The One Step Multi-Drug, Multi-Line Screen Test Device is a rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in urine. For healthcare professionals including professionals at point of care use.

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMPHETAMINE</td>
<td>1,000 ng/mL</td>
<td></td>
</tr>
<tr>
<td>BZODIAZEPINES</td>
<td>200 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methylenedioxymethamphetamine (MDMA)</td>
<td>500 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine (mAMP)</td>
<td>1,000 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Cocaine (COC)</td>
<td>500 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methadone (MTD)</td>
<td>300 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines (BZO)</td>
<td>300 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methadone (MTD)</td>
<td>300 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methylene dioxyamphetamine (MDMA)</td>
<td>500 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Morphine (MOP or OPI)</td>
<td>300 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Methamphetamine (mAMP)</td>
<td>1,000 ng/mL</td>
<td></td>
</tr>
<tr>
<td>Urine</td>
<td>1,000 ng/mL</td>
<td></td>
</tr>
</tbody>
</table>

Configurations of the One Step Multi-Drug, Multi-Line Screen Test Device can consist of any combination of the above test lines. The One Step Multi-Drug, Multi-Line Screen Test Device is an immunoassay based on the principle of competitive binding. The presence or absence of specific reagents or test lines in the test kit should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**SUMMARY**

The One Step Multi-Drug, Multi-Line Screen Test Device is a rapid urine testing screen that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

**AMPHETAMINE (AMP)**

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available over-the-counter under the trade name of Benzedrine®. Amphetamine is a central nervous system stimulant with numerous therapeutic applications. It is chemically related to the human body's natural catecholamines, epinephrine and norepinephrine. Acute dose increases lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses include anxiety, nervousness, hallucinations, and psychic behavior. The effects of Amphetamines last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted unchanged, with the remaining 70% being hydroxylated and deaminated derivatives.

The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive test results by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). Urine contains an immunosorbent layer with monoclonal antibodies specific to Amphetamines which is used to identify the presence of Amphetamines in urine.

**BZODIAZEPINES (BZO)**

Benzodiazepines are central nervous system depressants that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma-aminobutyric acid (GABA). Benzodiazepines are frequently used to treat anxiety, insomnia, and agitation associated with other psychiatric disorders. Benzodiazepines also have been used to treat various forms of pain and sleep disorders. Benzodiazepines are metabolized in the body and are excreted in the urine. The effects of Benzodiazepines last 3-7 days. The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when the Benzodiazepines in urine exceed 300 ng/mL.

**METHADONE (MTD)**

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate addiction (heroin, Vincidin, Percocet, Morphone). The pharmacology of Oral Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone is metabolized very rapidly in the liver to its inactive metabolite and is not stored. The One Step Multi-Drug, Multi-Line Screen Test Device yields a positive result when Methadone in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive test results by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

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**SUMMARY**

The One Step Multi-Drug, Multi-Line Screen Test Device is an immunoassay based on the principle of competitive binding. Drugs are 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, binds to the drug conjugate, preventing the drug conjugate from interacting with the bound site of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites for that specific drug, and a visible colored line will show up in the test line region of the specific drug strip. 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 corresponding to the absence of drug competition.

**PRINCIPLE**

The One Step Multi-Drug, Multi-Line Screen Test Device is an immunoassay based on the principle of competitive binding. Drugs are 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, binds to the drug conjugate, preventing the drug conjugate from interacting with the bound site of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites for that specific drug, and a visible colored line will show up in the test line region of the specific drug strip. 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 corresponding to the absence of drug competition.

**REAGENTS**

Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. Control line contains goat anti-rabbit IgG polyclonal antibody and rabbit IgG.
**PRECAUTIONS**

- For healthcare professionals including professionals at point of care sites.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- 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 until use. 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**

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

- **Specimen Storage**
  
  Urine specimens may be stored at 2-30°C or frozen up to 30 days prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well prior to testing.

**MATERIALS**

- **Materials Provided**
  
  - Test devices
  - Disposable droppers
  - Package insert

- **Materials Required But Not Provided**
  
  - Specimen collection container
  - External controls
  - Timers

**DIRECTIONS FOR USE**

Allow the test device, 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 test device from the sealed pouch and use 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 test initiation.

3. Wait for the color(s) to appear. The results should be read at 5 minutes or up to 4 hours after test initiation.

**FEATURES**

- A Side-by-side comparison was conducted using the ACON® Spectrum Multi-Drug, Multi-Line Screen Test Device and commercially available drug rapid tests. 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 more concentrated clinical specimens with the next lowest concentration. The positive results were confirmed by GC/MS. Negative urine samples were prepared initially by Predicate test. Approximately 10% negative specimens were confirmed by GC/MS. The following compounds were added to the total amounts of being held in predicable positive urine samples tested in the following clinical study:

  - BZO Oxazepam, Nordiazepam, a-OH-Alprazolam, Desalkylflurazepam
  - COC Benzoylecgonine
  - THC 9-tetrahydrocannabinol-9-carboxylic acid
  - TCA Thymoquinone
  - AMP Methamphetamine
  - BAR Barbiturates
  - BZO Benzodiazepines
  - mAMP Methamphetamine
  - MTD Metadon
  - MDMA Methylenedioxymethamphetamine
  - COP Morphine, Codeine
  - PCP Phencyclidine
  - TCA** Test does not distinguish between drugs of abuse and certain medications.

- A positive test result might be obtained from certain foods or food supplements.

- A negative test result might not necessarily indicate drug-free urine.

- 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. If adulteration is suspected, the test should be repeated with another urine specimen.

- 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**

An 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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>129</td>
<td>0</td>
</tr>
<tr>
<td>BAR</td>
<td>124</td>
<td>9</td>
</tr>
<tr>
<td>BZO</td>
<td>130</td>
<td>9</td>
</tr>
<tr>
<td>COC</td>
<td>112</td>
<td>186</td>
</tr>
<tr>
<td>MTD</td>
<td>125</td>
<td>97</td>
</tr>
<tr>
<td>MDMA</td>
<td>88</td>
<td>97</td>
</tr>
<tr>
<td>mAMP</td>
<td>121</td>
<td>99</td>
</tr>
<tr>
<td>OPI</td>
<td>157</td>
<td>97</td>
</tr>
<tr>
<td>PCP</td>
<td>72</td>
<td>95</td>
</tr>
<tr>
<td>TCA</td>
<td>180</td>
<td>94</td>
</tr>
<tr>
<td>TCA**</td>
<td>177</td>
<td>99</td>
</tr>
</tbody>
</table>

**Drug Concentration (Cut-off range)**

<table>
<thead>
<tr>
<th>Drug Concentration (Cut-off range)</th>
<th>AMP</th>
<th>BZO</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤-50% cut-off</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>-50% cut-off to -25% cut-off</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>-25% cut-off to 0</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Cut-off</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
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<td>30</td>
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<tr>
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<td>30</td>
<td>30</td>
</tr>
<tr>
<td>-25% cut-off to 0</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

**Analysis 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.
### AMPHETAMINE

- **ng/mL**
  - D-Amphetamine: 1,000
  - D,L-Amphetamine: 3,000
  - L-Amphetamine: 50,000
  - (±)-3,4-Methylenedioxyamphetamine: 2,000
  - Phentermine: 3,000

### BARBITURATES

- **mg/mL**
  - Secobarbital: 300
  - Barbituric acid: 300
  - Aminobutyric: 150
  - Aprodol: 200
  - Butabarbital: 75
  - Butalbarbit: 2,500
  - Butalbarbit: 150
  - Cyclobarbital: 600
  - Pentobarbital: 300
  - Phenobarbital: 100

### BENZODIAZEPINES

- **ng/mL**
  - Oxazepam: 300
  - Alprazolam: 196
  - a-Hydroxyalprazolam: 1,262
  - Bromazepam: 1,562
  - Clonazepam: 1,562
  - Clonazepam HCl: 781

### METHAMPHETAMINE

- **ng/mL**
  - D-Methamphetamine: 1,000
  - (±)-3,4-Methylenedioxyamphetamine: 2,000
  - Mephentermine: 50,000

### METHYL/METHAMPHETAMINE (MDMA)

- **ng/mL**
  - D,L-3,4-Methylenedioxymethamphetamine HCI (MDMA): 500
  - 3,4-Methylenedioxyethylamphetamine (MDE): 2,000

### MARIJUANA (THC)

- **ng/mL**
  - 11-nor-Δ⁹-THC-9 COOH: 50
  - 11-nor-Δ⁸-THC-9 COOH: 30
  - Δ⁹-THC: 15,000
  - Δ⁸-THC: 15,000

### METHADONE

- **ng/mL**
  - Methadone: 300
  - Dextromethadone: 50,000

### METHAMPHETAMINE (MDMA)

- **ng/mL**
  - D,L-3,4-Methylenedioxymethamphetamine HCI (MDMA): 500
  - 3,4-Methylenedioxyethylamphetamine (MDE): 2,000

### OPIATES (2000)

- **ng/mL**
  - Morphine: 2,000
  - Codeine: 2,000
  - Ethylmorphine: 5,000
  - Hydrocodone: 12,500
  - Hydromorphone: 5,000
  - Levophanol: 75,000
  - Morphine-3-β-D-glucuronide: 5,000
  - Norcodeine: 12,500
  - Norcodeine: 50,000
  - Oxycodone: 25,000
  - Oxymorphone: 15,000
  - Thebaine: 100,000

### PCP

- **ng/mL**
  - Phencyclidine: 25
  - 4-Hydroxyphencyclidine: 12,500

### PCE

- **ng/mL**
  - Phencyclidine: 25
  - 4-Hydroxyphencyclidine: 12,500

### TCA

- **ng/mL**
  - Nortriptyline: 1,000
  - Norapine: 1,000
  - Trimipramine: 3,000
  - Amitriptyline: 1,500
  - Promazine: 1,500
  - Desipramine: 200
  - Imipramine: 400
  - Clozapine: 12,500
  - Doxepin: 2,000
  - Maprotiline: 2,000
  - Promethazine: 25,000

### OPIATE 300 (MOP)

- **ng/mL**
  - Morphine: 300
  - Codeine: 300
  - Ethylmorphine: 6,250
  - Hydromorphone: 100,000
  - Oxymorphone: 25,000
  - Thebaine: 6,250

### 6-Monoacetylmorphine

- **ng/mL**
  - Morphine: 400
  - Morphine-3-β-D-glucuronide: 1,000
  - Norcodeine: 8,250
  - Norbinal: 100,000
  - Oxycodone: 50,000
  - Hydromorphone: 100,000
  - Thebaine: 15,000

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, Opium 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>100</td>
<td>90</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>±50% Cut-off</td>
<td>100</td>
<td>90</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>±25% Cut-off</td>
<td>100</td>
<td>88</td>
<td>88</td>
<td>88</td>
</tr>
<tr>
<td>±50% Cut-off</td>
<td>100</td>
<td>34</td>
<td>34</td>
<td>34</td>
</tr>
</tbody>
</table>

A study was conducted at three physician offices for Barbiturates, Benzodiazepines, Methadone, Mephylenedioxymethamphetamine, Morphone, and Tricyclics 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:

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<td>100</td>
<td>28</td>
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</tr>
<tr>
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<td>100</td>
<td>3</td>
<td>3</td>
<td>3</td>
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</table>

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.

<table>
<thead>
<tr>
<th>Effect of Urinary Specific Gravity</th>
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<tbody>
<tr>
<td>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.</td>
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</tbody>
</table>

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<thead>
<tr>
<th>Effect of the Urinary pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>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. The 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.</td>
</tr>
</tbody>
</table>

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, Opium 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
- Acetylsalicylic acid
- Aminopyrine
- Ampicillin
- Apomorphine
- Atropine
- Benzocaine
- Bilirubin
- Caffeine
- Chloralhydrate
- Chlorochromate
- Chlorpromazine
- Chloroethanol
- Cortisone
- Creatinine
- Dextromethorphan
- Difluorane
- Diphenhydramine
- D-L-Ephedrine
- Estrone-3-sulfate
- Estrone
- Estradiol
- Estradiol
- Estriol
- Ethenidine
- Furosemide

**Cross-Reactive Compounds**

- Acetylsalicylic acid
- Aminopyrine
- Amphetamine
- Apomorphine
- Atropine
- Benzocaine
- Bilirubin
- Caffeine
- Chloralhydrate
- Chlorpromazine
- Chloroethanol
- Cortisone
- Creatinine
- Dextromethorphan
- Difluorane
- Diphenhydramine
- D-L-Ephedrine
- Estrone-3-sulfate
- Estrone
- Estradiol
- Estriol
- Ethenidine
- Furosemide

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