

The Clinical Laboratory		The Clinical Laboratory (cont)		CCL: According to Functions (cont)	
Clinical laboratory	essential component of health institutions		important member of the health care delivery system	Anatomic Pathology	focuses in the areas of histology, cytology, autops
	main task: provide accurate and reliable information to medical doctors for the diagnosis, prognosis, treatment, and management of diseases		plays a very significant role in the performance of laboratory testing and ensuring the reliability of test results		concerned with the diagnostic examination of tissues
	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		Assays in the past: manual, taxing, labor-intensive, and time-consuming	CCL: According to Institutional Character	
	place where specimens (e.g., blood and other body fluids, tissues, feces, hair, nails) collected from individuals are processed analyzed, preserved, and properly disposed.		Presently, with the advent of automation: less laborious, with shortened turn around time (TAT)	Institution-based	operates within the premises of hospital, school, medical clinic, overseas workers and seafarers facility, and drug rehabilitation facility
	vary according to size, function, and the complexity of tests performed		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	free-standing	not part of an established institution most common example: Hospital
Laboratory Test Results	basis for 70% of all decisions performed by medical doctors	CCL: According to Functions		CCL: According to Ownership	
Medical Technologist/Clinical Laboratory Scientist	serves as the integral partner of medical doctors	Clinical Pathology	focuses in the areas of clinical chemistry, immunohematology, and blood banking, medical microbiology, toxicology, therapeutic drug monitoring, and endocrinology	Government-owned	owned, wholly or partially, by government units Examples: clinical and anatomical government hospitals (San Lazaro Memorial Medical Center, Unilab, Philippine General Hospital and other hospital-based clinical laboratories like the National Kidney and Urology Center, Sta. Ana Hospital, etc.)



CCL: According to Ownership (cont)		CCL: According to Service Capability (cont)		CCL: According to Service Capability	
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		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		Microbiology, differential staining, identification of specimens, and testing Special clinical pathology, therapeutic drug monitoring, and toxicology for certain diseases Special hemat ology special staining and red cell morphology Immunohe matology blood donation and identification of components
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		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		Minimum floor area 20 square meters Equipment: microscope, Hematocrit centrifuge, semi-automated chemistry analyzers, autoclave, incubator, and oven, automated chemistry cabinet class II
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	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)

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
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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)	Sections of the Clinical Laboratory (cont)	Sections (cont)
<p>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)</p>	<p>Coagulation studies: focuses on blood testing for determination of various coagulation factors</p>	
<p>Other activities: preparation of culture media and stains, quality assurance and control, infection control, and biosafety and proper waste disposal</p>	<p>Bone marrow examination: performed in automated hematology analyzers</p>	<p>Immunologic and Serology</p>
<p>Mycobacteriology: identification of mycobacterium (e.g., <i>Mycobacterium tuberculosis</i>)</p>	<p>Clinical Microscopy</p> <p>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)</p> <p>Second Area: examination of stool or routine fecalysis</p>	
<p>Hematology and Coagulation Studies</p> <p>enumeration of cells in the blood and other body fluids (CSF and pleural fluid)</p>	<p>Routine fecalysis: identification of parasitic worms and ova</p>	
<p>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</p>	<p>Blood Bank/I-mmunohematology</p> <p>screening for all antibodies and identification of antibodies and blood components used for transfusion</p>	
	<p>Tests: blood typing and compatibility testing most critical in the clinical laboratory</p>	<p>Anatomic Pathology Section o Histopathology/Cytology</p>



Sections of the Clinical Laboratory (cont)	Laboratory Testing Cycle	Laboratory Testing Cycle (con
<p>Specialized Sections of the Laboratory: Immunohistochemistry</p> <p>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</p> <p>useful in the diagnosis of some types of cancers by detecting the presence of tumor-specific antigens, oncogenes, and tumor suppressor genes.</p> <p>assess the responses of patients to cancer therapy as well as diagnosis for certain neurodegenerative disorders</p>	<p>Laboratory Testing Cycles</p> <p>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</p> <p>Three phases: pre-analytic, analytic, and post analytic</p> <p>Pre-analytic phase: receipt of laboratory request, patient preparation, specimen collection, and proper transport and processing of specimen to the clinical laboratory</p>	<p>Medical Technologist/Clinical Laboratory Scientist</p> <p>Must have clear cycle to avoid errors</p> <p>variables may affect the quality of the request</p> <p>variables that may affect factors, diet, medication, exercise, and identification of patient specimens, anticoagulant specimen collection</p>
<p>Molecular Biology and Biotechnology</p> <p>uses different enzymes and other reagents, DNA and RNA are identified and sequenced to detect any pathologic conditions/disease processes</p> <p>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)</p>	<p>Analytic phase: actual testing of the submitted/collected specimen</p> <p>Equipment and instruments: reagents and internal quality control program</p> <p>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</p>	<p>Post-analytic phase: TAT and transcription used, result given</p>
		<p>Quality Assurance in the Clinical Laboratory</p> <p>Quality Assurance encompasses all laboratory personnel and results</p>



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Published 25th October, 2021.
 Last updated 25th October, 2021.
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Quality Assurance in the Clinical Laboratory (cont)		Quality Assurance in the Clinical Laboratory (cont)	
	organized, systematic, well-planned, and regularly done with the results properly documented and consistently reviewed	Certificate of Performance	given to the participating clinical laboratory
Two Major Components	Internal Quality Assurance System (IQAS) and External Quality Assurance System (EQAS)	Designated NRL-EQAS	National Kidney and Transplant Institute Coagulation
Internal Quality Assurance System (IQAS)	day-to-day activities that are undertaken in order to control factors or variables that may affect test results		Research Institute of Tropical Medicine identification and antibiotic susceptibility testing of ova and quaternary malaria)
	Regular review and audit of test results: done to identify weaknesses and consequently perform corrective actions		Lung Center of the Philippines (LCP) 10 analytes, namely glucose, creatinine, urea nitrogen, uric acid, cholesterol, sodium
External Quality Assurance System (EQAS)	system for checking performance among clinical laboratories and is facilitated by designated external agencies		East Avenue Medical Center (EAMC) etamine and cannabinoids)
	National Reference Laboratories (NRL): DOH-designated EQAS		San Lazaro Hospital STD-AIDS Cooperative (SACCL) - Infectious immunology hepatitis human immunodeficiency virus (HIV), HIV
	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)		

