Urine Adulteration Test Dipsticks (Urine)
Package Insert

For rapid, semi-quantitative detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity and Oxidants/Pyridinium Chlorochromate in human urine.
For forensic use only.

【INTENDED USE】

The Urine Adulteration Test Dipsticks (Urine) are a semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate 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 Dipsticks contains six chemically treated reagent pads. One minute following the activation of the reagent pads by the urine specimen, 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, Oxidants and Pyridinium Chlorochromate in human urine, which can help assess the integrity of the urine specimen.

【PRINCIPLE AND EXPECTED VALUES】

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 the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

Creatinine (CRE): Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a drug test by drinking excessive amounts of water or 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 to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with human urine.

Nitrite (NIT): Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH.[2] Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde (GLU): Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can 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 indicates 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 that the specimen has been altered.

Specific Gravity (SG): Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.[3] Normal human urine should not contain Oxidants or PCC.

【PRINCIPLE】

The test is based on the chemical reaction between the chemical reagent on each test pad and the urine specimen, which effects a color change in the test pad.

【REAGENTS】

Adulteration Pad	Reactive Indicator	Buffer and Non-reactive Ingredient
Creatinine	0.04%	99.95%
Nitrite	0.07%	99.94%
Glutaraldehyde	0.02%	99.97%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.78%
Oxidants / PCC	0.36%	99.70%

【PRECAUTIONS】

- For forensic use only. Do not use after the expiration date.
- The Dipstick should remain in the closed canister until use.
- Do not touch the reagent areas of the Dipstick.
- Discard any discolored Dipsticks that may have deteriorated.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used Dipstick should be discarded according to local regulations after testing.

【STORAGE AND STABILITY】

Store as packaged in the sealed canister at room temperature or refrigerated (2-30°C). The test Dipsticks must remain sealed in the canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date. Keep out of direct sunlight.

Note: Once the canister has been opened, the remaining test Dipsticks are 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 (15-30°C) or 4 hours refrigerated (2-8°C) prior to testing.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Color Card
- Package Insert

Materials Required But Not Provided

- Specimen collection containers
- Timer

【DIRECTIONS FOR USE】

Allow the Dipstick, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the Dipstick from the closed canister and use it within one hour. Immediately close the canister tightly after removing the required number of Dipstick(s). Completely immerse the reagent areas of the Dipstick in fresh, well-mixed urine and immediately remove the Dipstick out of the urine specimen to avoid dissolving the reagents. See illustration 1 below.
2. Hold the Dipstick in a horizontal position and immediately bring the edge of the Dipstick into contact with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas and/or soiling hands with urine. See illustration 2 below.
3. **Read results in 1 minute** by comparing the reagent areas to the corresponding color blocks on the Color Card. Hold the Dipstick close to the color blocks and match carefully. **Do not interpret results after 4 minutes.**

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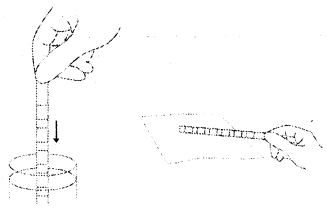

【INTERPRETATION OF RESULTS】

Results are obtained by visually comparing the reacted color blocks on the test Dipstick to the printed color blocks on the canister.

【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.

【LIMITATIONS】

The Urine Adulteration Test Dipsticks (Urine) 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.[4]

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.[5]

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.

Glutaraldehyde: 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.

Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

【BIBLOGRAPHY】

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