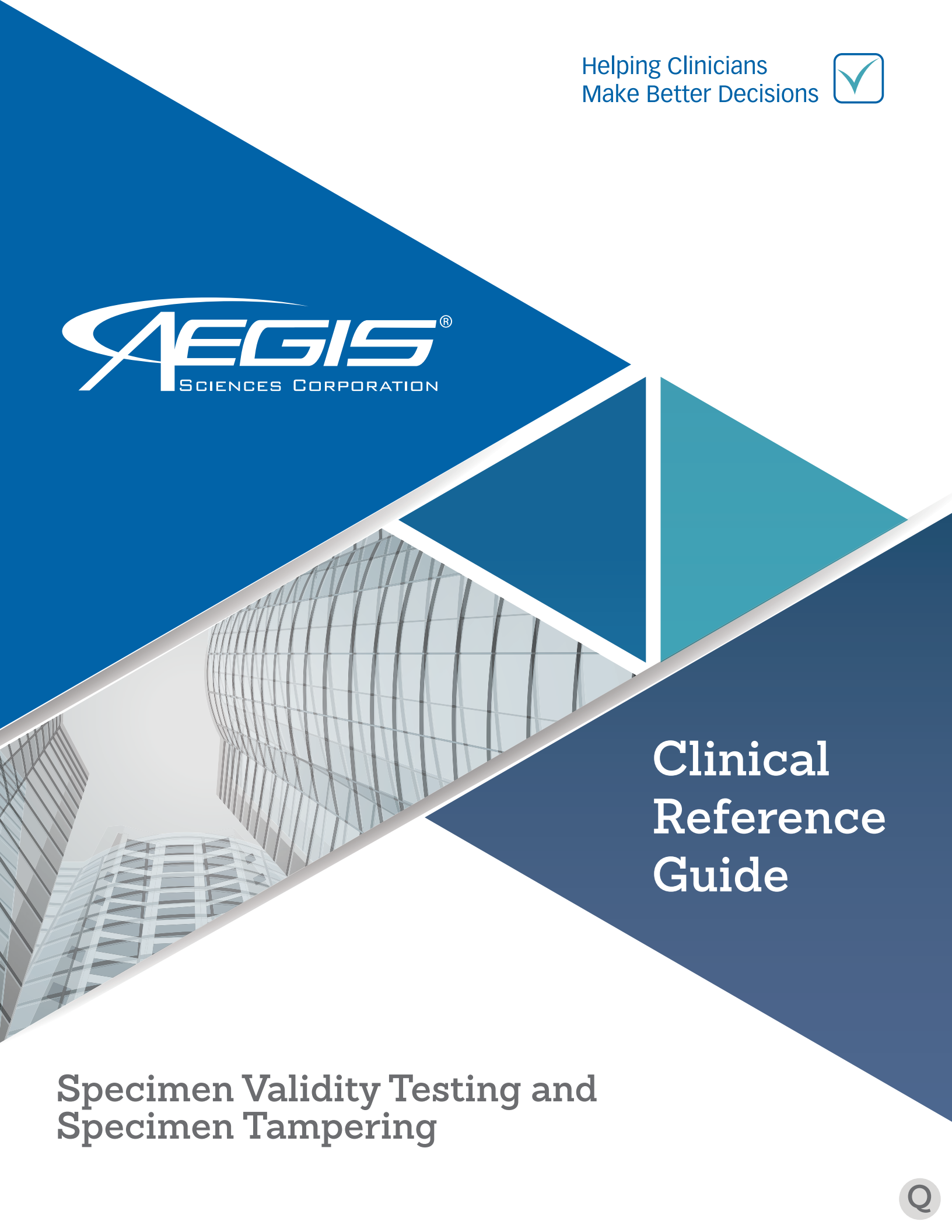


Helping Clinicians
Make Better Decisions



Clinical Reference Guide

Specimen Validity Testing and Specimen Tampering

Specimen Validity Testing and Specimen Tampering

Specimen validity testing (SVT) can be used to help determine if a urine specimen is dilute or has been adulterated or substituted.

Aegis performs SVT on all urine specimens submitted for drug testing to help detect substituted, adulterated or dilute samples. SVT includes the analytes listed in Table 17.1. A specimen consistent with normal human urine should have a creatinine concentration and pH within the normal range.

Table 17.1: *Specimen Validity Testing*

ANALYTE	NORMAL RANGE ON AEGIS REPORT
Creatinine	20-370 mg/dL
pH	4.5-9.0

A. Substitution

Substitution of a urine specimen may be accomplished with urine from another person, an animal, or synthetic urine smuggled into the collection site in any number of vessels. Substitution efforts may be difficult to detect analytically as commercial products are available that mimic many urine properties.¹ However, there are some critical steps that may be taken at the point of collection to evaluate for possible substitution:

- The temperature of the urine specimen should be between 90 and 100°F when measured within four minutes of collection. The urine collection cup should contain a temperature strip to ensure the specimen temperature is in the appropriate range. Temperatures outside this range may indicate a sample substitution, as smuggling attempts may fail to produce urine at the correct temperature.^{1,2} In addition, heating pads may not work correctly and smuggled urine may have an increased temperature higher than 100°F.³
- Urine may be inspected for precipitate or cloudiness. Aged alkaline urine may become cloudy because of crystal precipitation. However, freshly voided urine may also be cloudy in appearance following a fatty meal or if white blood cells, red blood cells, epithelial cells, or bacteria are present.¹
- Normal urine is typically odorless, whereas aged urine may smell especially strong due to the presence of ammonia, putrefaction compounds,

and hydrogen sulfide. However, other factors such as foods may affect the scent of urine (e.g., coffee, garlic, or asparagus). Diabetic patients in ketoacidosis may produce urine with a fruity smell caused by excretion of ketone bodies or fermentation of glucose to ethanol by micro-organisms.¹

B. Adulteration

A patient may add chemicals to a urine sample after voiding in an attempt to mask the presence of illicit or prescription drugs; this is called sample “adulteration.” Many products have been used as adulterants, including household products such as bleach, vinegar, various juices (e.g., lemon juice), eye drops, dish soap, drain cleaners, ammonia, meat tenderizer (peptidase), and hydrogen peroxide. Commercial adulterants include glutaraldehyde, sodium or potassium nitrite, peroxide and peroxidase, and pyridinium chlorochromate (PCC).⁴

Many of these adulterants alter the pH outside of normal limits, with pH less than 3 or higher than 11.^{2,5} Specimens treated with liquid soap or fabric conditioner are usually cloudy and can produce foam with a rainbow appearance or an odor that is uncharacteristic for urine.⁵

Pectin is a fruit compound derived from the cell wall of plants and is used as a gelling agent for canning purposes. Pectin has been used as an adulterant for immunoassay drug tests because it acts as a surfactant, surrounding the drug molecules and preventing detection by the immunoassay antibody. Pectin ingestion will have little effect on the composition of the urine as normal digestive processes render the compound inactive. However, the addition of pectin directly to the urine specimen may result in false negatives on immunoassay. The addition of pectin at high concentrations will decrease pH (potentially below 3) and may be visually detectable in urine as gel or strands.⁶ See Table 17.2 for an interpretation of pH values in urine.

Table 17.2: *pH Interpretation*

pH	CLASSIFICATION
<3	Adulterated
3-4.4	Abnormal Low
4.5-9.0	Normal
9.1-10.9	Abnormal High
≥11	Adulterated

C. Dilution

Intentional Dilution

This is the most common method of attempting to beat a drug test. Patients who ingest excessive water may dilute their excreted drug concentrations below testing thresholds, resulting in false negative tests. Many “cleansing” teas and products available on the internet are based on this principle and include vitamin B to restore color so the urine will not appear to be obviously dilute. Alternatively, patients may add water from the toilet to dilute a sample. This practice can be deterred by adding bluing agent to the toilet prior to each collection.

Unintentional Dilution

Urine dilution may also be unintentional, especially in patients with specific disease states (e.g., patients with nephrogenic diabetes insipidus who cannot concentrate their urine) or other drug use (e.g., diuretics or caffeine which may increase water excretion). Patients may also simply ingest large amounts of fluids in anticipation of providing a urine specimen. If a patient is unable to void an adequate volume, it is reasonable to provide water, up to a point. General recommendations are to provide 8 ounces of water every 30 minutes; however, it is recommended not to exceed 40 ounces over 3 hours.⁷

D. Creatinine

Creatinine, in addition to providing a marker of human urine, serves as a measure of dilution; a urine creatinine concentration less than 20 mg/dL is traditionally considered dilute. However, because creatinine is a product of muscle breakdown and varies with age and muscle mass, some patients may excrete lower amounts of creatinine. Creatinine levels less than 2 mg/dL are considered non-physiologic and are a sign that the specimen has been substituted with some other fluid (e.g., water, Sprite™, etc).¹ Although it is often assumed that a patient’s daily creatinine excretion is constant, diet and lifestyle may cause creatinine concentrations to change independent of the level of dilution. The concentration of creatinine does however vary throughout the day and is also heavily dependent on water intake and hydration status. See Table 17.3 for a summary of creatinine interpretation in urine.

REFERENCES:

1. Cook JD, Caplan YH, LoDico CP, et al. The characterization of human urine for specimen validity determination in workplace drug testing: a review. *J Anal Toxicol.* 2000;24:579-88.
2. Moeller KE, Lee KC, Kissack JC. Urine drug screening: practical guide for clinicians. *Mayo Clin Proc.* 2008;83(1):66-76.
3. Black DL, Robert T, Stout P. Beating the drug test: sample manipulation, adulteration, and masking. College Athletic Trainers’ Society Newsletter. Accessed November 4, 2010.
4. Cone EJ, Caplan YH, Moser F, et al. Normalization of urinary drug concentrations with specific gravity and creatinine. *J Anal Toxicol.* 2009;33:1-7.
5. Dasgupta A. The effects of adulterants and selected ingested compounds on drugs-of-abuse testing in urine. *Am J Clin Pathol.* 2007;128:491-503.
6. Wong RC, Wong B, Chan O, et al. Use of pectin as a drug screen adulterant and its detection by Intect 7. The International Association of Forensic Toxicologists 44th International Meeting. Ljubljana, Slovenia. 2006.
7. Department of Health and Human Services. Substance Abuse and Mental Health Services Administration. Mandatory guidelines for federal workplace drug testing programs. *Fed Register.* January 23, 2017; 82(13):7920-70.

Table 17.3: *Creatinine Interpretation*

CONCENTRATION	CLASSIFICATION	POSSIBLE REASONS
>370 mg/dL	Concentrated	Strenuous exercise; dehydration; muscle damage; dietary sources
20-370 mg/dL	Normal	Typical findings; substituted sample
<20 mg/dL	Dilute	Adulteration; increased water intake
<2 mg/dL	Invalid	Specimen is not urine