**One Step Ketamine Test Dip Card (Urine)**

**Package Insert**

A rapid, one step test for the qualitative detection of Ketamine-Metabolites in human urine. For healthcare professionals including professionals at point of care sites. For forensic use only.

**INDICATIONS**

The One Step Ketamine Test Dip Card is a lateral flow chromatographic immunoassay for the detection of Ketamine in urine.

- **Test dip card**
- **Desiccant**
- **Package insert**
- **Specimen collection container**
- **Timer**
- **External controls**

**DIRECTIONS FOR USE**

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

1. Remove the test device from the foil pouch.
2. Remove the cap from the test device. Label the device with patient or control identifications.
3. Immerse the absorptive tip into the urine sample for 10-15 seconds. Urine sample should not touch the plastic support line.
4. Replace the cap over the absorptive tip and lay the device flatly on a non-absorbent clean surface.
5. Read results at 5 minutes.

**DO NOT INTERPRET RESULT AFTER 10 MINUTES.**

**INTERPRETATION OF RESULTS**

(Please refer to the previous illustration)

**NEGATIVE:** Two lines appear. One color line should be in the control region (C), and another apparent red or purple line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

**NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative if it is below the discernible level.

**POSITIVE:** One color line appears in the control region (C). No line appears in the test region (T).

This positive result indicates that the drug concentration is above the detectable level.

**INTERMEDIATE result** indicates that the test device was exposed to an insufficient specimen volume or incorrect procedural technique. If the problem persists, discontinue use immediately and contact your supplier.

**QUALITY CONTROL**

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**PRECAUTIONS**

- For healthcare professionals including professionals at point of care sites.
- For professional in vitro diagnostic only. Not for use after the expiration date.
- The test Dip Card should be used within the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**MATERIALS PROVIDED**

- Test dip card
- Desiccant
- Package insert
- Specimen collection container
- Timer
- External controls

**PERFORMANCE CHARACTERISTICS**

**Analytical Specificity**

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by One Step Ketamine Test Dip Card at a read time of 5 minutes.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Percent of Cut-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketamine (KET)</td>
<td>1500</td>
<td>-95%</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>1000</td>
<td>-95%</td>
</tr>
<tr>
<td>Digoxin</td>
<td>500</td>
<td>-95%</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>500</td>
<td>-95%</td>
</tr>
<tr>
<td>Metabolite</td>
<td>500</td>
<td>-95%</td>
</tr>
<tr>
<td>Propoxyphene</td>
<td>500</td>
<td>-95%</td>
</tr>
<tr>
<td>4-Hydroxypropoxyphene</td>
<td>500</td>
<td>-95%</td>
</tr>
</tbody>
</table>

**Effect of Urinary Specific Gravity**

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.030) were spiked with drug-free urine and 50% above and below respective control urine. The One Step Ketamine Test Dip Card was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that variations of urinary specific gravity do not affect the test results.

**Effect of Urinary pH**

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0, and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with The One Step Ketamine Test Dip Card. The results demonstrate that variations of urine pH do not influence the performance of the test.

**Cross-Reactivity**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug-free positive urine containing Ketamine. The following compounds showed no cross-reactivity when tested with the One Step Ketamine Test Dip Card at concentrations of 100 ng/mL.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cross-Reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>Trace</td>
</tr>
<tr>
<td>Codeine</td>
<td>Trace</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>Trace</td>
</tr>
<tr>
<td>Labetalol</td>
<td>Trace</td>
</tr>
<tr>
<td>L-carnitine</td>
<td>Trace</td>
</tr>
<tr>
<td>N-Acetylprocaine</td>
<td>Trace</td>
</tr>
<tr>
<td>Tryptoquinine</td>
<td>Trace</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>Trace</td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td>Trace</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Trace</td>
</tr>
<tr>
<td>Difenidone</td>
<td>Trace</td>
</tr>
<tr>
<td>Amphetamine</td>
<td>Trace</td>
</tr>
<tr>
<td>Methylphenidate</td>
<td>Trace</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>Trace</td>
</tr>
<tr>
<td>Difenidone</td>
<td>Trace</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>Trace</td>
</tr>
</tbody>
</table>

**Non-Cross-Reacting Compounds**

- *Parent compound only.
- Amphetamine
- Codeine
- Dihydrocodeine
- Labetalol
- L-carnitine
- N-Acetylprocaine
- Tryptoquinine
- Acetaminophen
- Diphenhydramine
- Amoxicillin
- Difenidone
- Amphetamine
- Methylphenidate
- Acetaminophen
- Difenidone
- Acetaminophen

**SPECIMEN COLLECTION AND PREPARATION**

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**Urine Assay**

The urine specimen must be collected in a clean and dry test container. Urine collected at any time of the day may be used.

**Specimen Storage**

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48-hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

**LIMITATIONS**

1. The One Step Ketamine Test Dip Card provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility of 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 and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
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. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.
Aspartame
Ethyl-p-aminobenzoate
Naproxen
Tetrahydrocortisone,

Atropine
β-Estradiol
Niasamide
3-Acetoic

Benzoic acid
Estriol-3-sulfate
Nifedipine
Tetrahydrocortisone

Benzonic acid
Erythromycin
Norethindrone
Tetrahydrozoline

Bilirubin
Fenoprofen
Nicotinamide
Thiamine

β-D-Brompheniramine
Furosémide
d,β-Octopamine
Theobromine

Caffeine
Gelatinic acid
Osatic acid
d,β-Tyrosine

Carnitibol
Hemoglobin
Oxalacid
Tobutamidé

Chloramphenicol
Chloroform
Hydralazine
Oxymetazoline
Triamterene

Chloroformic acid
Hydrocortisone
Oxalic acid
Tyramine

Chlorothiazide
β-Hydroxyhippuric acid
Papaverine
Trihexyphenidyl

d,β-Chloroformic acid
β-Hydroxytyramine
Pentazocine
Triamcylol

Cholesterol
d,β-Isopropyl
Hydroxytyramine
Propriodine
Uracil

Clonidine
Hydroxybenzaldehyde
Isoniazid
Verapamil

CNS
Tolbutamide
Triamcinol
Zolpidem