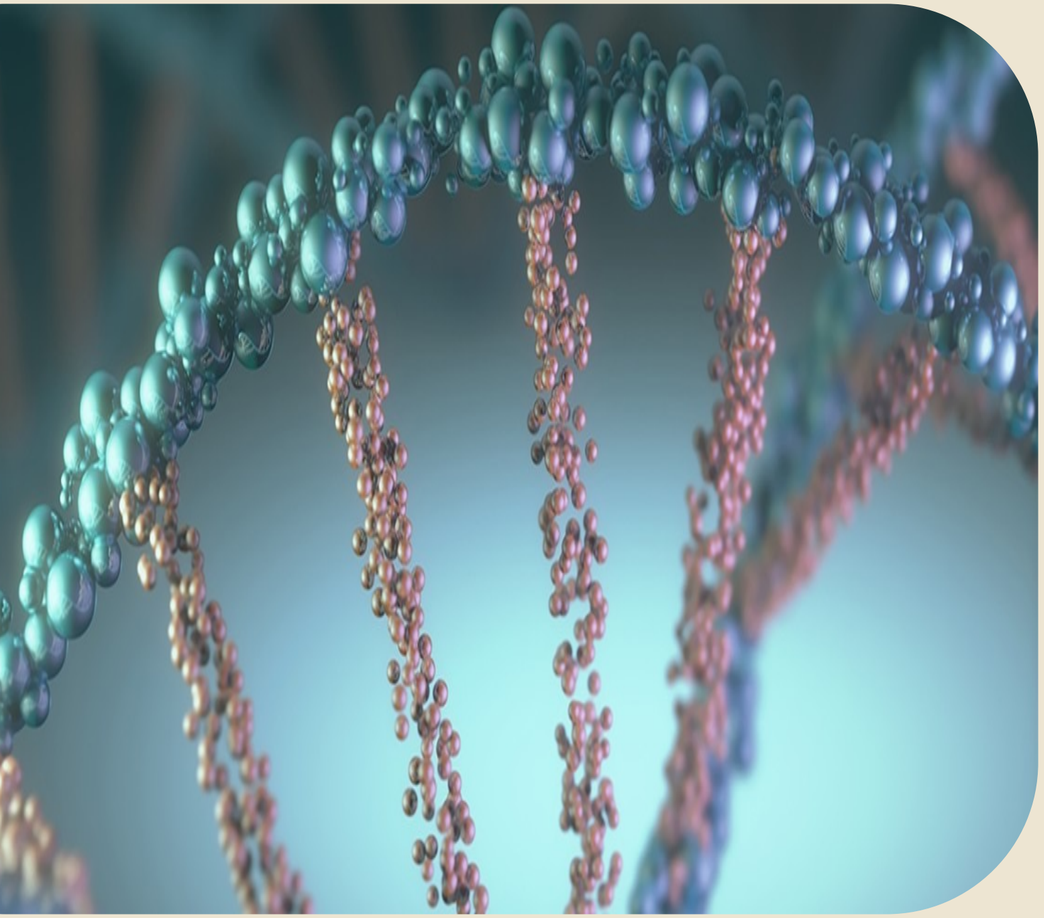
1. **Clinical pathology** – focused with the diagnosis and treatment of diseases performed through laboratory testing of blood and other body fluids

According to Function

2. **Anatomic pathology –** concerned with the diagnosis of diseases through microscopic examination of tissues and organs

- histopathology, immunohistopathology, cytology, autopsy, and forensic pathology

According to Function



3. **Molecular pathology –** deals with the analysis of certain genes, proteins and other molecules in samples from organs, tissues or bodily fluids in order to diagnose disease and/or to guide in its prevention and treatment

According to Institutional Characteristics

1. **Institution-based –** clinical laboratory that operates within the premises or part of an institution such as hospital, school, medical clinic, medical facility for overseas workers and seafarers, birthing home, psychiatric facility, drug rehabilitation center

Hospital-based – most common

According to Institutional Characteristics

Before: free-standing laboratory

2. **Non-institution based –** a laboratory that operates independently and is not attached to any DOH licensed health facility.

According to Ownership

1. **Government-owned –** owned wholly or partially by national or local government units.

Example: PGH, Philippine Children Center

According to Ownership

2. **Privately-owned –** established and operated by an individual corporation, institution, association, or organization

Primary	Secondary	Tertiary training grounds for intern
• licensed to perform basic, routine laboratory testing.	• Laboratory tests done by primary category plus the following tests indicated in the second column • Can be hospital-based or school- based	• Perform lab tests performed in primary and secondary category.
Tests: Routine urinalysis, routine stool exam, routine hematology, Routine clinical chemistry, blood typing, and TB (DSSM) **Equipment:** Microscope	Tests:, Gram stain, KOH mount, and coagulation studies, serum electrolytes Equipment: semiautomated chemistry and hematology analyzers, serofuge, incubators,	Tests: tumor markers, thyroid function tests, hepatitis profile Equipment: Automated chemistry analyzer, Biosafety cabinet class II, Microtome

more complex in testing →

basic to complex

NRL -> National Relative Laboratory

IV. Limited

Provides one (I) or /wo (2) specialized tests that are not classified under Anatomic or Molecular Pathology, as exemplified below:

- Hormones
- Trace Metals
- Tumor markers
- Allergy Panel

- This classification shall also apply to facilities offering DOH-program related tests, e.g. Kato Katz for schistosomiasis, malarial smear, filaria smear, rapid plasma regain for syphilis

4. Classification by **Service Capability**

a. Clinical Laboratory for Clinical and Anatomic Pathology

Section	Category			
	i. Primary	**ii. Secondary**	**iii. Tertiary**	**iv. Limited**
	Provides the following minimum service capabilities:	*Provides the minimum service capabilities of a primary category, plus the following:*	*Provides the minimum service capabilities of a secondary category, plus the following:*	*Provides one (1) or two (2) specialized tests that are not classified under Anatomic or Molecular Pathology, as exemplified below:* - *Hormones* - *Trace Metals* - *Tumor markers* - *Allergy Panel* - *This classification shall also apply to facilities offering DOH-program related tests, e.g.,*
Clinical Microscopy	- Urinalysis - Fecalysis - Fecal Occult Blood Test - Pregnancy Test (Rapid Test Kits – Lateral Flow) - Wet Smear for Trichomonas			
Clinical Chemistry	- Fasting and Random Blood Sugar - Oral Glucose Tolerance Test - Lipid Profile (Total Cholesterol, HDL, LDL, Triglycerides) - Creatinine - Blood Urea Nitrogen - Blood Uric Acid	- Serum Electrolytes (Sodium, Potassium, Chloride) - ALT - AST	- Other Clinical Chemistry Examinations Hospital-based: Arterial Blood Gases	

Section	Category			
	i. Primary	**ii. Secondary**	**iii. Tertiary**	**iv. Limited**
	Provides the following minimum service capabilities:	*Provides the minimum service capabilities of a primary category, plus the following:*	*Provides the minimum service capabilities of a secondary category, plus the following:*	*Kato Katz for Schistosomiasis, Malarial Smear, Filaria Smear, Slit-skin Smear, Rapid Plasma Reagin for Syphilis*
Hematology	- Complete Blood Count (Hemoglobin, Hematocrit, Red Blood Cell Count, White Blood Cell Count with Differential Count, Quantitative Platelet Count) - Forward and reverse ABO grouping and Rh (D) typing (tube method)	For Hospital-based - Coagulation studies (PT, aPTT)		
Serology/ Immunology	- Dengue - Syphilis - Hepatitis B (Screening)		- Any machine-based serological and immunological testing such as, but	

Licenses and Permits

- **Permit to Construct (PTC) –** required for construction of new clinical laboratory and for renovation or expansion of existing clinical laboratory, including change in ownership and transfer of location.

- **License to Operate (LTO) –** whether initial or renewal, shall only be issued after the HFSRB/CHD-RLED, in accordance with the current DOH guidelines, has determined that the laboratory is fully compliant.
  - non-transferable and a new application for DOH-LTO shall be required in case of change of ownership or transfer of location.
  - LTO is valid for **one (1) year** and must be displayed where the public can see it

Licenses and Permits

- **Certificate of Registration –** required for research and teaching laboratories.
  - valid for three (3) years

Key Personnel Requirements

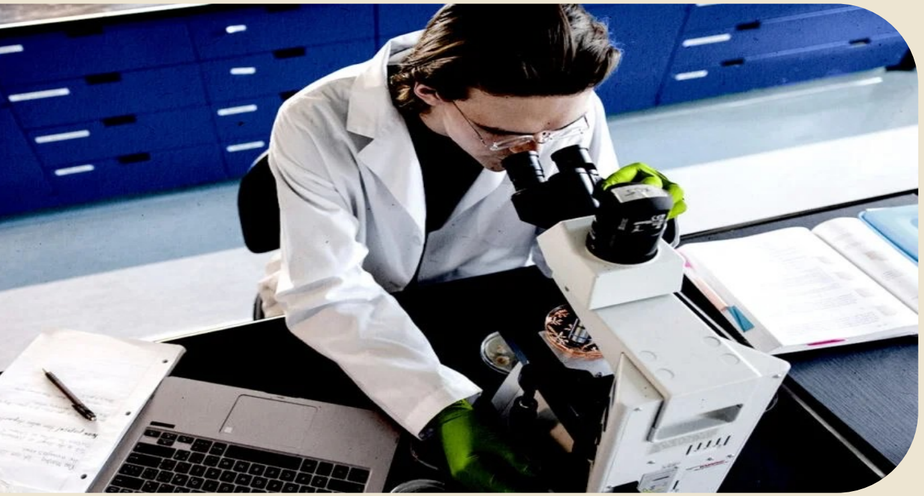
- Every laboratory shall have an adequate number of trained personnel, depending on the workload, to provide safe, effective, and efficient services to clients

1. Head of the Laboratory
2. Registered Medical Technologist
3. Support Staff
4. POCT Coordinator and Operator (if applicable)
5. Mobile Clinical Laboratory Personnel

Key Personnel Requirements

1. Head of the Laboratory - The lab must be headed by a certified Pathologist who shall oversee administrative and technical activities.
    - HOL shall visit once a month and twice a week supervisory calls or videoconference OR physical visit once a week
    - For hospital-based laboratory – once a week physical visit
    - For GIDAs - where no pathologist is available, a physician with complete training in Laboratory Medicine, Quality Assurance and Laboratory Management, may head a primary lab

Key Personnel Requirements



2. **Registered Medical Technologist –** employ an adequate number of full-time RMTs to conduct procedures, with the number depending on the workload
3. **Support Staff –** lab technicians, aides, and administrative staff like encoders and receptionists
4. **POCT Coordinator and Operator (if applicable) –** a senior staff from the laboratory should be assigned as coordinator
5. **Mobile Clinical Laboratory Personnel –** shall include RMTs and support staff

Operational Safety and Standards

- **Physical Plant :** Labs must have adequate, well-ventilated, and clean areas for activities like blood extraction and specimen collection

- **Equipment:** must have operational equipment and a program for calibration and maintenance.
  - machines/devices, reagents and test kits that are used in the CL and MCL as well as POCT shall be approved by the Philippine Food and Drug Administration and validated by the proper government institutions (e.g. National Reference Laboratory).

Operational Safety and Standards

- **Quality Improvement –** there shall be an internal and external quality control program for clinical laboratories for continuous quality improvement
  - Clinical laboratories shall participate in **External Quality Assessment Program (EQAP)** that may be administered by a designated NRL or other local and international EQAP approved by the DOH.

- Environmental management - There must be procedures for the proper disposal of infectious and hazardous waste in accordance with national laws

Prohibited Acts and Sanctions

Prohibited acts include:

- Refusal to allow HFSRB/CHD-RLED authorized personnel to conduct inspection or monitoring visits of the clinical laboratory at any appropriate time;
- Issuing fraudulent results or reports without the head's approval
- Operating beyond the lab's authorized service capability
- Refusal or nonparticipation to EQAP
- Giving and receiving any commission, bonus, kickback or rebate or engaging in any split-fee arrangement
- Using expired reagents
- Violation of data privacy act

Prohibited Acts and Sanctions

Acts that will Result in Immediate Revocation of LTO:

- unauthorized or unregistered personnel to perform technical procedures and access to records
- Lending or using the name of the DOH-licensed CL or the head of the laboratory or medical technologist to an unlicensed CL;
- Unauthorized use of the name and signature of the pathologist and RMT to secure LTO;

Prohibited Acts and Sanctions

Acts that will Result in Immediate Revocation of LTO:

- Issuance of fraudulent laboratory results, or tests not actually done or inaccurate results;
- Change in the ownership, location, and head of the laboratory or laboratory personnel without informing the HFSRB/CHD-RLED;
- Any material false statement in the application of LTO.

Prohibited Acts and Sanctions

Sanctions:

1st offense : Stern warning

2nd offense: Thirty thousand pesos (Php 30,000.00)

3rd offense: Fifty thousand pesos (Php 50,000.00)

4th offense: Revocation of DOH-LTO

NOTE: Clinical laboratories with revoked licenses can only re-apply after one year from the date of revocation

III.Sections of the Laboratory

SECTIONS OF THE LABORATORY

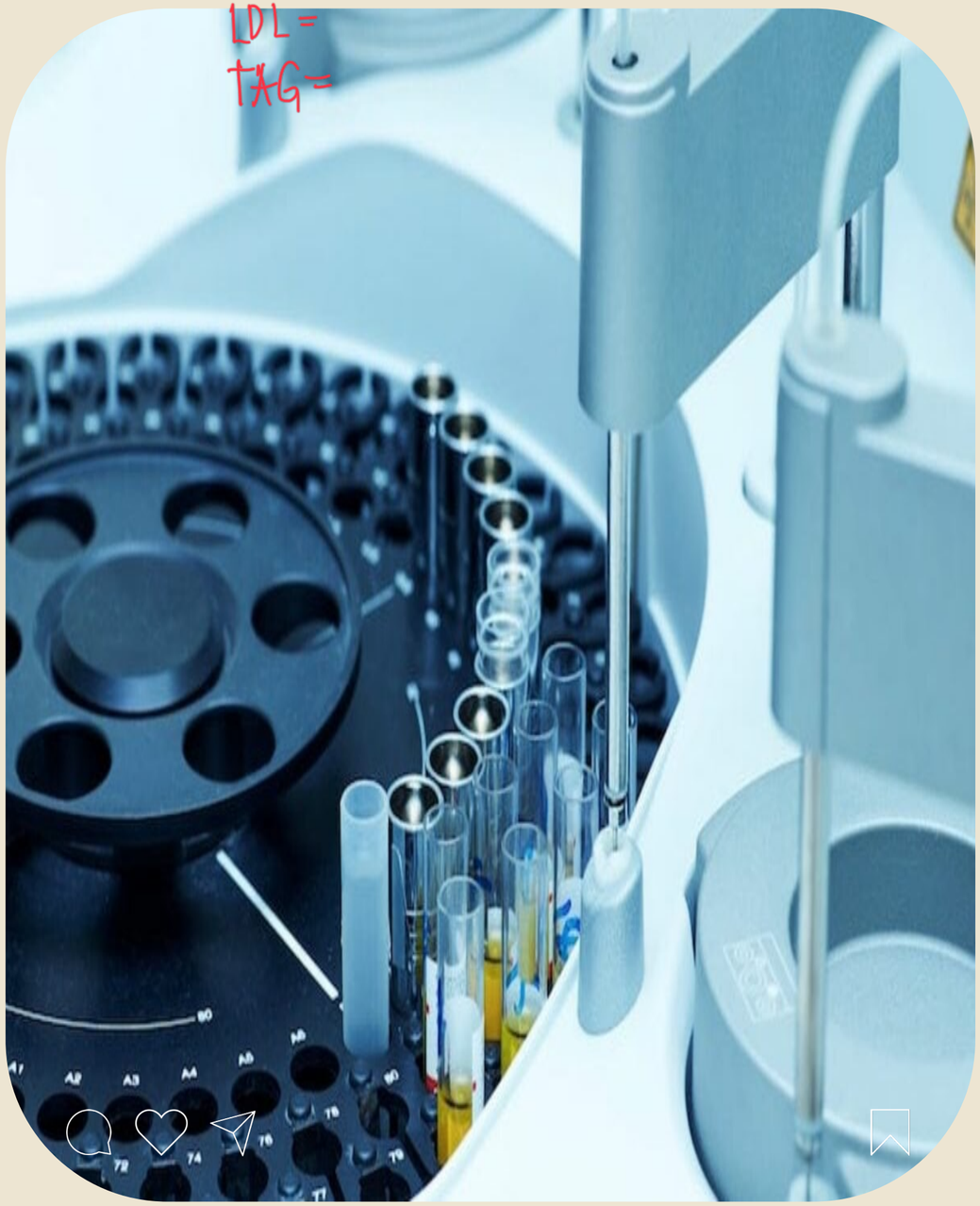
CLINICAL LABORATORY

1. Clinical Chemistry
2. Microbiology
3. Hematology and Coagulation Studies
4. Clinical Microscopy
5. Blood Bank
6. Immunology and Serology

ANATOMIC PATHOLOGY

1. Histopathology and Cytology
2. Immunohistochemistry

BUA = blood uric acid
LDL =
TAG =



Clinical Chemistry

- Intended for the testing of blood and other body fluids to quantify essential soluble chemicals including waste products useful for the diagnosis of certain diseases.

blood & urine = blood (common)

Tests Performed:

- **FBS & HbA1c –** diagnosis of diabetes
  - Fasting Blood Sugar
- **Total Cholesterol, HDL and LDL, TAG –** used for the diagnosis of cardiovascular diseases
  - lipid profile
- **BUA, BUN, and Creatinine–** for diagnosis of diseases involving kidney
  - glycosylated hemoglobin

Clinical Chemistry

- Considered to be one of the busiest section in the laboratory
- In majority of tertiary laboratories, this section is characterized as state-of-the-art, fully automated facility
- Other laboratories also have toxicology and drug testing sections

MICROBIOLOGY

↳ many

- Subdivided into : Bacteriology, Mycobacteriology, Mycology, Virology

- focused on the identification of bacteria and fungi on specimens received.

MICROBIOLOGY

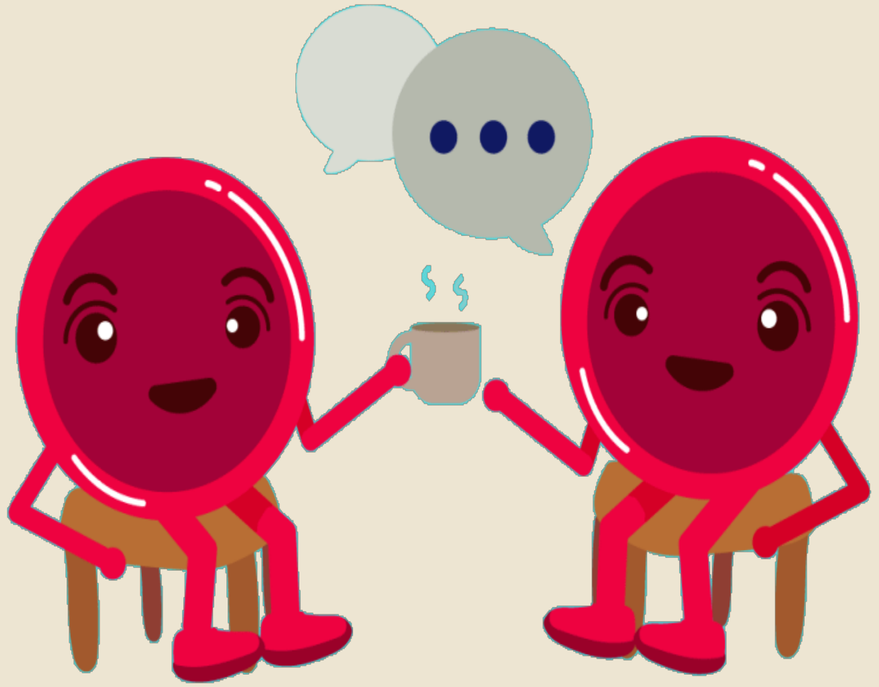
gram stained

bacteria (agar plates)

Tests Performed:

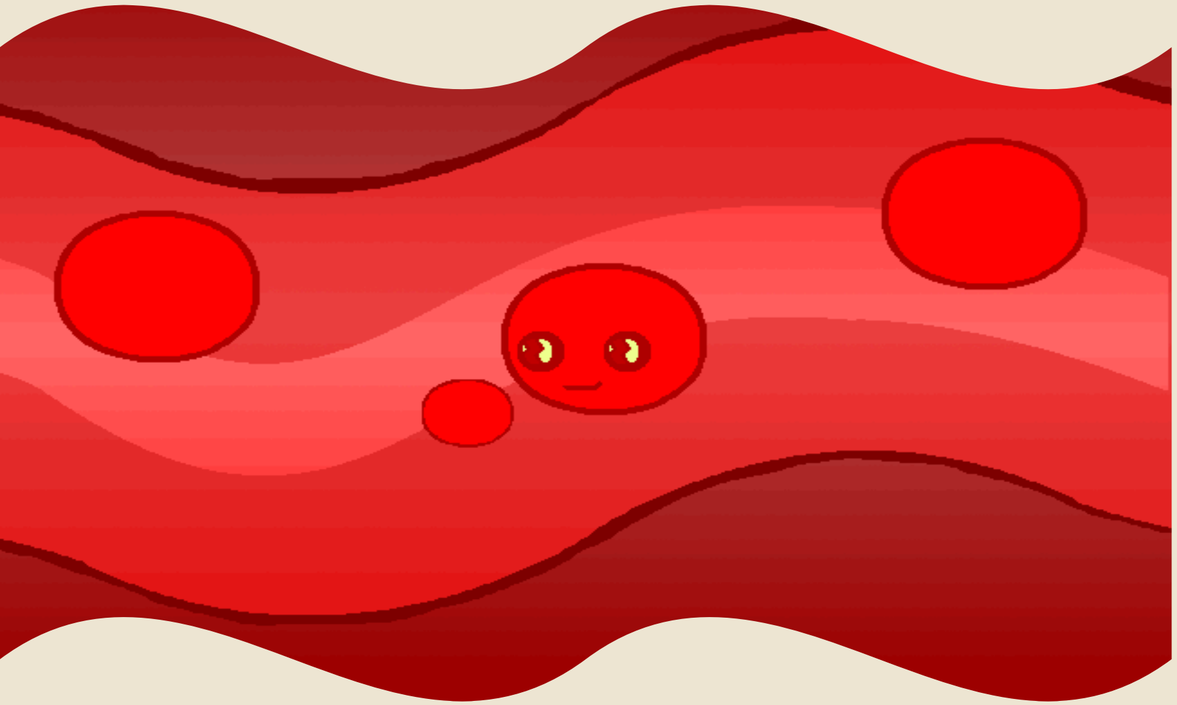
- Microscopic visualization of microorganisms after staining, isolation, and identification
- Preparation of culture media
- Culture and Sensitivity
- Blood culture

HEMATOLOGY AND COAGULATION



- Deals with the enumeration of cells in the blood and other body fluids

- **Coagulation studies** focus on blood's ability to form and dissolve clot, and determine coagulation factors.

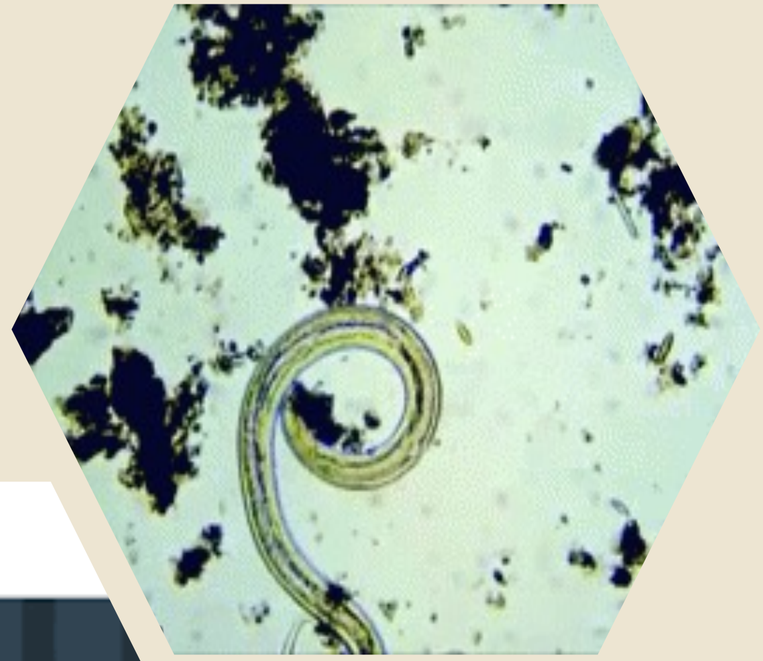


HEMATOLOGY AND COAGULATION

Tests Performed:

- Complete blood count
- Red cell morphology
- Quantitative platelet count
- Blood smear preparation
- Bleeding time
- Clotting time

] Coag



CLINICAL MICROSCOPY

Two major areas:

1. Routine and other special examinations of urine. Examination of other body fluids.
2. Examination of stool or routine fecalysis. Detection and identification of parasitic worms and ova.

BLOOD BANK

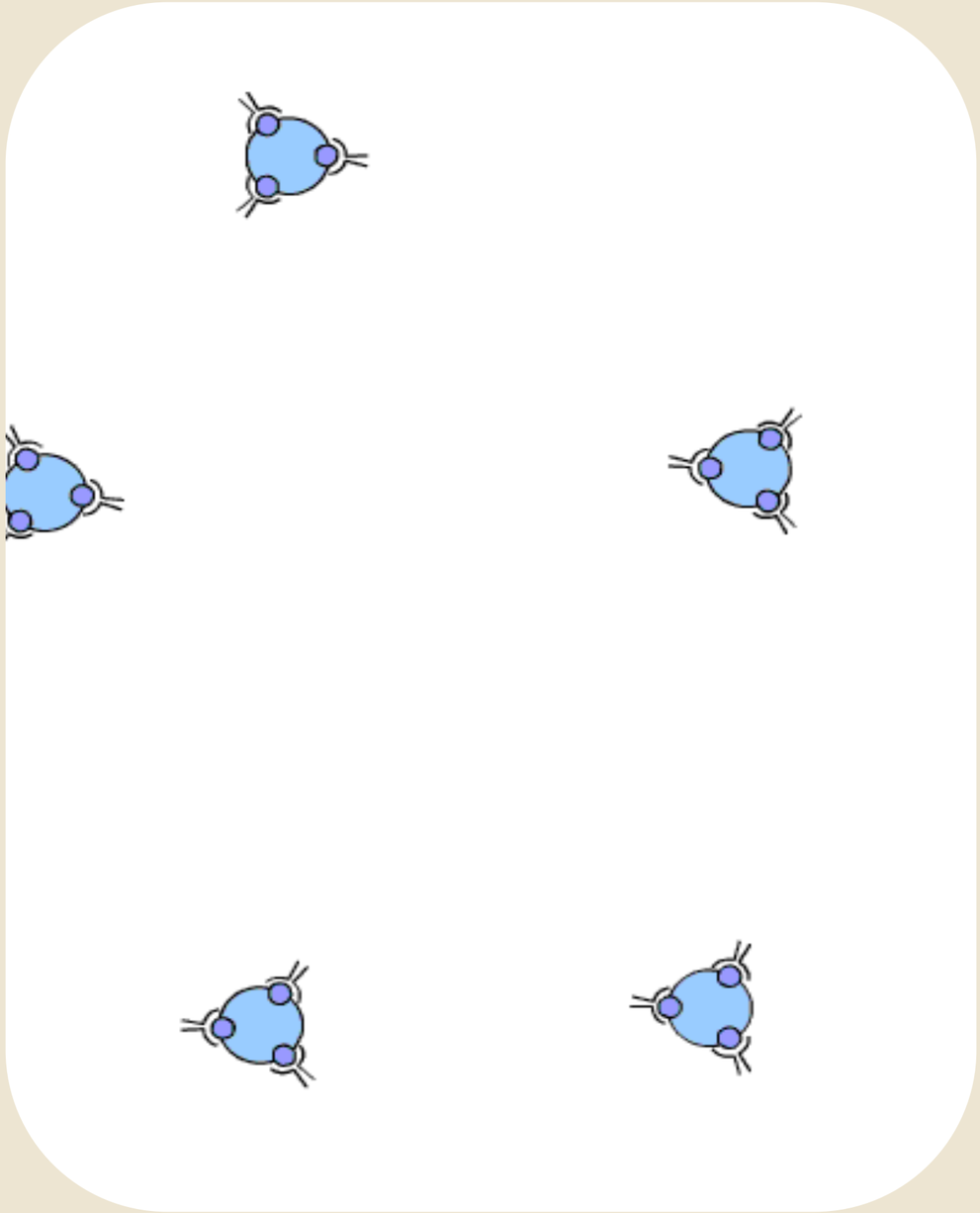
- Considered the most critical in the clinical laboratory

- Blood donation activities, donor recruitment and screening, bleeding of donors, and post-donation care

BLOOD BANK

Tests performed:

- Blood typing
- Compatibility testing
- Screening and identification of antibodies
- Blood component preparation

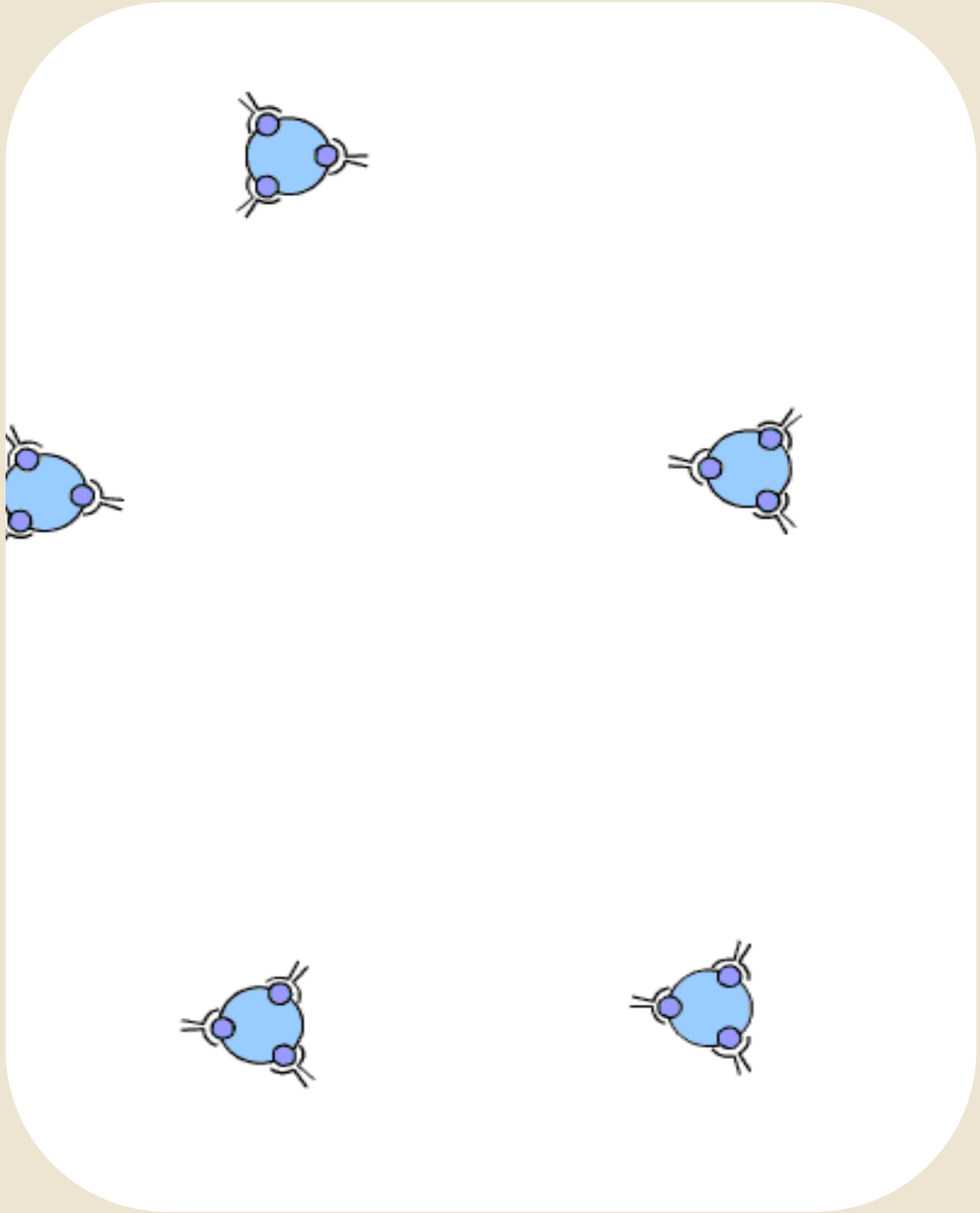


IMMUNOLOGY AND SEROLOGY

- Analysis of serum to detect certain infectious agents (primary viral agents)

Tests performed:

- Hepatitis B profile tests
- Serological test for syphilis
- Test for Hepatitis C
- Test for dengue fever



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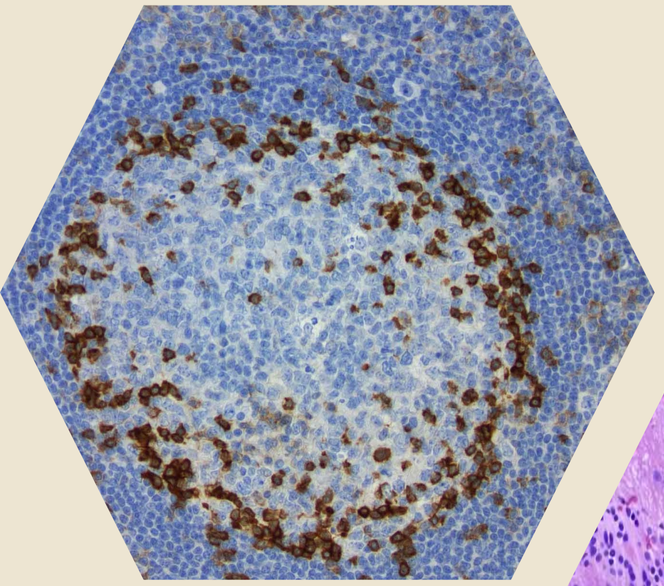
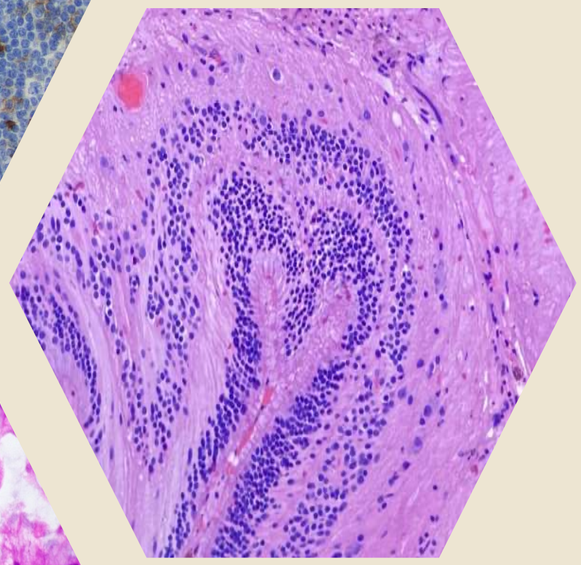
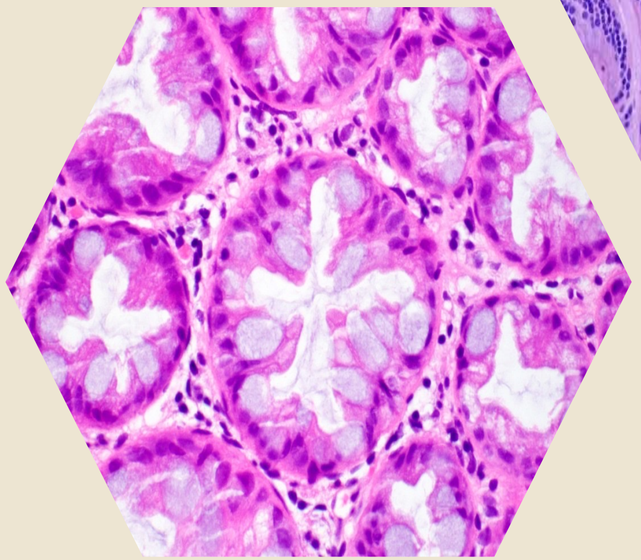






ANATOMIC PATHOLOGY

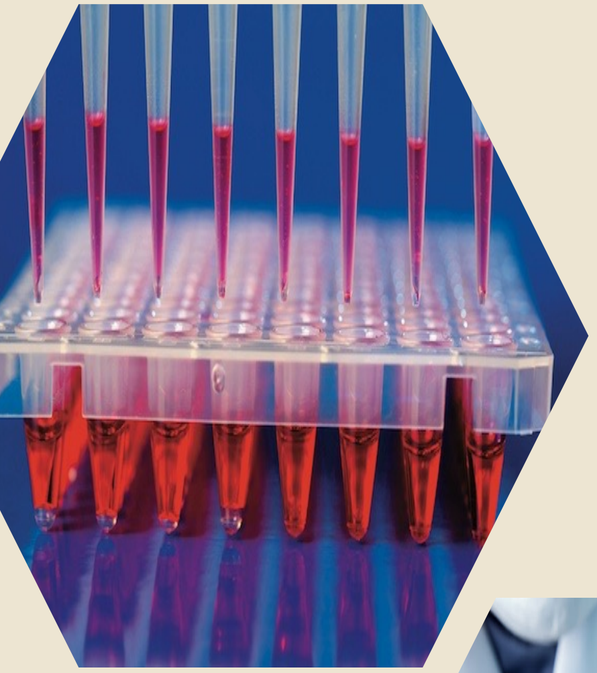
Histopathology and Cytology

- Include tissue processing, cutting into sections, staining, an preparation for microscopic examination by a pathologist.

Immunohistochemistry

- Combines anatomical, clinical, and biochemical techniques where antibodies bounded to enzymes and fluorescent dyes are used to detect presence of antigens in tissues.

- Useful in diagnosis of cancers, response to cancer therapy, and diagnosis of certain neurodegenerative diseases.



MOLECULAR BIOLOGY AND BIOTECHNOLOGY

- Primarily using different enzymes and other reagents, DNA and RNA are identified and sequenced to detect any pathologic conditions/disease processes.

PCR –most common technique currently used.

- This technique is used as screening indicators of disease and diagnosis of cancer and infectious disease

IV. Laboratory Testing Cycle

LABORATORY TESTING CYCLE

- Encompasses all activities starting from a medical doctor writing a lab request up to the time the results are generated and become useful information for the treatment and management of patients.

THREE PHASES:

- Pre-analytic
- Analytic
- Post-analytic

Pre-analytical Phase

- Receipt of laboratory request
- Patient preparation
- Specimen collection
- Transport and processing of specimen

Analytical Phase

- actual testing of the specimen
- Equipment and instruments used
- Reagents
- Internal QC

Post-analytic Phase

- Transmission of test result to the medical doctor
- TAT
- Application of doctor’s recommendations

Pre-analytic phase

Laboratory test requisition/order

Order reception

Patient preparation
Specimen collection

Specimen transport and processing

Actual testing

Post-analytic phase

Data transmission/interpretation
Results application
TAT

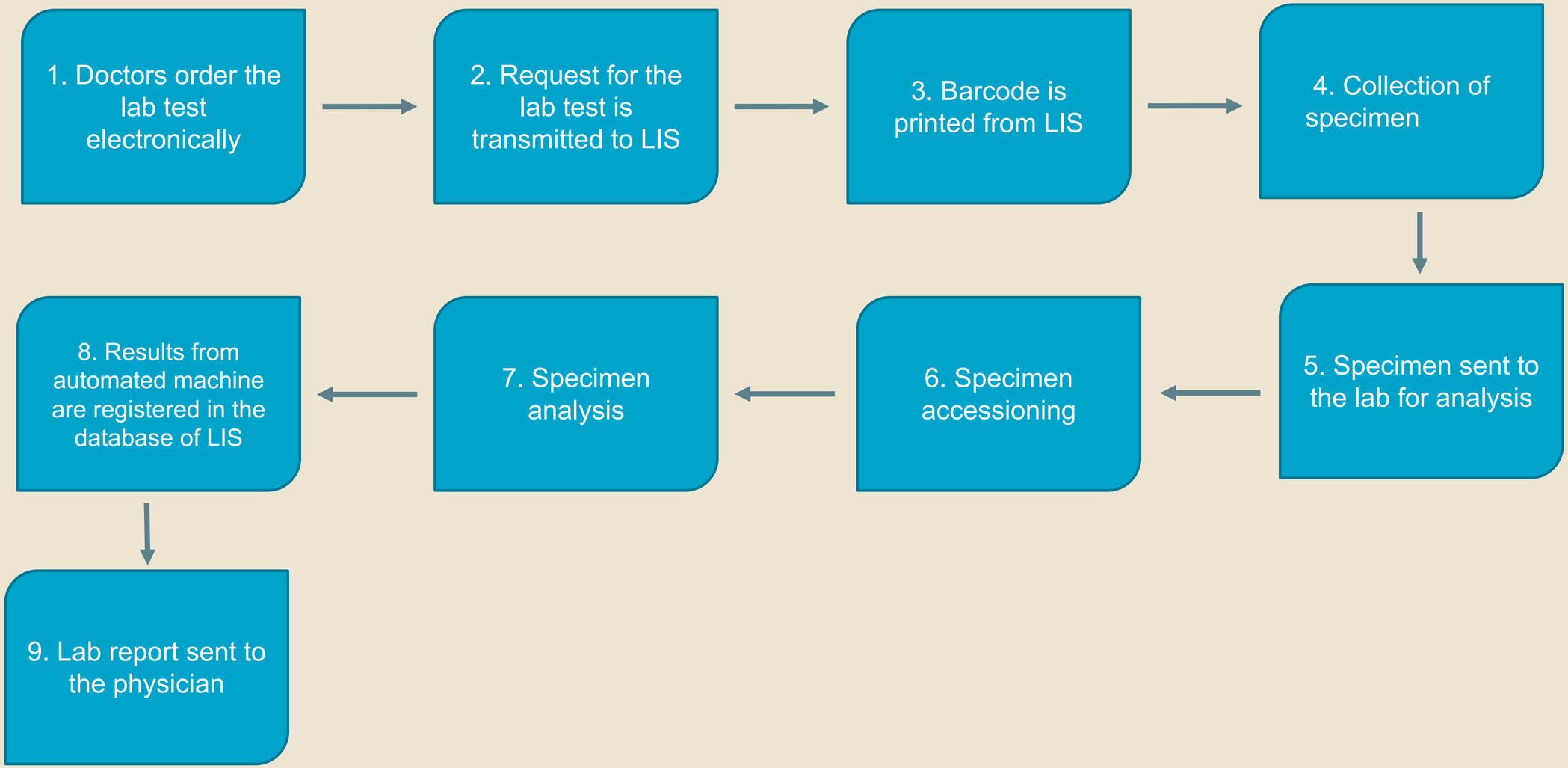
Analytic phase

V. Laboratory Information System

Laboratory Information System

- Electronic, web-based application that streamlines and optimizes the workflow, maximizes productivity, enhances efficiency, and improves laboratory quality control in the clinical laboratory
- Software-based laboratory that process, store, and manage data from all stages of medical processes and tests

Workflow in LIS



Advantages:

1. Decreased TAT
2. Increased productivity of laboratory staff
3. Reduced waiting time for patients

Disadvantages:

1. Cost of the laboratory system
2. Maintenance of the system
3. Periodic upgrade of lab equipment to maintain compatibility to LIS

VI. Quality Assurance in the Laboratory

Laboratory Information System

Quality Assessment – encompasses all activities performed by laboratory personnel to ensure reliability of test results.

Quality Control – refers to the materials, procedures, and techniques that monitor the accuracy, precision, and reliability of a laboratory test.

Laboratory Information System

Quality Control:

Internal QC – includes day-to-day activities that are undertaken in order to control factors that may affect test results

External QC (EQAS) – system for checking performance among clinical laboratories and is facilitated by designated external agencies.

The National Reference Laboratories (NRL) : is the DOH-designated EQAS.

Institution	National Reference Laboratories
National Kidney and Transplant Institute (NKTI)	• hematology and coagulation • Immunohematology • Urinalysis IBB
Research Institute of Tropical medicine (RITM)	• Microbiology (identification and antibiotic susceptibility testing) • Parasitology (Identification of ova and quantitation of malaria) ERID
Lung Center of the Philippines (LCP)	• General chemistry (glucose, creatinine, total protein, albumin, BUN, uric acid, cholesterol, sodium, potassium, and chloride

Institution	National Reference Laboratories
East Avenue Medical Center (EAMC)	• Drugs of abuse (metamphetamines and cannabinoids) • Toxicology • Micronutrient assay
San Lazaro Hospital / STD-AIDS Cooperative Center Laboratory (SACCL)	• HIV/AIDS • Hepatitis B and Hepatitis C • Syphilis and other sexually transmitted infections
Philippine Heart Center	• Anatomic pathology for cardiac diseases • Cardiac markers
Food and Drug Administration – Common Services Laboratory	• Testing laboratory for pregnancy test kit

THANK YOU!

REFERENCES:

- II. Republic of the Philippines Department of Health OFFICE OF THE SECRETARY SUBJECT: New Rules and Regulations Governing the Regulation of Clinical Laboratories in the Philippines RATIONALE. (n.d.). https://hfsrb.doh.gov.ph/wp-content/uploads/2021/06/ao2021-0037-2.pdf
- REPUBLIC ACT NO. 4688 - AN ACT REGULATING THE OPERATION AND MAINTENANCE OF CLINICAL LABORATORIES AND REQUIRING THE REGISTRATION OF THE SAME WITH THE DEPARTMENT OF HEALTH, PROVIDING PENALTY FOR THE VIOLATION THEREOF, AND FOR OTHER PURPOSES. - Supreme Court E-Library. (n.d.). Elibrary.judiciary.gov.ph. https://elibrary.judiciary.gov.ph/thebookshelf/showdocs/2/7111
- Benitez, P. A., Dumaoal, O. S. R., Estrella, F. P., Mortel, F. A., & Nava, M. R. G. (2026). Principles of Medical Laboratory Science 1 (2nd ed.). C&E Publishing Inc.