The urine specimen should be collected in a clean and dry container. Urine collected should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for 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 uncontaminated urine.

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. This test does not distinguish between drugs of abuse and certain medications.}

**EXPECTED DETECTED VALUES**

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

**PERFORMANCE CHARACTERISTICS**

Accuracy

A side-by-side comparison was conducted using the Multi-Drug Rapid Test Panel and commercially available drug rapid tests. Testing was performed on approximately 1000 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS.

**LIMITATIONS**

For healthcare professionals including professionals at point of care sites.

Immunoassay for in vitro diagnostic use only. The test Panel 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 Panel should be discarded according to federal, state and local regulations.

**STORAGE AND STABILITY**

Store as packaged in the sealed pouch at 2-20°C. The test is stable through the expiration date printed on the sealed pouch. The Test Panels 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 should 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 specimen for testing.

**MATERIALS**

- **Test Panels**
- **Materials Provided**
- **Specimen collection**
- **Timer**

**PRECAUTIONS**

- For healthcare professionals including professionals at point of care sites.
- Immunoassay for in vitro diagnostic use only. The test Panel 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 Panel should be discarded according to federal, state and local regulations.

**EERE ATING RESULTS**

(See the illustration above)

NEGATIVE: A colored line appears in the Control region (C) and colored lines appear in the Test region (T). The test result means that the concentration in the urine sample is below the designated cut-off levels for a particular drug tested.

NOTE: The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The result means that the drug concentration in the urine specimen is greater than the designated cut-off for a specific drug.

IN Valid: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.

**QUALITY CONTROL**

A procedural control is included in the test. A line appearing in the Control region (C) is 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 Multi-Drug Rapid Test Panel provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result.

2. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

3. There is a possibility that technical or procedural errors, as well as interfering substances in the urine may cause erroneous results.

4. 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 uncontaminated urine.

5. A positive 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. This test does not distinguish between drugs of abuse and certain medications.

**PREPARATION**

A study was conducted at three hospitals by laypersons using three different lots of product to demonstrate the within run, between run and between operator precision.

An identical card of coded specimens, containing drugs at concentrations of 50% and 25% cut-off level, was labeled, blinded MARUJANA (THC300).
A drug-free urine pool was spiked with drugs at the listed concentrations. The results are summarized below.

### Analytical Sensitivity

<table>
<thead>
<tr>
<th>Drug Concentration Cut-off Range</th>
<th>THC300</th>
<th>THC150</th>
<th>THC500</th>
<th>THC250</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>-50% Cut-off</td>
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<td>+</td>
<td>+</td>
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<td>-25% Cut-off</td>
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<tr>
<td>THC150</td>
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<tr>
<td>THC50</td>
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<td>+</td>
</tr>
<tr>
<td>THC25</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

The following table lists the concentrations of compounds (ng/mL) that are detected as positive in urine by the Multi-Drug Rapid Test Panel at 5 minutes.

### Index of Symbols

- **Attention, see instructions for use**
- **For in vitro diagnostic use only**
- **Do not use if package is damaged**
- **Store between 2-30°C**
- **Tests per kit**
- **Use by**
- **Lot Number**
- **Authorized Representative**

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005-1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Multi-Drug Rapid Test Panel was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges 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 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 Multi-Drug Rapid Test Panel. The results demonstrate that varying ranges of pH do 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 Marijuana. The following compounds show no cross-reactivity when tested with the Multi-Drug Rapid Test Panel at a concentration of 100 µg/mL.

#### Non Cross-Reactive Compounds

- Acetaminophen
- Cortisone
- d-Acetylprocainamide
- Creatinine
- Dextromethorphan
- Aspartame
- Diazepam
- Acetylsalicylic acid
- Diclofenac
- Benzoic acid
- Atropine
- Chloramphenicol
- Chlorothiazide
- Chlorpheniramine
- Clofibrate
- Chlorpromazine
- Clofibrate

#### Cross-Reactive Compounds

- Clonidine
- Isoxsuprine
- d,l-Propanolol

### Bibliography