

# GLOSSARY

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**Ambient:** room temperature.

**Analyte:** a substance or chemical constituent of any body fluid that is analyzed.

**Analyte Specific Reagents (ASR):** This test was developed and its performance characteristics determined by Covance Central Laboratory Services. It has not been cleared or approved by the U. S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Covance CLS is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as qualified to perform high complexity clinical laboratory testing.

**Blinding:** some protocols require that the results of one or more laboratory tests performed at Covance CLS are kept blinded when, for example, a certain value could give an indication of which treatment the patient is receiving. The results are therefore not communicated to the investigator or sponsor during the course of the study.

**Centrifuge:** an apparatus used to separate particles in suspension by centrifugal force. Processing a blood specimen in a centrifuge will separate serum or plasma from blood cells. Centrifuge for 15 minutes at 1500 to 2000 x g to separate the blood specimen. Please consult your protocol for special specimen collection procedures that require centrifugation at higher speed.

**Clotted blood:** results cannot be reported from such a specimen. This cancellation refers to small blood clots consisting of RBCs, WBCs, platelets and clotting factors which alter the proportions of cellular and soluble elements remaining in the specimen.

**Consumed in testing:** this phrase is used when the entire volume of specimen is used for testing, yet a valid result is not obtained. Typically, this occurs when a small amount of specimen is originally received, or a questionable result is obtained and insufficient volume is available to repeat the test.

**Covance Central Laboratory Services reference ranges:** individualized test reference ranges established specifically for pharmaceutical clinical trial patients. They may be age and sex specific.

**Delta:** a flag alert indicating that a laboratory result represents a statistically significant change from the patient's baseline value; +d is the designation if the result is a positive change from baseline, -d is the designation if the result is a negative change from baseline or pre-drug level. These flags appear to the left of the result on the laboratory report. These results are not telephoned to the investigator or sponsor.

**Dye interference:** a phrase used when the color of the urine is such that the dipstick chemistry tests are unable to be read.

**Error in specimen identification:** this indicates that the accession number and/or the patient identifier written on the container does not match the accession number and/or the patient identifier written on the requisition form.

**Exclusion flags: EX** is used to indicate an exclusion value according to the exclusion criteria set by the sponsor according to protocol requirements. This flag will appear to the left of the result on the laboratory report.

**Frozen:** this term indicates the specimen was properly maintained in a frozen state, preferably below -20 °C. Frozen specimens require dry ice to maintain a frozen state during shipment. Avoid a frost-free refrigerator during storage of specimens. Please consult your investigator manual for proper storage instructions.

## GLOSSARY (CONTINUED)

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**Hemolysis:** indicates the rupture of red cells with release of hemoglobin and other analytes into the specimen. Hemolysis will interfere with the performance of particular tests, which will result in specific cancellations.

**High and Low flags:** **H** for high and **L** for low flags appear to the right of the test result on the laboratory report if the result falls outside the reference range. High and low results are not telephoned to the investigator or sponsor.

**Improper ratio of blood to anticoagulant:** this is the result of the lavender or blue top tube not being filled completely during collection, causing inconsistent results.

**Incorrect specimen type:** this phrase indicates that an incorrect specimen type was submitted, based on protocol testing requirements, (e.g. serum received when plasma is required or vice versa, urine is received for serum, etc.)

**Invalid:** in terms of calculations, an “invalid” comment would indicate that one component of the calculation renders the calculation of a meaningful result impossible. Can also be used when the result is not reasonable due to specimen irregularities; used when one component of a calculation is out of stability. Example: MCV, MCHC and HCT resulted as invalid if specimen is greater than 60 hours old.

**Investigational use only (IUO):** the manufacturer of the reagent has informed us the performance characteristics of this assay have not been fully established as required by the Food and Drug Administration (FDA) regulations as outlined in 21 CFR (Code of Federal Regulations) 809 (In Vitro Diagnostic Products For Human Use). Accordingly, test results for this assay may not presently be used as a diagnostic tool alone, without confirmation by another medically established procedure.

**Lipemic:** serum or plasma with a turbid or milky appearance. This is caused by an elevation in triglycerides and may be seen in a nonfasting specimen or in certain disorders of lipid metabolism. Lipemia will interfere with several laboratory tests.

**Microclots:** “Microclots” may be reported for the platelet count when a valid count cannot be obtained due to platelet clumping. Please consult your investigator manual for proper mixing instructions.

**Myeloperoxidase deficiency:** a common inherited disorder of neutrophil function. It is detected when using an automated hematology instrument which performs a white blood cell differential using a peroxidase channel. Patients rarely know they have the disorder and usually require no treatment. Myeloperoxidase deficiency can also be acquired and is mostly seen in acute myelogenous leukemia, myelodysplastic syndrome and Batten’s disease.

**Panic alerts:** **HP** for a high panic or **LP** for a low panic alert. They are associated with critical laboratory values which may indicate medical emergencies. These flags appear to the right of the test result on the laboratory report. These values are telephoned **immediately** to the investigator and confirmation of receipt for these critical results must be obtained.

**Pharmacokinetics:** the study of the action of drugs within the body, including the routes and mechanisms of absorption, distribution, excretion, and metabolism; onset of action; duration of effect; biotransformation; effects and routes of excretion of the metabolites of the drug; rate of appearance and disappearance in blood, urine or other body tissues.

**Plasma:** the fluid portion of the blood in which blood cells are suspended. This yellowish fluid separates from a blood specimen which was mixed with an anticoagulant (e.g. EDTA, heparin, citrate or other anticoagulants) upon centrifugation.

## GLOSSARY (CONTINUED)

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**Prolonged cell contact:** the condition which occurs when a serum is allowed to remain in contact with cells for a prolonged period of time. This may occur at the investigator site prior to centrifugation or may be due to red blood cells present in the serum or plasma during transport. A combination of cellular metabolism and cellular damage produces a pronounced decrease in serum glucose and elevations in potassium and phosphorus.

**Quantity not sufficient:** this phrase is used when an insufficient sample volume is received for testing.

**Refrigeration during collection:** This phrase means the specimen must be 2-8°C during the entire collection procedure, (e.g. 24 hour urine collection). Please consult your specific collection instructions.

**Repeat reactive (positive), confirmed:** screening testing indicates specimen was positive; confirmation by a more specific test also indicates that the specimen was positive. Specimen result is positive for the analyte.

**Repeat reactive (positive), unconfirmed:** screening testing indicates specimen was positive; however, specific confirmation testing was not positive. Results are indeterminate. Recollection may be requested.

**Sample drawn in expired tube:** specimen received in expired container - Due to regulatory requirements, Covance cannot report results from collection containers that are past the expiration date placed on the container from the manufacturer. Results from expired containers will be cancelled.

**Serum:** the clear fluid portion of the blood obtained after the cells have formed a clot and the specimen is centrifuged. This clear, straw-colored liquid portion of the blood does not contain fibrinogen or blood cells. Sample is collected in a tube which does not contain an anticoagulant.

**Short draw collection tubes:** Covance is providing short draw collection tubes for this study. The short draw Vacutainer brand tubes with Hemogard Closure are designed for collecting a small volume of blood. The short draw tubes are the same size as adult size vacutainer tubes but contain only enough vacuum to fill the tube to the indicator line. Short draw tubes fill more slowly than full volume tubes due to a lower vacuum.

**Specimen received ambient:** this phrase is used when a specimen intended for refrigerated or frozen shipment is received at Covance Central Laboratory Services not in required shipping condition. Reasons include: Dry ice evaporated, too little dry ice used, incorrectly packaged for frozen shipment, shipment delayed, etc.

**Specimen received beyond stability:** this indicates too much time has elapsed to perform a valid assay when the specimen is received at Covance Central Laboratory Services. The test will be cancelled if the specimen is received beyond the established stability period for a given analyte. It can also indicate that the specimen should have been received frozen but was received ambient and the test will be cancelled as received beyond stability since the ambient stability has expired.

**Telefacsimile alerts:** HT for a high fax alert or LT for a low fax alert. They are associated with laboratory values which may indicate clinical problems and need prompt evaluation by the investigator. Covance CLS standard is that these values are faxed to the investigator site, but sponsor may also request telephone notification.

**TNTC:** Too Numerous To Count. Too many cells to be counted under high power field microscopy. For example: on a laboratory report for urinalysis, the red blood cells (RBC) and/or the white blood cells (WBC) in the urine microscopy can be "TNTC".

**Unable to verify test result:** this cancellation is applied to specimens that fail the required confirmatory analysis following the initial analysis.