This Instruction Sheet is for testing of any of the following drugs:

AMP/BAR/KET/BZO/COC/MAM/MOR/OPX/YPP/PKX/TKA/EDDS/P-AC/CTG/IC/PZT4/ATG/ALCO

AMP/BAR/KET/BZO/COC/MAM/MOR/OPX/YPP/PKX/TKA/EDDS/P-AC/CTG/IC/PZT4/ATG/ALCO

Including Adult Drugs (Specimen Validity for): Oxidants (OX), Specific Gravity (S.G.), pH, Creatinine (CRE), Nitrite (NIT) and Glutathionyl (GLU).

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical test if the result is positive.

The AMP 1000 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Benzoylecgonine in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

The AMP 500 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Buprenorphine in urine exceeds 50 ng/mL.

The AMP 300 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Methamphetamine in urine exceeds 300 ng/mL.

The AMP 100 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Pseudoephedrine in urine exceeds 10 ng/mL.

The AMP 100 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Oxazepam in urine exceeds 100 ng/mL.

The AMP 50 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Secobarbital in urine exceeds 50 mg/mL.

The AMP 10 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Oxycodone in urine exceeds 10 ng/mL.

The AMP 1 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Buprenorphine in urine exceeds 1 ng/mL.

This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical test if the result is positive.

The AMP 1000 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Benzoylecgonine in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

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hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and its oxidized and delaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The 1000 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Methamphetamine in urine exceeds 500 ng/mL.

METHAMPHETAMINE (mAMP 500)
The mAMP 1000 assay contained within the One Step Drug of Abuse Test yields a summary of the pharmacological effects and interactions of methamphetamine.

The OPI 300 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Morphine in urine exceeds 500 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)
MDMA is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be due to the enhancement of the neurotransmitter serotonin and its accumulation in the synaptic cleft. The general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The MDMA assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

OPiates (OPI 300, MOR, MDP)
Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semisynthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. They are used for their anticonvulsant, relaxing, and sedative properties. These are very hard to manufacture, and are used to stop some types of pain.

Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opioid dose.3

The OPI 300 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Morphine in urine exceeds the 300 ng/mL.

OPiates (OPI 200)
Opiates refer to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semisynthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

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, and it is also highly addictive. Methadone is prescribed in the treatment of addiction and is widely used in clinical medicine.

The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse liability. Oxycodone is generally detectable in the urine for 3-5 days, depending on urine pH level.

Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical trade names such as Percocet (hydrocodone and acetaminophen), Vicodin (hydrocodone and aspirin), and Lortab (hydrocodone and acetaminophen). Oxycodone is known for its potential to produce respiratory depression, constipation, paronychia, and cough suppression.

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The oxycodone assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Oxycodone in urine exceeds 100 ng/mL.

PHENCYCLIDINE (PCP)
Phencyclidine, also referred to as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1960s. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is excreted in the urine as unchanged (80%) and conjugated metabolites. The powder is either smoked or snorted, and in clinical trials, the duration of action is 8-12 hours. The controlled-release product, Roxicodone, has a longer duration of action (8-12 hours).

The OXY assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Oxycodone in urine exceeds 100 ng/mL.

The PCP assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Phencyclidine in urine exceeds 25 ng/mL.

The 6-ACM assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of 6-Acetylmorphine in urine exceeds 10 ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA)
Tricyclic Antidepressants (TCA) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and antiarrhythmic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are detected in urine in 3 to 4 days. The long half-life (6-8 days) of TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to 10 days.

The TCA assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Norpropoxyphene in urine exceeds 300 ng/mL.

2-ETHYLDENE-1,5-DIMETHYL-3,3-DIHYDROLYPROLLREDINE (EDDP)
EDDP is an immunassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. EDDP, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody coated particles in the test line region. The unreacted antibody coated particles will remain attached to the test line region and a visible colored line will show up in the test line region. The colored line will not form in the test line region when the specimen contains EDDP at levels exceeding 300 ng/mL.

The EDDP assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of EDDP in urine exceeds 300 ng/mL.

6-ACETYL MORPHINE (6-ACM)
6-ACM is a metabolite of morphine which is mostly eliminated in the urine within 1-2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach levels of 100-1200 ng/mL. The EDDP assay for propoxyphene yields a positive result for propoxyphene and its metabolite. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene. The accumulation of norpropoxyphene seen with repeated doses may make it detectable using the EDDP assay.

The EDDP assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL.

COTinine (COT)
Cotinine is a non-narcotic metabolite of nicotine, a highly alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually all smokers are addicted. Its pharmacological effect on the human body is dose dependent, and second-hand inhalation. In addition to tobacco, nicotine is also commercially available as therapeutic smoking replacement therapies such as nicotine gum, transdermal patches and nicotine lozenges.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydrosaline, the concentrations of other metabolites are believed to accocated to the metabolite profile. The metabolite profile of cotinine is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good marker of recent tobacco use. The concentration of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney, the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is approximately 4 days.

The K2 50 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Synthetic Cannabinoids compounds in urine exceeds 20 ng/mL.

SYNTHETIC CANNABINOIDS (K2 50)
See SYNTHETIC CANNABINOIDS (K2 50) for the summary.

The K2 50 assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Synthetic Cannabinoids in urine exceeds 5 ng/mL.

KETAMINE (KET)
Ketamine is a short-acting “disassociating” anaesthetic due to its ability to separate perception from consciousness, and is used mainly for inhalational anaesthesia. Ketamine has hallucinogenic and paralyzing qualities that seem to affect people in different ways.

Ketamine is chemically related to PCP (Angel Dust). Ketamine is occasionally administered to people, but is most commonly used by pets for surgery. Generally, ket OR is most commonly used in veterinary medicine and the veterinary patients are often premeditated with benzodiazepines to produce sedation.

Ketamine is detectable in urine within 1-5 hours after use, and a visible colored line will show up in the control line region indicating that the concentration of soman in specimens has been detected in urine.

The KET assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Ketamine in urine exceeds 1,000 ng/mL.

FENTANYL (FEN)
Fentanyl is a synthetic opioid analgesic with a rapid onset and short duration of action. It is a strong agonist at the μ-opioid receptors. Historically, it has been used to treat breakthrough pain and is also commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with other agents.

Fentanyl is a synthetic opioid analgesic with a rapid onset and short duration of action. It is a strong agonist at the μ-opioid receptors. Historically, it has been used to treat breakthrough pain and is also commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with other agents.

The FEN assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Fentanyl in urine exceeds 200 ng/mL.

TRAMADOL (TRA)
Tramadol is a synthetic opioid analgesic used in the treatment of moderate to severe pain. It is a faint synthetic analogue of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses of tramadol cause central nervous system depression and can be fatal. It is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in the urine unchanged. The metabolites are strongly bound to plasma proteins.

The TRA assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of tramadol in urine exceeds 50 ng/mL.
ETHYL GLUCURONIDE (EtG)
Ethyl glucuronide (EtG) is the major metabolite of ethyl alcohol, which is formed by enzymatic conjugation of ethanol with glucuronic acid.\textsuperscript{1,2} Alcohol in urine is normally detected for only a few hours, whereas EtG can be detected for much longer, up to 96 hours after complete elimination from the body.\textsuperscript{3} Therefore, EtG can be a useful diagnostic biomarker for recent alcohol consumption, and in monitoring abstinence in alcoholics in alcohol withdrawal treatment programs.\textsuperscript{4,5} EtG can be produced in vitro and its concentration in urine samples containing sugars, bacteria or yeast when samples are exposed to warm temperatures.\textsuperscript{6} In such cases, EtG test can be used, as a confirmatory test to determine if the alcohol in the sample is a result of consumption of alcohol or it is formed in vitro as a result of fermentation. Currently EtG is monitor by GCMS and LC/MS/MS.\textsuperscript{7,8}

Ethyl glucuronide (EtG) is a minor non-oxidative metabolite of ethyl alcohol formed by the in vivo conjugation of ethanol with glucuronic acid. EtG is a product of normal metabolism of ingested alcohol (ethanol) rapidly metabolized in the body, which is excreted in the blood, hair and urine. By using, the One Step Drug of Abuse Test EtG can be detected in urine with a sensitivity of approximately 10 ng/mL. Therefore, there is a more useful window of detection of 8 to 80 hours. EtG testing is an excellent option for zero-tolerance alcohol consumption or for rehabilitation programs.

The EtG assay contained within the One Step Drug of Abuse Test yields a positive result when the concentration of Ethyl Glucuronide in urine exceeds 300 ng/mL.\textsuperscript{9}

ALCOHOL (ALCO)
Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributing factor to many accidents, injuries and medical conditions. Urine alcohol test is intended for use as a rapid method to detect the presence of alcohol in urine greater than 0.04% (0.36 g/L).\textsuperscript{10} To confirm the presence of the substance in the urine, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY
The adulterant test strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity, pH, creatinine, nitrite and glutaraldehyde in human urine which can help to assess the integrity of the urine specimen.

ADULTERATION
Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in urine specimens can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and pH, and to detect the presence of oxidents, nitrites, glutaraldehyde and creatinine in urine are considered to be the best ways to test for adulteration or dilution.

• Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
• Specific Gravity (S.G.): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration, which can cause false dilution.
• pH: Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 8.0. Values below pH 4.0 or above pH 8.0 may indicate the sample has been altered.
• Nitrite (NIT): Tests for commercial adulterants such as Klear and Whizzies. Normal urine specimens should contain no trace of nitrite. Positive results for nitrite usually indicate the presence of an adulterant.
• Glutaraldehyde (GLU): Tests for the presence of an aldehyde. Glutaraldehyde is not normally found in a urine specimen. Detection of glutaraldehyde in a specimen is generally an indicator of adulteration.
• Creatinine (CRE): Creatinine is one way to check for dilution and flushing, which are some of the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine may indicate dilute urine.

PRINCIPLE
(1) The One Step Drug of Abuse Test is an immunocassette based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. The antibody will then react with the drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of djug above the cut-off concentration will 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. With 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 region, indicating the proper volume of specimen has been added and membrane wicking has occurred.

(2) Alcohol test is based on the high specificity of alcohol oxidase (AOx) for ethanol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

\[
{\text{EtOH}} + \text{TMB} \rightarrow \text{Alcohol Peroxidase} \rightarrow \text{CH}_3\text{CHO} + \text{Colored TMB}
\]

The distinct color on reactive pads could be observed in less than 60 seconds after the reaction pad was wetted with urine specimens with the ethanol alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in human urine.

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 allowed to settle to obtain a clear specimen for testing.

Urine specimens may be stored at 2-8°C (36-46°F) 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.

INTRODUCTION OF RESULTS
(Please refer to the previous illustration)

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

POSITIVE: At least one color line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

MATERIALS

- Test device
- Disposables
- Package (for test cup use only)
- Color chart for adulterant and alcohol interpretation (when applicable)
- Disposable specimen droppers (for test cassette only)
- Specimen collection container (for strip, cassette, dipcard)
- Disposable gloves

DIRECTIONS FOR USE

Allow the test device, and urine specimen to come to room temperature [15-30°C (59-86°F)] prior to testing.

[For Strip]

1) Remove the strip from the foil pouch or the desiccated container (bring the container to the room temperature before opening to avoid condensation of moisture in container). Label the strip with patient or control identifications.
2) Immerse the strip into the urine with the arrow end pointing toward the urine. Do not cover the strip with urine over the MAX (maximum) line. You may leave the strip in the urine or you may take the strip out after a minimum of 15 seconds in the urine and lay the strip flatly on a non-absorbent clean surface.
3) Read result at 5 minutes. DO NOT READ RESULT AFTER 10 MINUTES. (Fig. 1)

[For Cassette]

1) Remove the test cassette from its foil pouch by tearing along the slice. Label the cassette with patient or control identifications.
2) Using the specimen dropper, withdraw the urine sample from the specimen container and slowly dispense 3 drops of urine into the sample compartment, lay the strip flatly on a non-absorbent clean surface.
3) Read results of alcohol test at 2 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL TEST RESULT AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 2)

[For Dipcard]

1) Remove the test dip card from the foil pouch. Label the dip card with patient or control identifications.
2) Immerse the absorbent tip over the MAX (maximum) line. You may leave the strip in the urine or you may take the dip card out after a minimum of 15 seconds in the urine and lay the dip card flatly on a non-absorbent clean surface.
3) Read results of alcohol test at 2 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL TEST RESULT AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 3)

[For Multi-Drug Screen Test Cup]

1) Follow the instructions on the Procedure Card. Read results of alcohol test at 2 minutes, adulterant test at 5 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL AND ADULTERANT TESTS RESULTS AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 4)

[For Cassette]

1) Remove the test cassette from its foil pouch by tearing along the slice. Label the cassette with patient or control identifications.
2) Using the specimen dropper, withdraw the urine sample from the specimen container and slowly dispense 3 drops of urine into the sample compartment, lay the strip flatly on a non-absorbent clean surface.
3) Read results of alcohol test at 2 minutes, adulterant tests at 3 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL AND ADULTERANT TESTS RESULTS AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 3)

[For Dipcard]

1) Remove the test dip card from the foil pouch. Label the dip card with patient or control identifications.
2) Immerse the absorbent tip over the MAX (maximum) line. You may leave the strip in the urine or you may take the dip card out after a minimum of 15 seconds in the urine and lay the dip card flatly on a non-absorbent clean surface.
3) Read results of alcohol test at 2 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL TEST RESULT AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 2)

[For Multi-Drug Screen Test Cup]

1) Follow the instructions on the Procedure Card. Read results of alcohol test at 2 minutes, adulterant test at 5 minutes, and drug tests at 5 minutes. DO NOT READ ALCOHOL AND ADULTERANT TESTS RESULTS AFTER 5 MINUTES AND DRUG TESTS RESULTS AFTER 10 MINUTES. (Fig. 4)
The test should be considered invalid if only the edge of the reactive pad turned color.

In the comparison study, the One Step Drug of Abuse Test was compared to a GC/MS reference method to determine its accuracy. Clinical urine samples were collected for each of the drug types listed on the following table. Clinical specimens were quantified by GC/MS analysis before testing.

**Accuracy**

Reproducibility studies were carried out using commercially available stock solutions of the drug analytes listed. Dilutions were made from the stock solution of each drug to the concentrations specified in the following tables. The results are listed in the following tables.

### PERFORMANCE CHARACTERISTICS

**Reproducibility**

### AMPHETAMINE (AMP 1000)

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Total number of Determinations</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>BUP</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>AMP300</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>COT</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>KET</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>
**Barbiturates (BAR)**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Total number of Determinations</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seconal (barbiturates)</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>Seconal (barbiturates)</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>COT</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>BUP</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
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**Benzodiazepines (BZO)**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Total number of Determinations</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxazepam (BZO)</td>
<td>40 40 40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>COT</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>mAMP</td>
<td>40 40 40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>
## COCAINE (COC 300)

<table>
<thead>
<tr>
<th>Benzoylcegonine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>225</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>375</td>
<td>40</td>
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</tr>
<tr>
<td>450</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
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</table>

## COCAINE (COC 150)

<table>
<thead>
<tr>
<th>Benzoylcegonine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>75</td>
<td>30</td>
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<td>&gt;99%</td>
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<tr>
<td>112.5</td>
<td>15</td>
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<td>&gt;99%</td>
</tr>
<tr>
<td>187.5</td>
<td>15</td>
<td>15 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>225</td>
<td>30</td>
<td>30 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>300</td>
<td>30</td>
<td>30 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## MARIJUANA (THC 50)

<table>
<thead>
<tr>
<th>11-nor-∆9-THC-9-COOH conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>25</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>37.5</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>50</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>75</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## METHAMPHETAMINE (mAMP 500)

<table>
<thead>
<tr>
<th>Methamphetamine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>250</td>
<td>30</td>
<td>30 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>375</td>
<td>15</td>
<td>15 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>525</td>
<td>15</td>
<td>15 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>750</td>
<td>30</td>
<td>30 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1000</td>
<td>30</td>
<td>30 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## METHYленЕОXYМETHAMPHETAMINE (MMDA)

<table>
<thead>
<tr>
<th>Methoxymethamphetamine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>25</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>37.5</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>50</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>75</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## OPIATE (OPI 300, MOR, MOR)

<table>
<thead>
<tr>
<th>Morphine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>225</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>300</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>375</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>500</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## OPIATE (OPI 2000)

<table>
<thead>
<tr>
<th>Morphine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,000</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>2,000</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>3,000</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## OXYCODONE (OXY)

<table>
<thead>
<tr>
<th>Oxycodone conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>50</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>75</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>100</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## METHADONE (MTD)

<table>
<thead>
<tr>
<th>Methadone conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>225</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>300</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>450</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## METHAMPHETAMINE (mAMP 1000)

<table>
<thead>
<tr>
<th>Methamphetamine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>500</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>750</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,000</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,500</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## PHENCYCLIDINE (PCP)

<table>
<thead>
<tr>
<th>Phencyclidine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>12.5</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>19</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>25</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>37.5</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## TRICYCLIC ANTIDEPRESSANTS (TCA)

<table>
<thead>
<tr>
<th>Nortriptyline conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>500</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>750</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,000</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,500</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## 2-ETHYLIDENE-1,5-DIMETHYL-3,3-DIPHYLPROPYLIDINE (EDDP)

<table>
<thead>
<tr>
<th>EDDP conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>450</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>600</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## 6-ACETYMORPHINE (6-ACM)

<table>
<thead>
<tr>
<th>6-Acetylmorphine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>5</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>15</td>
<td>40</td>
<td>40 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>20</td>
<td>40</td>
<td>40 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## BUPRENORPHINE (BUP)

<table>
<thead>
<tr>
<th>Buprenorphine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>6</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>15</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>20</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## PROPOXYPHEN (PPX)

<table>
<thead>
<tr>
<th>Propoxyphene conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>150</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>450</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>600</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## KETAMINE (KET)

<table>
<thead>
<tr>
<th>Ketamine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>24</td>
<td>24 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>500</td>
<td>24</td>
<td>24 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,000</td>
<td>24</td>
<td>24 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>1,500</td>
<td>24</td>
<td>24 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>

## COTinine (COT)

<table>
<thead>
<tr>
<th>Cotinine conc. (ng/mL)</th>
<th>Total number of Determinations</th>
<th>Result</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>No drug present</td>
<td>60</td>
<td>60 negative</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>100</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>400</td>
<td>60</td>
<td>60 positive</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>
**SYNTHETIC CANNABINOIDS (K2 50)**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Cut-off Range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>JWH-073</td>
<td>Butanoic Acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYNTHETIC CANNABINOID (K2 50)</td>
<td>75</td>
<td>60</td>
<td>60 positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Cut-off Range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>JWH-018</td>
<td>Pentanoic Acid</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYNTHETIC CANNABINOID (K2 20)</td>
<td>10</td>
<td>60</td>
<td>60 negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Cut-off Range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>ETHYL GLUCURONIDE (ETG)</td>
<td>70</td>
<td>70</td>
<td>70 positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Cut-off Range</th>
<th>Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRAMADOL (TRA)</td>
<td>70</td>
<td>70</td>
<td>70 negative</td>
</tr>
</tbody>
</table>

**Analytical Specificity**

The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the One Step Drug of Abuse Test at a read time of 5 minutes.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Concentration (ng/mL)</th>
<th>Cut-off Range</th>
<th>Precision</th>
</tr>
</thead>
</table>

**Analytical Sensitivity**

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below:

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>n</th>
<th>AMP 100</th>
<th>BAR</th>
<th>BZO</th>
<th>COC 300</th>
<th>THC 50</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>50% Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>25% Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>n</th>
<th>MTD</th>
<th>AMP1000</th>
<th>MDMA</th>
<th>MOR</th>
<th>DPH 200</th>
<th>OXY</th>
<th>PCP</th>
<th>TCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>10</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>50% Cut-off</td>
<td>10</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>25% Cut-off</td>
<td>10</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>Cut-off</td>
<td>10</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>+25% Cut-off</td>
<td>10</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>+50% Cut-off</td>
<td>10</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>

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>n</th>
<th>AMP 300</th>
<th>COC 150</th>
<th>THC 20</th>
<th>nAMP 500</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>50% Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>25% Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>+25% Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>+50% Cut-off</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drug concentration Cut-off Range</th>
<th>n</th>
<th>SUP</th>
<th>PRX</th>
<th>EDDP</th>
<th>6-ACM</th>
<th>AMP1200</th>
<th>COT</th>
<th>THCO-27</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td>90</td>
<td>0</td>
<td>0</td>
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The following substances may interfere with the alcohol test: strong oxidizers, ascorbic acid, tannic acid, polyethylene glycol, dextran, and other compounds that may react with ethanol. The study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or spiked urine samples. The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0, and 7.0 to determine if these ranges do not interfere with the performance of the test.

**Effect of Urinary Specific Gravity**

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0, 4.5, 5.0, 6.0, and 7.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Drug of Abuse Test. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

**Effect of the Urinary PH**

A study was conducted to determine the cross-reactivity of the test compounds with either drug-free urine or spiked urine containing Cocaine, Barbiturates, Benzodiazepines, Methamphetamine, Phenylpropanolamine, Oxycodone, and Erythromycin. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

**Interference**

A parent compound only.

Acetone

Acetophenone

Acetophenone-

Acid 应该是

Acid

Acetophenone-

Acid 应该是

Acetophenone-

Acid 应该是
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