The Integrated iCup® yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. The suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).<ref>

**METHAMPHETAMINE (AMP)**

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of methamphetamine are greater. Methamphetamine is made in illegal laboratories and is often confused with amphetamine. Acute higher doses can cause hyperthermia and seizures. Methamphetamine produces a release of dopamine, a neurotransmitter that increases alertness and reduces fatigue. It also increases heart rate and blood pressure. Methamphetamine is excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The Integrated iCup® yields a positive result when Methamphetamine 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).

**PHENCYCLIDINE (PCP)**

Phencyclidine is also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in 1960. It was removed from the market because patients receiving it became delirious and showed signs of marked hallucinatory behavior. Phencyclidine is used in powder, tablet, capsule, and tablet form. The powder is either snorted or smoked after mixing with water or coffee. The tablet and capsule form are ingested orally. Some users have been known to use phencyclidine intravenously, nasally, and orally. Phencyclidine is metabolized to non-toxic compounds in the liver, with a half-life of 2-6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user’s age, weight, activity, and diet. Phencyclidine is excreted in the urine as such and/or as metabolites. The Integrated iCup® yields a positive result when the phencyclidine level in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

**AMPHETAMINE (AMP)**

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body’s natural catecholamines: epinephrine and norepinephrine. They are used to treat narcolepsy and narcolepsy-related sleep disorders. They also act to stimulate the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses are associated in hyperthermia and cardiac stimulation. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines can be seen within 10-30 minutes of use and can last for 3-5 hours. More than 30% of Amphetamines use occurs within the first 4 hours following use and the drug has a half-life of 4-6 hours in the body. Deeper sedation occurs after 4 hours. Some Amphetamines use can last for more than 12 hours, with the remainder excreted in the urine as metabolites.

The Integrated iCup® yields a positive result when Amphetamines in urine exceed 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).

**OPIATES (OPI)**

Opiates refer to any drug that is derived from the poppy poppy, including the natural products, morphine, and codeine, and the semi-synthetic drugs such as heroin. Opioids are generally referred to any drug that acts on the opioid receptor.

Opiates are a class of stimulants that act on a large group of substances which cause pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependence in use, and can lead to dependence in use. Opiates are commonly used in the form of oral medications and are metabolized in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The Integrated iCup® yields a positive result when Morphine 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).

**METHYLDIOXYMETHAMPHETAMINE (MDMA)**

Methylenedioxymethamphetamine (MDMA) is also known as Ecstasy or E, d-Methamphetamine 1,000 ng/mL. Methylenedioxymethamphetamine 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 produces a release of serotonin, a neurotransmitter associated with pleasure, and is found in the brain of patients who have undergone alcohol withdrawal. One of the most common side effects of MDMA is its potential to cause severe elevations in body temperature. Native MDMA is generally detectable in the urine within 3-5 days, depending upon use frequency.

The Integrated iCup® yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500 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)**

Tricyclic antidepressants are medications used for the treatment of depression, anxiety, and some pain conditions. They work by blocking the activity of neurotransmitters, such as serotonin, that help to regulate mood and emotional behavior. Tricyclic antidepressants are associated with an increased risk of suicidal behavior in children and adolescents. They are metabolized in the liver and are excreted in the urine as hydroxylated and deaminated derivatives.

The Integrated iCup® yields a positive result when the concentration of TCA 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).
A positive result does not indicate level of intoxication, administration route or concentration in urine.

4. A negative result does not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.

5. Positive test results may be obtained from certain foods or food supplements.

6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL.

7. The adulteration strips, if applicable, should be read between 3-5 minutes. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results.

8. If results do not indicate adulteration, read the drug test results from 3 to 5 minutes. The drug test results remain stable for up to sixty minutes. See the illustration below. For detailed operation instructions, please refer to the Procedure Card and Color Chart.

9. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

Cup without SVT

Cup with SVT

The following results are tabulated from these clinical studies:

<table>
<thead>
<tr>
<th>Test Compounds Contributing to GCMS Totals</th>
<th>Agreed with GCMS</th>
<th>Positive Agreement</th>
<th>Negative Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>COC</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>THC</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>mAMP</td>
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<td>100%</td>
<td>100%</td>
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<tr>
<td>MDMA</td>
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<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>OPI</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>PCP</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Integrated iCup:

| AMP | 1000 ng/mL |
| COC | 1000 ng/mL |
| THC | 1000 ng/mL |
| mAMP | 1000 ng/mL |
| MDMA | 1000 ng/mL |
| OPI | 1000 ng/mL |
| PCP | 1000 ng/mL |

A side-by-side comparison was conducted using the Integrated iCup and commercially available drug testing products. The testing was performed on 40 clinical samples using iCup, Urine Solution and Methamphetaphrine, from subjects presenting for drug screen testing. Presumptive positive results were confirmed by GCMS. The presumptive compounds were identified by GCMS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug spiked at 50% above and below the assay cutoff were provided to each site.

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BIBLIOGRAPHY