The Clinical Laboratory

Clinical laboratory	essential component of health institutions
	main task: provide accurate and reliable information to medical doctors for the diagnosis, prognosis, treatment, and management of diseases
	involved in: research, community outreach program, surveillance, infection control in the hospital and community settings, information dissemination, and evaluation of the applicability or current and innovative diagnostic technologies
	place where specimens **(e.g., blood and other body fluids, tissues, feces, hair, nails)** collected from individuals are processed analyzed, preserved, and properly disposed.
	vary according to size, function, and the complexity of tests performed
Laboratory Test Results	basis for 70% of all decisions performed by medical doctors
Medical Technologist/Clinical Laboratory Scientist	serves as the integral partner of medical doctors

The Clinical Laboratory (cont)

important member of the health care delivery system
plays a very significant role in the performance of laboratory testing and ensuring the reliability of test results
Assays in the past: manual, taxing, labor--intensive, and time-consuming
Presently, with the advent of automation: less laborious, with shortened turn around time (TAT)
Possible cause of changes in the future: shifting demographics, emergence of new and re-emergence of infectious and non-infectious diseases, demand for more efficient and effective workflow, and new government institutional policies

CCL: According to Functions

Clinical Pathology	focuses in the areas of **clinical chemistry, immunohematology, and blood banking, medical microbiology, toxicology, therapeutic drug monitory, and endocrinology**
	concerned in the diagnosis and treatment of the diseases performed through laboratory testing of blood and other body fluids

CCL: According to Functions (cont)

Anatomic Pathology	focuses in the areas of **histopathology, immunohistopathology, cytology, autopsy, and forensic pathology**
	concerned with the diagnostic of diseases through microscopic examination of tissues and organs

CCL: According to Institutional Characteristics

Institution--based	operates within the premises or part of an institution **(e.g., hospital, school, medical clinic, medical facility for overseas workers and seafarers, birthing home, psychiatric facility, and drug rehabilitation center)**
	most common example: Hospital-based clinical laboratories
free-standing	not part of an established institution
	Example: free-standing out-patient clinical laboratory

CCL: According to Ownership

Government-owned	owned, wholly or partially, by national or local government units
	Examples: clinical and anatomical laboratories of DOH-run government hospitals **(San Lazaro Hospital, Jose R. Reyes Memorial Medical Center, University of the Philippines-Philippine General Hospital and local government-run hospital-based clinical laboratories of the Ospital ng Maynila Medical Center, Sta. Ana Hospital, and Bulacan Medical Center)**

CCL: According to Ownership (cont)

Privately-owned	owned, established, and operated by an individual, corporation, institution, association, or organization
	Examples: St. Luke's Medical Center, Makati Medical Center, and MCU-FDTMF Hospital

CCL: According to Service Capability

Primary category	licensed to perform **routine laboratory testing** (**e.g.,** routine urinalysis and routine stool examination)
	routine hematology or complete blood count: hemoglobin, hematocrit, WBC and RBC count, WBC differential count and qualitative platelet count, blood typing, and Gram staining (if hospital-based)
	Equipment: microscopes, centrifuge, and hematocrit centrifuge
	Space requirement: at least 10 square meters
Secondary category (Hospital and non-hospital-based)	licensed to perform laboratory tests being done by the primary category clinical laboratories along with routine clinical chemistry tests

CCL: According to Service Capability (cont)

	routine chemical chemistry tests: blood glucose concentration, blood urea nitrogen, blood uric acid, blood creatinine, cholesterol determination, and qualitative platelet count
	If hospital-based: Gram stain, KOH mount, and cross-matching
	Minimum requirement: 20 square meters floor area
	Personnel requirement: depends on the workload
	Equipment: microscope, centrifuge, Hematocrit centrifuge, semi-automated chemistry analyzers, autoclave, incubator, and oven
Tertiary category (Hospital and non-hospital-based)	licensed to perform all the laboratory tests performed in the secondary category laboratory
	Immunology and serology: NS1-Ag for dengue, rapid plasma reagin, and Treponema pallidum particle agglutination tests

CCL: According to Service Capability (cont)

Microbiology, bacteriology, and mycology: differential staining techniques, culture and identification of bacteria and fungi from specimens, and antimicrobial susceptibility testing

Special clinical chemistry: clinical enzymology, therapeutic drug monitoring, and markers for certain diseases

Special hematology: bone marrow studies, special staining for abnormal blood cells, and red cell orphology

Immunohematology and blood banking: blood donation program, antibody screening and identification, and preparation for blood components

Minimum floor requirement: at least 60 square meters

Equipment: microscope, centrifuge, Hematocrit centrifuge, semi-automated chemistry analyzers, autoclave, incubator, oven, automated chemistry analyzer, biosafety cabinet class II, and serofuge

CCL: According to Service Capability (cont)

National Reference Laboratory	laboratory in a government hospital designated by the DOH
	provide special diagnostic functions and services for certain diseases
	Functions: Referral services, provision of confirmatory testing, assistance for research activities, implementation of External Quality Assurance Programs (EQAP) of the government, resolution of conflicts regarding test results of different laboratories, and training of medical technologists on certain specialized procedures that requires standardization

Republic Act No. 4688

Approved:	June 18, 1966

Sections of the Clinical Laboratory

Clinical laboratory	made up of different sections cohesively and comprehensively performing different activities and procedures for each specimen collected from patient to produce reliable test results

Sections of the Clinical Laboratory (cont)

	Clinical laboratory personnel: pathologists, medical technologists/clinical laboratory scientists, medical technicians, phlebotomists, and other laboratory personnel
Clinical Chemistry	intended for testing blood and other body fluids to quantify essential soluble chemicals including waste products useful for diagnosis of certain diseases
	Most common body fluids: blood and urine
	Test Performed: fasting blood sugar (FBS), glycosylated hemoglobin (HbA1c - diabetes), total cholesterol - HDL and LDL, triglycerides (TAG) - cardiovascular diseases, blood uric acid (BUA), blood urea nitrogen (BUN), creatinine - diseases involving the kidney, total protein (TP), albumin, electrolytes (sodium, potassium, chloride), clinical enzymology (aminotransferase and creatine kinase)
	One of the busiest sections of the clinical laboratory

Sections of the Clinical Laboratory (cont)

	characterized as **state-of-art, fully automated facility**
	Endocrinology: hormone in blood and urine
	Thyroid hormone tests: thyroid stimulating hormone (TSH), T3 and T4 (triiodothyronine and thyroxine)
	Other tests: estrogen, prolactin, and testosterone
	Other laboratories: Toxicology and Drug Testing
	Important activities: Internal Quality Assurance (IQA), Continuous Quality Improvement (CQA), and participation in National External Quality Assurance Program (NEQAP)
Microbiology	**Four major sections:** bacteriology, mycobacteriology, mycology, and virology
	focused on the identification on bacteria and fungi on specimens received
	Specimens: blood and other body fluids, stool, tissues, and swabs

Sections of the Clinical Laboratory (cont)	
	Tests: microscopic visualization of microorganisms after staining, isolation, and identification of bacteria (aerobes and anaerobes) and fungi using varied culture media and different biochemical tests (antigen typing and antibacterial susceptibility testing)
	Other activities: preparation of culture media and stains, quality assurance and control, infection control, and biosafety and proper waste disposal
	Mycobacteriology: identification of **mycobacterium (e.g., Mycobacterium tuberculosis)**
Hematology and Coagulation Studies	enumeration of cells in the blood and other body fluids **(CSF and pleural fluid)**
	Examinations: CBC, hemoglobin, hematocrit, WBC differential count, red cell morphology, total cell count and differential count, blood smear preparation, and staining for other body fluids

Sections of the Clinical Laboratory (cont)	
	Coagulation studies: focuses on blood testing for determination of various coagulation factors
	Bone marrow examination: performed in automated hematology analyzers
Clinical Microscopy	**First Area:** allotted to routine and other special examinations of urine (**macroscopic examination:** determine the color, transparency, specific gravity, and pH level and **microscopic examination:** detect the presence of abnormal cells and/or parasites as well as to quantify red cells and WBC and other chemicals found in urine
	Second Area: examination of stool or routine fecalysis
	Routine fecalysis: identification of parasitic worms and ova
Blood Bank/Immunohematology	screening for all antibodies and identification of antibodies and blood components used for transfusion
	Tests: blood typing and compatibility testing
	most critical in the clinical laboratory

Sections of the Clinical Laboratory (cont)	
	Hospital-based clinical laboratories: blood donation activities (donor recruitment and screening, bleeding of donor, and post-donation care
Immunology and Serology	analyses of serum antibodies in certain infectious diseases (primarily viral agents)
	Tests: Hepatitis B profile tests, serological tests for syphilis
	Antibody screening tests: test for hepatitis C and dengue fever
	Automated analyzers are also used in this section for different serological tests
Anatomic Pathology: Section of Histopathology/Cytology	**Activities:** tissue processing (removed surgically: biopsy/autopsy), cutting into sections, staining, and preparation for microscopic examination by a pathologist

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Sections of the Clinical Laboratory (cont)

Specialized Sections of the Laboratory: Immunohistochemistry	combines anatomical, clinical, and biochemical techniques where antibodies (monoclonal and polyclonal) bounded to enzymes and fluorescent dyes are used to detect presence of antigens and tissue
	useful in the diagnosis of some types of cancers by detecting the presence of tumor-specific antigens, oncogenes, and tumor suppressor genes.
	assess the responses of patients to cancer therapy as well as diagnosis for certain neurodegenerative disorders
Molecular Biology and Biotechnology	uses different enzymes and other reagents, **DNA and RNA** are identified and sequenced to detect any pathologic conditions/disease processes
	Most common technique: polymerase chain reaction (PCR) - contributed to scientific advancements in laboratory research; useful for clinical techniques (screening genetic indicators of disease & diagnosis of cancer and infectious diseases

Laboratory Testing Cycle

Laboratory Testing Cycles	encompasses all activities starting from the medical doctor writing a laboratory request up to the time (called the turnaround time [TAT]) the results are generated and become useful information for the treatment of patients
	Three phases: pre-analytic, analytic, and post analytic
	Pre-analytic phase: receipt of laboratory request, patient preparation, specimen collection, and proper transport and processing of specimen to the clinical laboratory
	Analytic phase: actual testing of the submitted/collected specimen
	Equipment and instruments: reagents and internal quality control program
	Post-analytic phase: transmission of test results to the medical doctor for interpretation, TAT, and application of doctor's recommendations; diagnosis and treatments are based in the generated data

Laboratory Testing Cycle (cont)

Medical Technologist/Clinical Laboratory Scientist	Must have clear understanding of the testing cycle to avoid erroneous test results
	variables may affect the tests results: preparation of the request slip for the patient
	variables that may cause errors: physiological factors, diet, medications, alcohol and caffeine intake, exercise, underlying disease conditions, identification of patients and labeling of specimens, anticoagulant used, and volume of specimen collected vis-a-vis volume of anticoagulant
	Post-analytic phase: control of the variables of TAT and transcription errors **(e.g., wrong value used, result given to the wrong patient).**

Quality Assurance in the Clinical Laboratory

Quality Assurance	encompasses all activities performed by laboratory personnel to ensure reliability of test results

Quality Assurance in the Clinical Laboratory (cont)	
	organized, systematic, well-planned, and regularly done with the results properly documented and consistently reviewed
Two Major Components	**Internal Quality Assurance System (IQAS)** and **External Quality Assurance System (EQAS)**
Internal Quality Assurance System (IQAS)	day-to-day activities that are undertaken in order to control factors or variables that may affect test results
	Regular review and audit of test results: done to identify weaknesses and consequently perform corrective actions
External Quality Assurance System (EQAS)	system for checking performance among clinical laboratories and is facilitated by designated external agencies
	National Reference Laboratories (NRL): DOH-designated EQAS
	Unknown sample with known test results -> clinical laboratory for testing -> results returned to external facility -> compared to the known result **(determines the performance of the laboratory)**

Quality Assurance in the Clinical Laboratory (cont)	
Certificate of Performance	given to the participating clinical laboratory
Designated NRL-EQAS	**National Kidney and Transplant Institute (NKTI)** - Hematology and Coagulation
	Research Institute of Tropical Medicine (RITM) - Microbiology (identification and antibiotic susceptibility testing) and Parasitology (identification of ova and quotation malaria)
	Lung Center of the Philippines (LCP) - Clinical chemistry (for testing 10 analytes, namely glucose, creatinine, total protein, albumin, blood urea nitrogen, uric acid, cholesterol, sodium, potassium, and chlorine
	East Avenue Medical Center (EAMC) - Drug of abuse (methamphetamine and cannabinoids)
	San Lazaro Hospital STD-AIDS Cooperative Center Laboratory (SACCL) - Infectious immunology hepatitis B surface antigen (HBsAg), human immunodeficiency virus (HIV), Hepatitis C virus (HCV)