precision diagnostics

Clinical Bulletin

URINE SPECIMEN VALIDITY TESTING

Specimen validity testing helps determine the integrity of a urine sample. Precision Diagnostics offers the following validity tests to assist in identifying whether a urine specimen has been adulterated or substituted.

TEST	DESCRIPTION	REFERENCE RANGE
Creatinine	Creatinine is a by-product of muscle metabolism that is continuously excreted by the kidneys. Its measurement is commonly used to evaluate kidney function. Additionally, urine creatinine can indicate whether a sample is diluted or concentrated. Values less than 20mg/dL can indicate a diluted urine specimen.[1] Scenarios yielding low creatinine and therefore dilute urine include intentional or unintentional intake of excess fluid prior to collection, the addition of fluid directly to the sample, or low muscle mass of the patient.[2] Concentrations less than or equal to 2mg/dL are not consistent with human urine, thus can be an indication of substitution.	Greater than (>) 20mg/dL
Oxidant	Oxidants are a normal constituent of human urine. Levels may be elevated by bacterial urinary tract infections and menstruation. Levels can also be elevated due to the addition of an adulterant such as Klear, UrineLuck, and bleach. Observation of specimen collection can prevent adulteration and inspection after collection can provide evidence of potential abnormal oxidant activity based on abnormal odor, color, or foreign material present.[3]	Less than (<) 200µg/mL
pH	Urine is excreted by the kidneys in a relatively narrow reference range.[1] An 'out of range' pH can result from attempted adulteration of the urine sample by adding a component such as vinegar or soap. Presence of bacteria in the urine, diet of the patient, and storage or transit time between when the urine sample is collected from the patient and when it arrives at the lab for testing can also result in an out of range pH outcome.[4]	4.7 – 9.0
Specific Gravity	Specific gravity is the measure of dissolved solids in the urine. Pure water is 1.000. A sample with a dilute specific gravity will generally also show a dilute creatinine level.[5]	1.003 – 1.035

Reference Ranges: Established per SAMHSA Workplace Guidelines[1]

Any results with 'out of range' validity components should be reviewed with caution and may suggest a need for recollection from the patient. Observed collection may be deemed necessary. If direct observation of urine collection is deemed necessary for either 'out of range' validity results or suspicion of substitution and cannot be performed, Precision offers oral fluid testing, which is easily observed in office and via telemedicine video. Common clinical interpretations of 'out of range' validity results can be found below:

RESULTS	CLINICAL INTERPRETATIONS
Creatinine ≥ 2 mg/dL and < 20 mg/dL; Specific Gravity > 1.001 and < 1.003	Dilution
Creatinine < 2 mg/dL; Specific Gravity ≤ 1.001 or ≥ 1.020	Substitution
pH < 4 or pH > 11; Oxidant ≥ 500 mcg/mL	Adulteration

Source: Medical Review Officer Manual for Federal Workplace Drug Testing Programs[1]

A Precision Diagnostics trained Clinical Support Specialist can assist with further review of your patient's results

(800) 635-6901 Option 2

References:

1. Medical Review Officer Manual for Federal Workplace Drug Testing Programs. Effective October 1, 2017; 21, 25-26, 88-94, 107-108. https://www.samhsa.gov/sites/default/files/workplace/mro-guidance-manual-oct2017_2.pdf
2. Cone, E.J., Lange, R., Darwin, W. D., (1998). In Vivo Adulteration: Excess Fluid Ingestion Causes False-Negative Marijuana and Cocaine Urine Test Results. Journal of Analytical Toxicology. 22: 460-473.
3. Urry, F.M., Komaromy-Hiller, G., Staley, B., Crockett, D. K., Kishnir, M., Nelson, G., Struempler, R. E., (1998). Nitrite Adulteration of Workplace Urine Drug-Testing Specimens I. Sources and Associated Concentrations of Nitrite in Urine and Distinction Between Natural Sources and Adulteration. Journal of Analytical Toxicology. 22(2): 89-95.
4. Cook, J. D., Strauss, K. A., Caplan, Y. H., LoDico, C. P., Bush, D. M., (2007). Urine pH: The Effects of Time and Temperature after Collection. Journal of Analytical Toxicology. 31: 486-496.
5. Cone, E.J., Caplan, Y. H., Moser, F., Robert, T., Shelby, M. K., Black, D. I., (2009). Normalization of urinary drug concentrations with specific gravity and creatinine. Journal of Analytical Toxicology. 33: 1-7.

Precision Diagnostics is a leader in clinical laboratory testing and medication adherence monitoring. Specializing in qualitative and quantitative drug testing, our innovative state-of-the art technology provides new levels of data visibility and pricing transparency.

Precision's role is to ensure each participant, from the patient to the provider and the payer, benefits from our continued commitment to the principles of value-based care and medically necessary test utilization.

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MRK-1130-4-2307