Specimen Validity Test

A rapid screening test for the simultaneous detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, and Oxidants in human urine.

For forensic use only.

INTENDED USE

Specimen Validity Test is a semi-quantitative, color comparison screen for the detection of creatinine, nitrite, glutaraldehyde, pH, specific gravity and oxidants in human urine.
This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a laboratory for confirmation.

SUMMARY

Each of the plastic strips contains six (6) chemically treated reagent pads. One (1) minute following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart on the canister. The color comparison provides a semi-quantitative screen for creatinine, nitrite, glutaraldehyde, pH, specific gravity and oxidants in human urine which can help assess the integrity of the urine sample.

What is adulteration?

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/ or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.
One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as creatinine, pH, and specific gravity and to detect thepresence of glutaradehyde, nitrite and oxidants in urine.

Creatinine is a waste product of creatine; an amino acid contained in muscle tissue and found in urine[1,2] .A person may attempt to foil a test by drinking excessive amounts of diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (<5mg/dl) is indicative of a specimen not consistent with human urine.

Specific gravity tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Nitrite tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.[3,4] Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[3] Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

pH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

Oxidants tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Normal human urine should not contain oxidants.

PRINCIPLE

The test is based on the color derived from the chemical reaction between the chemical reagent on each test pad and the urine sample.

REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Creatinine	0.04%	99.96%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.75%
Oxidants	0.36%	99.64%

PRECAUTIONS

For forensic use only. Do not use after the expiration date.
The adulteration strips should remain in the sealed canister until use.
All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
The used test strip should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed canister at 2-30°C. The test strips must remain sealed in the canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date period. Avoid direct exposure to sunlight. Once the canister has been opened, the remaining strips ate stable for up to 3 months.Stability may be reduced in high humidity conditions.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Test urine as soon as possible after collection.

Specimen Storage

For best results, test specimens immediately following collection. Storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated (2-8°C) prior to testing.

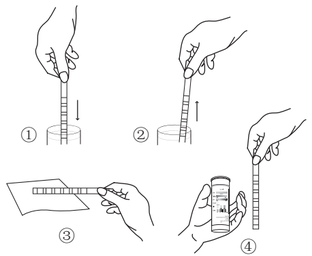
MATERIALS

Materials Provided
• Each canister contains 25 Strips
• Package insert
Materials Required But Not Provided
• Timer

DIRECTIONS FOR USE

Allow the adulteration strip to equilibrate to room temperature (15-30°C) prior to testing.
1. Remove the strip(s) from the canister and recap tightly. Dip test strip into the urine specimen and remove immediately.
2. Blot the test gently on its side to remove excess urine. NOTE: It is important to blot the test strip for consistent results.
3. Read results in one (1) minute by comparing each pad with the color chart printed on the canister. **Do not interpret test results after 4 minutes.**
4. If the test indicates adulteration, refer to your Drug Free Policy for guidelines on handling adulterated specimens.

INTERPRETATION OF RESULTS



(Please refer to the illustration above)
Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the canister. No instrumentation is required.

Quality Control

Control standards are not supplied with this kit. However, it is recommended that positive and negative specimens or controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

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LIMITATIONS

1. The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
2. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.
3. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
4. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
5. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
6. Oxidants: Normal human urine should not contain oxidants. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidant pad.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using Specimen Validity Tests and other commercially available adulteration tests. Testing was performed on 120 clinical samples per adulteration test.

%Agreement with commercial kit

	NIT	GLU	OX	CRE	pH	S.G.
Normal Agreement	100%	100%	98.3%	100%	100%	98.3%
Abnormal Agreement	98.3%	100%	100%	100%	100%	100%
Total Results	99.2%	100%	99.2%	100%	100%	99.2%

Analytical Sensitivity

A urine sample was adulterated at concentrations listed. The results are summarized below:

Concentration Range	n	NIT	
		Normal	Abnormal
0mg/dl	10	10	0
0.5mg/dl	10	10	0
20mg/dl	10	0	10

Concentration Range	n	GLU	
		Normal	Abnormal
0%	10	10	0
2%	10	0	10

Concentration Range	n	OX	
		Normal	Abnormal
0mg/dl	10	10	0
20mg/dl	10	0	10

Concentration Range	n	CRE	
		Normal	Abnormal
0mg/dl	10	0	10
10mg/dl	10	0	10
20mg/dl	10	10	0
100mg/dl	10	10	0

Concentration Range	n	pH	
		Normal	Abnormal
pH=2.0	10	0	10
pH=7.0	10	10	0
pH=12.0	10	0	10

Concentration Range	n	S.G.	
		Normal	Abnormal
1.000	10	0	10
1.005	10	10	0
1.020	10	10	0
1.035	10	0	10

BIBLIOGRAPHY OF SUGGESTED READING

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4. Hardman J, Limbird LE (Eds). Goodman & Gilman ’s The Pharmacological Basis of Therapeutics, 10th Ed. , McGraw-Hill Publishing. 2001, 1010.

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