

Drugs of Abuse Integrated Cup (Urine)

MD-U621

For Forensic Use only

| INTENDED USE  |                                       |                 |
|---|---------------------------------------|-----------------|
| Quick test cup™ Multi-Drug Urine Cup is a rapid visual immunoassay for the qualitative, presumptive detection of any combination of drugs of abuse in human urine specimens at the cut-off concentrations listed below: |                                       |                 |
| Test  | Calibrator                            | Cut-off (ng/mL) |
| ACE   | Acetaminophen                         | 5,000           |
| AMP   | D-Amphetamine                         | 300/500/1,000   |
| BAR   | Secobarbital                          | 300             |
| BUP   | Buprenorphine                         | 10              |
| BZO   | Oxazepam                              | 300             |
| COC   | Benzoylcegonine                       | 150/300         |
| COT   | Cotinine                              | 200             |
| EDDP  | EDDP                                  | 100             |
| FYL   | Fentanyl                              | 200             |
| KET   | Ketamine                              | 1,000           |
| MDMA  | Ecstasy                               | 500             |
| MET(MAMP)   | D-Methamphetamine                     | 300/500/1,000   |
| MTD   | Methadone                             | 300             |
| OPI/MOR   | Morphine                              | 100/300         |
| OPI2000   | Morphine                              | 2,000           |
| OXY   | Oxycodone                             | 100             |
| PCP   | Phencyclidine                         | 25              |
| PPX   | Propoxyphene                          | 300             |
| TCA   | Nortriptyline                         | 1,000           |
| THC   | 11-nor-Δ9-THC-9-COOH                  | 50              |
| HCG   | human chorionic gonadotropin          | 20mIU/mL        |
| ALC   | Alcohol                               | 0.02%           |
| Adulteration (StripA)   | Oxidants / Specific Gravity / PH      |                 |
| Adulteration (StripB)   | Nitrite / Glutaraldehyde / Creatinine |                 |

The DOA test is used to obtain visual qualitative result and is intended for health care professionals use including professionals at point of care sites to assist in the determination of drug compliance. It is not intended for over the counter sale to non-professionals.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC Chromatography/ Mass Spectrometry (GC/MS) or Liquid Chromatography/ Mass Spectrometry (LC/MS) are the 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 Urine Adulteration Test Strips (Urine) are a semi-quantitative color comparison screen for the detection of Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine.

This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Abnormal results should be sent to a laboratory for confirmation.

Quick test cup™ Multi-Drug Urine Cup also can be used to detect Human chorionic gonadotropin (hCG) in urine, is intended for using an aid in the early detection of pregnancy.

**PRINCIPLE**

Quick test cup™ Multi-Drug Urine Cup is an immunoassay based on the principle of competitive binding. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a portion of the urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will appear in the test line region of the corresponding drug strip. The presence of drug above the cut-off concentration in the urine specimen will saturate all the binding sites of the antibody. Therefore, no colored line will 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, while 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 line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

The Adulteration Strips of the colors that appear on the pads can be compared with the printed color chart on the canister. The color comparison provides a semi-quantitative screen for Creatinine, Nitrite, Glutaraldehyde, pH, Specific Gravity, Oxidants and Pyridinium Chlorochromate in human urine, which can help assess the integrity of the urine specimen.

The hCG Rapid Test Strip (Urine) detects human chorionic gonadotropin through visual interpretation of color development on the strip. Anti-hCG antibodies are immobilized on the test region of the

membrane and anti-mouse antibodies on the control region. During testing, the specimen reacts with anti-hCG antibodies conjugated to colored particles and precoated on the sample pad of the strip. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient hCG in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Materials Provided

Individually packed test cups with integrated drug of abuse test panels  
Caps  
Adulteration Color Chart (when applicable)  
Package insert

Materials Required but Not provided

Timer  
Centrifuge  
Positive and negative controls

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 reuse 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 specimen 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.
- Used 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.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

- SPECIMEN COLLECTION AND STORAGE
- Quick test cup™ Multi-Drug Urine Cup is intended for use with human urine specimens only.
  - Urine collected at any time of the day may be used.
  - Urine specimens must be collected in clean, dry containers.
  - Turbid specimens 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 completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
  - 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.

- Remove the cup from its sealed pouch and use it as soon as possible.
- Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
- Donor dates and initials the security seal label. Operator checks the cap for tightness and attaches the security seal label over the cap.
- Remove the peel-off label.
- Check the temperature strip label at 2-4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
- Drug test results are indicated by the presence or absence of colored band(s) in the result area. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
- 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

(See previous illustration)

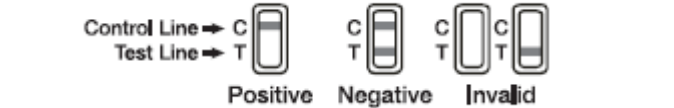
**POSITIVE:** Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

**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 review 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 intensity of color 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 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.



The Result for Urine Alcohol Test :



**NEGATIVE:** No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

**POSITIVE:** A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.

**INVALID:** The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

The Result for Urine HCG Test

C  
T

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

C  
T

NEGATIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T).

C  
T

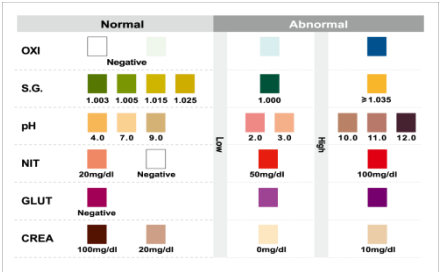
INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review

the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE of HCG:

The intensity of color 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 should be considered positive. 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 performing expired tests are the most likely reasons for control band failure

The Result of Adulteration Strips: For specific colour please reference the Adulteration Color Chart.



NOTE:

The Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens.

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.

**Nitrite:** Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite 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 antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

- Quick test cup<sup>TM</sup> Multi-Drug Urine Cup is for professional *in vitro* diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
- This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be 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 results are indicated.
- 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.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. Therefore, please preclude the possibility of urine adulteration prior to testing.
- A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
- A negative result does not at any time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
- This test does not distinguish between drugs of abuse and certain medications.

Adulteration Limitations

The Adulteration Test Strips (Urine) are meant to aid in the determination of abnormal specimens.

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.

**Nitrite:** Nitrite is not a normal component of human urine. However, Nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite 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 antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the Oxidants/PCC pad.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Quick test cup<sup>TM</sup> Multi-Drug Urine Cup was established by running urine samples against GC/MS.

| Specimen | ACE   | AMP   | AMP300 | BAR   | BUP* | BZO   | COC   |
|----------|-------|-------|--------|-------|------|-------|-------|
| Positive | 96.1% | 95.8% | 96.1%  | 97.8% | 100% | 88.6% | 98.2% |
| Negative | 100%  | 100%  | 100%   | 98.1% | 100% | 98.2% | 98.1% |
| Total    | 98.1% | 98.1% | 98.1%  | 98%   | 100% | 94.9% | 98.2% |

| Specimen | COT   | EDDP100 | FYL   | KET   | MDMA | MAMP  | MAMP500 |
|----------|-------|---------|-------|-------|------|-------|---------|
| Positive | 97.7% | 98.6%   | 94.4% | 98%   | 100% | 96.8% | 96.9%   |
| Negative | 97.9% | 100%    | 100%  | 98.6% | 100% | 100%  | 100%    |
| Total    | 98.0% | 99.1%   | 97.2% | 98.3% | 100% | 98.3% | 98.3%   |

| Specimen | MAMP300 | MTD   | MOP300 | MOP100 | OPI   | OXY | PCP   |
|----------|---------|-------|--------|--------|-------|-----|-------|
| Positive | 94%     | 96.1% | 96.8%  | 96.1%  | 97.6% | 98% | 97.8% |
| Negative | 92%     | 100%  | 100%   | 100%   | 98.4% | 97% | 100%  |
| Total    | 92%     | 98.1% | 98.2%  | 98.1%  | 98.1% | 97% | 98.9% |

| Specimen | PPX   | TCA   | THC   | AMP500 | COC150 |
|----------|-------|-------|-------|--------|--------|
| Positive | 97.8% | 92.1% | 96.8% | 95.9%  | 98.2%  |
| Negative | 100%  | 100%  | 98.3% | 100%   | 98.1%  |
| Total    | 99.0% | 96.8% | 97.5% | 98.1%  | 98.2%  |

\*NOTE: BUP was based on LC/MS data instead of GC/MS

A method comparison study was performed comparing the HCG Rapid Test Strip to Elisa. Testing was conducted at 2 POC sites. 140-160 individuals per site were enrolled in the study. The samples were collected from women who fit the following categories: childbearing age, suspected pregnant women, (e.g. within days of missing the expected menses), women early in pregnancy, (e.g. within the first 30 days of pregnancy), and the first trimester of pregnancy.

hCG Rapid Test

|     |   | +   | -   | Total |
|-----|---|-----|-----|-------|
| EIA | + | 130 | 0   | 130   |
|     | - | 0   | 178 | 178   |
|     |   | 130 | 178 | 308   |

Relative Sensitivity: >99.9% (97.2%-100.0%)\*

Relative Specificity: >99.9% (98.0%-100.0%)\*

Overall Agreement: >99.9% (98.8%-100.0%)\*

\*95% Confidence Interval

B. Sensitivity

The sensitivity of the Quick test cup<sup>TM</sup> Multi-Drug Urine Cup was determined by testing GC/MS confirmed controls at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times cut-off concentrations. The results are summarized below:

| Drug Conc.<br>(Cut-off Range) | n | AMP 1000 |   | BAR |   | BZO |   | COC |   | MAMP 1000 |   |
|-------------------------------|---|----------|---|-----|---|-----|---|-----|---|-----------|---|
|                               |   | -        | + | -   | + | -   | + | -   | + | -         | + |

|              |    |    |    |    |    |    |    |    |    |    |    |
|--------------|----|----|----|----|----|----|----|----|----|----|----|
| Negative     | 50 | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  |
| 50% Cut-off  | 50 | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  |
| 75% Cut-off  | 50 | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  |
| Cut-off      | 50 | 16 | 34 | 11 | 39 | 17 | 33 | 11 | 39 | 23 | 27 |
| 125% Cut-off | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 |
| 150% Cut-off | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 |
| 3X Cut-off   | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 | 0  | 50 |

| Drug Conc.<br>(Cut-off Range) | n  | MOR |    | MTD |    | TCA |    | PCP |    | THC |    |
|-------------------------------|----|-----|----|-----|----|-----|----|-----|----|-----|----|
|                               |    | -   | +  | -   | +  | -   | +  | -   | +  | -   | +  |
| Negative                      | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  |
| 50% Cut-off                   | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  |
| 75% Cut-off                   | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50  | 0  |
| Cut-off                       | 50 | 13  | 37 | 6   | 44 | 9   | 41 | 9   | 41 | 17  | 33 |
| 125% Cut-off                  | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 |
| 150% Cut-off                  | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 |
| 3X Cut-off                    | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0   | 50 |

| Drug Conc.<br>(Cut-off Range) | n  | EDDP |    | BUP |    | OXY |    | PPX |    | MDMA |    |
|-------------------------------|----|------|----|-----|----|-----|----|-----|----|------|----|
|                               |    | -    | +  | -   | +  | -   | +  | -   | +  | -    | +  |
| Negative                      | 50 | 50   | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50   | 0  |
| 50% Cut-off                   | 50 | 50   | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50   | 0  |
| 75% Cut-off                   | 50 | 50   | 0  | 50  | 0  | 50  | 0  | 50  | 0  | 50   | 0  |
| Cut-off                       | 50 | 16   | 34 | 23  | 27 | 19  | 31 | 20  | 30 | 13   | 37 |
| 125% Cut-off                  | 50 | 0    | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0    | 50 |
| 150% Cut-off                  | 50 | 0    | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0    | 50 |
| 3X Cut-off                    | 50 | 0    | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0    | 50 |

| Drug Conc.<br>(Cut-off Range) | n  | AMP300 |    | MAMP 500 |    | TML |    | MOR100 |    | COT |    | HCG20 |    |
|-------------------------------|----|--------|----|----------|----|-----|----|--------|----|-----|----|-------|----|
|                               |    | -      | +  | -        | +  | -   | +  | -      | +  | -   | +  | -     | +  |
| Negative                      | 50 | 50     | 0  | 50       | 0  | 50  | 0  | 50     | 0  | 50  | 0  | 50    | 0  |
| 50% Cut-off                   | 50 | 50     | 0  | 50       | 0  | 50  | 0  | 50     | 0  | 50  | 0  | 10    | 40 |
| 75% Cut-off                   | 50 | 50     | 0  | 50       | 0  | 50  | 0  | 50     | 0  | 50  | 0  | 30    | 20 |
| Cut-off                       | 50 | 15     | 35 | 15       | 35 | 19  | 31 | 20     | 30 | 13  | 37 | 0     | 50 |
| 125% Cut-off                  | 50 | 0      | 50 | 0        | 50 | 0   | 50 | 0      | 50 | 0   | 50 | 0     | 50 |
| 150% Cut-off                  | 50 | 0      | 50 | 0        | 50 | 0   | 50 | 0      | 50 | 0   | 50 | 0     | 50 |
| 3X Cut-off                    | 50 | 0      | 50 | 0        | 50 | 0   | 50 | 0      | 50 | 0   | 50 | 0     | 50 |

| Drug Conc.<br>(Cut-off Range) | n  | KET |    | FYL |    | ACE |    | MAMP 300 |    | AMP500 |    | COC150 |    |
|-------------------------------|----|-----|----|-----|----|-----|----|----------|----|--------|----|--------|----|
|                               |    | -   | +  | -   | +  | -   | +  | -        | +  | -      | +  | -      | +  |
| Negative                      | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50       | 0  | 50     | 0  | 50     | 0  |
| 50% Cut-off                   | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50       | 0  | 50     | 0  | 50     | 0  |
| 75% Cut-off                   | 50 | 50  | 0  | 50  | 0  | 50  | 0  | 50       | 0  | 50     | 0  | 50     | 0  |
| Cut-off                       | 50 | 16  | 34 | 23  | 27 | 19  | 31 | 35       | 15 | 17     | 33 | 11     | 39 |
| 125% Cut-off                  | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0        | 50 | 0      | 50 | 0      | 50 |
| 150% Cut-off                  | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0        | 50 | 0      | 50 | 0      | 50 |
| 3X Cut-off                    | 50 | 0   | 50 | 0   | 50 | 0   | 50 | 0        | 50 | 0      | 50 | 0      | 50 |

C. Specificity

The following tables list the concentrations of compounds (ng/mL) above which the Quick test cup<sup>TM</sup> Multi-Drug Urine Cup identified positive results at 5 minutes.

| Acetaminophen 5000 related compounds |          | Methamphetamine 500 related compounds |        |
|--------------------------------------|----------|---------------------------------------|--------|
| Acetaminophen                        | 5,000    | d-Methamphetamine                     | 500    |
| Acetophenetidine                     | 7,500    | Chloroquine                           | 12,500 |
| Amphetamine 1000 related compounds   |          | Fenfluramine                          | 12,500 |
| d-Amphetamine                        | 1,000    | l-Methamphetamine                     | 3,125  |
| l-Amphetamine                        | >100,000 | Mephentermine hemisulfate salt        | 25,000 |
| d-methamphetamine                    | >100,000 | MDEA                                  | 12,500 |
| l-methamphetamine                    | >100,000 | MDMA                                  | 1,875  |
| 3,4-Methylenedioxyamphetamine        | 1,250    | PMMA                                  | 625    |
| 3,4-Methylenedioxy-methamphetamine   | >100,000 | (-)-Ephedrine                         | 2,000  |
| 3,4-Methylenedioxyethylamphetamine   | >100,000 | Methamphetamine 300 related compounds |        |
| Paramethoxyamphetamine               | 625      | d-Methamphetamine                     | 300    |
| Phentermine                          | 1,250    | Chloroquine                           | 7,500  |
| Tyramine                             | >100,000 | Fenfluramine                          | 12,500 |
| Amphetamine 500 related compounds    |          | l-Methamphetamine                     | 10,000 |
| d-Amphetamine                        | 500      | Mephentermine hemisulfate salt        | 31,250 |
| l-Amphetamine                        | 50,000   | MDEA                                  | 50,000 |
| 3,4-Methylenedioxyamphetamine        | 625      | MDMA                                  | 313    |
| Phentermine                          | 1,250    | PMMA                                  | 625    |

|  |          |  |          |
|--|----------|--|----------|
| Paramethoxyamphetamine                       | 625      | (-)-Ephedrine                          | 2,000    |
| Tyramine                                     | >100,000 | <b>Morphine 300 related compounds</b>  |          |
| <b>Amphetamine 300 related compounds</b>     |          | Morphine                               | 300      |
| d-Amphetamine                                | 300      | Acetylcodeine                          | 150      |
| l-Amphetamine                                | 50,000   | Buprenorphine                          | 3,125    |
| Mephentermine hemisulfate salt               | >100,000 | Codeine                                | 250      |
| 3,4-Methylenedioxyamphetamine (MDA)          | 625      | Diacetyl Morphin                       | 250      |
| Phentermine                                  | 625      | Dihydrocodeine                         | 586      |
| Paramethoxyamphetamine (PMA)                 | 625      | Ethylmorphine                          | 200      |
| Paramethoxymethamphetamine (PMMA)            | >100,000 | Hydrocodone                            | 12,500   |
| Tyramine                                     | >100,000 | Hydromorphone                          | 12,500   |
| <b>Barbiturates 300 related compounds</b>    |          | 6-Monoacetylmorphine                   | 250      |
| Secobarbital                                 | 300      | Morphine-3-glucuronid                  | 2,500    |
| Allobarbitol                                 | 1,250    | Nalorphine                             | 25,000   |
| Alphenal                                     | 625      | Thebaine                               | 25,000   |
| Amobarbital                                  | 625      | <b>Methadone 300 related compounds</b> |          |
| Aprobarbital                                 | 188      | Methadone                              | 300      |
| Butabarbital                                 | 94       | (-)-alpha-methadol                     | 2,000    |
| Butalbital                                   | 2,500    | <b>Opiates 2000 related compounds</b>  |          |
| Butethal                                     | 200      | Morphine                               | 2,000    |
| Cyclopentobarbital                           | 400      | Acetylcodeine                          | 1,563    |
| Pentobarbital                                | 1,000    | Buprenorphine                          | 25,000   |
| Phenobarbital                                | 300      | Codeine                                | 2000     |
| <b>Buprenorphine 10 related compounds</b>    |          | Diacetylmorphine (Heroin)              | 5,000    |
| Buprenorphine                                | 10       | Dihydrocodeine                         | 1,563    |
| Buprenorphine-3-β-D-Glucuronide              | 10       | Ethylmorphine                          | 250      |
| Norbuprenorphine                             | 50       | Hydromorphone                          | 25,000   |
| Norbuprenorphine-3-β-D-Glucuronide           | 100      | Hydrocodone                            | 50,000   |
| <b>Benzodiazepines 300 related compounds</b> |          | Merperidine                            | >100,000 |
| Oxazepam                                     | 300      | 6-Monoacetylmorphine (6-MAM)           | 4,000    |
| Alprazolam                                   | 125      | Morphine-3-β-d-glucuronide             | 12,500   |
| Bromazepam                                   | 625      | Nalorphine Hydrochloride               | >100,000 |
| Chlordiazepoxide                             | 2500     | Oxycodone                              | >100,000 |
| Clobazam                                     | 63       | Oxymorphone                            | >100,000 |
| Clonazepam                                   | 2500     | Rifampicine                            | >100,000 |
| Clorazepate                                  | 3330     | Thebaine                               | 50,000   |
| Desalkflurazepam                             | 250      | <b>Morphine 300 related compounds</b>  |          |
| Diazepam                                     | 250      | Morphine                               | 300      |
| Estazolam                                    | 5000     | Acetylcodeine                          | 150      |
| Fentanyl                                     | >100,000 | Buprenorphine                          | 3,125    |
| Flunitrazepam                                | 375      | Codeine                                | 250      |
| Flurazepam                                   | >100,000 | Diacetyl Morphin                       | 250      |
| Lorazepam                                    | 1250     | Dihydrocodeine                         | 586      |
| Lormetazepam                                 | 1250     | Ethylmorphine                          | 200      |
| Medazepam                                    | >100,000 | Hydrocodone                            | 12,500   |
| Midazolam                                    | >100,000 | Hydromorphone                          | 12,500   |
| Nitrazepam                                   | 25000    | 6-Monoacetylmorphine                   | 250      |
| Norchlordiazepoxide                          | 250      | Morphine-3-glucuronid                  | 2,500    |
| Nordiazepam                                  | 500      | Nalorphine                             | 25,000   |
| Prazepam                                     | >100,000 | Thebaine                               | 25,000   |
| Temazepam                                    | 63       | <b>Morphine 100 related compounds</b>  |          |
| Triazolam                                    | 5000     | Morphine                               | 100      |
| <b>Cocaine 300 related compounds</b>         |          | Codeine                                | 100      |
| Benzoylcegonine                              | 300      | Diacetylmorphine (Heroin)              | 100      |
| Cocaine                                      | 1,000    | Ethylmorphine                          | 100      |
| Ecgonine                                     | 100,000  | Hydromorphone                          | 500      |
| Ecgonine Methyl Ester                        | >100,000 | Hydrocodone                            | 500      |
| <b>Cocaine 150 related compounds</b>         |          | 6-Monoacetylmorphine                   | 100      |
| Benzoylcegonine                              | 150      | Morphine-3-β-d-glucuronide             | 2,000    |
| Cocaine HCl                                  | 500      | Oxycodone                              | 20,000   |

|   |           |  |          |
|---|-----------|--|----------|
| Cocaethylene                                  | 7500      | <b>Oxymorphone</b>                                 | 20,000   |
| Ecgonine                                      | 15000     | <b>Promethazine</b>                                | >100,000 |
| Norcocaine                                    | 50000     | <b>Rifampicine</b>                                 | 8,400    |
| <b>Cotinine 200 related compounds</b>         |           | <b>Thebaine</b>                                    | 8,400    |
| (-)-Cotinine                                  | 200       | <b>Trimipramine</b>                                | 20,000   |
| (-)-Nicotine                                  | 6,250     | <b>Oxycodone 100 related compounds</b>             |          |
| <b>EDDP 100 related compounds</b>             |           | Oxycodone  | 100      |
| EDDP  | 100       | Hydrocodone  | 25,000   |
| Meperidine                                    | >100,000  | Hydromorphone                                      | 50,000   |
| Methadone                                     | >100,000  | Naloxone   | 50,000   |
| Norfentanyl                                   | >100,000  | Oxymorphone  | 250      |
| Phencyclidine                                 | >100,000  | <b>Phencyclidine 25 related compounds</b>          |          |
| Promazine                                     | 50,000    | Phencyclidine                                      | 25       |
| Promethazine                                  | 25,000    | Hydrocodone  | >100,000 |
| Prothipendyl                                  | 50,000    | Hydromorphone                                      | >100,000 |
| Prozine                                       | 12,500    | 4-hydroxyphencyclidine                             | 75       |
| <b>Fentanyl 200 related compounds</b>         |           | <b>Propoxyphene 300 related compounds</b>          |          |
| Fentanyl and Fentanyl metabolites             | 200       | D-Propoxyphene                                     | 300      |
| Fentanyl                                      | 200       | D-Norpropoxyphene                                  | 5,000    |
| Norfentanyl                                   | >10,000   | <b>Tricyclic Antidepressants related compounds</b> |          |
| <b>Ketamine 1000 related compounds</b>        |           | Nortriptyline HCl                                  | 1,000    |
| Ketamine                                      | 1000      | Amitriptyline                                      | 1,500    |
| Norketamine                                   | 1000      | Clomipramine                                       | >100,000 |
| Dextromethorphan                              | >1 00000  | Cyclobenzaprine                                    | 12,500   |
| Dextrorphan tartrate                          | >100000   | Desipramine  | 188      |
| D-Norpropoxyphene                             | 31250     | Doxepin  | 2,000    |
| EDDP  | >1 000000 | Imipramine   | 2,500    |
| Meperidine                                    | 12500     | Maprotiline  | 750      |
| Mephentermine hemisulfate salt                | 50000     | Nortriptyline                                      | 3,125    |
| Methadone                                     | 12500     | Nordoxepin   | 500      |
| D-Methamphetamine                             | 12500     | Opipramol  | 1,563    |
| 3,4-Methylenedioxyethylamphetamine            | 25000     | Promazine  | 1,000    |
| Nordoxepin hydrochloride                      | 25000     | Promethazine                                       | 6,250    |
| Phencyclidine                                 | 5000      | Prothipendyl                                       | 25,000   |
| Promazine                                     | 8000      | Protryptiline                                      | 6,250    |
| Promethazine                                  | 25000     | Prozine  | 1,250    |
| <b>Ecstasy 500 related compounds</b>          |           | Trimipramine                                       | >100,000 |
| 3,4-Methylenedioxy-methamphetamine            | 500       | <b>Marijuana 50 related compounds</b>              |          |
| d- Amphetamine                                | >100,000  | 11-nor-Δ9-THC-9-COOH                               | 50       |
| l-Amphetamine                                 | >100,000  | 11-nor-Δ8-THC-9-COOH                               | 50       |
| d-methamphetamine                             | >100,000  | 11-hydroxy-Δ9-Tetrahydrocannabinol                 | 50       |
| l-methamphetamine                             | >100,000  | Δ8-Tetrahydrocannabinol                            | 15,000   |
| 3,4-Methylenedioxyamphetamine                 | 2,500     | Δ9-Tetrahydrocannabinol                            | 15,000   |
| 3,4-Methylenedioxyethylamphetamine            | 156       | Cannabinol   | 20,000   |
| Paramethoxyamphetamine                        | 50,000    | Cannabidiol  | >100,000 |
| Paramethoxymethamphetamine                    | >100,000  |  |          |
| <b>Methamphetamine 1000 related compounds</b> |           |  |          |
| d-Methamphetamine                             | 1,000     |  |          |
| Chloroquine                                   | 25,000    |  |          |
| Fenfluramine                                  | 12,500    |  |          |
| l-Methamphetamine                             | 10,000    |  |          |
| Mephentermine hemisulfate salt                | 31,250    |  |          |
| 3,4-Methylenedioxyethylamphetamine            | 50,000    |  |          |
| 3,4-Methylenedioxy-methamphetamine            | 313       |  |          |
| Paramethoxymethamphetamine                    | 625       |  |          |
| (-)-Ephedrine                                 | 4,000     |  |          |

The specificity of the hCG Rapid Test (Urine) was determined from cross reactivity studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all produced negative results.









A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the QuickCup Drugs of Abuse Integrated Cup when tested at concentrations up to 100 µg/mL.

|                              |                                   |                 |
|------------------------------|-----------------------------------|-----------------|
| (-)-Ephedrine (Except MET)   | Chlorpheniramine                  | Oxalic Acid     |
| (+)-Naproxen                 | Creatine                          | Penicillin-G    |
| (+/-)-Ephedrine (Except MET) | Dextromethorphan (Except KET)     | Pheniramine     |
| 4-Dimethylaminoantiryrine    | Dextrorphan tartrate (Except KET) | Phenothiazine   |
| Acetaminophen                | Dopamine                          | Procaine        |
| Acetone                      | Erythromycin                      | Protonix        |
| Albumin                      | Ethanol                           | Pseudoephedrine |
| Amitriptyline (Except TCA)   | Furosemide                        | Quinidine       |
| Ampicillin                   | Glucose                           | Ranitidine      |
| Aspartame                    | Guaiacol Glyceryl Ether           | Sertraline      |
| Aspirin                      | Hemoglobin                        | Tyramine        |
| Benzocaine                   | Imipramine (Except TCA)           | Trimепrazine    |
| Bilirubin                    | (+/-)-Isoproterenol               | Venlafaxine     |
| b-Phenylethyl-amine          | Methadone (Except MTD)            | Ibuprofen       |
| Caffeine                     | Vitamin C (Ascorbic Acid)         | Lidocaine       |
| Chloroquine (Except MET)     |                                   |                 |

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#### GLOSSARY OF SYMBOLS

|   |  |   |                        |
|---|--|---|------------------------|
|  | Catalog number                         |  | Temperature limitation |
|  | Consult instructions for use           |  | Batch code             |
|  | <i>In vitro</i> diagnostic medical cup |  | Use by                 |
|  | Manufacturer                           |  | Do not reuse           |

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