One Step Multi-Drug Urine Test T-Cup (+Adulteration)

One Step Multi-Drug Urine Test T-Cup (+Adulteration) offers any combination from 2 to 15 drugs of abuse tests for 15 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZD), Cocaine (COC), Marijuana (THC), Methadone (MDT), Methamphetamine (MET), Methylenedioxymethamphetamine (MDMA), Morphine (MOP), Opiate (OPI 2000), Phenacyclidine (PCP), Tricyclic Antidepressants (TCA), Buprenorphine (BUP), Oxycodone (OXY), Propoxyphene (PPX). This drug test cup also provides one or more of the following adulterant controls: Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants, Bleach and Pyridinium Chlorochromate, to evaluate specimens for adulteration prior to drugs of abuse urine testing.

This package insert applies to all combinations of multi-drug tests panel with integrated cup. Therefore, some information on the performance characteristics of the product may not be relevant to your test. We refer to the labels on the packaging and the prints on the test strip to identify which drugs are included in your test.*

A rapid one step test for the qualitative detection of drug of abuse and their principal metabolites in human urine at specified cut off level.

For healthcare professional use only. For in vitro diagnostic use.

INTENDED USE

One Step Multi-Drug Urine Test T-Cup(+Adulteration) is rapid urine screening test. The test is a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their metabolites in human urine at the following cut off concentrations:

<table>
<thead>
<tr>
<th>Test</th>
<th>Calibrator</th>
<th>Cut off (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>Amphetamine</td>
<td>1,000</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Secobarbital</td>
<td>300</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>Oxazepam</td>
<td>300</td>
</tr>
<tr>
<td>Cocaine</td>
<td>Benzoylcochine</td>
<td>300</td>
</tr>
<tr>
<td>Marijuana</td>
<td>Marijuana</td>
<td>50</td>
</tr>
<tr>
<td>Methadone</td>
<td>Methadone</td>
<td>300</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>Methamphetamine</td>
<td>1,000</td>
</tr>
<tr>
<td>Methyleneoxymethamphetamine</td>
<td>3,4-Methylenedioxymethamphetamine HCl(MDMA)</td>
<td>500</td>
</tr>
<tr>
<td>Morphine</td>
<td>Morphine</td>
<td>300</td>
</tr>
<tr>
<td>Opiate</td>
<td>Opine</td>
<td>2000</td>
</tr>
<tr>
<td>Phenacyclidine</td>
<td>Phenacyclidine</td>
<td>25</td>
</tr>
<tr>
<td>Tricyclic Antidepressants</td>
<td>Norpineylvine</td>
<td>1,000</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Buprenorphine</td>
<td>10</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Oxycodone</td>
<td>100</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>Propoxyphene</td>
<td>300</td>
</tr>
</tbody>
</table>

This assay provides only a preliminary test result. A more specific alternative 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 preliminary results are positive.

PRINCIPLE

DRUG TESTS

One Step Multi-Drug Urine Test T-Cup (+Adulteration) is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites. When testing, the urine is absorbed upward by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff, the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedure control, a colored line will appear on the control region (C), if the test has been performed properly.

One Step Multi-Drug Urine Test T-Cup (+Adulteration) results may be useful for assessing the integrity of the urine sample prior to drugs-of-abuse testing. Test detects whether the sample contains adulterants including nitrite, glutaraldehyde, bleach, pyridinium chlorochromate and other oxidizing agents. Test can also assess whether the sample is possibly contaminated by acidic (vinaigre) or basic (ammonia solution) adulterants as indicated by the pH test.

ADULTERATION CONTROL

In general, all seven tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the color chart.

Creatinine: Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

Glutaraldehyde: Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Nitrite: Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink/red/purple color.

Oxidants: Testing for presence of oxidizing reagents. In this reaction, a color indicator reacts with oxidants such as hydrogen peroxide, ferricyanide, persulfate, or pyridinium chloro-hrome to form a blue color complex. Other colors may indicate the presence of other oxidants.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Specific Gravity: Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

Bleach: Testing for the presence of bleach in urine. In this test, the presence of bleach forms a blue-green color complex.

Pyridinium Chlorochromate: Testing for the presence of chromate in urine. In this test, the presence of chromate forms a blue-green color complex.

ALCOHOL

Alcohol Test is intended for use to detect the presence of alcohol in urine greater than 0.04%. Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since the urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine was set at 0.04%. Normally, it will take at least 30 minutes for the alcohol to be detected in saliva, blood and urine after drinking.

WARNINGS AND PRECAUTIONS

This kit is for external use only. Do not swallow.
Discard after first use. The test cannot be used more than once.
Do not use test kit beyond expiration date.
Do not use the kit if the pouch is punctured or not well sealed.
Keep out of the reach of children.

STORAGE AND STABILITY

Store at 4 ºC ~ 30 ºC up to the expiration date.
Keep away from sunlight, moisture and heat.
DO NOT FREEZE.

MATERIAL

One pouch containing a test T-cup and a desiccant.
Package insert
A color chart for the adulteration strips
Timer

SPECIMEN COLLECTION AND PREPARATION

Wash your hands with soap and warm water. Open the sealed pouch and remove the urine test T-cup.
The donors collect their urine samples. Open the cap of the cup and urinate directly into the test cup. The sample volume should be higher than...
the minimum urine level. Re-cap the cup.

### TEST PROCEDURE

1. After the urine has been collected, re-cap the cup and place the test T-cup on a flat surface.
2. Start the timer.
3. Peel the label from right to left and read the result. For the adulteration strip(s), compare each reagent area to its corresponding color blocks on the color chart and read at the times specified. Proper read time is critical for optimal results. If the results indicate adulteration, do not read the drug test results.
4. Read the results for the drugs at 5 minutes. Do not read after 5 minutes.

### DRUGS

**Positive (+)**
A rose-pink band is visible in each control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

**Negative (-)**
A rose-pink band is visible in each control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is zero or below the detection limit of the test.

**Invalid**
If a color band is not visible in each of the control region or a color band is only visible in each of the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

**Note:** There is no meaning attributed to line color intensity or width.

### QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials. Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

### LIMITATIONS

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyses. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
4. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
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 result does not distinguish between drugs of abuse and certain medicines.
7. A positive result might be obtained from certain foods or food supplements.

### PERFORMANCE CHARACTERISTICS

<table>
<thead>
<tr>
<th>Drug</th>
<th>Test Result</th>
<th>Less than the cutoff concentration by GC/MS analysis</th>
<th>Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)</th>
<th>Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)</th>
<th>High Positive (greater than 50% above the cutoff concentration)</th>
<th>%Agreement with GC/MS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viewer A</td>
<td>+ 0</td>
<td>- 4</td>
<td>- 11</td>
<td>- 29</td>
<td>- 100</td>
<td></td>
</tr>
<tr>
<td>Viewer B</td>
<td>+ 0</td>
<td>- 8</td>
<td>- 0</td>
<td>- 0</td>
<td>- 90</td>
<td></td>
</tr>
<tr>
<td>Viewer C</td>
<td>+ 0</td>
<td>- 28</td>
<td>- 11</td>
<td>- 29</td>
<td>- 97</td>
<td></td>
</tr>
</tbody>
</table>

### INTERPRATATION OF RESULTS

For each test, the results were read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:
To investigate the precision and sensitivity, for AMP, BAR, BZO, COC, THC, MTD, MET, MDMA, MOP, OPI, PCP and TCA, each drug samples were analyzed at the following concentrations: - 50% cutoff, - 25% cutoff, cutoff, + 25% cutoff and + 50% cutoff. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots of the corresponding the drug of abuse test. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot of the corresponding the drug of abuse test. For OXY, BUP and PPX, precision and sensitivity was assessed with three lots tested by three individuals over five consecutive days. In the study, seven separate normal urine samples were spiked with each drug to the following concentrations: Zero, -50% cutoff, -25% cutoff, +25% cutoff and +100% cutoff. Level of the each drug for these samples was confirmed by GC/MS. Then each sample was divided into 75 aliquots that were further divided into 3 sets of 25 (one set for each lot). Each of the three operators tested 5 aliquots at each concentration for each lot per day. A total of 75 determinations by each operator, at each concentration, were made.

To test the specificity of the test, the test device was used to test various drugs, drug metabolites and other components that are likely to be present in urine. All the components were added to drug-free normal human urine. These concentrations (ng/mL) below also represent the limits of detection for the specified drugs or metabolites.
### Cross-Reactivity

Considering the complexity of clinical urine specimens and the possibility that various urine specimens contain potentially interfering substances, we simulated above situations by adding the potentially interfering substances to a certain concentration as specimen. The following components show no cross-reactivity when tested with One Step Multi-Drug Urine Test T-Cup(+Adulteration) at a concentration of 100 μg/ml.

<table>
<thead>
<tr>
<th>Non Cross-Reacting Compounds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetophenetidin</td>
</tr>
<tr>
<td>Butabarbital</td>
</tr>
<tr>
<td>Amphetamine</td>
</tr>
<tr>
<td>Butalbital</td>
</tr>
<tr>
<td>Phenobarbital</td>
</tr>
<tr>
<td>Phencyclidine</td>
</tr>
<tr>
<td>Phenelzine</td>
</tr>
<tr>
<td>Prazepam</td>
</tr>
<tr>
<td>Flunitrazepam</td>
</tr>
<tr>
<td>Diazepam</td>
</tr>
<tr>
<td>Flunitrazepam</td>
</tr>
<tr>
<td>Diazepam</td>
</tr>
<tr>
<td>Flunitrazepam</td>
</tr>
<tr>
<td>Diazepam</td>
</tr>
</tbody>
</table>

From the results above, it is clear that One Step Multi-Drug Urine Test T-Cup(+Adulteration) resists well against interference from these substances.

### Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with each drug at 50% below and 50% above cutoff level. One Step Multi-Drug Urine Test T-Cup(+Adulteration) was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

### Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with morphine at 50% below and 50% above cutoff levels. One Step Multi-Drug Urine Test T-Cup(+Adulteration) was tested in duplicate. The result demonstrate that varying ranges of PH do not interfere with the performance of the test.

### BIBLIOGRAPHY OF SUGGESTED READING


### MEANING OF SYMBOLS ON PACKAGE

- **Keep away from sunlight**
- **Store between 4°C and 30°C**
- **Keep dry**
- **Do not re-use**

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