Atlas Medical CE

# One Step Multi-Line Screen Test Panel with Cup (Urine)

## Instruction Sheet for testing of any combination of the following drugs:

Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana,Methadone, Methamphetamine, Methylenedioxymethamphetamine, Opiates/Morphine, Opiates Phencyclidine, Tramadol, Tricyclic Antidepressants, EDDP, Buprenorphine, Ketamine, Oxycodone, Propoxyphene and Lysergic acid diethylamide.

*A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine.*

IVD *For professional in vitro diagnostic use only.*

2-30°C **Store at 2-30 °C**

**INTENDED USE & INTRODUCTION**

The Multi-Drug One Step Screen Test Cup (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of any combination listed below:

| Test | Calibrator | Cut-off |
|---|---|---|
| Amphetamine (AMP) | D-Amphetamine | 1,000 ng/mL |
| Amphetamine (AMP) | D-Amphetamine | 500 ng/mL |
| Barbiturates (BAR) | Secobarbital | 300 ng/mL |
| Benzodiazepines (BZO) | Oxazepam | 300 ng/mL |
| Cocaine (COC) | Benzoylecgonine | 300 ng/mL |
| Marijuana (THC) | 11-nor-$\Delta^9$-THC-9 COOH | 50 ng/mL |
| Methadone (MTD) | Methadone | 300 ng/mL |
| Methamphetamine (MET) | D-Methamphetamine | 1,000 ng/mL |
| Methamphetamine (MET) | D-Methamphetamine | 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | D,L Methylenedioxymethamphetamine | 500 ng/mL |
| Opiates/Morphine (OPI/MOP 300) | Morphine | 300 ng/mL |
| Opiates (OPI 2000) | Morphine | 2,000 ng/mL |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL |
| Tricyclic Antidepressants (TCA) | Nortriptyline | 1,000 ng/mL |
| EDDP (Methadone metabolite) | 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 100 ng/ml |
| TML (Tramadol) | Cis-Tramadol | 100 ng/ml |
| Buprenorphine(BUP) | Buprenorphine | 10 ng/ml |
| KET (Ketamine) | Ketamine | 1000 ng/ml |
| Oxycodone (OXY) | Oxycodone | 100 ng/ml |
| Propoxyphene (PPX) | Propoxyphene | 25 ng/ml |
| Lysergic acid diethylamide (LSD) | 9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide | 20 ng/ml |

**INTRODUCTION**

Drug of abuse is any substances thatis illegal or legal drug used inapporoperiate way. This include the repeated use of drugs to produce pleasure,alleviate stressand or avoid reality it also include using prescription drugs other than prescribed or using someone elses prescription.

**PRINCIPLE**

The Multi-Drug One Step Multi-Line Screen Test Panel Cup (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region.

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.

**MATERIALS**

**Materials Provided**

- Cups with multi-drug panels
- Package insert

**Materials Required But Not Provided**

- Timer

**PRECAUTIONS**

- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test panel should be discarded according to federal, state and local regulations.

**STORAGE AND STABILITY**

- The kit can be stored at room temperature or refrigerated (2-30°C). The test panel is stable through the expiration date printed on the sealed pouch.
- The test panel must remain in the sealed pouch until use.
- **Do not freeze.**
- Do not use beyond the expiration date.

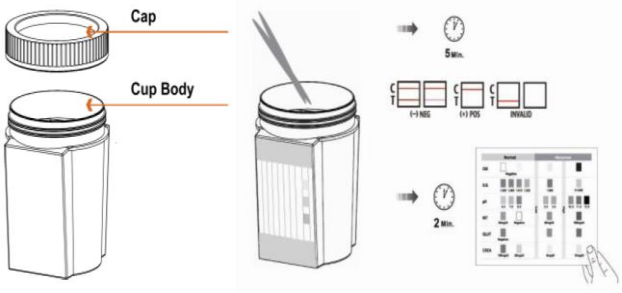
**SPECIMEN COLLECTION AND PREPARATION**

- The Multiple Drugs Test Cup is intended for use with human urine specimens only.
- Urine collected at any time of the day may be used.
- 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**

**Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.**

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 body label. 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. 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. 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.




**INTERPRETATION OF RESULTS**

(Please refer to the illustration above)

**NEGATIVE: * Two lines adjacent to each drug name appear**.

One red line should be in the control region (C) of the specific drug test, and another apparent red or pink line adjacent to each drug test should be in the test region (T) of the specific drug test.

**NOTE:**

The shade of red in the test region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE: One red line appears in the control region (C) of the specific drug test.** No line appears in the test region (T) of the specific drug test. The absence of a test line indicates a positive result for that drug.

**INVALID: Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

**QUALITY CONTROL**

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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

**LIMITATIONS**

- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive result might be obtained from certain foods or food supplements.

**PERFORMANCE CHARACTERISTICS**

**Accuracy**

A side-by-side comparison was conducted using One Step Multi-Line Screen Test Panel with Integrated Cup (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

**% Agreement with Commercial Kit**

| | Positive Agreement | Negative Agreement | Total Results |
|---|---|---|---|
| **AMP 1000** | 97% | 100% | 98% |
| **AMP 500** | 99% | 100% | >99% |
| **BAR** | >99% | >99% | 99% |
| **BZO** | 90% | 97% | 94% |
| **COC** | 95% | >99% | 98% |
| **THC** | 98% | 100% | 99% |
| **MTD** | 99% | >99% | >99% |
| **MET 1000** | 98% | 100% | 99% |
| **MET 500** | 99% | 100% | >99% |
| **MDMA** | 100% | 99% | 99% |
| **OPI/MOP 300** | 100% | 100% | 100% |
| **OPI 2000** | >99% | >99% | >99% |
| **PCP** | 98% | 100% | 99% |
| **TCA** | 95% | >99% | 99% |
| **EDDP** | 100% | 100% | 100% |
| **BUP** | 88% | >99% | 97% |
| **TML** | 95.8% | 100% | 98.1% |
| **KET** | >99% | 100% | >99% |
| **OXY** | >99% | 95.7% | 96% |
| **PPX** | >99% | 97.1% | 97.3% |
| **LSD** | 100% | 100% | 100% |

**% Agreement with GC/MS**

| | Positive Agreement | Negative Agreement | Total Results |
|---|---|---|---|
| **AMP 1000** | 97% | 95% | 96% |
| **AMP 500** | 99% | 97% | 98% |
| **BAR** | >99% | >99% | 99% |
| **BZO** | 96% | 96% | 96% |
| **COC** | 96% | >90% | 93% |
| **THC** | 97% | 88% | 91% |
| **MTD** | 99% | >94% | >96% |
| **MET 1000** | 99% | 94% | 96% |
| **MET 500** | 100% | 96% | 98% |
| **MDMA** | 96% | 98% | 97% |
| **OPI/MOP 300** | 100% | 94% | 97% |
| **OPI 2000** | >99% | >90% | >95% |
| **EDDP** | 100% | 94% | 97% |
| **PCP** | 100% | 97% | 98% |
| **TCA*** | 99% | 89% | 91% |
| **TML** | 99.9% | 99.9% | 99.9% |
| **BUP** | 98% | 99% | 99% |
| **KET** | 98% | 99% | 98.5% |
| **OXY** | >99% | 95.7% | 96% |
| **PPX** | >99% | 97.1% | 97.3% |
| **LSD** | 100% | 100% | 100% |

*Note: TCA was based on HPLC data instead of GC/MS.

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

**Analytical Sensitivity**

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

| Drug conc. (Cut-off range) | n | AMP | | BAR | | BZO | | BUP | | COC | | THC | | MTD | | MET | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| **0** | 25 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 |
| **Cut-off-50%** | 25 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 |
| **Cut-off-25%** | 25 | 25 | 0 | 24 | 1 | 25 | 0 | 25 | 0 | 25 | 0 | 24 | 1 | 25 | 0 | 25 | 0 |
| **Cut-off+25%** | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 1 | 24 | 0 | 25 | 0 | 25 | 0 | 25 |
| **Cut-off+50%** | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |

| Drug conc. (Cut-off range) | n | MDMA | | MOP | | OPI | | OXY | | PCP | | PPX | | TCA | | KET | | LSD | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + | - | + |
| **0** | 25 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 |
| **Cut-off-50%** | 25 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 |
| **Cut-off-25%** | 25 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 24 | 1 | 25 | 0 | 25 | 0 | 24 | 1 |
| **Cut-off+25%** | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 2 | 25 | 0 | 25 | 0 | 25 |
| **Cut-off+50%** | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 | 0 | 25 |

**Analytical Specificity**

The following tables lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug One Step Multi-Drug Screen Panel (Urine) at 5 minutes.

| **AMPHETAMINE 1000** | **(ng/ml)** |
|---|---|
| d-Amphetamine | 1,000 |
| l-Amphetamine | 100,000 |
| MDA | 1,250 |
| Phentermine | 1,250 |
| PMA | 625 |
| Tyramine | 100,000 |
| **AMPHETAMINE 500** | **(ng/ml)** |
| d-Amphetamine | 500 |
| l-Amphetamine | 50,000 |
| MDA | 625 |
| Phentermine | 625 |
| PMA | 313 |
| Tyramine | 50,000 |
| **METHAMPHETAMINE 1000** | **(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 500** | **(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 |
| **METHYLENEDIOXYMETHAMPHETAMINE** | **(ng/ml)** |
| 3,4–MethylenedioxymethamphetamineHCl | 500 |
| 3,4–MethylenedioxyamphetamineHCl | 3,000 |
| 3,4–Methylenedioxyethylamphetamine | 300 |
| **BARBITURATES** | **(ng/ml)** |
| Secobarbital | 300 |
| Amobarbital | 300 |
| Alphenol | 150 |
| Aprobarbital | 200 |
| Butabarbital | 75 |
| Butethal | 100 |
| Butalbital | 2,500 |
| Cyclopentobarbital | 600 |
| Pentobarbital | 300 |
| Phenobarbital | 100 |
| **OPIATES/MORPHINE 300** | **(ng/ml)** |
| Morphine | 300 |
| Codeine | 300 |
| Ethylmorphine | 6,250 |
| Hydrocodone | 50,000 |
| Hydromorphone | 3,125 |
| Levophanol | 1,500 |
| 6-Monoacetylmorphine | 400 |
| Morphine 3-β-D-glucuronide | 1,000 |
| Norcodeine | 6,250 |
| Normorphone | 100,000 |
| Oxycodone | 30,000 |
| Oxymorphone | 100,000 |
| Procaine | 15,000 |
| Thebaine | 6,250 |
| **BENZODIAZEPINES** | **(ng/ml)** |
| Oxazepam | 300 |
| Alprazolam | 196 |
| α-Hydroxyalprazolam | 1,262 |
| Bromazepam | 1,562 |
| Chlordiazepoxide | 1,562 |
| Clonazepam HCl | 781 |

| | |
|---|---|
| Clobazam | 98 |
| Clonazepam | 781 |
| Clorazepate dipotassium | 195 |
| Delorazepam | 1,562 |
| Desalkylflurazepam | 390 |
| Diazepam | 195 |
| Estazolam | 2,500 |
| Flunitrazepam | 390 |
| D,L- Lorazepam | 1,562 |
| RS-Lorazepam glucuronide | 156 |
| Midazolam | 12,500 |
| Nitrazepam | 98 |
| Norchlordiazepoxide | 195 |
| Nordiazepam | 390 |
| Temazepam | 98 |
| Triazolam | 2,500 |
| **OPIATES 2000** | **(ng/ml)** |
| Morphine | 2,000 |
| Codeine | 2,000 |
| Ethylmorphine | 5,000 |
| Hydrocodone | 12,500 |
| Hydromorphone | 5,000 |
| Levophanol | 75,000 |
| 6-Monoacetylmorphine | 5,000 |
| Morphine 3-β-D-glucuronide | 2,000 |
| Norcodeine | 12,500 |
| Normorphone | 50,000 |
| Oxycodone | 25,000 |
| Oxymorphone | 25,000 |
| Procaine | 150,000 |
| Thebaine | 100,000 |
| **PHENCYCLIDINE** | **(ng/ml)** |
| Phencyclidine | 25 |
| 4-Hydroxyphencyclidine | 12,500 |
| **COCAINE** | **(ng/ml)** |
| Benzoylecgonine | 300 |
| Cocaine HCl | 780 |
| Cocaethylene | 12,500 |
| Ecgonine HCl | 32,000 |
| **TRICYCLIC ANTIDEPRESSANTS** | **(ng/ml)** |
| Notriptyline | 1,000 |
| Nordoxepine | 1,000 |
| Trimipramine | 3,000 |
| Amitriptyline | 1,500 |
| Promazine | 1,500 |
| Desipramine | 200 |
| Imipramine | 400 |
| Clomipramine | 12,500 |
| Doxepine | 2,000 |
| Maprotiline | 2,000 |
| Promethazine | 25,000 |
| **MARIJUANA** | **(ng/ml)** |
| 11-nor-$\Delta^9$ -THC-9 COOH | 50 |
| Cannabinol | 20,000 |
| 11-nor-$\Delta^8$-THC-9 COOH | 30 |
| $\Delta^8$ -THC | 15,000 |
| $\Delta^9$ -THC | 15,000 |
| **METHADONE** | **(ng/ml)** |
| Methadone | 300 |
| Doxylamine | 50,000 |
| **EDDP** | **(ng/ml)** |
| EDDP 100 | 100 |
| **TRAMADOL** | **(ng/ml)** |
| (+/-) Chlorpheniramine | 50,000 |
| Dimenhydrinate | 50,000 |
| Diphenhydramine | 50,000 |
| Phencyclidine | 50,000 |
| (+)-Chlorpheniramine | 100,000 |
| **BUPRENORPHINE** | **(ng/ml)** |
| Buprenorphine | 10 |
| Norbuprenorphine | 20 |
| Buprenorphine 3-D-Glucuronide | 15 |
| Norbuprenorphine 3-D-Glucuronide | 200 |
| **KETAMINE** | **(ng/ml)** |
| Ketamine | 1,000 |
| Norketamine | 1,000 |
| Dextromethorphan | 500 |
| Dextrorphan tartrate | 500 |
| D-Norpropoxyphene | 31,250 |
| Meperidine | 12,500 |
| Mephentermine hemisulfate salt | 15,625 |
| D-Methamphetamine | 12,500 |
| 3,4-Methylenedioxyethylamphetamine (MDEA) | 25,000 |
| Nordoxepin hydrochloride | 25,000 |
| Phencyclidine | 5,000 |
| Promazine | 8,000 |
| Promethazine | 25,000 |
| **OXYCODONE** | **ng/mL** |
| Oxycodone | 100 |
| Morphine | 50000 |
| Codeine | 25000 |
| Morphine 3-b-D-glucuronide | 50000 |
| Hydrocodone | 1600 |
| Hydromorphone | 15000 |
| Normorphone | 100000 |
| Oxymorphone | 1500 |
| **PROPOXYPHENE** | **ng/mL** |
| propoxyphene | 300 |
| Norpropoxyphene | 7500 |
| Methadone | > 100000 |
| **Lysergic acid diethylamide** | |
| Lysergic acid diethylamide | 20 |

**Precision**

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as blind and tested at each site. The results are given below:

**AMPHETAMINE (AMP 1000)**

| Amphetamine 1000 conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 500 | 15 | 15 | 0 | 15 | 0 | 14 | 1 |
| 750 | 15 | 13 | 2 | 11 | 4 | 11 | 4 |
| 1,250 | 15 | 6 | 9 | 4 | 11 | 4 | 11 |
| 1,500 | 15 | 2 | 13 | 1 | 14 | 1 | 14 |

**AMPHETAMINE (AMP 500)**

| Amphetamine 500 conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 250 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 375 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 625 | 15 | 6 | 9 | 4 | 11 | 7 | 8 |
| 750 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**BARBITURATES (BAR)**

| Secobarbital conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 150 | 15 | 13 | 2 | 15 | 0 | 15 | 0 |
| 225 | 15 | 5 | 10 | 7 | 8 | 10 | 5 |
| 375 | 15 | 2 | 13 | 5 | 10 | 5 | 10 |
| 450 | 15 | 0 | 15 | 1 | 14 | 1 | 14 |

**BENZODIAZEPINE (BZO)**

| Oxazepam conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 150 | 15 | 14 | 1 | 14 | 1 | 15 | 0 |
| 225 | 15 | 11 | 4 | 14 | 1 | 14 | 1 |
| 375 | 15 | 0 | 15 | 1 | 14 | 3 | 12 |
| 450 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**COCAINE (COC)**

| Benzoylecgonine conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 14* | 0 | 15 | 0 | 15 | 0 |
| 150 | 15 | 14 | 1 | 15 | 0 | 14 | 1 |
| 225 | 15 | 4 | 11 | 5 | 10 | 8 | 7 |
| 375 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |
| 450 | 15 | 0 | 15 | 0 | 15 | 1 | 14 |

*Note: One invalid result was obtained.

**MARIJUANA (THC)**

| 11-nor-$\Delta^9$–THC-9-COOH conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 25 | 15 | 15 | 0 | 15 | 0 | 14 | 1 |
| 37.5 | 15 | 9 | 6 | 14 | 1 | 9 | 6 |
| 62.5 | 15 | 2 | 13 | 0 | 15 | 0 | 15 |
| 75 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**METHADONE (MTD)**

| Methadone conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 150 | 15 | 12 | 3 | 15 | 0 | 15 | 0 |
| 225 | 15 | 8 | 7 | 14 | 1 | 15 | 0 |
| 375 | 15 | 0 | 15 | 0 | 15 | 1 | 14 |
| 450 | 15 | 1 | 14 | 0 | 15 | 0 | 15 |

**METHAMPHETAMINE (MET 1000)**

| Methamphetamine 1000 conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 500 | 15 | 15 | 0 | 14 | 1 | 13 | 2 |
| 750 | 15 | 11 | 4 | 10 | 5 | 10 | 5 |
| 1,250 | 15 | 8 | 7 | 4 | 11 | 6 | 9 |
| 1,500 | 15 | 1 | 14 | 1 | 14 | 0 | 15 |

**METHAMPHETAMINE (MET 500)**

| Methamphetamine 500 conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 250 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 375 | 15 | 13 | 2 | 15 | 0 | 14 | 1 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 625 | 15 | 6 | 9 | 3 | 12 | 7 | 8 |
| 750 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**METHYLENEDIOXYMETHAMPHETAMINE (MDMA)**

| MDMA conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 250 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 375 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 625 | 15 | 6 | 9 | 4 | 11 | 7 | 8 |
| 750 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**OPIATES/MORPHINE 300 (Not to be combined with OPI 2000)**

| Morphine conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 150 | 15 | 13 | 2 | 13 | 2 | 15 | 0 |
| 225 | 15 | 3 | 12 | 7 | 8 | 10 | 5 |
| 375 | 15 | 0 | 15 | 1 | 14 | 0 | 15 |
| 450 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**OPIATES 2000 (Not to be combined with MOP 300)**

| Morphine conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 1,000 | 15 | 15 | 0 | 15 | 0 | 14 | 1 |
| 1,500 | 15 | 13 | 2 | 11 | 4 | 7 | 8 |
| 2,500 | 15 | 4 | 11 | 1 | 14 | 2 | 13 |
| 3,000 | 15 | 0 | 15 | 0 | 15 | 2 | 13 |

**PHENCYCLIDINE (PCP)**

| Phencyclidine conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 12.5 | 15 | 15 | 0 | 14 | 1 | 14 | 1 |
| 18.75 | 15 | 11 | 4 | 13 | 2 | 10 | 5 |
| 31.25 | 15 | 8 | 7 | 5 | 10 | 1 | 14 |
| 37.5 | 15 | 4 | 11 | 0 | 15 | 0 | 15 |

**TRICYCLIC ANTIDEPRESSANTS (TCA)**

| Nortriptyline conc. (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 500 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 750 | 15 | 14 | 1 | 11 | 4 | 14 | 1 |
| 1,250 | 15 | 8 | 7 | 2 | 13 | 6 | 9 |
| 1,500 | 15 | 1 | 14 | 0 | 15 | 1 | 14 |

**BUPRENORPHINE**

| Buprenorphine Concentration (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 5 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 7.5 | 15 | 8 | 7 | 10 | 5 | 9 | 6 |
| 12.5 | 15 | 0 | 15 | 1 | 14 | 0 | 15 |
| 15 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**EDDP**

| EDDP Concentration (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 50 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 75 | 15 | 10 | 5 | 11 | 4 | 9 | 6 |
| 125 | 15 | 2 | 13 | 0 | 15 | 1 | 14 |
| 150 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**TRAMADOL**

| Tramadol Concentration (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 50 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 75 | 15 | 9 | 6 | 14 | 1 | 13 | 2 |
| 125 | 15 | 1 | 14 | 0 | 15 | 1 | 14 |
| 150 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**KETAMINE (KET)**

| Ketamine Concentration (ng/mL) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 500 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 750 | 15 | 10 | 5 | 13 | 2 | 12 | 3 |
| 1,250 | 15 | 1 | 14 | 0 | 15 | 2 | 13 |
| 1,500 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**OXCODONE (OXY)**

| Oxcodone concentration (ng/ml) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 50 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 75 | 15 | 8 | 7 | 14 | 1 | 13 | 2 |
| 125 | 15 | 0 | 15 | 1 | 14 | 1 | 14 |
| 150 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**PROPOXYPHENE (PPX)**

| Propoxyphene concentration (ng/ml) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 12.5 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 18.75 | 15 | 9 | 6 | 14 | 1 | 14 | 1 |
| 31.25 | 15 | 1 | 14 | 0 | 15 | 1 | 14 |
| 37.5 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**Lysergic acid diethylamide (LSD)**

| Lysergic acid diethylamide concentration (ng/ml) | n per site | Site A | | Site B | | Site C | |
|---|---|---|---|---|---|---|---|
| | | - | + | - | + | - | + |
| 0 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 12.5 | 15 | 15 | 0 | 15 | 0 | 15 | 0 |
| 18.75 | 15 | 10 | 5 | 14 | 1 | 14 | 1 |
| 31.25 | 15 | 1 | 14 | 0 | 15 | 1 | 14 |
| 37.5 | 15 | 0 | 15 | 0 | 15 | 0 | 15 |

**Cross-Reactivity**

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine (1000,500), Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine (1000,500), Methylenedioxymethamphetamine, Morphine/Opiates 300, Opiates 2000, Phencyclidine, Ketamine, Tricyclic Antidepressants positive urine. The following compounds show no cross-reactivity when tested with the Multi-Drug One Step Multi-Drug Screen Tests cassette (Urine) at a concentration of 100 g/mL.

**Non Cross-Reacting Compounds**

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

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| | | | |
|---|---|---|---|
| REF | Catalogue Number | | Temperature limit |
| IVD | In Vitro diagnostic medical device | | Caution |
| Σ | Contains sufficient for <n> tests and Relative size | | Consult instructions for use (IFU) |
| LOT | Batch code | | Manufacturer |
| | Do not re-use | | Use-by date |
| | Manufacturer fax number | | Do not use if package is damaged |
| | Manufacturer telephone number | | Date of Manufacture |
| | Keep away from sunlight | | Keep dry |