The configurations of the DOA Panel Test Cup come with any of the combination of the above listed drug analytes. 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 test result. Glu chromatophotometry by enzymatic (Glu-ATP) is the preferred analytical method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are reported.

**SUMMARY**

The One Step Drug Screen Test Cup is a rapid urine screening test that can be performed where immediacy is required. The test is based on the principle of competitive inhibition. Opiate or Tricyclic antidepressant (TCA) are taken orally or sometimes by injection. TCA are the Tricyclic antidepressants, a capacity to increase the norepinephrine and dopamine levels in the brain. Methadone is the most commonly used methadone, and the major effects of methadone are delirium tremens, glutathione peroxidase, and even convulsions. The effects of Methadone generally last 2-4 hours and the drug has a half-life of 2-4 hours in the body. Methadone can be detected in the urine for up to ten days. The main metabolite is the parent drug, Methadone. Methadone is generally detectable in the urine for 3-5 days, depending on drug intake. The One Step Drug Screen Test Cup yields a positive result when the concentration of Methadone in urine exceeds 500 ng/mL.

**METHYLENEDIOXYMETHAMPHETAMINE (MDMA)**

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug chemist. MDMA is an abused drug of abuse and dependence. The drug is often referred to as the drug that frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly stimulant, sedative, or hallucinogen. MDMA is a psychotropic drug. MDMA is detectable in the urine for several days after an opiate dose.

The One Step Drug Screen Test Cup yields a positive result when the urine concentration of Methamphetamine exceeds 300 ng/mL.

**OPiates (OP000)**

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is generally defined as a general state, including any drug that acts on the opioid receptors.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, with the result when the morphine concentration in urine exceeds 500 ng/mL. Most of the concentration is excreted in the urine, and some is excreted in the stool. Opioid forms a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, with the result when the morphine concentration in urine exceeds 500 ng/mL. Most of the concentration is excreted in the urine, and some is excreted in the stool. Opioid forms a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, with the result when the morphine concentration in urine exceeds 500 ng/mL. Most of the concentration is excreted in the urine, and some is excreted in the stool. Opioid forms a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, with the result when the morphine concentration in urine exceeds 500 ng/mL. Most of the concentration is excreted in the urine, and some is excreted in the stool.

The One Step Drug Screen Test Cup yields a positive result when the morphine in urine exceeds 2,000 ng/mL. The test is based on the principle of competitive inhibition. The metabolite in urine exceeds 25 ng/mL.

**BARBITURATES (BAR)**

Barbiturates are short-acting to long-lasting hypnotics. They are depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally a times of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Opiates and Barbiturates are excreted unaltered in the urine. The approximate dose-time limits for Barbiturates are: 

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short acting Barbiturates</td>
<td>100 mg (oral)</td>
<td>4-5 days</td>
</tr>
<tr>
<td>Long acting (e.g. Phenobarbital)</td>
<td>400 mg PO</td>
<td>7 days</td>
</tr>
</tbody>
</table>

The One Step Drug Screen Test Cup yields a positive result when the Barbiturates in urine exceed 300 ng/mL.

**BENZODIAZEPINES (BZO)**

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors in the brain and are potent as well as more effective. Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used sedatives before some surgical and diagnostic procedures. They are used to treat some conditions of seizure activity. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than 30 days. Benzodiazepines are metabolized in the liver and the half-life of metabolites is 8-30 hours. The metabolite in urine exceeds 300 ng/mL.

The approximate dose-time limits for Benzodiazepines are: 

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short acting Benzodiazepines</td>
<td>100 mg (oral)</td>
<td>4-5 days</td>
</tr>
<tr>
<td>Long acting (e.g. Oxazepam)</td>
<td>300 mg PO</td>
<td>7 days</td>
</tr>
</tbody>
</table>

The One Step Drug Screen Test Cup yields a positive result when Benzodiazepines in urine exceed 300 ng/mL.

**COCAINE (COCA)**

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitization and seizures. In large amounts, cocaine causes fever, unresponsiveness, and death within hours. Cocaine is also self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine (Coca). It is also excreted unaltered in the urine. The approximate dose-time limits for Cocaine are: 

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short acting Cocaine</td>
<td>100 mg (oral)</td>
<td>2-3 hours</td>
</tr>
<tr>
<td>Long acting (e.g. Phentoyin)</td>
<td>500 mg PO</td>
<td>4-6 days</td>
</tr>
</tbody>
</table>

The One Step Drug Screen Test Cup yields a positive result when the Cocaine in urine exceeds 300 ng/mL.
**SPECIMEN COLLECTION AND PREPARATION**

**Urine Assay**

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, blended, or allowed to settle before selection for testing.

**Specimen Storage**

Urine specimens may be stored at 2-8°C 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.

**MATERIALS**

- **Test cards**
- **Materials Provided**
- **Timers**
- **Instruction for use**

**Test cards**

- **Materials Required But Not Provided**
- **External control**
- **Interpretation of results**

**DIRECTIONS FOR USE**

Allow the test card, urine specimen, and/or controls to equilibrate to room temperature (15-35°C) prior to testing.

1. Bring test card and specimen to the room temperature (15-28°C) if they have been refrigerated.
2. Remove the urine test cup from the sealed foil pouch.
3. Remove the lid and collect the sample, ensuring that the sample is above the minimum fill line.
4. Secure the lid tightly and place the urine test cup on a flat surface.
5. Remove key from the lid to insert in the side chamber, push to release the sample into the test zone, then shake the cup body slightly to mix urine flow into the specimen zone.
6. Remove the test window cover along the perforated line.
7. Read the results at 3-5 minutes. Do not interpret the results after 10 minutes.

**INTERPRETATION OF RESULTS**

(Refer to the illustration above)

**NEGATIVE**: Two lines appear. One red line should be in the test region (C), and another red or pink 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 (T) will vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE**: One red 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.

**INVALID**: Control line fails to appear. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

**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. 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 One Step Drug Screen Test 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) or a similar confirmatory method.
2. There is a possibility 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 alums, 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 does not indicate level or 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. 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.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A side-by-side comparison was conducted using the One Step Single Drug Test Strip and commercially available control strips. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of each drug, as determined in presumptive positive urine samples tested:

<table>
<thead>
<tr>
<th>Test Compounds Contributed to the Totals of GCMS</th>
<th>AMP</th>
<th>BZO</th>
<th>BAR</th>
<th>COC</th>
<th>THC</th>
<th>ME</th>
<th>MDA</th>
<th>MOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Results with Commercial Kit</td>
<td><strong>Positive Agreement</strong> 99%</td>
<td>99%</td>
<td>98%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td><strong>Total Agreement</strong> 99%</td>
<td>99%</td>
<td>98%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td>99%</td>
<td></td>
</tr>
</tbody>
</table>

The following results are reported from these clinical studies:

**Percent Agreement with Commercial Kit**

<table>
<thead>
<tr>
<th>AMP</th>
<th>BAR</th>
<th>BZO</th>
<th>COC</th>
<th>THC</th>
<th>MDA</th>
<th>MOP</th>
<th>ME</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positive Agreement</strong> 99%</td>
<td>97%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
</tr>
<tr>
<td><strong>Total Agreement</strong> 99%</td>
<td>97%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
<td>96%</td>
</tr>
</tbody>
</table>

For 110 clinical samples for each drug were run using each of the One Step Single Drug Test Strip from an untainted operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.

**Note**: TCA was based on HPLC data.

**Precision**

A study was conducted at three physician offices by untrained operators using three different kits to demonstrate the within-run, between-run, and total imprecision. An identical panel of coded specimens, containing drugs at the concentration of ≤ 50% and ≤ 25% cut-off level, was labeled, blinded and tested at each site. The results are below:

**AMPHETAMINE (AMP)**

<table>
<thead>
<tr>
<th>AMP</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
<th>Site D</th>
<th>Site E</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**METHAMPHETAMINE (MET)**

<table>
<thead>
<tr>
<th>MET</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
<th>Site D</th>
<th>Site E</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
### Drug Concentration Table

#### Cut-off Range

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>0% Cut-off</th>
<th>10% Cut-off</th>
<th>20% Cut-off</th>
<th>30% Cut-off</th>
<th>40% Cut-off</th>
<th>50% Cut-off</th>
<th>60% Cut-off</th>
<th>70% Cut-off</th>
<th>80% Cut-off</th>
<th>90% Cut-off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methadone</td>
<td>0.1 ng/mL</td>
<td>3.0 ng/mL</td>
<td>6.0 ng/mL</td>
<td>9.0 ng/mL</td>
<td>12.0 ng/mL</td>
<td>15.0 ng/mL</td>
<td>18.0 ng/mL</td>
<td>21.0 ng/mL</td>
<td>24.0 ng/mL</td>
<td>27.0 ng/mL</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>0.1 ng/mL</td>
<td>3.0 ng/mL</td>
<td>6.0 ng/mL</td>
<td>9.0 ng/mL</td>
<td>12.0 ng/mL</td>
<td>15.0 ng/mL</td>
<td>18.0 ng/mL</td>
<td>21.0 ng/mL</td>
<td>24.0 ng/mL</td>
<td>27.0 ng/mL</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>0.1 ng/mL</td>
<td>3.0 ng/mL</td>
<td>6.0 ng/mL</td>
<td>9.0 ng/mL</td>
<td>12.0 ng/mL</td>
<td>15.0 ng/mL</td>
<td>18.0 ng/mL</td>
<td>21.0 ng/mL</td>
<td>24.0 ng/mL</td>
<td>27.0 ng/mL</td>
</tr>
</tbody>
</table>

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Drug Screen Test Cup was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

### Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit before being spiked with drugs at 50% below and 50% above cut-off levels. The spiked pH-adjusted urine was tested with One Step Drug Screen Test Cup. The results demonstrate that varying ranges of pH does not interfere with 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 positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylphenidate, Opiates, Morphine, Phencyclidine or Tricyclic Antidepressants. The following compounds showed no cross reactivity when tested with One Step Drug Screen Test Cup at a concentration of 100 ng/mL.

### Non Cross-Reacting Compounds

- Acetaminophen (Tylenol)
- Amphetamine (Dexedrine)
- Atropine (Scopolamum)
- Barbiturate (Nembutal)
- Benzoic acid
- Benzilic acid
- Benzoin
- Benzylamine
- Buprenorphine (Subutex)
- Butylamine
- Captopril
- Carbachol
- Carisoprodol
- Captopril
- Caffeine
- Canabidiol
- Chloroform
- Chlorpromazine
- Chloroform
- Chlorpromazine
- Cimetidine
- Clomipramine
- Codeine
- Colchicine
- Cotinine
- Corticotropin
- Cotinine
- Corticosteroids
- Cotinine
- Cortisol
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