CLIAwaived™ Inc.

# Multi-Drug Screen Test Cup Plus

## Package Insert

For *In Vitro* Diagnostic Use

For HCP/Professional use

### INTENDED USE

The CLIAwaived Inc. Multi-Drug Screen Test Cup Plus is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

| Abbreviation | Analyte | Calibrator | Cutoff (ng/mL) |
|---|---|---|---|
| 6AM | 6-Acetylmorphine | 6-Monoacetylmorphine | 10 |
| AMP | Amphetamine | d-Amphetamine | 500 / 1000 |
| BAR | Secobarbital | Secobarbital | 300 |
| BUP | Buprenorphine | Buprenorphine | 10 |
| BZO | Oxazepam | Oxazepam | 300 |
| COC | Cocaine | Benzoylecgonine | 150 / 300 |
| EDDP | EDDP | 2-ethylidene-1,5-dimethyl-3-3-diphenylpyrrolidine | 300 |
| FEN | Fentanyl | Fentanyl | 1 |
| FEN | Norfentanyl | Norfentanyl | 5 |
| MDMA | Ecstasy | d,l-Methylenedioxy methamphetamine | 500 |
| MET | Methamphetamine | d-Methamphetamine | 500 / 1000 |
| MOR | Morphine | Morphine | 300 |
| MTD | Methadone | d/l-Methadone | 300 |
| OPI | Opiates | Morphine | 2000 |
| OXY | Oxycodone | Oxycodone | 100 |
| PCP | Phencyclidine | Phencyclidine | 25 |
| PPX | Propoxyphene | Propoxyphene | 300 |
| TCA | Nortriptyline | Nortriptyline | 1000 |
| THC | Marijuana | 11-nor-Δ⁹-THC-9-COOH | 20 / 50 |

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device.

This *in vitro* diagnostic device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory method.

### PRINCIPLE

All tests included in this device are rapid lateral flow immunoassays, based on the principle of competitive binding, between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites, which may be present in the urine sample, competing for the limited antibody binding sites. Urine migrates via capillary action along the nitrocellulose (NC) membrane strip pre-coated with a drug-protein conjugate band on the test line (T) region and a colored antibody-colloidal gold conjugate pad, and rehydrates the antibody colloidal gold conjugate on test strip. This urine-gold conjugate mixture then migrates along the NC membrane to the immobilized drug-protein band. If a target drug is absent or present in the urine specimen below its cut-off concentration, the colored antibody-gold conjugates specifically bind with the immobilized drug-protein conjugates to form a visible line on the (T) region. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, the formation of the visible T band indicates a negative result, while absence of T band indicates a positive result.

A visible line generated by a different antigen-antibody reaction is also present but located in the control region of the test strip. This line will always appear at the control line region, regardless of the presence of target drugs in urine, as long as proper volume of specimen has been added and membrane wicking has occurred. The presence of a control line serves as a built-in procedural control, which indicates that the test was properly performed.

### REAGENTS

Each test strip contains a colloidal gold pad coated with drug-specific antibodies. It also contains a membrane coated with drug-protein conjugates in the test line region and control IgG in the control line region.

### ADULTERATION TEST (OPTIONAL COMPONENT)

Urine sample adulteration is usually achieved by substitution, dilution or the addition of adulterants including so-called "masking agents" sold commercially. The use of adulterants can cause false negative results in drug tests by either interfering with the test and/or destroying drugs present in the urine. Dilution may also be used in an attempt to produce false negative drug test results.

The adulteration test strip contains chemically treated reagent pads, which can be activated by a urine sample.

### PRECAUTIONS

- All urine specimens should be regarded as potentially hazardous or infectious. Wear gloves and proper attire to avoid skin contact and handle with universal precautions.
- Do not open the sealed pouch until ready to perform the test.
- Do not use the device after the expiration date.
- Do not re-use the device.

### MATERIAL SUPPLIED

- Twenty-five (25) individually pouched test cups
- One (1) Package Insert

### MATERIAL REQUIRED BUT NOT PROVIDED

- Timer

### STORAGE AND STABILITY

- Store as package in the sealed pouch at 2°C - 30°C (35.6°F – 86.0°F).
- Once pouch open, the test cup must be used within 1 hour.
- The test is stable through the expiration date printed on the sealed pouch.
- Do not use beyond the expiration date.
- Do not freeze the pouch.

### SPECIMEN COLLECTION AND PREPARATION

- A fresh urine sample should be collected in a clean, dry plastic or glass container.
- Fresh urine does not require any special handling or pretreatment.

### DIRECTIONS FOR USE

- Remove the test cup from the pouch and use it within 1 hour after pouch opening.
- Remove the lid of the cup and set it aside.
- Collect urine in the cup.
- Screw the lid back on and place the cup on a flat surface, start the timer and wait for the colored line(s) to appear.
- Remove the Peel-off label and read the test result at 5 minutes, following the result interpretation below.
- The result remains stable for 30 minutes. Do not read the result after 30 minutes.

### RESULT INTERPRETATION

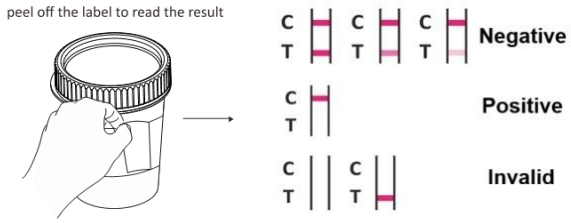
**Negative (-):** Two colored lines appear. One in the control region (C) and another in the test region (T). The line in the control region is to indicate the proper performance of the device. The appearance of another line in the test region indicates that the concentration of target drug in urine is below the cutoff level.

**NOTE:** The intensity of the test line may vary. It should be considered negative whenever there is even a faint colored line.

**Positive (+):** One colored line appears in the control region (C). No line appears in the test region (T). A positive result indicates that the concentration of target drug in urine is at or above the cutoff level.

**Invalid:** No colored line appears in the control region (C).

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 kit. If the problem persists, contact your local distributor.




### QUALITY CONTROL

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

### LIMITATIONS

- This device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory methods.
- Both inaccurate techniques or procedures and the existence of interfering substances or adulterants in urine specimen can cause erroneous results.
- A positive result only indicates the presence of drug or its metabolites in urine but does not provide information on drug concentration, administration route and level of intoxication.
- A negative result only indicates that the concentration of drug in urine is below the cutoff level. It may not necessarily indicate drug free.
- The test does not distinguish between drugs of abuse and prescribed medication.

### PERFORMANCE CHARACTERISTICS

**Precision/Reproducibility**

The precision/reproducibility study was carried out by testing samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. Each sample was tested in 50 replicates per lot using three lots of devices, and testing was performed two runs per day for 25 days. The results obtained are summarized in the table below:

| Drug | Lot Number | +100% cutoff | +75% cutoff | +50% cutoff | +25% cutoff | Cutoff | -25% cutoff | -50% cutoff | -75% cutoff | -100% cutoff |
|---|---|---|---|---|---|---|---|---|---|---|
| 6AM 10 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| AMP 500 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| AMP 1000 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BAR 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BUP 10 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BZO 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| COC 150 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| COC 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| EDDP 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| FEN 1 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 13-/37+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| FEN 5 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MDMA 500 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 12-/38+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MET 500 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MET 1000 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MOR 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MTD 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| OPI 2000 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| OXY 100 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| PCP 25 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 11-/39+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| PPX 300 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 7-/43+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| TCA 1000 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| THC 20 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 10-/40+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| THC 50 | Lot 1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 8-/42+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot 3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 9-/41+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |

**Method Comparison (Accuracy)**

Method comparison was performed by testing unaltered clinical urine specimens with both the CLIAwaived Inc. Multi-Drug Screen Test Cup Plus and LC/MS as gold standard reference method. Eighty samples (40 negative and 40 positive) with blind labels were tested for each drug by three operators, and then compared to the LC-MS/MS results. The results are presented in the table below:

| Drug Test | Test Cup Result | | Drug Free | Low Negative by LC/MS (<-50% Cutoff) | Near Cutoff by LC/MS (Between -50% and Cutoff) | Low Positive by LC/MS (Between Cutoff and +50%) | High Positive by LC/MS (> + 50% Cutoff) |
|---|---|---|---|---|---|---|---|
| 6AM 10 | Operator A | - | 12 | 16 | 11 | 1 | 0 |
| | | + | 0 | 0 | 1 | 15 | 24 |
| | Operator B | - | 12 | 16 | 11 | 0 | 0 |
| | | + | 0 | 0 | 1 | 16 | 24 |
| | Operator C | - | 12 | 16 | 11 | 0 | 0 |
| | | + | 0 | 0 | 1 | 16 | 24 |
| AMP 500 | Operator A | - | 12 | 16 | 12 | 1 | 0 |
| | | + | 0 | 0 | 0 | 12 | 27 |
| | Operator B | - | 12 | 16 | 12 | 2 | 0 |
| | | + | 0 | 0 | 0 | 11 | 27 |
| | Operator C | - | 12 | 16 | 12 | 1 | 0 |
| | | + | 0 | 0 | 0 | 12 | 27 |
| AMP 1000 | Operator A | - | 12 | 17 | 11 | 0 | 0 |
| | | + | 0 | 0 | 0 | 15 | 25 |
| | Operator B | - | 12 | 17 | 11 | 1 | 0 |
| | | + | 0 | 0 | 0 | 14 | 25 |
| | Operator C | - | 12 | 17 | 11 | 1 | 0 |
| | | + | 0 | 0 | 0 | 14 | 25 |
| BAR 300 | Operator A | - | 8 | 13 | 18 | 0 | 0 |
| | | + | 0 | 0 | 1 | 16 | 24 |
| | Operator B | - | 8 | 13 | 17 | 0 | 0 |
| | | + | 0 | 0 | 2 | 16 | 24 |
| | Operator C | - | 8 | 13 | 17 | 0 | 0 |
| | | + | 0 | 0 | 2 | 16 | 24 |
| BUP 10 | Operator A | - | 15 | 14 | 10 | 1 | 0 |
| | | + | 0 | 0 | 1 | 17 | 22 |
| | Operator B | - | 15 | 14 | 10 | 1 | 0 |
| | | + | 0 | 0 | 1 | 17 | 22 |
| | Operator C | - | 15 | 14 | 10 | 1 | 0 |
| | | + | 0 | 0 | 1 | 17 | 22 |
| BZO 300 | Operator A | - | 8 | 17 | 13 | 0 | 0 |
| | | + | 0 | 0 | 2 | 12 | 28 |
| | Operator B | - | 8 | 17 | 14 | 0 | 0 |
| | | + | 0 | 0 | 1 | 12 | 28 |
| | Operator C | - | 8 | 17 | 13 | 0 | 0 |
| | | + | 0 | 0 | 2 | 12 | 28 |
| COC 150 | Operator A | - | 12 | 13 | 14 | 2 | 0 |
| | | + | 0 | 0 | 1 | 13 | 25 |
| | Operator B | - | 12 | 13 | 14 | 1 | 0 |
| | | + | 0 | 0 | 1 | 14 | 25 |
| | Operator C | - | 12 | 13 | 14 | 1 | 0 |
| | | + | 0 | 0 | 1 | 14 | 25 |
| COC 300 | Operator A | - | 12 | 18 | 10 | 1 | 0 |
| | | + | 0 | 0 | 0 | 15 | 24 |
| | Operator B | - | 12 | 18 | 9 | 1 | 0 |
| | | + | 0 | 0 | 1 | 15 | 24 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Operator C | - | 12 | 18 | 10 | 0 | 0 |
| | | + | 0 | 0 | 0 | 16 | 24 |
| EDDP 300 | Operator A | - | 11 | 16 | 12 | 1 | 0 |
| | | + | 0 | 0 | 1 | 13 | 26 |
| | Operator B | - | 11 | 16 | 13 | 1 | 0 |
| | | + | 0 | 0 | 0 | 13 | 26 |
| | Operator C | - | 11 | 16 | 11 | 1 | 0 |
| | | + | 0 | 0 | 2 | 13 | 26 |
| FEN 1 | Operator A | - | 9 | 15 | 14 | 0 | 0 |
| | | + | 0 | 0 | 2 | 15 | 25 |
| | Operator B | - | 9 | 15 | 14 | 1 | 0 |
| | | + | 0 | 0 | 2 | 14 | 25 |
| | Operator C | - | 9 | 15 | 13 | 0 | 0 |
| | | + | 0 | 0 | 3 | 15 | 25 |
| FEN 5 | Operator A | - | 10 | 16 | 11 | 0 | 0 |
| | | + | 0 | 0 | 3 | 16 | 24 |
| | Operator B | - | 10 | 16 | 12 | 1 | 0 |
| | | + | 0 | 0 | 2 | 15 | 24 |
| | Operator C | - | 10 | 16 | 11 | 0 | 0 |
| | | + | 0 | 0 | 3 | 16 | 24 |
| MDMA 500 | Operator A | - | 10 | 20 | 10 | 0 | 0 |
| | | + | 0 | 0 | 0 | 12 | 28 |
| | Operator B | - | 10 | 20 | 9 | 1 | 0 |
| | | + | 0 | 0 | 1 | 11 | 28 |
| | Operator C | - | 10 | 20 | 9 | 0 | 0 |
| | | + | 0 | 0 | 1 | 12 | 28 |
| MET 500 | Operator A | - | 13 | 14 | 13 | 1 | 0 |
| | | + | 0 | 0 | 0 | 11 | 28 |
| | Operator B | - | 13 | 14 | 12 | 0 | 0 |
| | | + | 0 | 0 | 1 | 12 | 28 |
| | Operator C | - | 13 | 14 | 11 | 1 | 0 |
| | | + | 0 | 0 | 2 | 11 | 28 |
| MET 1000 | Operator A | - | 13 | 16 | 11 | 1 | 0 |
| | | + | 0 | 0 | 0 | 14 | 25 |
| | Operator B | - | 13 | 16 | 11 | 1 | 0 |
| | | + | 0 | 0 | 0 | 14 | 25 |
| | Operator C | - | 13 | 16 | 11 | 1 | 0 |
| | | + | 0 | 0 | 0 | 14 | 25 |
| MOR 300 | Operator A | - | 12 | 15 | 12 | 0 | 0 |
| | | + | 0 | 0 | 1 | 14 | 26 |
| | Operator B | - | 12 | 15 | 13 | 1 | 0 |
| | | + | 0 | 0 | 0 | 13 | 26 |
| | Operator C | - | 12 | 15 | 13 | 1 | 0 |
| | | + | 0 | 0 | 0 | 13 | 26 |
| MTD 300 | Operator A | - | 11 | 14 | 15 | 1 | 0 |
| | | + | 0 | 0 | 0 | 12 | 27 |
| | Operator B | - | 11 | 14 | 14 | 0 | 0 |
| | | + | 0 | 0 | 1 | 13 | 27 |
| | Operator C | - | 11 | 14 | 15 | 1 | 0 |
| | | + | 0 | 0 | 0 | 12 | 27 |
| OPI 2000 | Operator A | - | 12 | 14 | 14 | 0 | 0 |
| | | + | 0 | 0 | 0 | 18 | 22 |
| | Operator B | - | 12 | 14 | 14 | 1 | 0 |
| | | + | 0 | 0 | 0 | 17 | 22 |
| | Operator C | - | 12 | 14 | 14 | 2 | 0 |
| | | + | 0 | 0 | 0 | 16 | 22 |
| OXY 100 | Operator A | - | 11 | 15 | 13 | 1 | 0 |
| | | + | 0 | 0 | 1 | 12 | 27 |
| | Operator B | - | 11 | 15 | 13 | 1 | 0 |
| | | + | 0 | 0 | 1 | 12 | 27 |
| | Operator C | - | 11 | 15 | 12 | 1 | 0 |
| | | + | 0 | 0 | 2 | 12 | 27 |
| PCP 25 | Operator A | - | 13 | 15 | 10 | 0 | 0 |
| | | + | 0 | 0 | 2 | 14 | 26 |
| | Operator B | - | 13 | 15 | 11 | 0 | 0 |
| | | + | 0 | 0 | 1 | 14 | 26 |
| | Operator C | - | 13 | 15 | 11 | 1 | 0 |
| | | + | 0 | 0 | 1 | 13 | 26 |
| PPX 300 | Operator A | - | 11 | 15 | 13 | 0 | 0 |
| | | + | 0 | 0 | 1 | 13 | 27 |
| | Operator B | - | 11 | 15 | 13 | 0 | 0 |
| | | + | 0 | 0 | 1 | 13 | 27 |
| | Operator C | - | 11 | 15 | 13 | 0 | 0 |
| | | + | 0 | 0 | 1 | 13 | 27 |
| TCA 1000 | Operator A | - | 9 | 16 | 14 | 0 | 0 |
| | | + | 0 | 0 | 1 | 14 | 26 |
| | Operator B | - | 9 | 16 | 13 | 0 | 0 |
| | | + | 0 | 0 | 2 | 14 | 26 |
| | Operator C | - | 9 | 16 | 14 | 0 | 0 |
| | | + | 0 | 0 | 1 | 14 | 26 |
| THC 20 | Operator A | - | 13 | 15 | 12 | 2 | 0 |
| | | + | 0 | 0 | 0 | 14 | 24 |
| | Operator B | - | 13 | 15 | 10 | 1 | 0 |
| | | + | 0 | 0 | 2 | 15 | 24 |
| | Operator C | - | 13 | 15 | 11 | 1 | 0 |
| | | + | 0 | 0 | 1 | 15 | 24 |
| THC 50 | Operator A | - | 11 | 17 | 12 | 0 | 0 |
| | | + | 0 | 0 | 0 | 14 | 26 |
| | Operator B | - | 11 | 17 | 12 | 2 | 0 |
| | | + | 0 | 0 | 0 | 12 | 26 |
| | Operator C | - | 11 | 17 | 12 | 1 | 0 |
| | | + | 0 | 0 | 0 | 13 | 26 |

**Specificity and Cross-Reactivity**

Specificity was evaluated by testing various concentrations of compounds that structurally related to each drug. The lowest concentration of each compound leading to positive result and the percent cross reactivity of each compound are listed below. If no cross reactivity was observed, the data are shown with > or < symbols.

| Drug/Cutoff | Compound | Minimum concentration required to obtain a positive result | % Cross-Reactivity |
|---|---|---|---|
| 6AM 10 | 6-Acetylmorphine | 10 | 100% |
| | Heroin | 25 | 40% |
| | Morphine | >100,000 | <0.01% |
| | Normorphine | >100,000 | <0.01% |
| | Nalorphine | >100,000 | <0.01% |
| | Hydrocodone | >100,000 | <0.01% |
| | Hydromorphone | >100,000 | <0.01% |
| | Chlordiazepoxide | >100,000 | <0.01% |
| | Clobazam | >100,000 | <0.01% |
| | D-Amphetamine | >100,000 | <0.01% |
| | (±)-Amphetamine | >100,000 | <0.01% |
| | Levorphanol | >100,000 | <0.01% |
| | Codeine | >100,000 | <0.01% |
| | Ethylmorphine | >100,000 | <0.01% |
| | Morphine3-β-D-glucuronide | >100,000 | <0.01% |
| | Norcodeine | >100,000 | <0.01% |
| | Oxycodone | >100,000 | <0.01% |
| | Oxymorphone | >100,000 | <0.01% |
| | Procaine | >100,000 | <0.01% |
| | Thebaine | >100,000 | <0.01% |
| | 6-Acetylcodeine | 50,000 | 0.02% |
| | Buprenorphine | >10,000 | <0.1% |
| | Dihydrocodeine | >100,000 | <0.01% |
| | Dextromethorphan | >100,000 | <0.01% |
| | Imipramine | >100,000 | <0.01% |
| | Meperidine | >100,000 | <0.01% |
| | (±)-Methadone | >100,000 | <0.01% |
| | Mitragynine(Kratom) | >10,000 | <0.1% |
| | Morphine-6-β-D-glucuronide | >10,000 | <0.1% |
| | Naloxone | >100,000 | <0.01% |
| | Naltrexone | >100,000 | <0.01% |
| | Naproxen | >100,000 | <0.01% |
| | Norbuprenorphine | >10,000 | <0.1% |
| | Norbuprenorphine-3-D-Glucuronide | 10,000 | 0.10% |
| | Noroxycodone | >100,000 | <0.01% |
| | Noroxymorphone | >10,000 | <0.1% |
| | Norpropoxyphene | >100,000 | <0.01% |
| | Oxymorphone-3β-D-glucuronide | >10,000 | <0.1% |
| | Tapentadol | >100,000 | <0.01% |
| | cis-Tramadol | >100,000 | <0.01% |
| AMP 500 | (±)-3,4-Methylenedioxyamphetamine (MDA) | 2,000 | 25% |
| | (±)-Amphetamine | 1,000 | 50% |
| | D-Amphetamine | 500 | 100% |
| | Diethylstilbestrol | >10,000 | <5% |
| | L-Amphetamine | 50,000 | 1% |
| | Phentermine | 15,000 | 3.33% |
| | β-Phenylethylamine | >100,000 | <0.5% |
| | Tyramine | >100,000 | <0.5% |
| | p-Hydroxynorephedrine | >100,000 | <0.5% |
| | p-Hydroxyamphetamine | 5,000 | 10% |
| | D-Methamphetamine | >100,000 | <0.5% |
| | L-Methamphetamine | >100,000 | <0.5% |
| | Ephedrine | >100,000 | <0.5% |
| | (±)-3,4-Methylenedioxymethamphetamine | >100,000 | <0.5% |
| | Phenylpropanolamine (Norephedrine) | >100,000 | <0.5% |
| | Benzphetamine | >100,000 | <0.5% |
| | (1R,2S)-(-)-Ephedrine | >100,000 | <0.5% |
| | L-Epinephrine | >100,000 | <0.5% |
| | D,L-Epinephrine | >100,000 | <0.5% |

| | | | |
|---|---|---|---|
| | (±)-3,4-Methylenedioxyethylamphetamine (MDEA) | >100,000 | <0.5% |
| AMP 1000 | (±)-3,4-Methylenedioxyamphetamine (MDA) | 5,000 | 20% |
| | (±)-Amphetamine | 2,000 | 50% |
| | D-Amphetamine | 1,000 | 100% |
| | Diethylstilbestrol | >10,000 | <10% |
| | L-Amphetamine | >100,000 | <1% |
| | Phentermine | 25,000 | 4% |
| | β-Phenylethylamine | >100,000 | <1% |
| | Tyramine | >100,000 | <1% |
| | p-Hydroxynorephedrine | >100,000 | <1% |
| | p-Hydroxyamphetamine | 10,000 | 10% |
| | D-Methamphetamine | >100,000 | <1% |
| | L-Methamphetamine | >100,000 | <1% |
| | Ephedrine | >100,000 | <1% |
| | (±)-3,4-Methylenedioxymethamphetamine (MDMA) | >100,000 | <1% |
| | Phenylpropanolamine (Norephedrine) | >100,000 | <1% |
| | Benzphetamine | >100,000 | <1% |
| | (1R,2S)-(-)-Ephedrine | >100,000 | <1% |
| | L-Epinephrine | >100,000 | <1% |
| | D,L-Epinephrine | >100,000 | <1% |
| | (±)-3,4-Methylenedioxyethylamphetamine (MDEA) | >100,000 | <1% |
| BAR 300 | Alphenal | 400 | 75% |
| | Amobarbital | 500 | 60% |
| | Aprobarbital | 150 | 200% |
| | Barbital | 1000 | 30% |
| | Butabarbital | 70 | 428.57% |
| | Butethal | 20 | 1500% |
| | Cyclopentobarbital | 1,000 | 30% |
| | Pentobarbital | 200 | 150% |
| | Phenobarbital | 250 | 120% |
| | Secobarbital | 300 | 100% |
| | Butalbital | 10,000 | 3% |
| BUP 10 | Buprenorphine | 10 | 100% |
| | Buprenorphine -3-D-Glucuronide | 20 | 50% |
| | Norbuprenorphine | 150 | 6.67% |
| | Norbuprenorphine glucuronide | 500 | 2% |
| | Codeine | >100,000 | <0.01% |
| | Nalorphine | >100,000 | <0.01% |
| | Morphine | >100,000 | <0.01% |
| | Oxymorphone | >100,000 | <0.01% |
| | Hydromorphone | >100,000 | <0.01% |
| BZO 300 | a-Hydroxyalprazolam | 5,000 | 6% |
| | Alprazolam | 250 | 120% |
| | Bromazepam | 600 | 50% |
| | Chlordiazepoxide | 500 | 60% |
| | Clobazam | 300 | 100% |
| | Clonazepam | >100,000 | <0.3% |
| | Clorazepate | 500 | 60% |
| | Desalkylflurazepam | 500 | 60% |
| | Diazepam | 1,000 | 30% |
| | Estazolam | >100,000 | <0.3% |
| | Flunitrazepam | 1,000 | 30% |
| | Lorazepam | 1,000 | 30% |
| | Lormetazepam | >100,000 | <0.3% |
| | Midazolam | >100,000 | <0.3% |
| | Nitrazepam | 250 | 120% |
| | Norchlordiazepoxide | 70 | 428.57% |
| | Nordiazepam | 1,000 | 30% |
| | Oxazepam | 300 | 100% |
| | Oxazepam glucuronide | 30 | 1000% |
| | Lorazepam glucuronide | 100 | 300% |
| | Temazepam | 200 | 150% |
| | Triazolam | 5,000 | 6% |
| | Demoxepam | 25 | 1200% |
| | Flurazepam | >100,000 | <0.3% |
| | Delorazepam | >10,000 | <3% |
| COC 150 | Benzoylecgonine | 150 | 100% |
| | Cocaethylene | 2,000 | 7.50% |
| | Cocaine | >100,000 | <0.15% |
| | Ecgonine | >100,000 | <0.15% |
| | Norcocaine | >100,000 | <0.15% |
| | Ecgonine methyl ester | >100,000 | <0.15% |
| COC 300 | Benzoylecgonine | 300 | 100% |
| | Cocaethylene | 3,000 | 10% |
| | Cocaine | >100,000 | <0.3% |
| | Ecgonine | >100,000 | <0.3% |
| | Norcocaine | >100,000 | <0.3% |
| | Ecgonine methyl ester | >100,000 | <0.3% |
| EDDP 300 | EDDP | 300 | 100% |
| | Methadone | >100,000 | <0.3% |
| | EMDP | >100,000 | <0.3% |
| | Doxylamine | >100,000 | <0.3% |
| | Disopyramide | >100,000 | <0.3% |
| | LAAM(Levo-alpha-acetylmethadol) hydrochloride | >100,000 | <0.3% |
| | Alpha Methadol | >100,000 | <0.3% |
| FEN 1 | Norfentanyl | 25,000 | 0.004% |
| | Fentanyl | 1 | 100% |
| | Acetyl fentanyl | 3 | 33.33% |
| | Acetyl norfentanyl | 20,000 | 0.005% |
| | (±)-β-Hydroxythiofentanyl | 5 | 20% |
| | Acryl fentanyl | 4 | 25% |
| | Butyryl fentanyl | 5 | 20% |
| | Cyclopropylfentanyl | 10 | 10% |
| | (±)-cis-3-methyl Fentanyl | 1 | 100% |
| | Furanyl fentanyl | 10 | 10% |
| | para-Fluorobutyryl fentanyl (PFBF) | 10 | 10% |
| | para-Fluorofentanyl | 5 | 20% |
| | 9-Hydroxyrisperidone | >100,000 | <0.001% |
| | Alfentanil | >100,000 | <0.001% |
| | Isobutyryl fentanyl | 10 | 10% |
| | 4-Fluoro-isobutyryl fentanyl | 5 | 20% |
| | Norcarfentanil | >10,000 | <0.01% |
| | Remifentanil | 500 | 0.20% |
| | Valeryl fentanyl | 10 | 10% |
| | Thienyl Fentanyl | 30 | 3.33% |
| | (±)-trans-3-methyl Fentanyl | 5 | 20% |
| | Despropionyl fentanyl (4-ANPP) | 250 | 0.4% |
| | MT-45 | 50 | 2% |
| | Ocfentanil | 2 | 50% |
| | Risperidone | >100,000 | <0.001% |
| | Sufentanil | 20 | 5% |
| | Carfentanil | 5 | 20% |
| | Labetalol | >100,000 | <0.001% |
| | Trazodone | >100,000 | <0.001% |
| | U-47700 | >100,000 | <0.001% |
| | ω-1-Hydroxyfentanyl | 2 | 50% |
| | 6-Acetylmorphine | >100,000 | <0.001% |
| | AH-7921 HCL | 2,500 | 0.04% |
| | Amphetamine | >100,000 | <0.001% |
| | Buprenorphine | >10,000 | <0.01% |
| | Buprenorphine -3-D-Glucuronide | >10,000 | <0.01% |
| | Codeine | >100,000 | <0.001% |
| | Dextromethorphan | >100,000 | <0.001% |
| | Dihydrocodeine | >100,000 | <0.001% |
| | EDDP | >100,000 | <0.001% |
| | EMDP | >100,000 | <0.001% |

| | | | |
|---|---|---|---|
| | Fluoxetine | >100,000 | <0.001% |
| | Heroin | >100,000 | <0.001% |
| | Hydrocodone | >100,000 | <0.001% |
| | Hydromorphone | >100,000 | <0.001% |
| | Isotonitazene | >100,000 | <0.001% |
| | Ketamine | >100,000 | <0.001% |
| | Levorphanol | >100,000 | <0.001% |
| | Meperidine | >100,000 | <0.001% |
| | Methadone | >100,000 | <0.001% |
| | Morphine | >100,000 | <0.001% |
| | Morphine-3-β-D-glucuronide | >100,000 | <0.001% |
| | Naloxone | >100,000 | <0.001% |
| | Naltrexone | >100,000 | <0.001% |
| | Norbuprenorphine | 5,000 | 0.02% |
| | Norcodeine | >100,000 | <0.001% |
| | Norketamine | >100,000 | <0.001% |
| | Normeperidine | >100,000 | <0.001% |
| | Normorphine | >100,000 | <0.001% |
| | Noroxycodone | >100,000 | <0.001% |
| | Oxycodone | >100,000 | <0.001% |
| | Oxymorphone | >100,000 | <0.001% |
| | Pentazocine (Talwin) | 80,000 | <0.00125% |
| | Pipamperone | 5,000 | 0.02% |
| | Tapentadol | >100,000 | <0.001% |
| | Thioridazine | >100,000 | <0.001% |
| | Tilidine | >100,000 | <0.001% |
| | cis-Tramadol | >100,000 | <0.001% |
| | O-Desmethyl-cis-tramadol | 80,000 | 0.00125% |
| | N-Desmethyl-cis-tramadol | >100,000 | <0.001% |
| **FEN 5** | Norfentanyl | 5 | 100% |
| | Fentanyl | 10,000 | 0.05% |
| | Acetyl fentanyl | >10,000 | <0.05% |
| | Acetyl norfentanyl | 200 | 2.5% |
| | (±)-β-Hydroxythiofentanyl | >10,000 | <0.05% |
| | Acryl fentanyl | >10,000 | <0.05% |
| | Butyryl fentanyl | >10,000 | <0.05% |
| | Cyclopropylfentanyl | >10,000 | <0.05% |
| | (±)-cis-3-methyl Fentanyl | >10,000 | <0.05% |
| | Furanyl fentanyl | >10,000 | <0.05% |
| | para-Fluorobutyryl fentanyl (PFBF) | 10,000 | 0.05% |
| | para-Fluorofentanyl | >10,000 | <0.05% |
| | 9-Hydroxyrisperidone | >100,000 | <0.005% |
| | Alfentanil | 5,000 | 0.1% |
| | Isobutyryl fentanyl | >100,000 | <0.005% |
| | 4-Fluoro-isobutyryl fentanyl | >100,000 | <0.005% |
| | Norcarfentail | >10,000 | <0.05% |
| | Remifentanil | >10,000 | <0.05% |
| | Valeryl fentanyl | >10,000 | <0.05% |
| | Thienyl Fentanyl | >100,000 | <0.005% |
| | (±)-trans-3-methyl Fentanyl | >10,000 | <0.05% |
| | Despropionyl fentanyl (4-ANPP) | >10,000 | <0.05% |
| | MT-45 | >100,000 | <0.005% |
| | Ocfentanil | >10,000 | <0.05% |
| | Risperidone | >100,000 | <0.005% |
| | Sufentanil | >10,000 | <0.05% |
| | Carfentanil | >10,000 | <0.05% |
| | Labetalol | >100,000 | <0.005% |
| | Trazodone | >100,000 | <0.005% |
| | U-47700 | >100,000 | <0.005% |
| | ω-1-Hydroxyfentanyl | >100,000 | <0.005% |
| | 6-Acetylmorphine | >100,000 | <0.005% |
| | AH-7921 HCL | >100,000 | <0.005% |
| | Amphetamine | >100,000 | <0.005% |
| | Buprenorphine | >10,000 | <0.05% |
| | Buprenorphine -3-D-Glucuronide | >10,000 | <0.05% |

| | | | |
|---|---|---|---|
| | Codeine | >100,000 | <0.005% |
| | Dextromethorphan | >100,000 | <0.005% |
| | Dihydrocodeine | >100,000 | <0.005% |
| | EDDP | >100,000 | <0.005% |
| | EMDP | >100,000 | <0.005% |
| | Fluoxetine | >100,000 | <0.005% |
| | Heroin | >100,000 | <0.005% |
| | Hydrocodone | >100,000 | <0.005% |
| | Hydromorphone | >100,000 | <0.005% |
| | Isotonitazene | >100,000 | <0.005% |
| | Ketamine | >100,000 | <0.005% |
| | Levorphanol | >100,000 | <0.005% |
| | Meperidine | >100,000 | <0.005% |
| | Methadone | >100,000 | <0.005% |
| | Morphine | >100,000 | <0.005% |
| | Morphine-3-β-D-glucuronide | >100,000 | <0.005% |
| | Naloxone | >100,000 | <0.005% |
| | Naltrexone | >100,000 | <0.005% |
| | Norbuprenorphine | >100,000 | <0.005% |
| | Norcodeine | >100,000 | <0.005% |
| | Norketamine | >100,000 | <0.005% |
| | Normeperidine | >100,000 | <0.005% |
| | Normorphine | >100,000 | <0.005% |
| | Noroxycodone | >100,000 | <0.005% |
| | Oxycodone | >100,000 | <0.005% |
| | Oxymorphone | >100,000 | <0.005% |
| | Pentazocine (Talwin) | >100,000 | <0.005% |
| | Pipamperone | >100,000 | <0.005% |
| | Tapentadol | >100,000 | <0.005% |
| | Thioridazine | >100,000 | <0.005% |
| | Tilidine | >100,000 | <0.005% |
| | cis-Tramadol | >100,000 | <0.005% |
| | O-Desmethyl-cis-tramadol | >100,000 | <0.005% |
| | N-Desmethyl-cis-tramadol | >100,000 | <0.005% |
| **MDMA 500** | (±)-3,4-Methylenedioxyethylamphetamine (MDEA) | 500 | 100% |
| | (±)-3,4-Methylenedioxyamphetamine (MDA) | 5,000 | 10% |
| | (±)-3,4-Methylenedioxymethamphetamine (MDMA) | 500 | 100% |
| | L-Methamphetamine | >100,000 | <0.5% |
| | 7-Aminoclonazepam | >100,000 | <0.5% |
| | D-Methamphetamine | >100,000 | <0.5% |
| | D-Amphetamine | >100,000 | <0.5% |
| | L-Amphetamine | >100,000 | <0.5% |
| **MET 500** | (±)-3,4-Methylenedioxyethylamphetamine (MDEA) | 30,000 | 1.67% |
| | (±)-3,4-Methylenedioxymethamphetamine (MDMA) | 5,000 | 10% |
| | D-Methamphetamine | 500 | 100% |
| | L-Methamphetamine | 15,000 | 3.33% |
| | Fenfluramine | >100,000 | <0.5% |
| | p-Hydroxymethamphetamine | 3,000 | 16.67% |
| | (±)-Methamphetamine | 500 | 100% |
| | β-Phenylethylamine | >100,000 | <0.5% |
| | Mephetermine | 10,000 | 5% |
| | Methoxyphenamine | >100,000 | <0.5% |
| | L-Amphetamine | >100,000 | <0.5% |
| | D-Amphetamine | >100,000 | <0.5% |
| | (±)-Amphetamine | >100,000 | <0.5% |
| | Chloroquine | >100,000 | <0.5% |
| | Ephedrine | >100,000 | <0.5% |
| | (±)-3,4-Methylenedioxyamphetamine (MDA) | >100,000 | <0.5% |
| | Trimethobenzamide | >100,000 | <0.5% |
| | l-phenylephrine | >100,000 | <0.5% |

| | | | |
|---|---|---|---|
| | (1R,2S)-(-)-Ephedrine | >100,000 | <0.5% |
| | Procaine | >100,000 | <0.5% |
| MET 1000 | (±)-3,4-Methylenedioxyethylamphetamine (MDEA) | >100,000 | <1% |
| | (±)-3,4-Methylenedioxymethamphetamine (MDMA) | 10,000 | 10% |
| | D-Methamphetamine | 1,000 | 100% |
| | L-Methamphetamine | 25,000 | 4% |
| | Fenfluramine | >100,000 | <1% |
| | p-Hydroxymethamphetamine | 5,000 | 20% |
| | (±)-Methamphetamine | 2,000 | 50% |
| | β-Phenylethylamine | >100,000 | <1% |
| | Mephetermine | 30,000 | 3.33% |
| | Methoxyphenamine | >100,000 | <1% |
| | L-Amphetamine | >100,000 | <1% |
| | D-Amphetamine | >100,000 | <1% |
| | (±)-Amphetamine | >100,000 | <1% |
| | Chloroquine | >100,000 | <1% |
| | Ephedrine | >100,000 | <1% |
| | (±)-3,4-Methylenedioxyamphetamine (MDA) | >100,000 | <1% |
| | Trimethobenzamide | >100,000 | <1% |
| | l-phenylephrine | >100,000 | <1% |
| | (1R,2S)-(-)-Ephedrine | >100,000 | <1% |
| | Procaine | >100,000 | <1% |
| MOR 300 | 6-Acetylmorphine | 500 | 60% |
| | Codeine | 250 | 120% |
| | Dihydrocodeine | 500 | 60% |
| | Ethylmorphine | 300 | 100% |
| | Heroin | 500 | 60% |
| | Hydrocodone | 500 | 60% |
| | Hydromorphone | 500 | 60% |
| | Levorphanol | 5,000 | 6% |
| | Morphine | 300 | 100% |
| | Nalorphine | 3,000 | 10% |
| | Thebaine | >100,000 | <0.3% |
| | Morphine-3-β-d-glucuronide | 300 | 100% |
| | Codeine-6-β-D-glucuronide | 250 | 120% |
| | Morphine-6-β-D-glucuronide | 5,000 | 6% |
| | 6-Acetylcodeine | 1,000 | 30% |
| | Normorphine | >100,000 | <0.3% |
| | Oxycodone | >100,000 | <0.3% |
| | Oxymorphone | 50,000 | 0.6% |
| | Norcodeine | >100,000 | <0.3% |
| | Procaine | >100,000 | <0.3% |
| | Norpropoxyphene | >100,000 | <0.3% |
| MTD 300 | (±)-Methadone | 300 | 100% |
| | EDDP | >100,000 | <0.3% |
| | EMDP | >100,000 | <0.3% |
| | LAAM (Levo-alpha-acetylmethadol) | 10,000 | 3% |
| | Alpha Methadol | 100 | 300% |
| | Doxylamine | 50,000 | 0.6% |
| OPI 2000 | 6-Acetylmorphine | 10,000 | 20% |
| | Codeine | 10,000 | 20% |
| | Dihydrocodeine | 10,000 | 20% |
| | Ethylmorphine | 5,000 | 40% |
| | Heroin | 20,000 | 10% |
| | Hydrocodone | 25,000 | 8% |
| | Hydromorphone | 25,000 | 8% |
| | Levorphanol | >100,000 | <2% |
| | Morphine | 2,000 | 100% |
| | Nalorphine | >100,000 | <2% |
| | Thebaine | >100,000 | <2% |
| | Morphine-3-β-d-glucuronide | 50,000 | 4% |
| | Codeine-6-β-D-glucuronide | 2,500 | 80% |
| | Morphine-6-β-D-glucuronide | 500 | 400% |
| | 6-Acetylcodeine | 10,000 | 20% |
| | Normorphine | >100,000 | <2% |
| | Oxycodone | >100,000 | <2% |
| | Oxymorphone | >100,000 | <2% |
| | Norcodeine | >100,000 | <2% |
| | Procaine | >100,000 | <2% |
| | Norpropoxyphene | >100,000 | <2% |
| OXY 100 | Hydrocodone | 20,000 | 0.5% |
| | Hydromorphone | 25,000 | 0.4% |
| | Levorphanol | 50,000 | 0.2% |
| | Naloxone | 30,000 | 0.33% |
| | Naltrexone | 20,000 | 0.5% |
| | Oxycodone | 100 | 100% |
| | Oxymorphone | 200 | 50% |
| | Oxymorphone-3β-D-glucuronide | 750 | 13.33% |
| | Noroxycodone | 2,500 | 4% |
| | Noroxymorphone | 1,000 | 10% |
| | Dihydrocodeine | >100,000 | <0.1% |
| | Codeine | >100,000 | <0.1% |
| | Morphine | >100,000 | <0.1% |
| | Buprenorphine | >10,000 | <0.1% |
| | Ethylmorphine | >100,000 | <0.1% |
| | Thebaine | >100,000 | <0.1% |
| | 6-Acetylmorphine | >100,000 | <0.1% |
| PCP 25 | Phencyclidine | 25 | 100% |
| | 4-Hydroxyphencyclidine | >100,000 | <0.025% |
| PPX 300 | Norpropoxyphene | 500 | 60% |
| | Propoxyphene | 300 | 100% |
| TCA 1000 | Amitriptyline | 10,000 | 10% |
| | Chlorpheniramine | >100,000 | <1% |
| | Clomipramine | 50,000 | 2% |
| | Cyclobenzaprine | >100,000 | <1% |
| | Desipramine | 500 | 200% |
| | Doxepine | 10,000 | 10% |
| | Duloxetine | >100,000 | <1% |
| | Imipramine | 50,000 | 2% |
| | Norclomipramine | >100,000 | <1% |
| | Nordoxepin | 5,000 | 20% |
| | Nortriptyline | 1,000 | 100% |
| | Promazine | 10,000 | 10% |
| | Trimipramine | 10,000 | 10% |
| | Maprotiline | 5,000 | 20% |
| | Promethazine | >100,000 | <1% |
| THC 20 | (-)-11-nor-$\Delta^8$-THC -9-COOH | 50 | 40% |
| | (-)-11-nor-9-carboxy-$\Delta^9$-THC | 20 | 100% |
| | (±)-11-nor-9-carboxy-Δ9-THC | 50 | 40% |
| | 11-nor-$\Delta^9$-THC-carboxy glucuronide | 5,000 | 0.4% |
| | $\Delta^8$-THC | 8,000 | 0.25% |
| | $\Delta^9$-THC | >10,000 | <0.2% |
| | Cannabinol | >10,000 | <0.2% |
| | Cannabidiol | >100,000 | <0.02% |
| | (±)-11-hydroxy-$\Delta^9$-THC | 8,000 | 0.25% |
| THC 50 | (-)-11-nor-$\Delta^8$-THC -9-COOH | 70 | 71.43% |
| | (-)-11-nor-9-carboxy-$\Delta^9$-THC | 50 | 100% |
| | (±)-11-nor-9-carboxy-Δ9-THC | 150 | 33.33% |
| | 11-nor-$\Delta^9$-THC-carboxy glucuronide | 7,500 | 66.67% |
| | $\Delta^8$-THC | 10,000 | 0.5% |
| | $\Delta^9$-THC | >10,000 | <0.5% |
| | Cannabinol | >10,000 | <0.5% |
| | Cannabidiol | >100,000 | <0.05% |
| | (±)-11-hydroxy-$\Delta^9$-THC | 10,000 | 0.5% |

**Interference Substance**

Potential interfering substances that could be found in human urine under physiological and pathological conditions compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff. These urine samples were tested in triplicates with 3 lots of CLIAwaived Inc. Multi-Drug Screen Test Cup Plus.

Compounds that showed no interference at a concentration of 100 µg/ml are listed in the following table.

| | | | |
|---|---|---|---|
| (-) Cotinine | Conjugated Estrogens | LAAM (except MTD test) | Phenobarbital (except BAR test) |
| 7-Aminoclonazepam | Cortisone | Labetalol | Phentermine (except AMP test) |
| 7-Aminoflunitrazepam | Creatine | Lamotrigine | Phenylpropanolamine |
| 7-Aminonitrazepam | Creatinine | L-Ephedrine | Prednisone |
| Acetaminophen | Cyclobenzaprine | L-Epinephrine | Pregabalin |
| Acetone (1000 mg/dL) | Cyproheptadine | Levofloxacin | Procaine |
| Acetophenetidin | D,L-Epinephrine | Levonorgestrel | Promazine (except TCA test) |
| Acyclovir | D,L-Isoproterenol | Levothyroxine sodium | Promethazine |
| Albumin (100mg/dL) | D,L-Lorazepam (except BZO test) | Lidocaine | Propoxyphene (except PPX test) |
| Albuterol | D,L-Octopamine | Lisinopril | Propranolol |
| Alpha Methadol (except MTD test) | D,L-Propranolol | Loperamide | Pseudoephedrine |
| Aminophylline | D,L-Tryptophan | Loratidine | Pyridoxine |
| Aminopyrine | D,L-Tyrosine | Lorazepam Glucuronide (except BZO test) | Pyrilamine |
| Amitriptyline (except TCA test) | Delorazepam (10ug/mL) | L-phenylephrine | Pyrogallol |
| Amlodipine | Demoxepam (except BZO test) | LSD | Quetiapine |
| Amobarbital (except BAR test) | Deoxycorticosterone | Maprotiline (except TCA test) | Quinidine |
| Amoxicillin | Desloratadine | Meperidine | Quinine |
| Ampicillin | Desipramine (except TCA test) | Meprobamate | Quinolinic Acid |
| Apomorphine | Dextromethorphan | Metformin | Ranitidine |
| Aripiprazole | Diclofenac | Methapyrilene | Riboflavin |
| Ascorbic acid (Vitamin C) | Diclofenac sodium | Methaqualone | Rifampicin |
| Aspartame | Diflunisal | Methoxyphenamine | Risperidone |
| Aspirin (Acetylsalicylic acid) | Digoxin | Methylphenidate | Salicylic acid |
| Atomoxetine | Diphenhydramine | Metoprolol | Secobarbital (except BAR test) |
| Atorvastatin Calcium | Diphenylhydantoin | Metronidazole | Serotonin (5- Hydroxytyramine) |
| Atropine | Disopyramide | Mifepristone | Sertraline |
| Azithromycin | Dopamine (3-Hydroxytyramine) | N-Acetylprocainamide | Sildenafil Citrate |
| Baclofen | Doxepine (except TCA test) | NaCl (4000 mg/dL) | Simvastatin |
| Benzilic acid | Doxylamine (except MTD test) | Nalidixic acid | Sodium Azide |
| Benzocaine | Duloxetine | Naloxone (except OXY test) | Sulfamethazine |
| Benzoic acid | Ecgonine methyl ester | Naltrexone (except OXY test) | Sulindac |
| Benzoylecgonine (except COC test) | EMDP | Naproxen | Telmisartan |
| Benzphetamine | Ephedrine | N-desmethyl Tapentadol | Tetracycline |
| Benzylpiperiazine | Erythromycin | Nicotine | Tetrahydrocortisone 3-(β-Dglucuronide) |
| Bilirubin | Esomeprazole Magnesium | Nicotinamide (Niacinamide) | Tetrahydrocortisone, 3-acetate |
| Boric Acid (1%) | Estrone | Nicotinic Acid | Tetrahydrozoline |
| 4-Bromo-2,5-dimethoxyphenethylamine | Ethanol (1%) | Nifedipine | (-)-11-nor-9-carboxy-$\Delta^9$-THC (except THC test) |
| Brompheniramine | Fenfluramine | Nitroglycerin | Theophylline |
| Bupropion | Fenofibrate | Nordoxepin (except TCA test) | Thiamine |
| Caffeine | Fenoprofen | Norethindrone | Thioridazine |
| Cannabidiol | Fentanyl (except FEN1 and FEN5 tests) | Norfentanyl (except FEN1 and FEN5 tests) | Tramadol |
| Captopril | Fluoxetine | Norpropoxyphene (except PPX test) | Trazodone |
| Carbamazepine | Fluphenazine | Norpseudoephedrine | Triamterene |
| Carfentanil (10ug/mL) (except FEN1 test) | Fotemustine | Nortriptyline (except TCA test) | Trifluoperazine |
| Carisoprodol | Furosemide | Noscapine | Trifluoromethylphenyl-piperazine |
| Cefradine | Gabapentin | O-Hydroxyhippuric acid | Trimethobenzamide |
| Cephalexin | Galactose | Olanzapine | Trimethoprim |
| Cetirizine | Gatifloxacin | Omeprazole | Tryptamine |
| Chloral hydrate | Gemfibrozil | Oxalic acid (100mg/dL) | Tyramine |
| Chloramphenicol | Gentisic acid | Oxazepam (except BZO test) | Urea (2000 mg/dL) |
| Chlordiazepoxide (except BZO test) | D-(+)-Glucose (3000 mg/dL) | Oxazepam Glucuronide (except BZO test) | Uric acid |
| Chloroquine | Guaiacolglyceryl ether | Oxolinic acid | Valproic acid (250 µg/mL) |
| Chlorothiazide | Hemoglobin | Oxymetazoline | Venlafaxine |
| Chlorpheniramine | Hexobarbital | Paliperidone | Verapamil |
| Chlorpromazine | Hydralazine | Papaverine | Vitamin B2 |
| Cholesterol | Hydrochlorothiazide | Penicillin-G | Zaleplon |
| Ciprofloxacin | Hydrocortisone | PenicillinV Potassium | Zolpidem |
| Citalopram | Hydroxybutyric Acid | Perphenazine | Zomepirac |
| Clarithromycin | Ibuprofen | Phenacetin | β-Estradiol |
| Clofibrate | Imipramine (except TCA test) | Phencyclidine (except PCP test) | γ-Cyclodextrin |
| Clomipramine (except TCA test) | Isoxsuprine | Phenelzine | γ-Globulin (500mg/dL) |
| Clonidine | Ketamine | Pheniramine | L-thyroxine |
| Clozapine | Ketoprofen | Phenylethylamine | Magnesium Chloride |

**Effect of Urinary pH and Specific Gravity**

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

**Index of Symbols**

| | | | | | |
|---|---|---|---|---|---|
| | Consult Instruction for use | Σ | Contains sufficient for <n> tests | 2°C (35.6°F) – 30°C (86°F) | Store between 2-30°C |
| IVD | For in vitro diagnostic use only | | Use by | | Do not reuse |
| | Do not use if package is damaged | LOT | Lot Number | REF | Catalog # |

CE EC REP

Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,
20537 Hamburg, Germany

Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou-311121
P. R. China

FOR TECHNICAL ASSISTANCE
Call 1-888-882-7739

CLIAwaived, Inc.
2721 Loker Ave. W
Carlsbad, CA 92010
www.cliawaived.com
sales@cliawaived.com
Toll free: 1-888-882-7739
Mon-Fri 8am-5pm PST

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