

Glossary

A

B

■ **BEAMing**

An acronym for “Bead, Emulsion, Amplification, and Magnetics,” this gene analysis method combines digital PCR (ultrahigh-sensitivity PCR) and flow cytometry technologies.

■ **Bioinformatics**

Information technology used to analyze genetic and protein information and explain vital phenomena; in particular, technology for analyzing the relationships between genetic information and disease.

■ **Blood smear sample**

Prepared for microscopy of blood cell morphology by placing a drop of blood on a glass slide, and then drying and staining it.

■ **Blood coagulation testing**

Tests run on plasma from which red blood cells have been removed. They are used to investigate a diagnosis of hemophilia and to check on susceptibility to hemorrhage, tendency to thrombosis, and the state of liver function.

C

■ **Cervical cancer**

The second most common form of gynecological cancer. However, if it is discovered early a higher proportion of patients can be successfully treated than with other cancers.

■ **Clinical testing**

Tests carried out by a hospital during routine examinations or when a person is sick, to obtain data on physical health. Clinical tests are divided into laboratory tests, carried out on specimens such as blood, urine, or cells, and tests such as X-rays, ECGs and EEGs that are performed directly on the body itself.

■ **Clinical trial**

Unlike a therapeutic trial for the purpose of gaining approval to manufacture or market a drug, clinical trials in this sense use laboratory tests on blood or tissue samples from a patient to evaluate the performance of the testing method.

■ **Companion diagnostic drugs**

Drugs for clinical testing used to predict the efficacy and side effects of drugs before using them for treatment, or for monitoring the effects of treatment, particularly test drugs developed at the same time as drugs for treatment.

■ **Confirmed diagnosis**

General confirmation by a physician of the nature and degree of a suspected disease via examination, medical history, and the results of clinical tests.

D

■Diagnosis procedure combination (DPC)

System for paying medical bills consisting of set fees determined by individual hospitals. In the past, medical bills were payable on a per-visit basis, so they increased with the number of visits. Under the DPC system, medical costs are more effectively controlled.

■Digital PCR technology

A high-sensitive genetic detection technology that is expected to find applications to detect minute quantities of mutated cancer genes released into the blood.

■Disease management

The concept of providing healthcare services, optimized for individual patients, aimed at preventing the onset, recurrence, and deterioration of diseases.

■DNA chips (gene chips)

An analytical tool for measuring gene expression at a cellular level, whereby a large number of DNA fragments are densely arranged on a plastic or glass substrate.

E

■Establishment of usefulness

Evaluation of new testing methods in terms of whether they improve efficiency and accuracy.

■Evidence- based medicine (EBM)

A new concept in medicine that aims to base treatment on evidence as opposed to previous experience.

■Exosomes

Exosomes are granular vesicles measuring around 100–200nm that are secreted by many types of cells and circulate in the blood, saliva, urine and other bodily fluids. Exosomes contain many substances, including proteins, mRNA and microRNA. In recent years, attention has focused on using exosomes as biomarkers for various diseases, including cancer and Alzheimer's disease.

F

■FISH testing

A technique that uses fluorescent material binding only specific genes to detect target genes within chromosomes.

■Flowcytometry

Method involving the flow dispersion of minute particles and the use of laser light to optically analyze the minute flows. Used primarily to measure individual cells.

G

■Gene diagnostic panel

A type of assay that enables simultaneous analysis of the mutation, amplification and combination of multiple diagnostically important genes.

■Genome

The minimum amount of genetic information common to all members of a species. Genes form the blueprint for an organism's makeup; a genome is the set of genes that carries the minimum amount of information necessary to construct a single organism.

■ **Glycosylated hemoglobin**

A widely used test item for the diagnosis and screening of diabetes and controlling blood sugar. This item reflects average blood-sugar levels over the past one or two months.

H

■ **Healthcare testing (business sector)**

Generic term for all testing in a healthcare context, including testing in hospital laboratories, POC testing, home testing, and preventative testing.

■ **Hematological testing**

Measuring the number, type and size of red blood cells, white blood cells, and platelets, as well as hemoglobin concentration, these tests are diagnostic for anemia and erythrocytosis. White blood cell count is used to check for leukemia or type of inflammation, while platelet count is used to investigate hemostatic function.

I

■ **Imaging flow cytometry**

Flow cytometry (FCM) is a method involving the flow dispersion of minute particles and the use of laser light to optically analyze minute flows. Used primarily to observe individual cells, imaging FCM is a proprietary Millipore technology that combines FCM for processing large quantities of cells with the rapid capture of images of cell morphology, fluorescent imaging and automated digital image analysis.

■ **Immune serum testing**

Tests that check for the hepatitis virus or the appearance of specific proteins indicating the presence of cancer.

■ **Infection**

A disease caused by organisms that invade a living body through the mouth, skin or other transmission route and either propagate or generate toxins within the body. (This is a wider definition than "infectious disease".)

■ **Insurance points**

Units of payment from medical insurance organizations to medical facilities for medical services, such as sample testing fees.

■ **ISO 15189**

Specialized quality management standard for lab tests.

■ **ISO, including 9001, 14001 and 15189**

ISO is the International Organization for Standardization. The ISO body of standards was created to establish international standards in place of conflicting industrial standards in each country, to promote the smooth development of international commerce. In recent years, medical institutions have been focusing on ISO certification as an international indication of high-quality service.

J

K

L

■ Laboratory testing (diagnostics)

Tests that examine samples taken from the body, such as blood, urine, or cells. In the diagnostics field Sysmex is a comprehensive manufacturer of devices, reagents, and related software used for testing specimens such as blood, immune serum, and urine. The company's activities stretch from research and development through to manufacturing, sales, service and support.

■ Liquid biopsy

Detection of cancer or other diseases by testing blood or other bodily fluids. This type of testing is less invasive than conventional physical biopsies.

■ Lymph node metastasis

One way in which cancer spreads. Cancer cells that propagate in a given organ enter the lymphatic system and are carried via the lymph ducts to nearby lymph nodes. As this process is repeated, the cancer invades new organs and begins to propagate there. When this occurs, remission can only be prevented by removing (dissecting) not only the cancer itself but the affected lymph nodes as well.

M

■ MicroRNA

MicroRNA (miRNA) is a single-stranded RNA molecule of around 20 bases in length involved in controlling the expression of numerous genes and proteins, thereby making fine adjustments in vital phenomena. In recent years, attention has focused on the miRNA present in exosomes for diagnosing disease, as they are stable, preventing them from being broken down by enzymes in the blood, and their quantities and types vary substantially depending on various disease pathologies and degree of progression.

■ Minimally invasive blood glucose self-monitoring technology

Technology for measuring glucose levels in samples of interstitial fluid rather than blood. This method enables measurement with virtually no pain or difficulty for the patient.

■ Modular concept

Individual modules can be combined to create a diverse variety of product configurations. The series also allows for flexibility in testing throughput, increasing or reducing capacity in line with customer needs.

■ Molecular diagnosis

Molecular diagnosis is a diagnostic method that relies on the detection of molecules that cause a disease or determine its characteristics. In a broad sense, it's also includes diagnosis by using molecules of unknown function selected by a DNA chip. It is expected that in future this sort of molecular diagnosis will enable the selection of anticancer agents and other therapies on the basis of drug sensitivity diagnosis, as a form of evidence-based medicine (EBM).

■ Monoclonal antibody

Antibodies are substances that play a central role in the immune response that protects the human body from disease when it is invaded by foreign organisms such as viruses and bacteria. Monoclonal antibodies are artificially produced antibodies that are identical clones generated from an original cell

called a hybridoma. They are widely used in medicine and food hygiene, to diagnose cancer and detect disease bacteria and food poisoning.

■ mRNA

Messenger RNA (mRNA) is a family of RNA molecules that conveys genetic information on protein synthesis from DNA sequence information.

N

■ Next-generation sequencer

An analyzer capable of simultaneously reading large quantities of DNA bases and sequences that contain genetic information.

■ Noninvasive measurement technologies

Methods of measuring blood hemoglobin concentration that do not require blood sampling decrease the burden on the person being tested. This technology is currently highly valued in sports medicine, and may well find future use in examination of children and pregnant women.

■ Non-laboratory clinical testing

Tests carried out directly on the body such as X-rays, electrocardiograms (ECGs), and electroencephalograms (EEGs).

O

■ OncoBEAM

The name of a technology using the BEAMing technology (BEAM being an acronym for bead, emulsion, amplification and magnetics, this gene analysis method combines highly sensitive PCR and flow cytometry technologies) developed by Johns Hopkins University for the blood-based detection of minute gene mutations.

■ One step nucleic acid amplification (OSNA)

A proprietary method developed by Sysmex that uses a newly developed solubilizing agent to enable direct amplification of the distinguishing genetic information (mRNA) of lymphatic cancer, without the necessity of first extracting it from lymph node tissue samples.

■ Online QC

Online QC refers to real-time monitoring of the status of the customer's equipment, which is connected to the SNCS server of the Sysmex Technical Support Center. In the event of an abnormality, this service immediately notifies the customer.

P

■ Particle measurement technology

Technology used to measure instantaneously the size and number of blood cells or industrial particles only a few microns across. Sysmex uses this technology to develop testing equipment and products for industrial testing devices.

■ PCR

A gene amplification technology for copying small quantities of DNA to produce larger quantities.

■ Personalized Medicine

Treatment designed to meet specific characteristics of an individual patient.

■ **Plasma sequencing technology**

This gene sequence analysis technology assigns a unique identifier to each DNA molecule, allowing each gene to be identified, and then amplifies the DNA, enabling a high degree of specificity and sensitivity. This technology features a lower error rate than general next-generation gene sequence analysis, allowing for highly sensitive multigene testing of liquid biopsy specimens.

■ **Point of care testing (POC testing)**

POC testing is defined as laboratory testing that takes place in the vicinity of the patient. It functions effectively in such settings as clinics, outpatient facilities, ICUs, and operating theaters. It may also be referred to by similar expressions such as Near Patient Testing or Bedside Testing.

■ **Postgenome**

This refers to the search for useful genes and identification of their functions, and the identification of the differences in base sequences that give rise to variation among individuals. Progress in postgenome research is expected to contribute to developments in medical technology such as “tailor-made therapies” produced according to an individual’s particular sequence of bases.

■ **Precision management**

A management method used to guarantee the values measured by customers’ testing equipment. Confirmation that the customer’s equipment is functioning correctly.

■ **Protein chip**

A chip used to test quickly and cheaply for a target protein. Sysmex is developing a protein chip that uses a new protein quantification method (patent pending) in which a single antibody is used against a single antigen. This chip will offer speed and outstanding cost-performance.

Q

■ **Quality of life (QOL)**

Quality of life (QOL) refers to the maintenance of human dignity and improved wellbeing. Recently, emphasis is being placed on more patient-oriented treatment that enables the individual to regain his or her original vitality and to live a more comfortable lifestyle.

R

■ **RAS gene**

A gene whose mutations are known to cause cancer.

■ **Reagent**

A pharmaceutical product for medical use in laboratory testing, also called an in vitro diagnostic product. It is not used directly on the human body, but on blood or other bodily fluids sampled from the body.

■ **Regenerative medicine**

Regenerative medicine refers to the active use of cells to restore the function of structures or organs in the living body that have suffered functional damage or failure.

■ **Risk diagnosis**

Tests that determine what types of disease a person may develop in future.

S

■ Screening

Screening is the process of between the normal and the abnormal. In laboratory testing, its purpose is to distinguish between items that require detailed investigation and those that do not.

■ Sensitivity (includes explanation of anticancer drugs)

Effectiveness of drugs on patients. Effects and efficacy of the same drug vary from patient to patient.

■ Service and support, technical explanations

Systemex provides service and support to help customers using Systemex testing devices to interpret test results and deal with problems with their equipment. Service and support also includes proposals for new testing methods from an academic perspective.

■ Specimen

Material necessary for testing. May include blood, cerebrospinal fluid, pus, punctured fluid, urine and feces. Also called test material.

■ Sugar chain, glycosylation marker

Sugar chains, the linked monosaccharides that link to the surface of a cell or a protein, are sometimes described as “cell and protein costumes.” Their roles include the transmission of information specific to individual cells and intercellular communications. A glycosylation marker is a biomarker that targets structural changes in sugar changes present in glycoproteins.

■ Systemex network communication systems (SNCS)

SNCS is a service that enables customers to connect their analytical equipment to the Systemex Technical Support Center via the Internet, providing real-time external precision management, automatic monitoring and Web-based information delivery.

T

■ Testing center

A testing center is a business specializing in testing. In recent years, some hospitals have begun to outsource routine testing work to testing centers.

■ Total laboratory automation (TLA)

A system product that uses a specimen transport device to connect a number of analytical devices. In conjunction with a testing information system it enables automation and streamlining of laboratory testing.

■ Tumor marker

Tumor markers are substances produced only by tumor cells that are detectable in urine and blood samples. The detection of these markers and measurement of their volume is used to aid cancer diagnosis and in assessing its clinical progress.

U

■ Uncovered treatment

Treatment not covered by medical insurance. All costs are borne by the patient.

■ Urinalysis/urine testing

Urinalysis investigates whether sugar, protein, or blood is present in urine. It is used to check for the

presence of urinary tract stones, kidney function, and signs of diabetes.

V

W

■ Whole blood testing

Testing of blood taken from the body in its original state, without the need for processing to prepare a test sample (as was previously the case). Sysmex's serum-testing equipment makes this possible.

X

Y

Z