

## Glossary

**Adiponectin** – a protein hormone produced by adipose (fat) tissue, which is very abundant relative to many hormones. It modulates a number of metabolic processes, including glucose regulation and lipid catabolism. Levels of the hormone are inversely correlated with body fat percentage in adults.

**Analyte** – a substance to be measured in a sample.

**Biomarkers** – Biomarkers are molecular measurements that allow diagnosis and assessment of disease processes.

**CE Mark** – a regulatory approval used in the European Union. Quality, performance data and records must be kept by the official manufacturer of a product.

**C-Peptide** – the peptide that connects the A and B chains in proinsulin. The cleavage of the A and B chains of proinsulin create C-Peptide and equal quantities of insulin. Recent studies are showing possible biological roles of C-Peptide including anti-inflammatory effects. In Type 2 diabetes, measurement of C-Peptide provides important clinical information on the amount of insulin production. Low values of C-Peptide indicate little or no production of insulin from the pancreatic beta-cells. For patients who are being treated with exogenous insulin, C-Peptide measurements provide accurate determination of insulin levels since C-Peptide only reflects the amount of endogenous insulin.

**Delivery system, or 'system'** – the instruments used to perform laboratory bench manipulations to perform a test, to read the results of a test, and to report the results of a test.

**Efficacy or Comparison clinical trials**– clinical trials that assess the performance of a product in measuring something or answering a medical question, often as compared with a gold standard measurement or in comparison with existing medical practice for the question(s) being answered.

**ELISA Assays** – ELISA is an acronym for enzyme-linked immunoassay. ELISA is a test that typically detects and measures analytes in your blood. This test can be used to determine if you have analyte concentrations that are related to certain disease conditions.

**510K** – a regulatory approval category used by The Food and Drug Administration (FDA). It is used when a new product's performance can be compared directly with an existing product, which measures the same thing. The new product must be equal to, or better than, the existing approved product. For diagnostic immunoassays, clinical data is often correlation data showing concordance with the reference method for a reasonable number of well-documented patient samples from normal, borderline and disease patients. The approval process is often less than six months and can occur in less than 90 days depending on backlogs at FDA.

**Good Clinical Practice (cGCP)** – is an international quality standard that is provided by International Conference on Harmonisation (ICH), an international body that defines standards, which governments can transpose into regulations for clinical trials involving human subjects. The guidelines among other things include, standards on how clinical trials should be conducted, define the roles and responsibilities of clinical trial sponsors, clinical research investigators, and monitors. They also provide assurance of the safety and efficacy of newly developed compounds.

**hsCRP** – high sensitivity (test method) C-reactive protein, a test for a biological marker protein for inflammation of vessel walls in the cardiovascular system. This inflammation is a precursor and component of atherosclerosis, which in turn leads to heart attacks, strokes, peripheral artery disease, and other cardiovascular conditions.

**Immunoassay kits** – a package of reagents and other necessary materials, with instructions and performance data, enabling the determination of an analyte in a sample.

**Insulin** – a polypeptide hormone produced exclusively in the  $\beta$  cells of the pancreas and is a key regulator of glucose levels in blood. Insulin levels are very low or absent in Type 1 diabetes as the  $\beta$  cells are destroyed by an autoimmune mechanism. In marked contrast in Type 2 diabetes, insulin is produced by the  $\beta$  cells but the cells in the body become resistant to insulin. As insulin resistance increases the  $\beta$  cells produce more insulin leading to more insulin resistance and further increases in hyperglycemia. Insulin resistance often leads to Type 2 diabetes. In the early stages of Type 2 diabetes insulin blood levels may be increased but later in the disease the blood levels will decrease due to dysfunction of the  $\beta$  cells. Some patients with Type 2 diabetes require insulin treatment. The measurement of insulin therefore provides important clinical information about  $\beta$  cell function in insulin resistance and Type 2 diabetes.

**Insulin Resistance** – the state or condition of diminished effectiveness of insulin, in which a person's body tissues have a lowered level of response to insulin, a hormone secreted by the pancreas that helps to regulate the level of glucose, or blood sugar, in the body.

**Menu** – the list of products that may be run or performed on a delivery system.

**Metabolic Syndrome** – a group of medical conditions that are present simultaneously in a patient, such as, insulin resistance, raised blood pressure, low HDL levels and an excess of abdominal fat, which increases the risk of Type 2 diabetes, stroke and cardiovascular disease.

**Monoclonal Antibodies** – Monospecific antibodies produced in the laboratory by a single clone of cells or a cell line and consisting of identical antibody molecules. These antibodies can be made homogeneously in large quantities in a laboratory.

**Multi Marker Panel** – a group of tests that are used in combination for disease assessment.

**NIH** – National Institute of Health (U. S.)

**Outcome clinical trials** – clinical trials that first assess the performance of a product in measuring something or answering a medical question, then make a therapeutic decision based on the test measurement or overall result, and then compare the result of that therapeutic decision against current medical practice. An example – take two groups of men aged 50 and above. One group is treated in the standard way. The other group is tested, and based on the test result, may be given a different therapy. The number of clinical events (e.g., cardiovascular events such as strokes, heart attacks, etc.), which is the outcome, in the group getting standard therapy is compared with the number of clinical events in the group that was given a different therapy based on the test results.

**PMA** – a regulatory approval category used by the FDA. It stands for Premarket Approval (since the FDA never grants 'permanent' or 'final' marketing approval; such approval can be modified or revoked at any time). It is used when a new product's performance incorporates elements that have never been

approved by the FDA previously, such as answering a medical question for the first time with a test, or combining several measurements into a single index or number to answer a medical question, in a way not done previously by other products.

**POC** – Point of Care, which usually means a site in a physician office, clinic, or dispersed (as opposed to central) laboratory. These tests are also referred to as rapid tests.

**Prediabetes** – the state in which some but not all of the diagnostic criteria for diabetes are met, and more specifically when a person's blood glucose levels are higher than normal but not high enough to be classified as Type 2 diabetes. People with prediabetes are at an increased risk of developing diabetes within 7-10 years.

**Proinsulin** – a precursor protein of insulin that is the direct product of  $\beta$  cells in the pancreas. Insulin is produced from the processing of proinsulin. Insulin is the primary regulator of blood glucose, while proinsulin retains a minor but important effect on glucose regulation.

**Sandwich Assay** – a test for an antigen utilizing two binding agents, usually antibodies, one of which is labeled in a way enabling detection; an application for the ELISA method in which the presence of antigen fixed to the antibody can be determined either directly by adding a second specific antibody linked to an enzyme of the indicator system or indirectly, by first adding unlabeled specific antibody, the attachment of which to the antigen can be demonstrated by addition of immunoglobulin-specific antibody linked to the enzyme. The detector antibody can be labeled with an enzyme that will trigger an appropriate substrate for a colorimetric, fluorescent, or chemiluminescent reaction.

**Type 2 Diabetes** – a lifelong, chronic disease in which there are high levels of glucose in the blood. It is the most common form of diabetes, and is seen most often in adults, and more recently in obese children. Type 2 diabetes results from impaired insulin utilization coupled with the body's inability to compensate with increased insulin production.