Adulteration Test Strip (Urine)
Package Insert

English

Instruction Sheet for testing of any combination of the following items: OXI(or PCC)/SG/pH/GLUT/NIT/CRE

【INTENDED USE】

The Adulteration Test Strip is a semi-quantitative, color comparison screen for the detection of creatinine, nitrite, glutaraldehyde, pH, specific gravity, and oxidants/pyridinium chlorochromate (PCC) 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.

【S.V.T SUMMARY】

The strips contain chemically treated reagent pads. 3-5 minutes 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 card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridiniumchlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help to 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 pH, specific gravity and creatinine and to detect the presence of oxidants/PCC, nitrites or glutaraldehyde in urine.

- **Oxidants/PCC (Pyridiniumchlorochromate)** tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridiniumchlorochromate (sold under the brand name UrineLuck) is a commonly used adulterant.8 Normal human urine should not contain oxidants of PCC.
- **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.
- **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.
- **Nitrite** tests for commonly used commercial adulterants such as Klear and Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.9 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 results by disrupting the enzyme used in some immunoassay tests.9 Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- **Creatinine** is a waste product of creatine; an amino-acid contained in muscle tissue and found in urine.[1] A person may attempt to foil a 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 in an attempt to circumvent drug testing. Low Creatinine and specific gravity levels may indicate dilute urine. The absence of Creatinine (<5 mg/dl) is indicative of a specimen not consistent with human urine.

【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.

【S.V.T REAGENTS】

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Creatinine	0.05%	99.95%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
pH	0.06%	99.94%
Specific Gravity	0.25%	99.75%
Oxidants / PCC	0.36%	99.64%

【PRECAUTIONS】

- Specimen Validity Tests are not considered medical devices as defined in the Food Drug & Cosmetic Act; therefore, they do not require FDA clearance. 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 and sample 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. Avoid direct exposure to sunlight. Once the canister has been opened, the remaining strips 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 or 4 hours refrigerated (2-8°C) prior to testing.

【MATERIALS】

Materials Provided

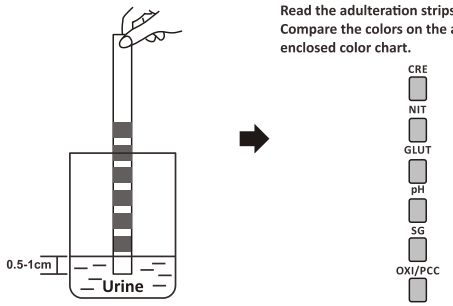
- Adulteration Color Chart (when applicable)
- Adulteration Test Strips
- Package insert

Materials Required But Not Provided

- Timer
- Specimen collection container

【INSTRUCTIONS】

1. Urinate into a clean, dry cup or container.
2. Bring the canister to room temperature before opening it. Remove the test strip from the sealed canister and use it within one hour.
3. Hold the test strip and immerse it vertically into the sample for at least 10-15 seconds. (Dip the test strip into the liquid level 0.5-1cm).
4. Place the test strip on a non-absorbent flat surface and start the timer. Read the adulteration strips between 3-5 minutes compare the colors on the adulteration pads to the enclosed color chart.



Note: The above illustration is for the user's reference only. The actual appearance of the test will depend on the combinations you order.

【S.V.T/ ADULTERATION INTERPRETATION】

(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 color chart.

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.

【S.V.T/ ADULTERATION LIMITATIONS】

1. The adulteration tests included with the 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. **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.
3. **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. **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.
5. **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.
6. **Creatinine:** Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

【BIBLIOGRAPHY】

1. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.

Index of Symbols

	Consult Instructionfor use	Σ	Tests per kit	EC REP	Authorized Representative within the European Community
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2–30 °C	LOT	Lot Number	REF	Catalog Number
	Do not use if package is damaged	CE	CE Marking		Manufacturer
	Importer		Distributor	UDI	Unique Device Identification

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

CE

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Importer and Distributor: Noviral Sweden AB.
Imported by: Noviral Sweden AB.

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