



# Laboratory Logistics Glossary of Terms

## ***aliquot***

A portion of a specimen that is separated out and is tested, stored, or sent to another laboratory for further analysis or storage. This portion is a representative of the whole. Aliquoting is used to prolong the life of samples because the samples are not subjected to multiple freeze/thaw cycles risking the compromise or loss of a sample. Aliquoting is used to manage specimens that are stored in a frozen state.

## ***analyte***

The substance that is being identified and/or measured in a laboratory test.

## ***assay***

The quantification of a substance of interest by a specific technique.

## ***backup equipment***

A second machine used when the primary machine is unavailable. In busy laboratories with more than one machine to do tests, one of the machines can be used as the main machine and another as backup when the main machine is broken, under repair, or experiencing other disruptions.

## ***Bio Safety Level 3 (BSL3)***

A BSL3 laboratory has a high level of containment for processing very dangerous pathogens. Access to these laboratories is strictly controlled.

## ***blood grouping antisera***

Blood banking reagents that are used to test patient samples before patients are given blood transfusions. These are stable reagents requiring a cold chain.

## ***calibrator***

Reagent used to set instrument parameters after they have deviated from the set values as a result of use, maintenance, repairs, or manufacturers' recommendations. Calibration is needed for a machine to work properly. Some machines require calibration more often than others, and calibrators are specific to the equipment.

## ***CD4***

Also known as T4 cells, CD4 cells are one of several types of T cells that are important to the immune response. They protect against viral, fungal, and protozoal infections and are immune cells most susceptible to HIV. A CD4 count is an indicator of the health of patients' immune systems indicative of their risk of developing an opportunistic infection. Test results from a CD4 count can also be used to judge when antiretroviral therapy should begin (see T cell count).



### ***closed systems***

Laboratory instruments that use only a specified brand of reagents. Closed systems are usually more expensive than open systems; they can be of higher quality because of the manufacturing practices. The reagents must come from a single source.

### ***coefficient of variation (CV)***

A measurement of the precision or reproducibility of a laboratory test or process, represented as a percentage. Modern instruments have a CV of 3 percent to 5 percent. When all other parameters are equal, the lower the CV, the more accurate the test.

### ***complete blood count CBC***

Also known as **full blood count (FBC)**, this test panel gives information about the cells in a patient's blood. This test is done using automated machines.

### ***consumables***

These are items that are used once in performing a test and are not reused; examples include microscope cover slips, pipette tips, and applicator sticks.

### ***controls***

Materials with known values that are used to validate test results. Commercially available, materials are often expensive. In-house controls are sometimes substituted to save costs and can be obtained among specimens received by the laboratory for analysis.

### ***cryotubes***

Specialized tubes for storing frozen cells, plasma, or serum specimens from a few days to several years. They can withstand temperatures as low as -190° C without leaking or causing structural damage to the tubes.

### ***culture***

A laboratory procedure in which a sample from a wound, blood, or other body fluid is taken from an infected person. The sample is placed in conditions under which bacteria can grow. If bacteria do grow, identification tests are done to determine the species causing the infection.

### ***culture media***

A liquid or gelatinous substance containing nutrients used for the cultivation, isolation, identification, or storage of microorganisms.

### ***durables***

Items that can be reused for multiple tests, such as glassware that can be sterilized and reused. Examples include measuring cylinders, centrifuge tubes, universal bottles, and glass pipettes.

### ***Enzyme-Linked Immunosorbent Assay (ELISA) test***

ELISA is used to detect the presence of antibodies in serum. For example, when used for first-line screening for HIV antibodies, a positive result indicates that HIV antibodies have been detected. This technology has wide application in clinical laboratories and is not limited to HIV testing.

### ***equipment start-up***

The process to get machines ready to run specimens following a time when they have been in shut-down or standby mode as recommended by the manufacturer. This involves doing background checks, priming, calibrating, and running controls. Specimens can only be processed if the start-up procedure is successful.

### ***external quality assurance (EQA)***

A program that allows testing sites to assess the quality of their performance by comparing their results with those of other laboratories by testing the same specimens. This is done by analyzing proficiency panels or rechecking randomly selected specimens and rerunning them to compare the previous lab result with the new result. EQA often includes an on-site evaluation of the laboratory where laboratory staff are observed as they conduct tests to review their adherence to standard operation procedures.

### ***Field's stain***

A commonly used laboratory staining technique used to stain blood films on slides to identify malaria parasites.

### ***good laboratory practice***

Good laboratory practice includes the practices, processes, and conditions required for high-quality laboratory studies to be planned, performed, monitored, and reported.

### ***hematology machine***

An analyzer that counts the cells in a patient's blood to give a panel of results known as complete blood count (CBC) or full blood count (FBC). The instruments range from low-**throughput**, semi-automated or fully automated, very-high-**throughput** analyzers. These machines are closed systems as they only use reagents supplied by the manufacturer of the equipment.

### ***indeterminate***

A test result that is neither positive nor negative. An indeterminate result usually means that a person has just begun to make antibodies following a recent infection at the time of his or her test. One way to resolve this is to retest the client after 3 months, by which time the antibodies are expected to have developed fully and are easily detectable.

### ***medical technician***

A medical technician typically has a two-year, specialized education and is supervised by a medical technologist.

### ***medical technologist***

A medical technologist (or clinical laboratory scientist) typically has completed a baccalaureate degree and a specialized internship. Many governments require certification examinations and continuing education; some states also require licensure.

### ***microscopist***

A laboratory cadre trained to examine TB and malaria slides and often supervised by a medical technologist.

### ***open systems***

Laboratory instruments that can use reagents produced by manufacturers other than the manufacturer of the equipment. Open systems do not rely on a single source but can use reagents from any manufacturer that develops the specifications needed for the test. The manufacturer of the reagents must provide the program to the user specifying how the reagent can be used on the specified equipment.

### ***panel cells***

Commercially prepared cells used for identifying antibodies to blood groups in a blood bank. They are usually purchased in vials of 10 or more and have a very short shelf life.

### ***pathologist***

A medical doctor specializing in disease or pathology.

## ***Polymerase Chain Reaction (PCR)***

A highly sensitive test that detects DNA fragments of viruses or other organisms in blood or tissue. It works by repeatedly copying genetic material using heat cycling and enzymes similar to those used by cells. This laboratory technique is used for rapidly synthesizing large quantities of a specific DNA segment. The synthesized material can be identified as the reaction takes place (real time) or by taking the final reaction products to another step for identification using the gel electrophoresis method. The real-time method is more convenient as it produces results faster since it has fewer steps and the technique is also less prone to contamination.

## ***preventive maintenance***

Tasks performed on equipment, based on the manufacturer's schedule, to prevent failure of an instrument. This is a proactive process to prevent testing errors from instrument failure; it is part of the quality assurance process.

## ***quality assurance (QA)***

The process of managing the quality of all aspects of the testing process. QA considers pre-analytic, analytic, and post-analytic processes; sample collection; quality control runs; and result reporting. It also includes training, interlaboratory comparison of results, **SOPs**, and equipment maintenance protocols.

## ***quality control (QC)***

A process that produces, then monitors statistical guidelines for precision and accuracy of laboratory results. Daily QC provides a benchmark to measure the quality of the testing process. When QC falls outside an acceptable range, laboratory results may not be released.

## ***reagents***

Chemical or biological substances used in laboratory testing to detect or measure an **analyte**. They vary widely in cost, stability, cold/cool chain requirements, availability, and associated hazards. They can be liquids as in "wet chemistry," or solids as in solid phase or "dry chemistry."

## ***reference ranges***

The range of normal test results for a given population. For example, for adult males the normal glucose range (for a particular technique) is from 85 mg percent to 110 mg/dL (milligrams per deciliter). This is considered the reference range for that population.

## ***reproducibility (or precision)***

The reproducibility of a test is the ability of a measurement to be reproduced consistently. Automated instruments provide more precision than manual techniques. As shown by the **coefficient of variation (CV)**, automated instruments typically have a CV of less than 8 percent, while manual procedures may have a CV of 15 percent or more.

## ***sensitivity***

The probability that a test is positive if the patient being tested has the disease or condition. High-sensitivity assays detect a high percentage of true positives. Screening tests, such as rapid HIV tests, must be highly sensitive. Screening tests require confirmation with a highly specific test.

## ***sharps***

Used needles and lancets and other biohazardous medical waste that must be discarded in sharps containers.

## ***specifications***

Operational parameters from the manufacturer of a reagent, test, or instrument. Specifications may be found in package inserts and instrument manuals. National and international approval of reagents, tests, or instruments is based on meeting these specifications.

## ***specificity***

The probability that a test is negative if the person being tested does not have the disease or condition. High-specificity assays detect a high percentage of true negatives. A highly specific test should be used when there is a need to minimize the number of false negatives—for example, when diagnosing an infection in an individual.

## ***standard operating procedures (SOPs)***

SOPs explain step-by-step how to perform a particular test; guidelines include specimen requirements, environmental conditions, reference ranges, and reporting units. SOPs should be defined or standardized across each level of the laboratory system for consistency. For example, every district lab should have the same set of SOPs for the test techniques carried out at the district level.

## ***standardization***

The process of ensuring that—

- the same menu of laboratory tests, defined by level of the laboratory system (central, regional, district), is offered;
- the same techniques, defined by level, are used to carry out those tests;
- the same technical SOPs are followed for those techniques; and
- laboratory instrumentation, defined by level, is agreed upon.

## ***standards***

Concepts, procedures, and designs needed to achieve and maintain the required levels of compatibility, interchangeability, or commonality in the operational, procedural, material, technical, and administrative fields.

## ***stock reagent***

A concentrated form of a reagent or other common solution, such as a buffer. Concentrated forms are used as stock reagents because they take up less space on the laboratory shelf. Because stock reagents are usually too concentrated to be used directly in reactions and procedures, they must be diluted before being used. For example, if the stock reagent is six times as concentrated as the reagent needed for the procedure, the scientist must perform a six-to-one dilution of the stock reagent. That dilution is achieved by mixing one part stock reagent with five parts water or other appropriate solvent. The shelf life of the stock solution in most cases is longer than that of the working solution.

## ***T cell (T lymphocyte)***

White blood cells that stimulate the immune system to fight disease, and the primary target of HIV. Referred to as “T” cells because they mature in the thymus gland. They include T4 and T8 cells, also known as CD4 and CD8 cells.

## ***T cell count (CD4 count)***

The number of T4 cells per cubic millimeter (mm<sup>3</sup>) of blood. As HIV progresses, the T4 cells fall from a normal count of 500–1,500 to as low as zero. When the T cell (CD4) count goes below 200, the risk of opportunistic infections increases; when the T cell count drops below 50, the risk rises dramatically.

### ***test menus***

Written guidelines that describe the defined list of tests that should be offered at a specific laboratory or level (central, regional, district, etc.) of the laboratory system.

### ***throughput***

The number of tests a machine can process per given time, usually per hour. This is not the same as the number of specimens, as many tests can be done on a single specimen.

### ***tie-breaker***

In HIV testing at least 2 tests are used. The first is the screening test, the second is the confirmatory test. A positive screening test is confirmed using the confirmatory test. If the confirmatory test is positive, then the result is reported as positive. There are times when the confirmatory test will repeatedly give a negative result while the screening test is giving a positive result. This disagreement or discordance is resolved by running a third test, known as a tie breaker. If the tie breaker is negative, the final result is negative; the reverse is also true.

### ***transport media***

When specimens are collected to investigate presence of disease-causing microorganisms, the specimens are preserved using special reagents. The reagents used to preserve microorganisms in specimens are known as transport media. Examples include Stewart transport media used to preserve bacteria and viral transport media used to preserve viruses.

### ***usage***

The amount of laboratory commodities consumed during a set period of time. The terms *consumption* or *dispensed to user* can describe amounts of health commodities or drugs used by patients. In the laboratory, the term *usage* is more appropriate because the supplies are not being consumed by or dispensed to a patient but are being used to conduct a laboratory test.

### ***viral load***

Viral load is the measurement of the number of viral particles in the circulating blood. HIV and hepatitis C are often quantified with the viral load test. Viral load and CD4 counts are both predictors of the risk of HIV disease progression. Viral load testing is also used to determine when to initiate or change antiretroviral therapy.

### ***viral transport media***

When specimens for investigating some viruses are collected, they are preserved in a specially prepared solution that keeps the viruses viable. This special preparation can be obtained commercially ready to use, or the laboratory can prepare the solution using a number of commodities. This preparation is known as viral transport medium as it preserves viruses from time of collection to time of processing the specimen.

### ***“walk away” analyzer***

A fully automated machine onto which a lab tech loads specimens for testing and leaves (walks away from) it to run and produce results without further intervention needed from the operator. These are high-tech, high-throughput machines that are ideal for very busy facilities with limited human resources.

# Disciplines in the Laboratory

## ***hematology***

Hematological information assesses the body's ability to carry oxygen, provide immunological surveillance, and prevent hemorrhage. Typical tests include complete blood counts, which measure the number of red blood cells, white blood cells, and platelets. Originally, these tests were done by diluting blood and counting cells, and measuring hemoglobin by comparing the color of the blood. Typically, in resource-poor settings, semi-automated instruments are used, with manual backup in the event of stockouts or instrument failure. The instruments used are almost always closed systems, using the manufacturers' reagents. When generic reagents have been used in the past, quality has suffered and most manufacturers would not support the instruments.

## ***chemistry***

Chemical information assesses the body's internal environment. Liver function, kidney function, glucose levels, and enzyme levels are typical chemistry tests. Usually, a specific chemical reaction produces a colored product proportional to its concentration. The instrumentation can range from a very simple filter photometer to an automated testing system. Chemistry tests provide an excellent opportunity to use open systems. Reagent test kits provide high-quality reagents and standards but may be expensive. Consolidated purchasing could provide high-quality reagent kits with competitively priced bulk reagents. Many of these reagents require a cold chain in transportation and storage.

## ***microbiology***

Microbiological investigations are among the most common laboratory procedures. The microbiology section of the laboratory can be divided into more specialized sections as follows, bacteriology, parasitology, virology, mycology, and serology. These divisions vary from laboratory to laboratory depending on how the laboratory is organized.

- Bacteriological cultures and drug sensitivity testing is done in the bacteriology lab. In this laboratory cultures are made on culture media and these media are needed to grow, isolate, identify, and carry out drug sensitivity tests to bacteria. This helps clinicians to select drugs that are effective against the offending bacteria. In resource-limited environments the techniques used are mostly manual. Culture media are generally very stable with a long shelf life prior to reconstitution and preparation.
- Parasitic infections are very common in developing countries and include malaria and schistosoma (which causes bilharzia). Microscopy is the mainstay of parasitic investigations due to its lower cost; however, this is also labor intensive and requires a considerable amount of skill to read and interpret the slides. Stains used for these investigations are easily available and have a very long shelf life.
- Virus isolation and cultures are done in the virology laboratory. The procedures are more complex than those used for bacteriology cultures. This is a specialized field with fewer suppliers, so commodity costs are high. Molecular techniques like PCR are commonly used in virology laboratories, such as the specialized Polymerase Chain Reaction (PCR).
- Fungal infections can be investigated in mycology laboratories where fungal cultures are carried out. The culture media used are similar to those used in bacteriology; these investigations are usually done at specialized facilities.
- Serologic techniques can also be used to identify microorganisms. The reagents are usually available as panels or in kit form from manufacturers. These are mostly short-shelf-life reagents and are expensive.

## ***immunology***

Classic immunological procedures could also be classified as hematological or microbiological tests; however, many new tests are based on the detection of antibodies or antigens. Immunology is a growing field with many new tests introduced each year. Tests for classifying white blood cells into CD type can be included as can viral load procedures.

Classic serological tests, such as the Weil-Felix and Widal tests, are labor-intensive and have some cold chain reagents. The enumeration of CD4 cells and measurement of viral load require sophisticated instrumentation; expensive, unstable reagents; and a high degree of training. Emerging low-cost, low-tech systems are being introduced into this dynamic field. This area requires very careful analysis of the appropriateness of any technology proposed.

## ***urinalysis***

The testing of urine is a low-technology, labor-intensive part of the laboratory. Test strip technology is used in many resource-limited settings; however, test strips require good laboratory practice to prevent premature expiration.

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