SmartNotes

Thermo Scientific Specimen Validity Tests for Drugs of Abuse Testing

Test for Urine Tampering Using Specimen Validity Tests

Urine is the most commonly used specimen for drugs of abuse testing. This is primarily because urine is readily available in large quantities and contains high concentrations of parent drugs and metabolites. It is hence, an accepted way of testing for specimen validity when monitoring for abused drugs whether within the workplace, criminal justice system (e.g. drug courts) or for compliance.[1] There is also scientific research that supports the well-established cutoffs used to determine whether drugs in the urine are above or below the cutoff. In general, human urine reflects drugs consumed within the past three days.

Despite all the benefits and ease in testing urine specimens, urine samples are extremely susceptible to tampering[1], making it tempting for participants to either use adulterants or dilute their urine. Direct observation at collection may help combat post collection tampering of urine.

Ways in which urine can be tampered with[1]

- **Pre-collection**
  - Dilution: Consuming large quantities of water or fluids prior to collection (water loading, flushing, hydrating, etc.)
  - Adulteration: Consuming products designed to “enhance” drug elimination or removal of drugs (Gold Seal™, Clean ‘n Clear™, Test-Free™, Naturally Klean™, etc.)
- **Post-collection**
  - Dilution / Substitution: Adding clean urine to the specimen or exchanging urine for such common substitutes as apple juice and tea.
  - Adulteration: Adding oxidizing agents which mask the presence of any drugs. [Nitrite (Klear™), Chromate (Urine Luck™), Iodine, Bleach, and Horse Radish Peroxidase (HRP) (Stealth™)].

What are Specimen Validity Tests?

Specimen validity tests (SVT) are methods used on a urine drug screen specimen to detect for substitution, adulteration, or dilution. Thermo Fisher Scientific provides Specimen Validity Tests for creatinine, specific gravity, oxidizing agents (e.g. nitrites) and pH.

“Adolescents who are chronic marijuana users, test positive with dip tests, even after 45 days. However, with creatinine normalization these results may test negative. It’s crucial for drug courts to test specimen validity on every specimen to ensure they are getting a robust and accurate test result.”
- J. Carter, Specialized Docket Coordinator / Probation Officer, Mount Vernon Municipal Court, Ohio

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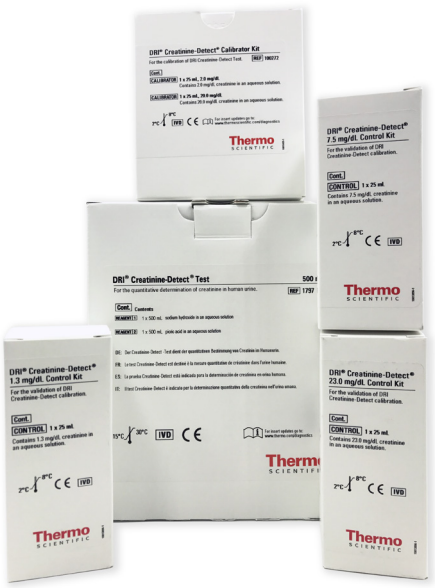
The Thermo Scientific Solution

Creatinine:
Thermo Scientific™ DRI™ Creatinine-Detect™ Test

Creatinine is a waste product produced by the body and excreted in urine at a relatively constant rate.[2] Since creatinine is released at a constant rate, fluctuations in the level of creatinine in urine, may be an indication of hydration, dilution or substitution. If no creatinine is present in the specimen, the sample submitted may be substituted. A creatinine measurement below 20 mg/dL is rare and is a reliable indicator of an intentional effort at dilution or excessive fluid consumption (in general, unusual medical or metabolic conditions do not impact creatinine levels).[2,3] A creatinine measurement below 2 mg/dL is an indication of possible substitution.[2,3]



However, drug levels can fluctuate with creatinine levels: more concentrated urine with a higher creatinine level could indicate increased drug usage, when in fact, the drug is just more concentrated. To get a true indication of drug usage, a creatinine adjustment should be performed. Creatinine normalized drug levels help monitor drug usage and assure effectivity of drug court programs. (See page 3 for more details).

Specific Gravity:
Thermo Scientific™ DRI™ Gravity-Detect™ Test

Specific gravity reflects the amount of solid particles that are dissolved in a urine sample. Normal urine has a higher specific gravity. The lower the specific gravity, the closer its consistency is to water, indicating possible dilution and/or substitution. The normal range of specific gravity for urine is 1.003 to 1.030.[2,3] If a urine sample has a specific gravity of less than 1.003, then the sample is considered dilute and a specific gravity of 1.000 is essentially water.[2,3]

Oxidizing Agents or Nitrites:
Thermo Scientific™ DRI™ General Oxidant-Detect™ Test

Oxidizing agents, when added to urine, do not show any significant change to the appearance of the urine and may not be detected by other methods such as pH, specific gravity or even creatinine concentration.[5] Several oxidizing adulterants are being sold with a claim to clear all positive drug test results.[3,6] The most commonly used oxidizing adulterants are nitrite (Klear™), chromate (Urine Luck™), iodine, bleach, and horseradish peroxidase (Stealth).[3,5,6] Urine samples containing THC (Marijuana) and adulterated with oxidants such as nitrite may produce a positive result in the initial screen by immunoassay, but they may not be confirmed by GC/MS or LC-MS/MS.[5,6,9]

pH:
Thermo Scientific™ DRI™ pH-Detect™ Specimen Validity Test

Normal urine should have a pH between 4.7 - 7.8.[4] Urine adulterated with bleach or ammonia will produce a basic pH (pH 11 or greater), while urine adulterated with lemon juice and vinegar will produce an acidic pH (pH 3 or lower).

To confirm if specimens have not been diluted and/or adulterated, it is important to validate results using more than one specimen validity test, as just one of these tests cannot capture all methods of adulteration. If any of the urine parameters are outside the specified range, there should be reason to believe that the urine sample is adulterated.

Characteristics of Normal Unadulterated Urine[2,3,4]:	
Temperature	32.5 - 37.7°C or 90.5 - 99.8°F
pH	within 4.7 - 7.8
Specific Gravity	1.003 - 1.030
Creatinine Concentration	80.0 - 200.0 mg/dL

Testing participant samples every time using multiple Specimen Validity Tests allows you to create a historical map of the expected “normal” results for a particular participant. A deviation from the normal parameters is evidence of dilution or adulteration. For problematic participants with a history of relapse, urine specimens should be routinely tracked using various specimen validity tests. Doing so allows drug courts, and workplace testing or pain management clinicians to track participants and creates a powerful tool to help confront denial. At the end, testing urine samples for specimen validity ensures for a more effective drug monitoring program.

*Creatinine Adjusted Formula[2,7]:

Drug concentrations in urine can be influenced by dilution (drinking large amounts of water) or dehydration. Creatinine levels in the urine are a good indicator of this phenomena.[2,3] The higher the creatinine, the more concentrated the urine and vice versa. Creatinine Adjustment, also referred to as Creatinine Normalization, is used to normalize the creatinine concentration of urine to an expected average creatinine concentration. Once normalized, that concentration factor is used to normalize to the drug concentration.[8] Doing so corrects for fluctuations of urine concentration and provides a more robust understanding and interpretation of the drug concentration present in the urine specimen.[8] Testing for creatinine, a commonly used specimen validity test, provides trend and historical data on average levels for specific individuals. This provides a more accurate assessment of drug concentration in urine due to sample dilution or substitution.[8] We’ve used the following formula to determine Creatinine Adjusted THC levels in the case studies discussed next.

(Directly Measured Drug Concentration (ng/mL) **x** Average Urine Creatinine Concentration (100 mg/dL)) **÷** Directly Measured Creatinine Concentration (mg/dL) **=** Creatinine Normalized Drug Concentration (ng/mL)

Case Study

Mark and Mary are participants at their local state drug court and regularly come in for testing based on their testing schedule. The in-house drug court lab performs various tests based on their needs and the needs of their participants. The in-house lab tests Mark and Mary for THC and creatinine regularly on every visit. Below we share two ways to interpret data (semi-quantitative values) collected from Mark and Mary:

Scenario 1:

Mark is tested four different times and his THC concentrations are indicated in table 1 and plotted in graph 1. Mark's THC test results indicate that his THC concentrations are rising over time (blue line). However, when the results are adjusted for creatinine concentration, we observe that Mark's THC levels are actually decreasing over time (yellow line).

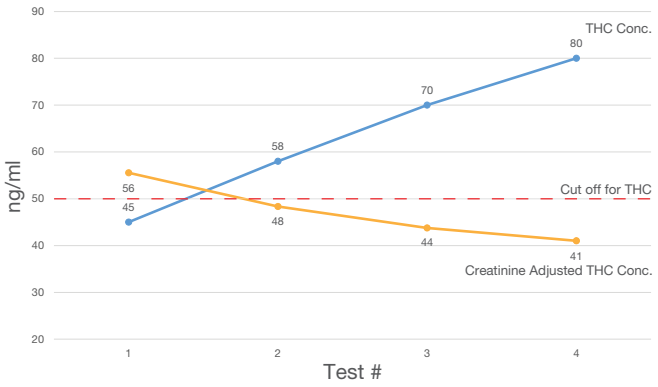
Explanation:

Consumption of fluids can play a critical role in determining urine drug concentration. Although within normal expected ranges for creatinine concentration, we observe that Mark's creatinine levels have increased significantly over time. Such an increase means Mark's urine is concentrated and hence his recorded THC concentration is high as well. When his drug levels are normalized to the creatinine levels, his THC drug test results are below the cutoff, suggesting that he was not taking the drug.

Table 1

Test #	THC Concentration (ng/mL)	Creatinine Concentration (mg/dL)	Creatinine Normalized THC Concentration (ng/mL)*
1	45	81	56
2	58	120	48
3	70	160	44
4	80	195	41

Graph 1



Scenario 2:

Mary is tested four different times and her drug results are summarized in table 2 and plotted in graph 2. Mary's THC test results indicate that her THC concentrations are decreasing over time (blue line). However, when the results are adjusted for her creatinine concentration, we observe that Mary's THC levels are actually increasing over time (yellow line).

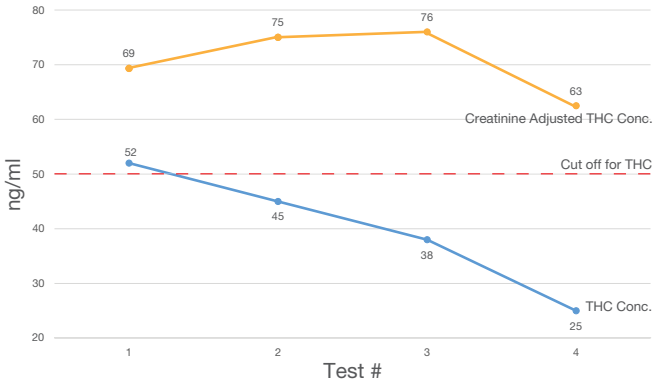
Explanation:

Urine dilution by excessive fluid consumption or substitution can play a major role in determining urine drug concentration. Although within close to normal ranges for Mary's creatinine concentration, we observe that her creatinine levels have decreased over time. Such a decrease means Mary's urine is dilute and hence her recorded THC concentration is low as well. In Mary's case, one can suspect continued use of marijuana, as her creatinine adjusted THC concentration is above the cutoff.

Table 2

Test #	THC Concentration (ng/mL)	Creatinine Concentration (mg/dL)	Creatinine Normalized THC Concentration (ng/mL)*
1	52	75	69
2	45	60	75
3	38	50	76
4	25	40	63

Graph 2



Product Information

DRI™ Creatinine-Detect™ Specimen Validity Test

Part Number	Description	Cut-off Level	Kit Size
Test			
1797	DRI Creatinine-Detect Specimen Validity Test		500 mL
10015638	DRI Indiko™ Creatinine-Detect Specimen Validity Test		3 x 18 mL
Calibrators			
100272	Creatinine-Detect Calibrator Set	2.0 & 20	2 x 25 mL
Controls			
100273	Creatinine 1.3 Control	1.3mg/dL	25 mL
100274	Creatinine 7.5 Control	7.5mg/dL	25 mL
100275	Creatinine 23.0 Control	23mg/dL	25 mL

DRI™ Gravity-Detect™ Specimen Validity Test

Part Number	Description	Cut-off Level	Kit Size
Test			
1194	DRI Gravity-Detect Specimen Validity Test		2 x 500 mL
10018532	DRI Indiko™ Gravity-Detect Specimen Validity Test		6 x 18 mL
Calibrators			
1754	Low Gravity Calibrator	1.010	2 x 25 mL
1755	High Gravity Calibrator	1.025	25 mL
Controls			
1756	Level 1 Gravity Control	1.015	25 mL
1757	Level 2 Gravity Control	1.030	25 mL

DRI™ General Oxidant-Detect™ Specimen Validity Test

Part Number	Description	Cut-off Level	Kit Size
Test			
10009958	DRI General Oxidant-Detect Specimen Validity Test		2 x 500 mL
10018528	DRI Indiko™ General Oxidant-Detect Specimen Validity Test		6 x 18 mL
Calibrators			
10009971	General Oxidant-Detect Calibrator Set	0 & 200	2 x 25 mL
Controls			
10009972	General Oxidant-Detect Control Set	100 & 300	2 x 25 mL

DRI™ pH-Detect™ Specimen Validity Test

Part Number	Description	pH Level	Kit Size
Test			
100054	DRI pH-Detect Specimen Validity Test		2 x 500 mL
10015654	DRI Indiko™ pH-Detect Specimen Validity Test		6 x 18 mL
Calibrators			
100283	pH Calibrator Set	3.0 & 11.0	2 x 25 mL
10024403	pH Calibrator Set*	4.0 & 11.0	2 x 25 mL
Controls			
100282	pH 3.6 Control	3.6	25 mL
10024083	pH 4.5 Control*	4.5	25 mL
100284	pH 7.0 Control	7.0	25 mL
100285	pH 10.0 Control	10	25 mL
100281	pH 11.5 Control	11.5	25 mL

* Meets new SAMHSA Guidelines, Effective October 1st 2017.

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11. Thermo Scientific DRI Creatinine-Detect Specimen Validity Test, Package Insert.
12. Thermo Scientific DRI Gravity-Detect Specimen Validity Test, Package Insert.

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