

SureStep Urine Drug Test Cup

6 Drugs + 6 Adulterants



INTENDED USE & SUMMARY

Urine based screen tests for multiple drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for multiple drugs of abuse. The SureStep Urine Drug Test Cup is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments.

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	300
Benzodiazepines (BZO)	Oxazepam	200
Cocaine (COC)	Benzoyllecgonine	300
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50
Methamphetamine (MET)	d-Methamphetamine	300
Morphine (MOP)	Morphine	300

This test will detect other related compounds, please refer to the Analytical Specificity table in the package insert. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when not-negative results are used.

SPECIMEN VALIDITY TEST (S.V.T.) SUMMARY

Each S.V.T. strip contains chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colours that appear on the pads can be compared with the printed colour chart card. The colour comparison provides a semi-quantitative screen for oxidants, specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

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 and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

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- **Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant. Normal human urine should not contain oxidants or 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 or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH. 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. 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.

PRECAUTIONS

- For medical and other professional in vitro diagnostic use only
- Do not use after the expiration date.
- The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test cup is stable through the expiration date printed on the sealed pouch. The test cup must remain in the sealed pouch until use. DO NOT FREEZE.

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MATERIALS

Materials Provided

- Cups with multi-drug panels with activation key
- Security seal labels
- SVT/Adulterant colour chart

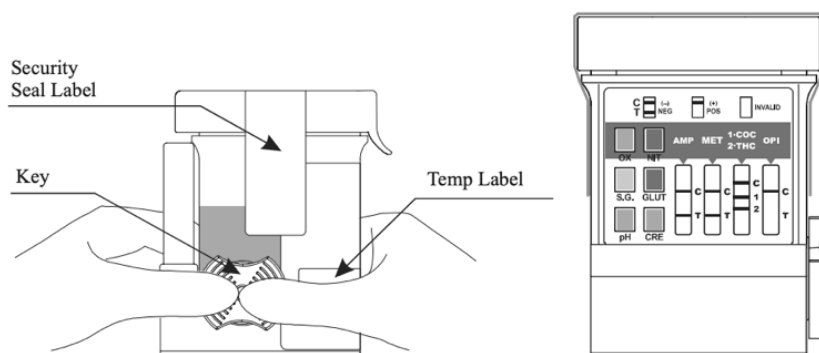
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
2. Remove the key by twisting it from the centre of the cup cap.
3. Collect specimen in the cup and secure the cap tightly by pressing down on the pull tab until an audible click is heard.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green colour will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 33-38°C.
5. Date and initial the security seal label then place it over the cap.
6. Place the cup on a flat surface and push the key into the socket of the cup to initiate the test. Start the timer.
7. Remove the peel off label covering the test results. Read the adulteration strip between 3 and 5 minutes.
8. Compare the colours on the adulteration strip to the enclosed colour chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen
9. Read the drug strip results at 5 minutes. The drug strip results remain stable for up to sixty minutes.



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INTERPRETATION OF RESULTS



- **NEGATIVE:*** A coloured line in the control line region (C) and a coloured line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug. *NOTE: The shade of colour in the test region (T) may vary, but it should be considered negative whenever there is even a faint coloured line.
- **POSITIVE / NOT-NEGATIVE:** A coloured line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.
- **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test cup. If the problem persists, discontinue using the lot immediately and contact Drug Test Warehouse.

SVT/ADULTERANT INTERPRETATION (Please refer to the colour chart)

Semi-quantitative results are obtained by visually comparing the reacted colour blocks on the strip to the printed colour blocks on the colour chart. No instrumentation is required.

QUALITY CONTROL

A procedural control is included in the test. A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The SureStep Urine Drug Test Cup provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

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2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

- 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.
- **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.
- **Specific Gravity:** Elevated levels of protein in urine may cause abnormally high specific gravity values.
- **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:** 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.
- **Creatinine:** Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

S.V.T. / ADULTERANT COLOUR CHART

- OX PCC Oxidants / Pyridinium chlorochromate
- NIT Nitrite
- S.G. Specific gravity
- GLUT Glutaraldehyde
- pH pH
- CRE Creatinine