Drugs of Abuse Integrated Cup (Urine)  

For Forensic Use Only

**INTENDED USE**

Quick test cup™ Multi-Drug Urine Cup is a rapid visual immunoassay for the presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cut-off (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMP</td>
<td>500/1,000</td>
</tr>
<tr>
<td>BAR</td>
<td>50</td>
</tr>
<tr>
<td>BUP</td>
<td>10</td>
</tr>
<tr>
<td>COC</td>
<td>300</td>
</tr>
<tr>
<td>COC</td>
<td>150/500</td>
</tr>
<tr>
<td>COT</td>
<td>200</td>
</tr>
<tr>
<td>EEDP</td>
<td>100</td>
</tr>
<tr>
<td>FLY</td>
<td>200</td>
</tr>
<tr>
<td>KET</td>
<td>1,000</td>
</tr>
<tr>
<td>MDMA</td>
<td>500</td>
</tr>
<tr>
<td>MPM</td>
<td>500/1,000</td>
</tr>
<tr>
<td>OPI</td>
<td>100/500</td>
</tr>
<tr>
<td>OPI200</td>
<td>200</td>
</tr>
<tr>
<td>OXY</td>
<td>100</td>
</tr>
<tr>
<td>PNP</td>
<td>25</td>
</tr>
<tr>
<td>TCA</td>
<td>300</td>
</tr>
<tr>
<td>TCA</td>
<td>1,000</td>
</tr>
<tr>
<td>THC</td>
<td>30</td>
</tr>
<tr>
<td>C/MS</td>
<td>200/500/300</td>
</tr>
<tr>
<td>HCG</td>
<td>20mIU/mL</td>
</tr>
<tr>
<td>ALC</td>
<td>0.02%</td>
</tr>
</tbody>
</table>

This test provides a preliminary screening test. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) or Liquid Chromatography/Mass Spectrometry (LC/MS) are preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The Drug of Abuse Test Strip (Urine) is a semi-quantitative color reaction for the detection of: Amphetamines, Barbiturates, Benzodiazepines, Benzylisoquinoline (including Codeine, Morphine, M360, Thebaine), Methaqualone, Methadone, Metamphetamine, Opiates (Morphine, Codeine, Norcodeine), Oxycodone, Phencyclidine, Propoxyphene, Tetrahydrocannabinol (THC), and Nitrites. The test is designed to measure the presence of these drugs in urine and is intended for use as a confirmatory test by public and private laboratories.

**PRECAUTIONS**

- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not retest tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Using testing materials should be discarded in accordance with local regulations.

**STORAGE AND STABILITY**

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Kits should be taken to protect the contents of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or test materials can lead to false results.

**SPECIMEN COLLECTION AND STORAGE**

- Collect specimens from clean, dry containers.
- Turbidity should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 2-8°C for up to 2 days. For long-term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be thawed and mixed well prior to testing.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

**PROCEDURE**

**Bring tests, specimens, and/or controls to room temperature (15-30°C) before use.**

1. Remove the cup from its sealed pouch and use it as soon as possible.
2. Place a urine specimen in the cup and screws the cap on to the cup. Start the timer.
3. Do not dates and initals the security seal label. Operate the check forlifters and attaches the security seal label over the cap.
4. Remove the peel-off label.
5. Check the temperature strip label at 2-4 minutes after specimen collection. A green color will indicate the temperature of the urine specimen. The proper range for an adulterated specimen is 20-32°C. Another color will indicate the temperature of the urine specimen. The proper range for an adulterated specimen is 20-32°C. The proper range for an adulterated specimen is 20-32°C.
6. Do test results are indicated by the presence or absence of colored band or bands on the result strip. The result should be read as 5 minutes. Do not interpret the results after 10 minutes.
7. Positive test results may be confirmed by another test method. By sending the cup and urine specimen intact to a toxicology laboratory for confirmation.

**INTERPRETATION OF RESULTS**

**POSITIVE:** One colored band appears. In the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

**NEGATIVE:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

**INVALID:** Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please refer to the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

**NOTE for DOA test:**

- The color of the signal in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered a positive result. Negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.
While comprehensive, these tests are not meant to be an all-inclusive representation of possible adulterants.

Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.

Nitrile: Nitrile is not a normal component of human urine. However, Nitrile found in urine may indicate urinary tract infections or bacterial infections. Nitrile levels of >20 mg/dL may produce false positive Glutaraldehyde results.

Glutaraldehyde: Glutaraldehyde is not normally found in urine. However, certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high protein diets) may interfere with the test results.

Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.

Oxidants/PCC: Normal human urine should not contain Oxidants or PCC. The presence of high levels of antidiuretic in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

### PERFORMANCE CHARACTERISTICS

#### A. Accuracy

<table>
<thead>
<tr>
<th>Specimen</th>
<th>AMP500</th>
<th>AMP100</th>
<th>BUP500</th>
<th>BAR500</th>
<th>COC500</th>
<th>OPI500</th>
<th>TCA500</th>
<th>TCA500</th>
<th>OXY500</th>
<th>MEP500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>96.1%</td>
<td>95.8%</td>
<td>96.1%</td>
<td>97.8%</td>
<td>100%</td>
<td>98.6%</td>
<td>96.1%</td>
<td>98.6%</td>
<td>98.2%</td>
<td>98.2%</td>
</tr>
<tr>
<td>Negative</td>
<td>100%</td>
<td>100%</td>
<td>98.2%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td>98.1%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### B. Sensitivity

<table>
<thead>
<tr>
<th>Specimen</th>
<th>AMP500</th>
<th>BAR500</th>
<th>BZO500</th>
<th>COC500</th>
<th>MAMP500</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>97.7%</td>
<td>94.4%</td>
<td>98.3%</td>
<td>100%</td>
<td>98.9%</td>
</tr>
<tr>
<td>Negative</td>
<td>97.9%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Total</td>
<td>98.0%</td>
<td>99.1%</td>
<td>98.3%</td>
<td>100%</td>
<td>98.3%</td>
</tr>
</tbody>
</table>

#### C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the test results are considered positive. The cut-off levels are based on LC/MS data instead of GC/MS. The following table includes positive results at 3 minutes and 15 minutes.

### LIMITATIONS OF THE TEST

1. Quick test cap™ Multi-Drug Urine Cup is for professional in vitro diagnostic use, and should be used only for the qualitative detection of drugs of abuse.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method, if not used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA) Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive test results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. Adultera, such as bleach and/or alain, in urine samples may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
5. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
6. A negative result does not at any rule out the presence of drugs/metabolites in urine, as they may be below the minimum detection level of the test.

### Adulteration Limitations

The Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens.
A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free FBS stock. The following compounds demonstrated no positive results on the QuickCap Drugs of Abuse Integrated Cup when tested at concentrations up to 100 μg/mL:

1. (-)-Ethylmorphine (Except MRT)
2. Dextromethorphan and Dextropropoxyphene
3. Metamizole
4. Methylphenidate
5. Phencyclidine
6. Buprenorphine
7. Methadone
8. Meperidine
9. Codeine
10. Hydrocodone
11. Hydromorphone
12. OxyContin
13. Oxycodone
14. Fentanyl
15. Alvimopan
16. Buprenorphine
17. Methadone
18. Hydrocodone
19. Hydromorphone
20. Methadone
21. Hydrocodone
22. Hydromorphone
23. Methadone
24. Hydrocodone
25. Hydromorphone
26. Methadone
27. Hydrocodone
28. Hydromorphone
29. Methadone
30. Hydrocodone
31. Hydromorphone
32. Methadone
33. Hydrocodone
34. Hydromorphone
35. Methadone
36. Hydrocodone
37. Hydromorphone
38. Methadone
39. Hydrocodone
40. Hydromorphone
41. Methadone
42. Hydrocodone
43. Hydromorphone
44. Methadone
45. Hydrocodone
46. Hydromorphone
47. Methadone
48. Hydrocodone
49. Hydromorphone
50. Methadone
51. Hydrocodone
52. Hydromorphone
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54. Hydrocodone
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56. Methadone
57. Hydrocodone
58. Hydromorphone
59. Methadone
60. Hydrocodone
61. Hydromorphone
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64. Hydromorphone
65. Methadone
66. Hydrocodone
67. Hydromorphone
68. Methadone
69. Hydrocodone
70. Hydromorphone
71. Methadone
72. Hydrocodone
73. Hydromorphone
74. Methadone
75. Hydrocodone
76. Hydromorphone
77. Methadone
78. Hydrocodone
79. Hydromorphone
80. Methadone
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82. Hydromorphone
83. Methadone
84. Hydrocodone
85. Hydromorphone
86. Methadone
87. Hydrocodone
88. Hydromorphone
89. Methadone
90. Hydrocodone
91. Hydromorphone
92. Methadone
93. Hydrocodone
94. Hydromorphone
95. Methadone
96. Hydrocodone
97. Hydromorphone
98. Methadone
99. Hydrocodone
100. Hydromorphone

The specificity of the ICG Rapid Test (Urine) was determined from cross-reactivity studies with known amounts of Latrogenic Hormone (LH), Follicle-stimulating Hormone (FSH) and Thyroid-stimulating Hormone (TSH). 300 μl/mL. LH, 1000 μl/mL. FSH and 100 μl/mL. TSH all produced negative results.