# Multi Drug Screen Testing cup

## INTENDED USE

The Multi Drug Screen Testing 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 | Amphetamine | 1,000 |
| AMP | Amphetamine | 300 |
| BAR | Barbiturates | 300 |
| BUP | Buprenorphine | 10 |
| BZO | Benzodiazepines | 300 |
| BZO | Benzodiazepines | 200 |
| COC | Cocaine | 300 |
| COT | Cotinine | 200 |
| EDDP | EDDP | 100 |
| FYL | Fentanyl | 200 |
| KET | Ketamine | 1,000 |
| K2 | JWH-073/JWH-018 | 50 |
| MDMA | Ecstasy | 500 |
| MET | Methamphetamine | 1,000 |
| MET | Methamphetamine | 500 |
| MET | Methamphetamine | 300 |
| MTD | Methadone | 300 |
| OPI/MOR | Morphine 300 | 300 |
| OPI/MOR | Morphine 100 | 100 |
| OPI2000 | Opiates 2000 | 2,000 |
| OXY | Oxycodone | 100 |
| PCP | Phencyclidine | 25 |
| PPX | Propoxyphen | 300 |
| TCA | Tricyclic Antidepressants | 1,000 |
| THC | Marijuana | 50 |
| TML | Tramadol | 100 |
| Adulteration（StripA） | Oxidants / Specific Gravity / PH | |
| Adulteration（StripB） | Nitrite / Glutaraldehyde / Creatinine | |
| ALC | Alcohol | |

## PRINCIPLE

The Multi Drug Screen Testing 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.

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 asCreatinine, 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.

The Alcohol Test is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the specimen, reacts with chemicals on the reaction pad and causes a color change.

The Urine Alcohol Test consists of a plastic card with a reaction pad attached at the strip in it. The reaction pad employs a solid-phase chemistry system which uses a highly specific enzyme reaction. On contact with specimens of alcohol, the reaction pad will rapidly change colors depending on the concentration of alcohol present. This color change is proportional to the concentration of alcohol in the specimen. By comparing with the color blocks on the color chart printed on the pouch, an approximate alcohol concentration can be determined.

## MATERIALS

**Materials Provided**

- Cups with multi-drug cards
- Package insert

**Materials Required but Not provided**

- A timer or any kind of a timing device such as a wrist watch is required to run this test.
- External 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 ℃ 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.

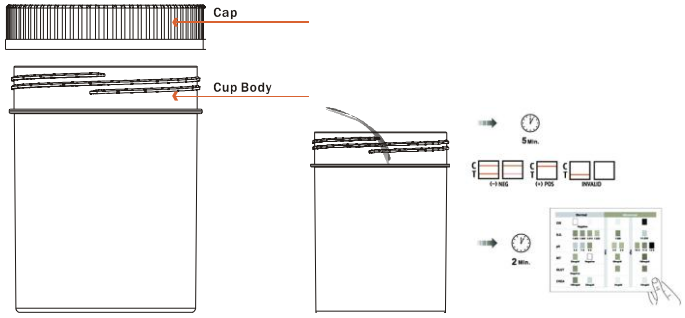
## SPECIMEN COLLECTION AND STORAGE

- The Multi Drug Screen Testing 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 ℃ for up to 2 days. For long term storage, specimens should be kept below -20 ℃.
- 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 ℃) before use.**

1. Remove the cup from its sealed pouch and use it as soon as possible.
2. Donor provides a urine specimen in the cup and screws the cap on to the cup. Start the timer.
3. Donor dates and initials the security seal label. Operator checks the cap for tightness 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 appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100 ℉ (32-38 ℃).
6. 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 8 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 the Alcohol, read results at 5 minutes by visually comparing the color of the reaction pad to the corresponding color blocks on the pouch to determine the alcohol concentration. Do not interpret the result after 10 minutes.




## INTERPRETATION OF RESULTS

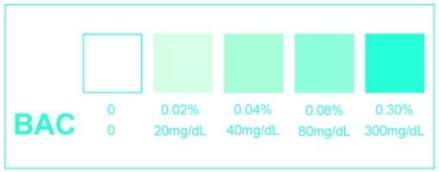
(See previous illustration)

**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.

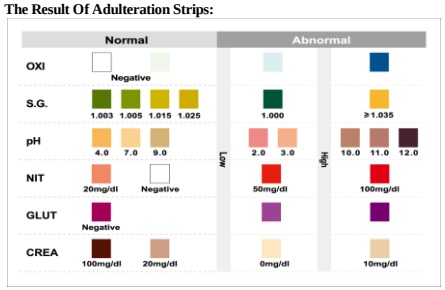
**NEGATIVE: Two colored bands appear** on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

**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.

**The Result Of Alcohol Strip：**




**The Result Of Adulteration Strips:**




**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.

**3.** 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.

**The Quality Control Of Alcohol strip:**

- This solution should produce a color change on the reaction pad corresponding to 0.02% or greater. The color reaction with alcohol in the human urine is somewhat slower and less intense than with alcohol in an aqueous solution.
- Do not perform the control test with undiluted alcohol, as pure alcohol solutions will not produce a positive result.

## LIMITATIONS OF THE TEST

**The Limitations Of DOA:**

1. The Multi Drug Screen Testing cup 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:**

8. 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.
9. Creatinine: Normal Creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases show dilute urine.
10. 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.
11. 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.
12. Specific Gravity: Elevated levels of protein in urine may cause abnormally high Specific Gravity values.
13. 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.

**The Limitations Of Urine Alcohol Strips:**

**14.** The Urine Alcohol Test provides only a preliminary result for detection alcohol concentration in human urine. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.

**15.** Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.

**16.** The Urine Alcohol Test should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.

**17.** Alcohol concentration in human body slowly increases after the alcohol ingestion. Generally, the maximum of alcohol concentration in human urine, appears in the range from 30 minutes to 60 minutes after the last alcohol ingestion. After the maximum appearance, the alcohol concentration in human body reduces. How long the alcohol concentration reduces to zero depends on how much alcohol ingested.

**18.** The Urine Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test strip. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.

**19.** Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.

## PERFORMANCE CHARACTERISTICS

**A. Accuracy**

The accuracy of the Multi Drug Screen Testing cup was established by running urine samples against GC/MS.

**Acetaminophen 5000ng/ml** (GC/MS values calibrated to acetaminophen): In this study, one hundred and six (106) negative and positive urine samples (0 to 86,256 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (4,986 and5,022ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 6 | 43 |
| (-) | 49 | 6 | 2 | 0 |
| Total | 49 | 6 | 8 | 43 |

Positive Agreement: 96.1% Negative Agreement: 100% Total Agreement: 98.1%

**Amphetamine 1000ng/ml** (GC/MS values calibrated to amphetamine): In this study, one hundred three (103) negative and positive urine samples (0 to 46,922 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (1,064 and 1,117 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 5 | 41 |
| (-) | 48 | 7 | 2 | 0 |
| Total | 48 | 7 | 7 | 41 |

Positive Agreement: 95.8% Negative Agreement: 100% Total Agreement: 98.1%

**Amphetamine 300ng/ml** (GC/MS values calibrated to amphetamine): In this study, one hundred three (105) negative and positive urine samples (0 to 34,922 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (275 and325 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 45 |
| (-) | 46 | 8 | 2 | 0 |
| Total | 46 | 8 | 6 | 45 |

Positive Agreement: 96.1% Negative Agreement: 100% Total Agreement: 98.1%

**Barbiturates 300ng/ml** (GC/MS values calibrated to secobarbital or phenobarbital): In this study, ninety-eight (98) negative and positive urine samples (0 to 6,941 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (282 and 304 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 3 | 42 |
| (-) | 45 | 6 | 1 | 0 |
| Total | 45 | 7 | 4 | 42 |

Positive Agreement: 97.8% Negative Agreement: 98.1% Total Agreement: 98.0%

**Benzodiazepines 300ng/ml** (GC/MS values calibrated to oxazepam, nordiazepam, or alprazolam): In this study, ninety-nine (99) negative and positive urine samples (0 to >10,000 ng/mL) were tested and compared with GC/MS. The six discrepant specimens were confirmed with GC/MS to have concentrations of oxazepam - 292 and 319 ng/mL, and alprazolam – 315, 317, 367 and 488 ng/mL. The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 3 | 1 | 5 | 36 |
| (-) | 47 | 5 | 2 | 0 |
| Total | 50 | 6 | 7 | 36 |

Positive Agreement: 95.3% Negative Agreement: 92.9% Total Agreement: 93.9%

**Benzodiazepines 200ng/ml** (GC/MS values calibrated to oxazepam, nordiazepam, or alprazolam): In this study, ninety-nine (99) negative and positive urine samples (0 to >10,000 ng/mL) were tested and compared with GC/MS. The six discrepant specimens were confirmed with GC/MS to have concentrations of oxazepam - 193and 211 ng/mL, and alprazolam – 211, 215, 254 and 324ng/mL. The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 4 | 1 | 6 | 35 |
| (-) | 46 | 5 | 1 | 1 |
| Total | 50 | 6 | 7 | 36 |

Positive Agreement: 95.3% Negative Agreement: 91.1% Total Agreement: 92.9%

**Buprenorphine 10ng/ml** (GC/MS specifications are the value of Buprenorphine): In this study, one hundred and ten (110) negative and positive urine samples (0 to 6941 ng/ml) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cutoff value (9.5 and 12.1 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 51 | 51 |
| (-) | 47 | 6 | 0 | 0 |
| Total | 47 | 7 | 51 | 51 |

Positive Agreement: 98.2% Negative Agreement: 98.1% Total Agreement: 98.1%

**Cocaine 300ng/ml** (GC/MS values calibrated to benzoylecgonine): In this study, one hundred ten (110) negative and positive urine samples (0 to 245,682 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (284 and 328 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 4 | 51 |
| (-) | 47 | 6 | 1 | 0 |
| Total | 47 | 7 | 5 | 51 |

Positive Agreement: 98.2% Negative Agreement: 98.1% Total Agreement: 98.2%

**Cotinine 200ng/ml** (GC/MS values calibrated to cotinine): In this study, ninety eight (98) negative and positive urine samples (0 to 4,962 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (190 and 220 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 1 | 42 |
| (-) | 45 | 2 | 1 | 0 |
| Total | 45 | 3 | 2 | 42 |

Positive Agreement: 97.7% Negative Agreement: 97.9% Total Agreement: 97.96%

**EDDP 100ng/ml** (GC/MS specifications are the value of EDDP): In this study, one hundred and three (103) negative and positive urine samples (0 to >10000 ng/ml) were tested and compared with GC/MS. The six discrepant specimens were confirmed with GC/MS to be close to the cut-off value (94 and 102 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 5 | 41 |
| (-) | 48 | 7 | 2 | 0 |
| Total | 48 | 7 | 7 | 41 |

Positive Agreement: 95.8% Negative Agreement: 100.0% Total Agreement: 98.1%

**Fentanyl 200ng/ml** (GC/MS specifications are the value of fentanyl): In this study, one hundred and nine (109) negative and positive urine samples (0 to 6,420 ng/ml) were tested and compared with GC/MS. The six discrepant specimens were confirmed with GC/MS to be close to the cut-off value (189 and 202 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 6 | 45 |

| | | | | |
|---|---|---|---|---|
| (-) | 52 | 3 | 3 | 0 |
| Total | 52 | 3 | 9 | 45 |

Positive Agreement: 94.4% Negative Agreement: 100.0% Total Agreement: 97.2%

**Ketamine 1000ng/ml** (GC/MS specifications are the value of ketamine): In this study, one hundred and nineteen (119) negative and positive urine samples (0 to 8,320 ng/ml) were tested and compared with GC/MS. The six discrepant specimens were confirmed with GC/MS to be close to the cut-off value (986 and 1055 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 2 | 46 |
| (-) | 63 | 6 | 1 | 0 |
| Total | 63 | 7 | 3 | 46 |

Positive Agreement: 97.96% Negative Agreement: 98.57% Total Agreement: 98.32%

**K2 50ng/ml** (GC/MS values calibrated to JWH-018/KWH-073): In this study, one hundred fifteen (110) negative and positive urine samples (0 to 46,106 ng/mL), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (42and 60 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 3 | 1 | 4 | 45 |
| (-) | 47 | 7 | 3 | 0 |
| Total | 50 | 8 | 7 | 45 |

Positive Agreement: 94.2% Negative Agreement: 93.1% Total Agreement: 93.6%

**MDMA 500ng/ml** (GC/MS specifications are the value of (±)3,4-Methylenedioxymethamhetamine): In this study, one hundred and fifteen (115) negative and positive urine samples (0 to 82120 ng/ml), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cutoff value (489 and 532 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 57 |
| (-) | 44 | 8 | 2 | 0 |
| Total | 44 | 8 | 6 | 57 |

Positive Agreement: 96.8% Negative Agreement: 100.0% Total Agreement: 98.3 %

**MDMA 3**00**ng/ml** (GC/MS specifications are the value of (±)3,4-Methylenedioxymethamhetamine): In this study, one hundred and fifteen (118) negative and positive urine samples (0 to 68411 ng/ml), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cutoff value (288 and 317 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 3 | 57 |
| (-) | 47 | 8 | 3 | 0 |
| Total | 47 | 8 | 6 | 57 |

Positive Agreement: 95.2% Negative Agreement: 100.0% Total Agreement: 97.5%

**Methadone 300ng/ml** (GC/MS values calibrated to methadone): In this study, one hundred five (105) negative and positive urine samples (0 to 22,400 ng/mL) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (275.5 and 325 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 45 |
| (-) | 46 | 8 | 2 | 0 |
| Total | 46 | 8 | 6 | 45 |

Positive Agreement: 96.1% Negative Agreement: 100% Total Agreement: 98.1%

**Methamphetamine 1000ng/ml** (GC/MS values calibrated to methamphetamine): In this study, one hundred fifteen (115) negative and positive urine samples (0 to 82,106 ng/mL), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (1,007 and 1,040 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 57 |
| (-) | 44 | 8 | 2 | 0 |
| Total | 44 | 8 | 6 | 57 |

Positive Agreement: 96.8% Negative Agreement: 100% Total Agreement: 98.3%

**Methamphetamine 500ng/ml** (GC/MS values calibrated to methamphetamine): In this study, one hundred fifteen (109) negative and positive urine samples (0 to 76,106 ng/mL), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (345 and 756 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 6 | 45 |
| (-) | 52 | 3 | 3 | 0 |
| Total | 52 | 3 | 9 | 45 |

Positive Agreement: 94.4% Negative Agreement: 100.0% Total Agreement: 97.2%

**Methamphetamine 300ng/ml** (GC/MS values calibrated to methamphetamine): In this study, one hundred fifteen (109) negative and positive urine samples (0 to 76,106 ng/mL), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cut-off value (268and 489 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 5 | 45 |
| (-) | 52 | 2 | 4 | 0 |
| Total | 52 | 3 | 9 | 45 |

Positive Agreement: 92.6% Negative Agreement: 98.2% Total Agreement: 95.4%

**Nortriptyline 1000ng/ml** (GC/MS values calibrated to nortriptyline): In this study, ninety-five (95) negative and positive urine samples (0 to 10,045 ng/mL) were tested and compared with GC/MS. The concentrations of three discrepant specimens were confirmed with GC/MS to be close to the cut-off value (1,018, 1,069 and 1,193 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 6 | 29 |
| (-) | 50 | 7 | 3 | 0 |
| Total | 50 | 7 | 9 | 29 |

Positive Agreement: 92.1% Negative Agreement: 100% Total Agreement: 96.8%

**OPI/MOR 300ng/ml** (GC/MS specifications are the value of Morphine or Codeine): In this study, one hundred eleven (111) negative and positive unaltered urine samples (0 to 5182 ng/ml) were tested by using cassette and dipstick device and were compared with GC/MS. The concentrations of both discrepant specimens were confirmed with GC/MS to be close to the cutoff value (308 and 309 ng/ml). The results are summarized below:

Positive Agreement: 96.8% and Negative Agreement: 97.9%

| Drug Screen | No Drug present | Negative (Less than 50% the cutoff conc. by GC/MS analysis) | Near Cutoff Negative (Between -50% and the cutoff Conc) | Near Cutoff Positive (Between the cutoff and 150% Conc.) | High Positive (> 150% Conc.) | % Agreement |
|---|---|---|---|---|---|---|
| + | 0 | 0 | 1 | 11 | 50 | 96.8% |
| - | 35 | 0 | 12 | 2 | 0 | 97.9% |
| Total | 35 | 0 | 13 | 13 | 50 | 97.3 % |

**OPI/MOR 100ng/ml** (GC/MS specifications are the value of Morphine or Codeine): In this study, one hundred eleven (105 negative and positive unaltered urine samples (0 to 5248 ng/ml) were tested by using cassette and dipstick device and were compared with GC/MS. The concentrations of both discrepant specimens were confirmed with GC/MS to be close to the cutoff value (98and 107 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 45 |
| (-) | 46 | 8 | 2 | 0 |
| Total | 46 | 8 | 6 | 45 |

Positive Agreement: 96.1% Negative Agreement: 100% Total Agreement: 98.1%

**OPI 2000 2000ng/ml** (GC/MS specifications are the value of morphine or codeine): In this study, one hundred and five (105) negative and positive urine samples (0 to 50236 ng/ml) were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cutoff value (1836 and 2041.5 ng/ml). The results are summarized below:

Positive Agreement: 97.6% and Negative Agreement: 98.4%

| | (-) | | (+) | | |
|---|---|---|---|---|---|
| Drug Screen | GC/MS Negative (0 ng/ml to 75%) | Near cutoff negative (75%-cutoff) | Near cutoff positive (cutoff to 125%) | GC/MS Positive (>125%) | % Agreement with GC/MS |
| (+) | 0 | 1 | 7 | 33 | 97.6 % |
| (-) | 56 | 7 | 1 | 0 | 98.4 % |
| Total | 56 | 8 | 8 | 33 | 98.1 % |

**Oxycodone 100ng/ml** (GC/MS specifications are the value of Oxycodone): In this study, one hundred and five (105) negative and positive urine samples (0 to 12400 ng/ml), were tested and compared with GC/MS. The concentrations of two discrepant specimens were confirmed with GC/MS to be close to the cutoff value (84 and 119ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 4 | 45 |
| (-) | 46 | 8 | 2 | 0 |
| Total | 46 | 8 | 6 | 45 |

Positive Agreement: 96.1% Negative Agreement: 100% Total Agreement: 98.1%

**PCP 25ng/ml** (GC/MS values calibrated to phencyclidine): In this study, ninety-four (94) negative and positive urine samples (0 to >1,000 ng/mL) were tested and compared with GC/MS. The concentration of the discrepant specimen was confirmed with GC/MS to be close to the cut-off value (23.5 and 27.8 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 5 | 40 |
| (-) | 46 | 2 | 1 | 0 |
| Total | 46 | 2 | 6 | 40 |

Positive Agreement: 97.8% Negative Agreement: 100% Total Agreement: 98.9%

**Propoxyphene 300ng/ml** (GC/MS specifications are the value of Propoxyphene ): In this study, ninety-four (94) negative and GC/MS confirmed positive urine samples (0 to >10000 ng/ml) were tested and compared with GC/MS. The concentration of the discrepant specimen was confirmed with GC/MS to be close to the cutoff value (289 and 314 ng/ml). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 5 | 40 |
| (-) | 46 | 2 | 1 | 0 |
| Total | 46 | 2 | 6 | 40 |

Positive Agreement: 97.8% Negative Agreement: 100.0% Total Agreement: 99.0%

**THC 50ng/ml** (GC/MS values calibrated to 11-nor-Δ9-THC-9-COOH): In this study, one hundred twenty-two (122) negative and positive urine samples (0 to >2,000 ng/mL) were tested and compared with GC/MS. The concentrations of three discrepant specimens were confirmed with GC/MS to be close to the cut-off value (48, 50 and 54 ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 1 | 7 | 53 |
| (-) | 45 | 14 | 2 | 0 |
| Total | 45 | 15 | 9 | 53 |

Positive Agreement: 96.8% Negative Agreement: 98.3% Total Agreement: 97.5%

**Tramadol 100ng/ml** (GC/MS values calibrated to tramadol): In this study, one hundred fifteen (115) negative and positive urine samples (0 to >1,500 ng/mL) were tested and compared with GC/MS. The concentrations of three discrepant specimens were confirmed with GC/MS to be close to the cut-off value (92 and 103ng/mL). The results are summarized below:

| | (-) | | (+) | |
|---|---|---|---|---|
| Multi Drug Screen Testing cup | GC/MS negative | Near cut-off negative (75% to cut-off) | Near cut-off positive (cut-off to 125%) | GC/MS positive (>125%) |
| (+) | 0 | 0 | 6 | 57 |
| (-) | 42 | 9 | 1 | 0 |
| Total | 42 | 9 | 7 | 57 |

Positive Agreement: 98.4% Negative Agreement: 100% Total Agreement: 99.1%

**B. Sensitivity**

The sensitivity of the SureCup Multi Drug Screen Testing 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. (Cut-off Range) | n | AMP 1000 | | BAR | | BZO | | COC | | MET1000 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 50% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 75% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| Cut-off | 50 | 16 | 34 | 11 | 39 | 17 | 33 | 11 | 39 | 23 | 27 |
| 125% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 150% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 3X Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |

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

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

| Drug Conc. (Cut-off Range) | n | AMP300 | | MET500 | | TML | | MOR100 | | COT | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 50% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 75% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| Cut-off | 50 | 15 | 35 | 15 | 35 | 19 | 31 | 20 | 30 | 13 | 37 |
| 125% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 150% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 3X Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |

| Drug Conc. (Cut-off Range) | n | KET | | FYL | | ACE | | BZO200 | | MET300 | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + |
| Negative | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 50% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| 75% Cut-off | 50 | 50 | | 50 | | 50 | | 50 | | 50 | |
| Cut-off | 50 | 16 | 34 | 23 | 27 | 19 | 31 | 21 | 29 | 15 | 35 |
| 125% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 150% Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |
| 3X Cut-off | 50 | | 50 | | 50 | | 50 | | 50 | | 50 |

| Drug Conc. (Cut-off Range) | n | MDMA300 | | K2 | |
|---|---|---|---|---|---|
| | | - | + | - | + |
| Negative | 50 | 50 | | 50 | |
| 50% Cut-off | 50 | 50 | | 50 | |
| 75% Cut-off | 50 | 50 | | 50 | |
| Cut-off | 50 | 16 | 34 | 24 | 26 |
| 125% Cut-off | 50 | | 50 | | 50 |
| 150% Cut-off | 50 | | 50 | | 50 |
| 3X Cut-off | 50 | | 50 | | 50 |

**B. Specificity**
The following tables list the concentrations of compounds (ng/mL) above which the Multi Drug Screen Testing cup identified positive results at 5 minutes.

| **Acetaminophen related compounds** | **Concentration (ng/ml)** |
|---|---|
| Acetaminophen | 5,000 |
| Acetophenetidine | 7,500 |
| **Amphetamine related compounds** | **Concentration(ng/ml)** |
| d-Amphetamine | 1,000 |
| l-Amphetamine | 100,000 |
| MDA | 1,250 |
| Phentermine | 1,250 |
| PMA | 625 |
| Tyramine | 100,000 |
| **Amphetamine related compounds** | **Concentration(ng/m** |
| d-Amphetamine | 300 |
| l-Amphetamine | 50,000 |
| MDA | 625 |
| Phentermine | 625 |
| PMA | 625 |
| Tyramine | 100,000 |
| **Barbiturates related compounds** | **Concentration(ng/ml)** |
| Secobarbital | 300 |
| Allobarbital | 1,250 |
| Alphenal | 625 |
| Amobarbital | 625 |
| Aprobarbital | 188 |
| Butabarbital | 94 |
| Butalbital | 2,500 |
| Butethal | 200 |
| Cyclopentobarbital | 400 |
| Pentobarbital | 1,000 |
| Phenobarbital | 300 |
| **Benzodiazepines related compounds** | **Concentration(ng/ml)** |
| Oxazepam | 300 |
| Alprazolam | 125 |
| Bromazepam | 625 |
| Chlordiazepoxide | 2,500 |
| Clobazam | 63 |
| Clonazepam | 2,500 |
| Clorazepate | 3,330 |
| Delorazepam | 2,500 |
| Desalkflurazepam | 250 |
| Diazepam | 250 |
| Estazolam | 5,000 |
| Flunitrazepam | 375 |
| Lorazepam | 1,250 |
| Lormetazepam | 1,250 |
| Midazolam | 100,000 |
| Nitrazepam | 25,000 |
| Norchlordiazepoxide | 250 |
| Nordiazepam | 500 |
| Sulindac | 100,000 |
| Temazepam | 63 |
| Triazolam | 5,000 |
| **Benzodiazepines related compounds** | **Concentration(ng/ml)** |
| Oxazepam | 200 |
| Alprazolam | 188 |
| Bromazepam | 500 |
| Chlordiazepoxide | 2,500 |
| Clobazam | 63 |
| Clonazepam | 1,250 |
| Clorazepate | 3,330 |
| Delorazepam | 1,250 |
| Desalkflurazepam | 250 |
| Diazepam | 250 |
| Estazolam | 2,500 |
| Flunitrazepam | 250 |
| Lorazepam | 1,250 |
| Lormetazepam | 1,250 |
| Midazolam | 6,250 |
| Nitrazepam | 25,000 |
| Norchlordiazepoxide | 125 |
| Nordiazepam | 500 |
| Sulindac | 100,000 |
| Temazepam | 125 |
| Triazolam | 780 |

| **Buprenorphine related compounds** | **Concentration(ng/ml)** |
|---|---|
| Buprenorphine | 10 |
| Buprenorphine Glucuronide | 25 |
| Buprenorphine–3–β–D–Glucuronide | 10 |
| Norbuprenorphine | 50 |
| Norbuprenorphine–3–β–D–Glucuronide Result 3 | 100 |
| **Cocaine related compounds** | **Concentration(ng/ml)** |
| Benzoylecgonine | 300 |
| Cocaine | 1,000 |
| Ecgonine | 100,000 |
| **Cotinine related compounds** | **Concentration (ng/ml)** |
| Cotinine | 200 |
| Buprenorphine | 100,000 |
| **EDDP related compounds** | **Concentration(ng/ml)** |
| 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 |
| **Fentanyl related compounds** | **Concentration (ng/ml)** |
| Fentanyl | 200 |
| Norfentanyl | 375 |
| **Ketamine related compounds** | **Concentration(ng/ml)** |
| Ketamine | 1,000 |
| Norketamine | 1,000 |
| Dextromethorphan | 500 |
| Dextrorphan tartrate | 500 |
| D-Norpropoxyphene | 31,250 |
| EDDP | 800 |
| Meperidine | 12,500 |
| Mephentermine hemisulfate salt | 15,625 |
| Methadone | 50,000 |
| D-Methamphetamine | 12,500 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | 25,000 |
| Nordoxepin hydrochloride | 25,000 |
| Phencyclidine | 5,000 |
| Promazine | 8,000 |
| Promethazine | 25,000 |
| **K2 related compounds** | **Concentration(ng/ml)** |
| WH-018 5-pentanoic acid metabolite | 50 |
| JWH-073- Butanoic acid | 50 |
| **Ecstasy related compounds** | **Concentration(ng/ml)** |
| 3,4-Methylenedioxy-methamphetamine (MDMA) | 500 |
| 3,4-Methylenedioxyamphetamine (MDA) | 2,500 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | 156 |
| Paramethoxyamphetamine (PMA) Result 1 | 50,000 |
| Paramethoxymethamphetamine(PMMA) | 10,000 |
| **Methadone related compounds** | **Concentration (ng/ml)** |
| Methadone | 300 |
| Doxylamine (New 4/4/06) | |
| (-)-alpha-methadol | 2,000 |
| **Methamphetamine related compounds** | **Concentration(ng/ml)** |
| d-Methamphetamine | 1,000 |
| Chloroquine | 25,000 |
| Fenfluramine | 12,500 |
| l-Methamphetamine | 10,000 |
| Mephentermine hemisulfate salt | 31,250 |
| MDEA | 50,000 |
| MDMA | 313 |
| PMMA | 625 |

| Methamphetamine related compounds | Concentration(ng/ml) |
|---|---|
| d-Methamphetamine | 500 |
| Chloroquine | 12,500 |
| Fenfluramine | 12,500 |
| l-Methamphetamine | 3,125 |
| Mephentermine hemisulfate salt | 25,000 |
| MDEA | 12,500 |
| MDMA | 1,875 |
| PMMA | 625 |

| Methamphetamine related compounds | Concentration(ng/ml) |
|---|---|
| d-Methamphetamine | 300 |
| Chloroquine | 12,500 |
| d-Amphetamine | 50,000 |
| (-)-Ephedrine | 100,000 |
| Fenfluramine | 6,250 |
| l-Methamphetamine | 1,563 |
| L-Phenylephrine | 100,000 |
| Mephentermine hemisulfate salt | 6,250 |
| 3,4-Methylenedioxyamphetamine (MDA) | 100,000 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | 6,250 |
| 3,4-Methylenedioxy-methamphetamine(MDMA) | 625 |
| Procaine | 50,000 |
| Ranitidine | 100,000 |

| Morphine 300 related compounds | Concentration(ng/ml) |
|---|---|
| Morphine | 300 |
| Acetylcodeine | 150 |
| Buprenorphine | 3,125 |
| Codeine | 250 |
| Diacetyl Morphin | 250 |
| Dihydrocodeine | 586 |
| Ethylmorphine | 200 |
| Hydrocodone | 12,500 |
| Hydromorphone | 12,500 |
| 6-Monoacetylmorphine | 250 |
| Morphine-3-glucuronid | 2,500 |
| Nalorphine | 25,000 |
| Thebaine | 25,000 |

| Morphine 100 related compounds | Concentration(ng/ml) |
|---|---|
| Morphine | 100 |
| Codeine | 100 |
| Diacetylmorphine (Heroin) | 100 |
| Ethylmorphine | 100 |
| Hydromorphone | 500 |
| Hydrocodone | 500 |
| 6-Monoacetylmorphine (6-MAM) | 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 |

| Opiates 2000 related compounds | Concentration(ng/ml) |
|---|---|
| Morphine | 2,000 |
| Acetylcodeine | 1,563 |
| Buprenorphine | 25,000 |
| Codeine | 500 |
| Diacetyl Morphin (Heroin) | 1,250 |
| Dihydrocodeine | 1,563 |
| Ethylmorphine | 800 |
| Hydrocodone | 50,000 |
| Hydromorphone | 25,000 |
| 6-Monoacetylmorphine | 1,250 |
| Morphine-3-β-d-glucuronid | 12,500 |
| Nalorphine | 100,000 |
| Thebaine | 50,000 |

| Oxycodone related compounds | Concentration(ng/ml) |
|---|---|
| Oxycodone | 100 |
| Hydrocodone Result 1 | 25,000 |
| Hydromorphone | 50,000 |
| Naloxone | 50,000 |
| Oxymorphone | 250 |

| Phencyclidine related compounds | Concentration(ng/ml) |
|---|---|
| Phencyclidine | 25 |
| Hydrocodone | 12,500 |
| Hydromorphone | 6,250 |

| Propoxyphen related compounds | Concentration(ng/ml) |
|---|---|
| D-Propoxyphene | 300 |
| D-Norpropoxyphene | 5,000 |

| Tricyclic Antidepressants related compounds | Concentration(ng/ml) |
|---|---|
| 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 |
| Opipramol | 1,563 |
| Promazine | 1,000 |
| Promethazine | 6,250 |
| Prothipendyl | 25,000 |
| Protryptyline | 6,250 |
| Prozine | 1,250 |
| Trimipramine | 100,000 |

| Marijuana related compounds | Concentration(ng/ml) |
|---|---|
| 11-nor-Δ9-THC-9-COOH | 50 |
| 11-nor-Δ8-THC-9-COOH | 50 |
| Δ9-tetrahydrocannabinol | 15,000 |
| Δ8-tetrahydrocannabinol | 15,000 |
| Cannabinol | >20,000 |

| Tramadol related compounds | Concentration (ng/ml) |
|---|---|
| Tramadol | 100 |
| Doxylamine (New 4/4/06) | |
| (+)-Chlorpheniramine | 100,000 |
| (+/-)Chlorpheniramine | 50,000 |
| Dimenhydrinate | 50,000 |
| Diphenhydramine | 50,000 |
| Phencyclidine | 50,000 |

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 SureCup Multi Drug Screen Testing cup when tested at concentrations up to 100 µg/mL.

Acetone
Albumin
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chlorpheniramine
Creatine
4-Dimethylaminoantipyrine
Dopamine
(±)-Ephedrine
Guaiacol glyceryl ether
Hemoglobin
Ibuprofen
(±)-Isoproterenol
Lidocaine
N-Methyl-ephedrine
(+)-Naproxen
Oxalic acid
Penicillin-G
Pheniramine
Phenothiazine
L-Phenylephrine
β-Phenylethylamine
Quinidine
Erythromycin
Ethanol
Furosemide
Ranitidine
Vitamin C

## LITERATURE REFERENCES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