# MD-U621 Drugs of Abuse Integrated Cup (Urine)

## INTENDED USE

The Drugs of Abuse Integrated Cup (Urine) 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 | 1,000 |
| AMP | d-Amphetamine | 300 |
| BAR | Secobarbital | 300 |
| BUP | Buprenorphine | 10 |
| BUP | Buprenorphine | 5 |
| BZO | Oxazepam | 300 |
| BZO | Oxazepam | 200 |
| COC | Benzoylecgonine | 300 |
| COC | Benzoylecgonine | 150 |
| COC | Benzoylecgonine | 100 |
| COT | Cotinine | 200 |
| EDDP | 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 |
| EDDP | 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine | 100 |
| FYL | Fentanyl | 200 |
| KET | Ketamine | 1,000 |
| MDMA | 3,4-Methylenediioxy-MET | 500 |
| MET | d-Methamphetamine | 1,000 |
| MET | d-Methamphetamine | 500 |
| MET | d-Methamphetamine | 300 |
| MTD | Methadone | 300 |
| OPI/MOP | Morphine | 300 |
| OPI/MOP | Morphine | 100 |
| OPI2000 | Morphine | 2,000 |
| OXY | Oxycodone | 100 |
| PCP | Phencyclidine | 25 |
| PPX | Propoxyphene | 300 |
| TCA | Nortriptyline | 1,000 |
| THC | 11-nor- Δ9-THC-9-carboxylic acid | 200 |
| THC | 11-nor- Δ9-THC-9-carboxylic acid | 50 |
| THC | 11-nor- Δ9-THC-9-carboxylic acid | 25 |
| TML | Tramadol | 100 |
| Synthetic cannabis(K2) | JWH-073/JWH-018 | 50 |
| ALC | Alcohol | 0.02% |

The Integrated Split Specimen Cup (Urine) can also come with adulteration strips listed below:

| | |
|---|---|
| Adulteration（StripA） | Oxidants / Specific Gravity / PH |
| Adulteration（StripB） | Nitrite / Glutaraldehyde / Creatinine |

## PRINCIPLE

The Drugs of Abuse Integrated Cup (Urine) 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.

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as Creatinine, pH, and Specific Gravity and to detect the presence of Glutaraldehyde, Nitrite and Oxidants/Pyridinium Chlorochromate in urine.

**Creatinine (CRE)**: Tests for specimen dilution. Creatinine is a waste product of Creatine, and is an amino-acid contained in muscle tissue and found in urine.1 A person may attempt to foil a drug test by drinking excessive amounts of water or diuretics such as herbal teas to flush the system. Creatinine and Specific Gravity are two ways to check for dilution and flushing, which are the most common mechanisms used to circumvent drug testing. Low Creatinine and Specific Gravity levels may indicate diluted urine. The absence of Creatinine (<5 mg/dL) is indicative of a specimen not consistent with **human urine.**

**Nitrite (NIT)**: Tests for commonly used commercial adulterants. They work by oxidizing the major cannabinoid metabolite THC-COOH.2 Normal urine should contain no trace of Nitrites. Positive results generally indicate the presence of an adulterant.

**Glutaraldehyde (GLUT)**: Tests for the presence of aldehydes. Adulterants can contain Glutaraldehyde and can cause false negative screening results by disrupting the enzyme used in some immunoassay tests.[3] Glutaraldehyde is not normally found in urine; therefore, detection of Glutaraldehyde in a urine specimen is generally indicates adulteration.

**pH:** Tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate that the specimen has been altered.

**Specific Gravity (SG)**: Tests for specimen dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

**Oxidants/Pyridinium Chlorochromate (OXI/PCC):** Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.[3] Normal human urine should not contain Oxidants or PCC.

## MATERIALS

### Materials Provided

Individually packed test cups with integrated drug of abuse test panels

Caps

Package insert

### Materials Required but Not provided

Timer

Centrifuge

Positive and negative controls

## PRECAUTIONS

- For professional in vitro diagnostic use only.
- 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.

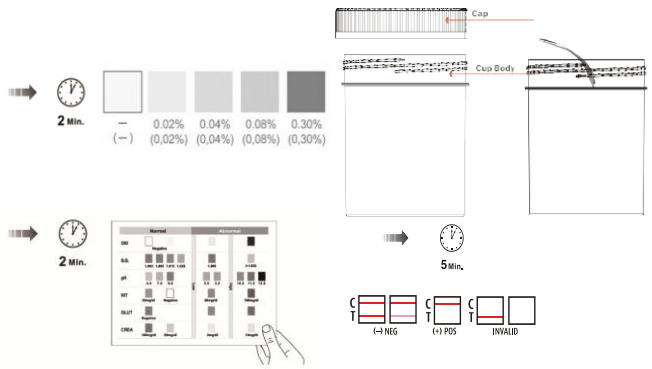
## SPECIMEN COLLECTION AND STORAGE

- The Drugs of Abuse Integrated Cup (Urine) 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 if stored at refrigerated temperatures.** Remove the cup from sealed pouch and use it as soon as possible.

1. Donor dates and initials body label.
2. Donor provides a urine specimen in the cup and screws cap on to it. Start timer immediately.
3. Operator checks the cap for tightness.
4. Remove the peel-off label.
5. Check the temperature strip label at 2-4 minutes after specimen collection for the fresh urine specimen. 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).
6. Drug test results are indicated by the presence or absence of colored band(s) in the result area of the test strips. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.
7. Positive test results must be confirmed by another test method. Send the cup and urine specimen intact to a toxicology laboratory for confirmation.
8. For the adulteration, compared with the color card, and the results should be read at 2 minutes , do not interpret the result after 5 minutes.
9. For alcohol test, read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the alcohol concentration. Do not interpret the result after 3 minutes. For the adulteration, compared with the color card and the results should be read at 2 minutes, do not interpret the result after 5 minutes.




## 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.

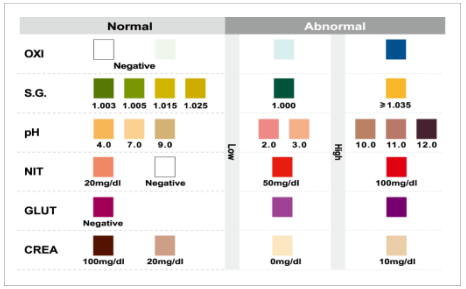
**NEGATIVE: Two colored bands appear** on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

**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:**

1. 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.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

**The Result Of Adulteration Strips:**




**NOTE:**

The Urine 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

**The Quality Control Of DOA:**

- 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.

**The Quality Control Of Adulteration Strips:**

Control standards are not supplied with this kit. However, it is recommended that positive and negative specimens or controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

## LIMITATIONS OF THE TEST

1. The Drugs of Abuse Integrated Cup(Urine) is for professional in vitro diagnostic use, and should be only used for the qualitative detection of drugs of abuse.
2. 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.
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. 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.
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 time rule out the presence of drugs/metabolites in urine, as they may be present below the minimum detection level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

**The Limitations Of Adulteration Strips:**

The Urine 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.

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

**2. 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.

**3. 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.

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

**5. 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 Drugs of Abuse Integrated Cup(Urine) was established by running urine samples against GC/MS.

| Specimen | AMP | AMP | AMP300 | BAR | BUP10 | BUP5* | BZO | BZO200 |
|---|---|---|---|---|---|---|---|---|
| Positive | 96.1% | 95.8% | 94.8% | 97.8% | 100% | 100% | 95.3% | 97.4% |
| Negative | 100% | 100% | 100% | 98.1% | 98.1% | 100% | 92.9% | 98.2% |
| Total | 98.1% | 98.1% | 97.6% | 98% | 99.4% | 100% | 93.9% | 97.8% |

| Specimen | COC | COC100 | COT | EDDP | EDDP100 | FYL | KET | MDMA |
|---|---|---|---|---|---|---|---|---|
| Positive | 98.2% | 98.2% | 97.7% | 95.8% | 96% | 96.8% | 97.9% | 96.8% |
| Negative | 98.1% | 98.1% | 97.9% | 100% | 100% | 100% | 98.1% | 100% |
| Total | 98.2% | 98.2% | 97.8% | 98.1% | 98.1% | 97.5% | 98.0% | 98.3% |

| Specimen | MET | MET500 | MET300 | MTD | MOP | MOP100 | OPI | OXY |
|---|---|---|---|---|---|---|---|---|
| Positive | 96.8% | 96.9% | 96.8% | 96.1% | 96.8% | 96.1% | 97.6% | 96.1% |
| Negative | 100% | 100% | 100% | 100% | 97.9% | 100% | 98.4% | 100% |
| Total | 98.3% | 98.3% | 98.4% | 98.1% | 97.3% | 98.1% | 98.1% | 98.1% |

| Specimen | PCP | PPX | TCA | THC | THC50 | THC25 | TML | K2 |
|---|---|---|---|---|---|---|---|---|
| Positive | 97.8% | 97.8% | 92.1% | 96.1% | 96.8% | 96.8% | 98.4% | 98.9% |
| Negative | 100% | 100% | 100% | 100% | 98.3% | 98.3% | 100% | 100% |
| Total | 98.9% | 99.0% | 96.8% | 98.1% | 97.5% | 97.5% | 99.1% | 99% |

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

**B. Sensitivity**

The sensitivity of The Drugs of Abuse Integrated Cup (Urine) 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. (Cut-off Range) | n | ACE | | AMP | | AMP300 | | BAR | | BUP10 | | BUP5 | | BZO | | BZO200 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | 0 | 50 | 0 | 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 | 50 | 0 | 50 | 0 |
| 75% Cut-off | 50 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 50 | 19 | 31 | 16 | 34 | 20 | 30 | 11 | 39 | 25 | 25 | 21 | 29 | 17 | 33 | 11 | 39 |
| 125% Cut-off | 50 | 0 | 50 | 0 | 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 | 0 | 50 | 0 | 50 |
| 3× Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off Range) | n | COC | | COC150 | | COC100 | | COT | | EDDP | | EDDP100 | | FYL | | KET | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | 0 | 50 | 0 | 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 | 50 | 0 | 50 | 0 |
| 75% Cut-off | 50 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 50 | 11 | 39 | 24 | 26 | 23 | 27 | 13 | 37 | 24 | 26 | 25 | 25 | 23 | 27 | 16 | 34 |
| 125% Cut-off | 50 | 0 | 50 | 0 | 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 | 0 | 50 | 0 | 50 |
| 3× Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off Range) | n | MDMA | | MET | | MET500 | | MET300 | | MTD | | MOP | | MOP100 | | OPI2000 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | 0 | 50 | 0 | 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 | 50 | 0 | 50 | 0 |
| 75% Cut-off | 50 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 50 | 25 | 25 | 23 | 27 | 10 | 40 | 17 | 33 | 6 | 44 | 18 | 32 | 20 | 30 | 13 | 37 |
| 125% Cut-off | 50 | 0 | 50 | 0 | 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 | 0 | 50 | 0 | 50 |
| 3× Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off Range) | n | OXY | | PCP | | PPX | | TCA | | THC | | THC50 | | THC25 | | TML | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | - | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | 0 | 50 | 0 | 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 | 50 | 0 | 50 | 0 |
| 75% Cut-off | 50 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 |
| Cut-off | 50 | 19 | 31 | 9 | 41 | 20 | 30 | 9 | 41 | 17 | 33 | 17 | 33 | 11 | 39 | 11 | 39 |
| 125% Cut-off | 50 | 0 | 50 | 0 | 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 | 0 | 50 | 0 | 50 |
| 3× Cut-off | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 | 0 | 50 |

| Drug Conc. (Cut-off Range) | K2 | |
|---|---|---|
| | - | + |
| Negative | 50 | 0 |
| 50% Cut-off | 50 | 0 |
| 75% Cut-off | 50 | 0 |
| Cut-off | 14 | 36 |
| 125% Cut-off | 0 | 50 |
| 150% Cut-off | 0 | 50 |
| 3× Cut-off | 0 | 50 |

**C. Specificity**

The following tables list the concentrations of compounds (ng/mL) above which the Drugs of Abuse Integrated Cup (Urine) identified positive results at 5 minutes.

| | | | | |
|---|---|---|---|---|
| **Acetaminophen 5000 related compounds** | | | Mephentermine hemisulfate salt | 15,625 |
| Acetaminophen | 5,000 | | Methadone | 50,000 |
| Acetophenetidine | 7,500 | | D-Methamphetamine | 12,500 |
| **Amphetamine 1000 related compounds** | | | 3,4-Methylenedioxyethylampheta mine | 25,000 |
| D - Amphetamine | 1000 | | Nordoxepin hydrochloride | 25,000 |
| L - Amphetamine | 20000 | | Phencyclidine | 5,000 |
| DL - Amphetamine | 3000 | | Promazine | 8,000 |
| Phentermine | 30000 | | Promethazine | 25,000 |
| Hydroxyamphetamine | 8000 | | **Ecstasy 500 related compounds** | |
| Methylenedioxyamphetamine (MDA) | 20000 | | 3,4-Methylenedioxy-methamphet amine | 500 |
| d-Methamphetamine | >100,000 | | d-Amphetamine | >100,000 |
| 1-Methamphetamine | >100,000 | | l-Amphetamine | >100,000 |
| Ephedrine | >100,000 | | d-methamphetamine | >100,000 |
| Methylenedioxyethylamphetamine (MDE) | >100,000 | | l-methamphetamine | >100,000 |
| 3,4-methylenedioxy-methamphetami ne (MDMA) | >100,000 | | 3,4-Methylenedioxyamphetamine | 2,500 |
| **Amphetamine 300 related compounds** | | | 3,4-Methylenedioxyethylampheta mine | 156 |
| D - Amphetamine | 300 | | Paramethoxyamphetamine | 50,000 |
| L - Amphetamine | 6000 | | Paramethoxymethamphetamine | >100,000 |
| DL - Amphetamine | 600 | | **Methamphetamine 1000 related compounds** | |
| Phentermine | 7500 | | d-Methamphetamine | 1,000 |
| Hydroxyamphetamine | 2000 | | Chloroquine | 25,000 |
| Methylenedioxyamphetamine (MDA) | 6000 | | Fenfluramine | 12,500 |
| d-Methamphetamine | >100000 | | l-Methamphetamine | 10,000 |
| 1-Methamphetamine | >100000 | | Mephentermine hemisulfate salt | 31,250 |
| Ephedrine | >100000 | | 3,4-Methylenedioxyethylampheta mine | 50,000 |
| Methylenedioxyethylamphetamine (MDE) | >100000 | | 3,4-Methylenedioxy-methamphet amine | 313 |
| 3,4-methylenedioxy-methamphetami ne (MDMA) | >100000 | | Paramethoxymethamphetamine | 625 |
| **Barbiturates 300 related compounds** | | | (-)-Ephedrine | 4,000 |
| Oxazepam | 300 | | **Methamphetamine 500 related compounds** | |
| Alprazolam | 150 | | d-Methamphetamine | 500 |
| Bromazepam | 1,000 | | Chloroquine | 12,500 |
| Chlordiazepoxide | 375 | | Fenfluramine | 12,500 |
| Clobazam | 100 | | l-Methamphetamine | 3,125 |
| Clonazepam | 2,500 | | Mephentermine hemisulfate salt | 25,000 |
| Clorazepate | 625 | | MDEA | 12,500 |
| Desalkflurazepam | 500 | | MDMA | 1,875 |
| Diazepam | 500 | | PMMA | 625 |
| Estazolam | 1,000 | | (-)-Ephedrine | 2,000 |
| Fentanyl | >100,000 | | **Methamphetamine 300 related compounds** | |
| Flunitrazepam | >50,000 | | d-Methamphetamine | 300 |
| Flurazepam | >100,000 | | Chloroquine | 7,500 |
| Lorazepam | 10,000 | | Fenfluramine | 12,500 |
| Lormetazepam | 2,500 | | l-Methamphetamine | 10,000 |
| Medazepam | >100,000 | | Mephentermine hemisulfate salt | 31,250 |
| Midazolam | 10,000 | | MDEA | 50,000 |
| Nitrazepam | 250 | | MDMA | 313 |
| Norchlordiazepoxide | 250 | | PMMA | 625 |
| Nordiazepam | 500 | | (-)-Ephedrine | 2,000 |
| Prazepam | >100,000 | | **Morphine 300 related compounds** | |
| Temazepam | 250 | | Morphine | 300 |
| Triazolam | 1,000 | | Acetylcodeine | 150 |
| **Buprenorphine 10 related compounds** | | | Buprenorphine | 3,125 |
| Buprenorphine | 10 | | Codeine | 250 |
| Buprenorphine–3–β–D–Glucuronid e | 10 | | Diacetyl Morphin | 250 |
| Norbuprenorphine | 50 | | Dihydrocodeine | 586 |
| Norbuprenorphine–3–β–D–Glucur onide | 100 | | Ethylmorphine | 200 |
| **Buprenorphine 5 related compounds** | | | Hydrocodone | 12,500 |
| Buprenorphine | 5 | | Hydromorphone | 12,500 |

| | |
|---|---|
| Buprenorphine–3–β–D–Glucuronid | 5 |
| Norbuprenorphine | 25 |
| Norbuprenorphine–3–β–D–Glucur | 50 |
| **Benzodiazepines 300 related compounds** | |
| Oxazepam | 300 |
| Alprazolam | 150 |
| Bromazepam | 1,000 |
| Chlordiazepoxide | 375 |
| Clobazam | 100 |
| Clonazepam | 2,500 |
| Clorazepate | 625 |
| Desalkflurazepam | 500 |
| Diazepam | 500 |
| Estazolam | 1,000 |
| Fentanyl | >100,000 |
| Flunitrazepam | >50,000 |
| Flurazepam | >100,000 |
| Lorazepam | 10,000 |
| Lormetazepam | 2,500 |
| Medazepam | >100,000 |
| Midazolam | 10,000 |
| Nitrazepam | 250 |
| Norchlordiazepoxide | 250 |
| Nordiazepam | 500 |
| Prazepam | >100,000 |
| Temazepam | 250 |
| Triazolam | 1,000 |
| **Benzodiazepines 200 related compounds** | |
| Oxazepam | 200 |
| Alprazolam | 75 |
| Bromazepam | 400 |
| Chlordiazepoxide | 1,667 |
| Clobazam | 40 |
| Clonazepam | 1,600 |
| Clorazepate | 2,220 |
| Desalkflurazepam | 225 |
| Diazepam | 225 |
| Estazolam | 3,333 |
| Fentanyl | >100,000 |
| Flunitrazepam | 250 |
| Flurazepam | >100,000 |
| Lorazepam | 1000 |
| Lormetazepam | 1000 |
| Medazepam | >100,000 |
| Midazolam | >100,000 |
| Nitrazepam | 25,000 |
| Norchlordiazepoxide | 200 |

| | |
|---|---|
| 6-Monoacetylmorphine | 250 |
| Morphine-3-glucuronid | 2,500 |
| Nalorphine | 25,000 |
| Thebaine | 25,000 |
| **Morphine 100 related compounds** | |
| Morphine | 100 |
| Codeine | 100 |
| Diacetylmorphine (Heroin) | 100 |
| Ethylmorphine | 100 |
| Hydromorphone | 500 |
| Hydrocodone | 500 |
| 6-Monoacetylmorphine | 100 |
| Morphine-3-β -d-glucuronide | 2,000 |
| Oxycodone | 20,000 |
| Oxymorphone | 20,000 |
| Promethazine | >100,000 |
| Rifampicine | 8,400 |
| Thebaine | 8,400 |
| Trimipramine | 20,000 |
| Methylphenidate | 300 |
| **Methadone 300 related compounds** | |
| Methadone | 300 |
| (-)-alpha-methadol | 2,000 |
| **Opiates2000 related compounds** | |
| Morphine | 2,000 |
| Acetylcodeine | 1,563 |
| Buprenorphine | 25,000 |
| Codeine | 500 |
| Diacetylmorphine (Heroin) | 1,250 |
| Dihydrocodeine | 1,563 |
| Ethylmorphine | 800 |
| Hydromorphone | 25,000 |
| Hydrocodone | 50,000 |
| Merperidine | >100,000 |
| 6-Monoacetylmorphine | 1,250 |
| Morphine-3-β-d-glucuronide | 12,500 |
| Nalorphine Hydrochloride | >100,000 |
| Oxycodone | >100,000 |
| Oxymorphone | >100,000 |
| Rifampicine | >100,000 |
| Thebaine | 50,000 |
| **Oxycodone 100 related compounds** | |
| Oxycodone | 100 |
| Hydrocodone | 25,000 |
| Hydromorphone | 50,000 |
| Naloxone | 50,000 |
| Oxymorphone | 250 |

| | |
|---|---|
| Nordiazepam | 350 |
| Prazepam | >100,000 |
| Temazepam | 40 |
| Triazolam | 5,000 |
| | |
| | |
| **Cocaine 300 related compounds** | |
| Benzoylecgonine | 300 |
| Cocaine HCl | 750 |
| Cocaethylene | 12500 |
| Ecgonine | 32000 |
| Norcocaine | 100,000 |
| **Cocaine 200 related compounds** | |
| Benzoylecgonine | 200 |
| Cocaine HCl | 600 |
| Cocaethylene | 8500 |
| Ecgonine | 20000 |
| Norcocaine | 65000 |
| **Cocaine 150 related compounds** | |
| Benzoylecgonine | 150 |
| Cocaine HCl | 500 |
| Cocaethylene | 7500 |
| Ecgonine | 15000 |
| Norcocaine | 50000 |
| **Cotinine 200 related compounds** | |
| (-)-Cotinine | 200 |
| (-)-Nicotine | 6,250 |
| **EDDP 100 related compounds** | |
| EDDP | 100 |
| Meperidine | >100,000 |
| Methadone | >100,000 |
| Norfentanyl | >100,000 |
| Phencyclidine | >100,000 |
| Promazine | 50,000 |
| Promethazine | 25,000 |
| Prothipendyl | 50,000 |
| Prozine | 12,500 |
| **EDDP 300 related compounds** | |
| EDDP | 300 |
| Meperidine | >100,000 |
| Methadone | >100,000 |
| Norfentanyl | >100,000 |
| Phencyclidine | >100,000 |
| Promazine | 80,000 |
| Promethazine | 75,000 |
| Prothipendyl | 80,000 |
| Prozine | 37,500 |

| | |
|---|---|
| **Phencyclidine 25 related compounds** | |
| Phencyclidine | 25 |
| Hydrocodone | 12,500 |
| Hydromorphone | 6,250 |
| 4-hydroxyphencyclidine | 75 |
| **Propoxyphene 300 related compounds** | |
| D-Propoxyphene | 300 |
| D-Norpropoxyphene | 5,000 |
| **Tricyclic Antidepressants related compounds** | |
| Nortriptyline HCl | 1,000 |
| Amitriptyline | 1,500 |
| Clomipramine | >100,000 |
| Cyclobenzaprine | 12,500 |
| Desipramine | 188 |
| Doxepin | 2,000 |
| Imipramine | 2,500 |
| Maprotiline | 750 |
| Nortriptyline | 3,125 |
| Nordoxepin | 500 |
| Doxepin | 500 |
| Promazine | 1,000 |
| Promethazine | 6,250 |
| Nortriptyline | 1000 |
| Protryptyline | 6,250 |
| Prozine | 1,250 |
| Trimipramine | >100,000 |
| **Marijuana 200 related compounds** | |
| 11-nor-Δ9-THC-9-COOH | 200 |
| 11-nor-Δ8-THC-9-COOH | 200 |
| Δ8-Tetrahydrocannabinol | 30,000 |
| Δ9-Tetrahydrocannabinol | 30,000 |
| Cannabinol | 20,000 |
| **Marijuana 50 related compounds** | |
| 11-nor-Δ9-THC-9-COOH | 50 |
| 11-nor-Δ8-THC-9-COOH | 50 |
| 11-hydroxy-Δ9-Tetrahydrocannabi | 50 |
| Δ8-Tetrahydrocannabinol | 15,000 |
| Δ9-Tetrahydrocannabinol | 15,000 |
| Cannabinol | 20,000 |
| Cannabidiol | >100,000 |
| **Marijuana 25 related compounds** | |
| 11-nor-Δ9-THC-9-COOH | 25 |
| 11-nor-Δ8-THC-9-COOH | 15 |
| Δ8-Tetrahydrocannabinol | 7,500 |
| Δ9-Tetrahydrocannabinol | 7,500 |
| Cannabinol | 10,000 |
| Cannabidiol | >100,000 |
| **Tramadol 100 related compounds** | |

| | |
|---|---|
| **Fentanyl 200 related compounds** | |
| Fentanyl and metabolites | 10 |
| Fentanyl | 200 |
| Norfentanyl | >10.000 |
| **Ketamine 1000 related compounds** | |
| Ketamine | 1,000 |
| Norketamine | 1,000 |
| Dextromethorphan | 500 |
| Dextrorphan tartrate | 500 |
| D-Norpropoxyphene | 31,250 |
| EDDP | 800 |
| Meperidine | 12,500 |

| | |
|---|---|
| Tramadol | 25 |
| (+/-)Chlorpheniramine | 15 |
| Dimenhydrinate | 7,500 |
| Diphenhydramine | 7,500 |
| Phencyclidine | 10,000 |
| (+)-Chlorpheniramine | >100,000 |
| **K2 50 related compounds** | |
| JWH-018-5-Pentanoic acid | 50 |
| JWH-073-4-Butanoic acid | 50 |

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 Drugs of Abuse Integrated Cup (Urine) 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-Dimethyllaminoantiyrine | 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 | Ibuprofen | Vitamin C (Ascorbic Acid) |
| Bilirubin | Imipramine (Except TCA) | Trimeprazine |
| b-Phenylethyl-amine | Isoproterenol | Venlafaxine |
| Caffeine | Lidocaine | |
| Chloroquine (Except MET) | Methadone (Except MTD) | |

## LITERATURE REFERENCES


1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd ed. Davis: Biomedical Publications; 1982.
2. Hawks RL, Chiang CN, eds. Urine Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute on Drug Abuse; 1986.
3. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register; 1988.
4. McBay AJ. Drug-analysis technology--pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl): 33B-40B.
5. Gilman AG, Goodman LS, Gilman A, eds. Goodman and Gilman's The Pharmacological Basis of Therapeutics. 6th ed. New York: Macmillan; 1980.


## GLOSSARY OF SYMBOLS

| | | | |
|---|---|---|---|
| REF | Catalog number | | Temperature limitation |
| | Consult instructions for use | LOT | Batch code |
| IVD | In vitro diagnostic medical device | | Use by |
| | Manufacturer | | Contains sufficient for <n> tests |
| | Do not reuse | EC REP | Authorized representative in the European Community |
| CE | CE marking according to IVD Medical Devices Directive 98/79/EC | | |


Number: 1110015593
REV 2.1/ Effective date: 2018-06-28