No matter how effective substance abuse testing is, individuals will always attempt to beat it. This may be done by diluting the specimen or by causing a chemical breakdown through something ingested into the body or added to the specimen. Donors may also attempt to substitute another substance for their own urine.

Alere provides a specimen validity test panel that determines the levels of creatinine, specific gravity, pH, and general oxidants. A client may elect to perform a specimen validity test that can indicate if a urine specimen has been diluted, substituted, or adulterated in any fashion. Results of these tests will appear on individual drug test result reports if they are abnormal.

A valid result is dependent upon the submission of a valid urine specimen. A valid specimen in this context is one where the concentration of the urine is sufficient to yield a result that gives an accurate reflection of the drug content of the urine. Since drug screening identifies drug present equal to or greater than a specific cut-off value, dilution of the urine may dilute the drug below the level of the cut-off.

The creatinine level and specific gravity of a specimen combine to determine specimen validity, particularly in determining if a specimen has been diluted. Creatinine is a waste product produced by the body and excreted in the urine. Alere has the capability of determining a quantitative level of creatinine in a urine specimen. A normal urine specimen has a creatinine level greater than or equal to 20 mg/dL. Specific gravity is the density of a substance relative to the density of water and provides an indication of the amount of solid particles dissolved in a urine specimen. Alere can determine a quantitative level of specific gravity in a urine specimen. A normal urine specimen has a specific gravity of greater than or equal to 1.003.

There are three categories of specimen validity related to an unacceptable urine specimen. These reflect the progression in the degree of dilution of the urine.

**Dilute**
If a urine specimen has a creatinine value less than or equal to 20 mg/dL but greater than 2.0 and a specific gravity of 1.0011 to 1.0029, then the specimen is considered dilute. This dilution can come from either drinking large volumes of liquid before providing a urine specimen or pouring something into the container at the time of collection. Donors attempting to dilute their urine may ingest one of the following commercially available products.

- Fast Flush® (pill)
- Green Clean™ (liquid concentrate)
- Naturally Klean Herbal Tea® (drink)
- Pre-tox (pill)
- Quick Flush® (liquid concentrate)
- Ready Clean® (drink)
- Ultimate Blend (drink)

**Invalid**
There are two instances where a specimen will be reported as “Invalid” due to the creatinine and specific gravity results. One instance is a urine specimen with a creatinine value less than or equal to 2.0 mg/dL and an acceptable specific gravity of
1.0011 to 1.0199; the second instance is a urine specimen with a creatinine level greater than 2.0 mg/dL and a specific gravity of less than 1.0010. In both of these instances, the specimen is considered diluted to a greater degree than the “Dilute” result. This type of dilution can come from either drinking large volumes of liquid before providing a urine specimen, or pouring something into the urine container at the time of collection.

Substituted
If a urine specimen has a creatinine value less than or equal to 2.0 mg/dL and a specific gravity of less than or equal to 1.0010 or a specific gravity greater than or equal to 1.0200, then the specimen is considered inconsistent with human urine. This will prompt the determination of “Substituted.” This can come from either pouring something into the urine container or providing another liquid (apple juice, certain soda drinks, a clean urine, etc.).

Donors attempting to substitute their urine may use one of the following commercially available products.

- Quick Fix (synthetic urine)
- The Urinator (prosthetic-like)
- The Whizzinator (prosthetic)
- Tinkle (synthetic urine)
- Ultra Pure™ (synthetic urine)

pH & Oxidant Testing
In addition to creatinine and specific gravity, the pH level of the specimen can be used to determine its validity. A pH test determines the degree of acidity or alkalinity of a urine sample. A normal urine specimen has a pH between 5 and 8. Alere’s initial pH test has a range from 5 to 8.5. A pH outside this range is confirmed by pH meter. Any specimen with a confirmed pH of greater than or equal to 3.0 but less than 4.5 or greater than or equal to 9.0 but less than 11.0 will be reported as “Invalid: Abnormal pH.” Any specimen with a pH of less than 3.0 or greater than or equal to 11.0 will be reported as “Adulterated,” meaning something has been added to the urine specimen after voiding. Substances which will produce a basic pH (11 or greater) include bleach and ammonia. Substances which will produce an acidic pH (3 or lower) are lemon juice and vinegar.

Finally, a general oxidant test can determine the presence of an oxidizing agent that may have been added to the urine specimen after voiding. If the general oxidant test is positive, the sample will be reported as “Invalid: Possible Oxidant Activity.”

Donors attempting to alter or interfere with tests may add one of the following commercially available adulterants to their urine.

- Amber-13
- Clear Choice Instant Clean Add-it-ive™
- Kifelex
- Klear™ and Klear™ II
- Mary Jane Superclean 13
- Minute Man
- Purafyzit® Ultra Pure
- Stealth™ & Stealth™ 51
- Sweet Pee’s Spoiler
- THC-Free
- Urinaid
- Urine Luck™ 5.4, Urine Luck™ 6.3, & Urine Luck™ 6.4

Meaning of Specimen Validity Test Results
This testing is an evaluation of the validity of the specimen and not the validity of the test result. A drug positive result on a report with any of the validity flags is still a valid result; however, a negative result with any of the above flags is cause for concern.

Alere recognizes that drug users may understand the principles of specimen validity and attempt to alter their urine specimens to avoid detection. We provide the tools to identify potentially invalid urine specimens.