

Glossary of Commonly Used Diagnostic Terms

Antibody (Ab)

A substance produced by the body in response to an antigen that specifically reacts with the antigen to destroy, inhibit, or neutralize it. The body produces antibodies as a defense against foreign substances. Antibodies may be identified and measured to determine whether an individual has been infected by a pathogen.

Array

Diagnostic modality involving conduction of multiple unique tests for different biomarkers on the same testing medium (e.g., plate, glass slide, microfluid chip).

Biomarker

A characteristic that is objectively measured and evaluated as an indicator of normal biologic or pathogenic processes, or pharmacological responses to a therapeutic intervention. It is used to measure or indicate the effects or progress of a disease, illness or condition.

Clinical Chemistry

Also known as clinical biochemistry or clinical pathology, clinical chemistry is the area of science that is generally concerned with analysis of bodily fluids.

Cytology

The branch of biology that deals with the formation, structure, and function of cells.

DNA

The molecule that encodes genetic information. DNA is a double-stranded molecule held together by weak bonds between base pairs of nucleotides.

DNA Sequencing

DNA sequencing is the determination of the precise sequence of nucleotides in a sample of DNA.

Dx

Dx is the abbreviation for diagnostics.

Flow Cytometry

A method of measuring physical and chemical attributes of cells or other biological particles by sensors, as they move by, one after the other, homogeneously suspended in fluid. This rapid (about 10,000 particles per second) analytic method allows identification of important cell types, such as malignant cells, T cells and B cells.

Fluorescence In Situ Hybridization (FISH)

FISH is a test that “maps” the genetic material in a person’s cells. This test can be used to visualize specific genes or portions of genes.

Genome

All of the DNA in an organism or a cell, including the DNA in the nucleus of a cell and the DNA in the cell mitochondria. Genes carry information for making all the



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proteins required by all organisms. These proteins determine, among other things, how the organism looks, how well its body metabolizes food or fights infection.

Hematology

The scientific study of blood and blood-forming tissues.

Immunoassay

Tests used to detect or quantify a specific substance, the analyte, in a blood or body fluid sample, using an immunological reaction. Immunoassays are highly sensitive and specific. Their high specificity results from the use of antibodies and purified antigens as reagents. High sensitivity is achieved by using an indicator system (e.g., enzyme label) that results in amplification of the measured product.

Immunochemistry

The study of the chemical properties of antigens and antibodies, complement, and T cell receptors.

Immunodiagnosics

The use of specific antibodies to measure a substance. This tool is useful in diagnosing infectious diseases and the presence of foreign substances in a variety of human and animal fluids (e.g., blood, urine, etc).

In Vitro Diagnostics (IVDs)

IVDs are reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to identify, cure, mitigate, treat, or prevent disease. They are medical devices.

Mass Spectrometry

Mass spectrometry (MS) is an analytical technique that measures the mass-to-charge ratio of charged particles. It is used for determining masses of particles, for determining the elemental composition of a sample or molecule, and for elucidating the chemical structures of molecules, such as peptides and other chemical compounds. The MS principle consists of ionizing chemical compounds to generate charged molecules or molecule fragments and measuring their mass-to-charge ratios.

Medicare Clinical Laboratory Fee Schedule

Outpatient clinical diagnostic laboratory tests are reimbursed by Medicare Part B under the Clinical Laboratory Fee Schedule. No beneficiary co-payments or deductibles apply for these laboratory tests. Providers submit claims for tests to local Medicare Administrative Contractors for payment. Claims are paid based on the local fee schedule rate that was established for the test in the locality where the lab is located.



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Microbiology

The branch of biology that is concerned with the study of microorganisms, including bacteria, archaea, viruses, algae, protozoa, and fungi, and their effect on humans.

Molecular Diagnostics

Diagnostic tests that identify a disease, predisposition for a disease, or progress in treating a disease by detecting specific molecules such as DNA, antibodies, proteins, etc.

Panel Testing

A laboratory procedure in which a series of tests is performed on one specimen, usually related to a single condition or disease, or for differential diagnosis.

Polymerase Chain Reaction

The polymerase chain reaction (PCR) is a scientific technique in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.

Reagent

A substance used to produce a specific chemical reaction. It may be used to detect, measure, or prepare other substances.

RNA

A chemical found in the nucleus and cytoplasm of cells; it plays an important role in protein synthesis and other chemical activities of the cell. The structure of RNA is similar to that of DNA. There are several classes of RNA molecules, including messenger RNA, transfer RNA, ribosomal RNA, and other small RNAs, each serving a different purpose.

Single Nucleotide Polymorphism (SNP)

DNA sequence variations that occur when a single nucleotide (A, T, C, or G) in the genome sequence is altered. Although the majority of human DNA sequences are the same, variations in DNA sequence can have a major impact on how humans respond to disease; environmental factors such as bacteria, viruses, toxins, and chemicals; and drugs and other therapies. This makes SNPs valuable for biomedical research and for developing medical diagnostics.

