One Step Multi-Drug Urine Test Panel offers any combination from 2 to 12 drugs of abuse tested for 16 different drugs: Amphetamine (AMP), Barbiturates (BAR), Benzodiazepines (BZO), Cocaine (COC), Marijuana (THC), Methadone (MDD), Methamphetamine (MET), Methylene dioxyamphetamine (MDMA), Morphine (MOP), Opiate (OP), Phencyclidine (PCP), Tricyclic Antidepressants (TCA), Buprenorphine (BUP), Oxycodeone (OXY), Ketamine (KET), Propoxyphene (PPX).

This package insert applies to all combinations of multi-drug tests panel. 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 cutoff level.

For professional use only. For in vitro diagnostic use.

One Step Multi-Drug Urine Test Panel is consisted of twelve individual one-step immunoassays. 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>Benzylecgonine</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>Methylene dioxyamphetamine</td>
<td>Methylene dioxyamphetamine</td>
<td>3.4-Methylenedioxyamphetamine (MDMA)</td>
</tr>
<tr>
<td>Morphine</td>
<td>Morphine</td>
<td>300</td>
</tr>
<tr>
<td>Opiate</td>
<td>Morphine</td>
<td>2,000</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>Phencyclidine</td>
<td>25</td>
</tr>
<tr>
<td>Tricyclic Antidepressants</td>
<td>Tricyclic Antidepressants</td>
<td>1,000</td>
</tr>
<tr>
<td>Buprenorphine</td>
<td>Buprenorphine</td>
<td>10</td>
</tr>
<tr>
<td>Oxycodeone</td>
<td>Oxycodeone</td>
<td>100</td>
</tr>
<tr>
<td>Ketamine</td>
<td>Ketamine</td>
<td>1,000</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.

The test is a qualitative screening assay. It is not designed to determine the concentration of drugs or the level of intoxication. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the “MAX” line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. Do not read after 10 minutes.

**Interpretation of Results**

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 below zero or 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.

**Preliminary results are positive.**

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To test the specificity of the test, the test device was used to test various drugs, drug metabolites, and other compounds that are likely to be present in urine. All the compounds 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.

### Analysed Sensitivity

<table>
<thead>
<tr>
<th>Drug Conc. Cut-off range</th>
<th>AMP</th>
<th>BAR</th>
<th>BZO</th>
<th>COC</th>
<th>THC</th>
<th>MTD</th>
<th>MET</th>
<th>MDMA</th>
<th>Ketone</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</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>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>30</td>
<td>25</td>
<td>5</td>
<td>26</td>
<td>4</td>
<td>26</td>
<td>4</td>
<td>25</td>
<td>4</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>30</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
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<td>30</td>
<td>0</td>
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<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

### Analytical Specificity

From the results above, it is clear that One Step Multi-Drug Urine Test Panel resists well against interference from these substances.

### 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**