The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when the phencyclidine concentration in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). See opiate (MOP 300) for summary.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950s. It was removed from the market because patients receiving it became delirious or had convulsions. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked and the capsules or tablets are usually taken orally. Phencyclidine causes effects such as increased alertness, euphoria, and temporary memory loss. It is usually used in conjunction with marijuana and is typically absorbed through the lung, gut wall, and mouth. Phencyclidine can cause conditions, such as intravascular coagulation, metabolically based hypothermia, and disseminated intravascular coagulation, which can lead to organ failure. PCP can be excreted in urine within 4 to 6 hours after use and will remain in urine for up to 14 days, depending on factors such as metabolic rate, user’s weight, activity, and diet.1 Phencyclidine is detected in the urine by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when the phencyclidine concentration in urine exceeds 9 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depression. TCA medications are often used to treat patients who are not adequately responsive to other antidepressants. TCA overdose is the most common cause of death from prescription drugs. TCA drugs are taken orally by mouth. TCA drugs have a long elimination half-life and metabolite levels in urine remain for up to 10 days.

The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when the concentration of TCA in urine exceeds 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

**PRINCIPLE**

The One Step Multi-Drug, Multi-Line Screen Test Device is an immunoassay based on the principle of competitive binding. When an antibody is present in the urine specimen, compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen, will compete with the conjugate for binding sites on the antibody. If the drug is not present in the urine specimen, the conjugate will be able to bind to the antibody. If the drug is present, the conjugate will not be able to bind to the antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region (line B). The urine specimen will pass over the test and control line regions, allowing all the anti-drug mouse antibodies to saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugate. Control line contains goat-anti-rabbit IgG polyclonal antibodies and rabbit IgG.

**CONCLUSIONS**

The One Step Multi-Drug, Multi-Line Screen Test Device contains a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

- **Test**
  - Amphetamine (AMP)
  - Barbiturates (BAR)
  - Benzodiazepines (BZO)
  - Cocaine (COC)
  - Methadone (MTD)
  - Methamphetamine (mAMP)
  - Marijuana (THC)
  - Methylenedioxymethamphetamine (MDMA)
  - Methylenedioxyamphetamine (MDA)

- **Calibrator**
  - secobarbital
  - oxazepam
  - 10 mg/mL
  - 10 mg/mL
  - d-methamphetamine
  - d,3-benzoylecgonine
  - 2,3-benzoylecgonine
  - 11-nor-9-tetrahydrocannabinol (THC-COOH)

- **Cut-off**
  - 500 ng/mL
  - 300 ng/mL
  - 300 ng/mL
  - 300 ng/mL
  - 300 ng/mL
  - 1,000 ng/mL

**SUMMARY**

The One Step Multi-Drug, Multi-Line Screen Test Device is a rapid urine screening test that can be performed without a lab setting or equipment. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.
There is even a faint line.

**PRECAUTIONS**

- For healthcare professionals including all professionals at point of care sites.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device 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 device should be discarded according to federal, state and local regulations.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2-30°C. The test device 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.

**SPECIMEN COLLECTION AND PREPARATION**

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

**Materials**

- Specimen collection container
- Specimen container collection
- Disposables
- Priority test device
- Timer

**DIRECTIONS FOR USE**

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µl total volume) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The results should be read at 5 minutes or up to 4 hours after test initiation.

**SPECIMEN RESULTS**

**SPECIMEN COLLECTION AND PREPARATION**

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, filtered, or allowed to settle to obtain a clear supernatant for testing.

**Materials**

- Specimen collection container
- Disposables
- Priority test device
- Timer

**DIRECTIONS FOR USE**

1. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100 µl total volume) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the colored line(s) to appear. The results should be read at 5 minutes or up to 4 hours after test initiation.

**TERM DEFINITIONS**

**NEGATIVE:** The appearance of a colored line in the Control region (C) and a colored line in the Test region (T), respectively for a specific drug indicates a negative test result. Up to four colored lines may appear in the C region, and up to three lines in the T region. This negative result indicates that the drug concentrations in the urine samples are below the designated cut-off levels for a particular drug tested.

**POSITIVE:** No line appears in the Test region (T) for a specific drug tested. One colored line appears in the Control region (C). The positive result indicates that the drug concentration in the urine samples exceeds the designated cut-off level for a 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 with a new test device. If the problem persists, contact your local distributor.

**CONTROL PRECAUTIONS**

A procedural control is included in the test. A colored 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 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 Multi-Drug, Multi-Line Screen Test Device 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 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 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. Test does not distinguish between drugs of abuse and certain medications.
7. A Positive test result might be obtained from certain foods or food supplements.

**PERFORMANCE CHARACTERISTICS**

A side-by-side comparison was conducted using the One Step Multi-Drug, Multi-Line Screen Test Device and commercially available rapid test devices. Testing was performed on approximately 1,000 specimens previously collected from subjects presenting for Drug Screen Testing. Some specimens in the +/- 25% cut-off levels were prepared by diluting from the most concentrated clinical specimens with the near urine. Presumptive positive results were confirmed by GC/MS. Negative urine samples were screened initially by the test device. Approximately 10% negative samples were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested in the following clinical studies:

**Analytical Sensitivity**

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

**Analytical Sensitivity**

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

**Drug Conc. (Cut-off range)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>AMP</th>
<th>BAR</th>
<th>BZO</th>
<th>COC</th>
<th>MDA</th>
<th>MDMA</th>
<th>PCP</th>
<th>TCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BAR</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>BZO</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>COC</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MDA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MDMA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>PCP</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TCA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
### Drug Concentration (Cut-off range)

<table>
<thead>
<tr>
<th>Drug Conc.</th>
<th>OPP</th>
<th>DIA</th>
<th>OPI</th>
<th>AMP</th>
<th>MDMA</th>
<th>MOP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0% Cut-off</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>-50% Cut-off</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
</tr>
<tr>
<td>-25% Cut-off</td>
<td>30</td>
<td>35</td>
<td>5</td>
<td>27</td>
<td>3</td>
<td>20</td>
</tr>
<tr>
<td>Cut-off</td>
<td>30</td>
<td>23</td>
<td>7</td>
<td>17</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>30</td>
<td>6</td>
<td>24</td>
<td>6</td>
<td>24</td>
<td>7</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>0</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

### Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the One Step Multi-Drug, Multi-Line Screen Test Device at 5 minutes.

#### AMPHETAMINE
- d-Amphetamine: 1,000
- d,l-Amphetamine: 3,000
- l-Amphetamine: 50,000
- (+)-3,4-Methylenedioxyamphetamine: 2,000
- Phenetermine: 3,000

#### BARBITURATES
- Secobarbital: 300
- Amobarbital: 300
- Phenobarbital: 150
- Aprobarbital: 200
- Butabarbital: 75
- Butalbarbital: 2,500
- Butal: 100
- Cyclobarbital: 600
- Ethobarbital: 300
- Phenobarbital: 100

#### BENZODIAZEPINES
- Chlordiazepoxide: 500
- Alprazolam: 198
- (+)-Hydroxyalprazolam: 1,262
- Flunitrazepam: 1,562
- Clozapine: 781
- Clobazam: 98
- Clonazepam: 781
- Clonazapate dipotassium: 195
- Desalkylflurazepam: 1,562
- Dexamfetamine: 390
- Diazepam: 195
- Estazolam: 2,500
- Flunitrazepam: 390
- (+)-Lorazepam: 1,562
- (+)-Lorazepam-glucuronide: 156
- Midazolam: 12,500
- Nitrazepam: 98
- Norflurazepam: 195
- Norflurazepam: 390
- Temazepam: 98
- Triazolam: 2,500

#### COCAINE
- Benzoylecgonine: 300
- Cocaine: 780
- Coctaine: 12,500
- Egonine: 32,000

#### MARUANA (THC)
- 11-nor-9-THC-9 COOH: 50
- Cannabidiol: 20,000
- 11-nor-9-THC-9 COOH: 50
- 11-nor-9-THC-9 COOH: 15,000
- 11-nor-9-THC-9 COOH: 15,000

#### METHADONE
- Methadone: 300
- Doxylamine: 50,000

#### METHAMPHETAMINE
- (+)-Methamphetamine: 1,000
- (+)-Hydroxymethamphetamine: 30,000
- I-Methamphetamine: 8,000
- (+)-3,4-Methylenedioxyamphetamine: 2,000
- Methamphetamine: 50,000

#### METHYLENEDIOXYMETAMPHETAMINE (MDMA)
- 3,4-Methylenedioxyamphetamine: 3,000
- 3,4-Methylenedioxyethylamphetamine: 300

#### MOP 300 (MOP)
- Morphine: 300
- Codeine: 300
- Ethylmorphine: 6,250
- Hydrocode: 50,000
- Hydromorphone: 3,125
- Levorphanol: 150
- Morphine 3-0-glucuronide: 400
- Norcodeine: 1,650
- Norcodeine: 100,000
- Oxycodone: 30,000

#### NORTIONAL ANTIDEPRESSANTS (TCA)
- Nortriptyline: 1,000
- Nortriptyline: 1,000
- Trimipramine: 3,000
- Amtipryline: 1,500
- Promazine: 1,500
- Desipramine: 200
- Imipramine: 400
- Clomipramine: 12,500
- Doxepin: 2,000
- Maprotiline: 2,000
- Piroxetine: 25,000

#### OPIATES (2000)
- Morphine: 15,000
- Thebaine: 6,250
- Codeine: 2,000
- Efyllymorphone: 5,000
- Hydrocode: 12,500
- Hydromorphone: 5,000
- Levorphanol: 76,000
- Morphine 3-0-glucuronide: 3,000
- Norcodeine: 12,500
- Norcodeine: 50,000
- Oxycodone: 25,000
- Oxydymorphone: 25,000
- Oxycodone: 150,000
- Thebaine: 100,000

### Eighty (80) of these samples for each drug test were also run using ACON's multi-drug test device by an untrained operator at a physician's office. Based on GC/MS data, the operator obtained a statistically similar positive agreement, negative agreement and overall agreement rate as the laboratory personnel.
A study was conducted at three physician offices for Amphetamine, Cocaine, Marijuana, Methamphetamine, Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ±50% and ±25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

<table>
<thead>
<tr>
<th>Drug Conc.</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>90</td>
<td>90</td>
<td>0</td>
<td>90</td>
</tr>
<tr>
<td>-50% Cut-off</td>
<td>90</td>
<td>90</td>
<td>0</td>
<td>90</td>
</tr>
<tr>
<td>-25% Cut-off</td>
<td>90</td>
<td>80</td>
<td>10</td>
<td>70</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>90</td>
<td>34</td>
<td>58</td>
<td>13</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>90</td>
<td>5</td>
<td>85</td>
<td>5</td>
</tr>
</tbody>
</table>

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Morphine, and Tricyclic Antidepressants by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ±50% and ±25% cut-off level, was labeled as a blind and tested at each site. The results are given below:

<table>
<thead>
<tr>
<th>Drug Conc.</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>90</td>
<td>90</td>
<td>0</td>
<td>90</td>
</tr>
<tr>
<td>-50% Cut-off</td>
<td>90</td>
<td>83</td>
<td>7</td>
<td>87</td>
</tr>
<tr>
<td>-25% Cut-off</td>
<td>90</td>
<td>67</td>
<td>23</td>
<td>75</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>90</td>
<td>28</td>
<td>62</td>
<td>30</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>90</td>
<td>1</td>
<td>89</td>
<td>0</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 Multi-Drug, Multi-Line Screen Test Device 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 increments and spiked with drugs at 50% below and 50% above cut-off levels. This spiked, pH-adjusted urine was tested with the One Step Multi-Drug, Multi-Line Screen Test Device. 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 Cocaine, Amphetamine, Methamphetamine, Marijuana, Opiate or Phencyclidine positive urine. The following compounds show no cross-reactivity when tested with the One Step Multi-Drug, Multi-Line Screen Test Device at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

- Acetaminophen
- N-Acetylprocainamide
- Aminophylline
- Apomorphine
- Atropine
- Benzoic acid
- Bilirubin
- Caffeine
- Chloramphenicol
- Chlorothiazide
to Chloropromazine
- Cholestesterol
- Corantine
- Creatinine
- Destromethorphan
- Enflurane
- Diphenhydramine
- I-EPHEDRINE/Epinephrine
- Estrone 3-sulfate
- Estriol
- Estrone
- Erythromycin
- Furosemida

### Non Cross-Reacting Compounds

- Acetylphenidate
- Analgesic acid
- Amoxicillin
- I-Acetic acid
- Aspartame
- Benzaldehyde
- Benzohydrochloride
- Dl-Bromobenzodioxin
- Cannabinol
- Chlorpromazine
- Chloroform
- Chlorpromazine
- Chloroquine
- Chloroquine
- Chloroquine
- Cloridina
- I-Catheine
- Decorticolosterone
- Digoxin
- Eperinephrine
- I-EPHEDRINE/Epinephrine
- Ester
to Estradiol
- Ether 

<table>
<thead>
<tr>
<th>Drug Conc.</th>
<th>n per site</th>
<th>Site A</th>
<th>Site B</th>
<th>Site C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non Cross-Reacting Compounds</td>
<td>902</td>
<td>902</td>
<td>0</td>
<td>902</td>
</tr>
</tbody>
</table>

### Cross-Reactivity

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.*

**BIBLIOGRAPHY**


DN: 1150108302
Eff. Date: 2005-05-13
Printed in China