August 27, 2025

Hangzhou Clongene Biotech Co.,Ltd.
℅ Jenny Xia
Director
LSI International Inc
504 E Diamond Ave, Suite H
Gaithersburg, Maryland 20877

Re: K252118
Trade/Device Name: CLUNGENE Multi-Drug Test Easy Cup; CLUNGENE Multi-Drug Home Test Easy Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: NFT, PTH, NGL, NFV, NFY, PTG, NGG, QBF, NGM, QAW, NFW
Dated: July 4, 2025
Received: July 7, 2025

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.08.27 12:37:03 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K252118

Device Name
CLUNGENE Multi-Drug Test Easy Cup
CLUNGENE Multi-Drug Home Test Easy Cup

Indications for Use *(Describe)*
The CLUNGENE Multi-Drug Test Easy Cup is a lateral flow immunoassay for the qualitative detection of Morphine, Methamphetamine, Cocaine, Marijuana, Methylenedioxymethamphetamine, Buprenorphine, Propoxyphene, Amphetamine, Phencyclidine, EDDP (Methadone metabolite), Oxycodone, Oxazepam, Nortriptyline, Secobarbital, Methadone, 6-Monoacetylmorphine and Fentanyl in human urine at the following cut off concentrations:

| Drug | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| Morphine (MOP/OPI300) | Morphine | 300 |
| Morphine (MOP/OPI2000) | Morphine | 2,000 |
| Methamphetamine (mAMP/MET1000) | D-Methamphetamine | 1,000 |
| Methamphetamine (mAMP/MET500) | D-Methamphetamine | 500 |
| Cocaine (COC300) | Benzoylecgonine | 300 |
| Cocaine (COC150) | Benzoylecgonine | 150 |
| Marijuana (THC) | 11-nor-9-THC-9-COOH | 50 |
| Methylenedioxymethamphetamine (MDMA) | D,L-Methylenedioxymethamphetamine | 500 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Propoxyphene (PPX) | D-Propoxyphene | 300 |
| Amphetamine (AMP1000) | D-Amphetamine | 1,000 |
| Amphetamine (AMP500) | D-Amphetamine | 500 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Methadone metabolite (EDDP) | 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Oxazepam (BZO) | Oxazepam | 300 |
| Nortriptyline (TCA) | Nortriptyline | 1,000 |
| Secobarbital (BAR) | Secobarbital | 300 |
| Methadone (MTD) | Methadone | 300 |
| 6-Monoacetylmorphine (6-MAM) | 6-Monoacetylmorphine | 10 |
| Fentanyl (FYL) | Fentanyl | 1 |

The single or multi-test cups can consist of any combination of the above listed drug analytes, but only one cut off concentration under same drug condition will be included per device.
This test provides only preliminary result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Evaluate preliminary positive results carefully. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The CLUNGENE Multi-Drug Home Test Easy Cup is a lateral flow immunoassay for the qualitative detection of Morphine, Methamphetamine, Cocaine, Marijuana, Methylenedioxymethamphetamine, Buprenorphine, Propoxyphene, Amphetamine, Phencyclidine, EDDP (Methadone metabolite), Oxycodone, Oxazepam, Nortriptyline, Secobarbital, Methadone, 6-Monoacetylmorphine and Fentanyl in human urine at the following cut off concentrations:

| Drug (Identifier) | Cut-off (ng/mL) |
|---|---|
| Morphine (MOP/OPI2000) | 300 or 2000 |
| Methamphetamine (mAMP/MET) | 500 or 1,000 |

| | |
|---|---|
| Cocaine (COC) | 150 or 300 |
| Marijuana (THC) | 50 |
| Methylenedioxymethamphetamine (MDMA) | 500 |
| Buprenorphine (BUP) | 10 |
| Propoxyphene (PPX) | 300 |
| Amphetamine (AMP) | 500 or 1,000 |
| Phencyclidine (PCP) | 25 |
| Methadone metabolite (EDDP) | 300 |
| Oxycodone (OXY) | 100 |
| Oxazepam (BZO) | 300 |
| Nortriptyline (TCA) | 1,000 |
| Secobarbital (BAR) | 300 |
| Methadone (MTD) | 300 |
| 6-Monoacetylmorphine (6-MAM) | 10 |
| Fentanyl (FYL) | 1 |

The single or multi-test cup offers any combination from above 1 to 17 drugs, but only one cut off concentration under same drug condition will be included per device.
The test provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC-MS/MS is the preferred confirmatory method.
It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**

K252118

**1. Date:** August 3, 2025

**2. Submitter:**
Hangzhou Clongene Biotech Co., Ltd.
No.1 Yichuang Road, Yuhang District.
Hongzhou, 311121
China

**3. Contact person:**
Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org

**4. Device Name:** CLUNGENE Multi-Drug Test Easy Cup
CLUNGENE Multi-Drug Home Test Easy Cup

**5. Classification:** Class II

| **Product Code**<br>**Target Drug** | **Regulation Section** | **Panel** |
|---|---|---|
| NFT<br>Amphetamine (AMP) | 862.3100, Amphetamine Test System | Toxicology |
| PTH<br>Secobarbital (BAR) | 862.3150, Barbiturate Test System | Toxicology |
| NGL<br>Buprenorphine (BUP)<br>Morphine (MOP/OPI)<br>Oxycodone (OXY)<br>6-Monoacetylmorphine (6-MAM)<br>Fentanyl (FYL) | 862.3650, Opiate Test System | Toxicology |
| NFV<br>Oxazepam (BZO) | 862.3170, Benzodiazepine Test System | Toxicology |
| NFY<br>Cocaine (COC) | 862.3250, Cocaine and cocaine metabolite test system | Toxicology |
| PTG<br>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)<br>Methadone (MTD) | 862.3620, Methadone Test System | Toxicology |
| NGG<br>Methylenedioxymethamphetamine (MDMA)<br>Methamphetamine (MET) | 862.3610,<br>Methamphetamine Test System | Toxicology |
| NGM<br>Phencyclidine (PCP) | Unclassified | Toxicology |

| | | |
|---|---|---|
| QBF<br>Propoxyphene (PPX) | 862.3700 Propoxyphene test system. | Toxicology |
| QAW<br>Nortriptyline (TCA) | 862.3910 Tricyclic antidepressant drugs test system | Toxicology |
| NFW<br>Cannabinoids (THC) | 862.3870, Cannabinoids Test System | Toxicology |

**6. Predicate Devices:**

AllTest Multi-Drug Urine Test Cup (K250727)

**7. Intended Use**

The CLUNGENE Multi-Drug Test Easy Cup is a lateral flow immunoassay for the qualitative detection of Morphine, Methamphetamine, Cocaine, Marijuana, Methylenedioxymethamphetamine, Buprenorphine, Propoxyphene, Amphetamine, Phencyclidine, EDDP (Methadone metabolite), Oxycodone, Oxazepam, Nortriptyline, Secobarbital, Methadone, 6-Monoacetylmorphine and Fentanyl in human urine at the following cut off concentrations:

| Drug | Calibrator | Cut-off (ng/mL) |
|---|---|---|
| Morphine (MOP/OPI300) | Morphine | 300 |
| Morphine (MOP/OPI2000) | Morphine | 2,000 |
| Methamphetamine (mAMP/MET1000) | D-Methamphetamine | 1,000 |
| Methamphetamine (mAMP/MET500) | D-Methamphetamine | 500 |
| Cocaine (COC300) | Benzoylecgonine | 300 |
| Cocaine (COC150) | Benzoylecgonine | 150 |
| Marijuana (THC) | 11-nor-$\Delta^9$-THC-9-COOH | 50 |
| Methylenedioxymethamphetamine (MDMA) | D,L-Methylenedioxymethamphetamine | 500 |
| Buprenorphine (BUP) | Buprenorphine | 10 |
| Propoxyphene (PPX) | D-Propoxyphene | 300 |
| Amphetamine (AMP1000) | D-Amphetamine | 1,000 |
| Amphetamine (AMP500) | D-Amphetamine | 500 |
| Phencyclidine (PCP) | Phencyclidine | 25 |
| Methadone metabolite (EDDP) | 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Oxazepam (BZO) | Oxazepam | 300 |
| Nortriptyline (TCA) | Nortriptyline | 1,000 |
| Secobarbital (BAR) | Secobarbital | 300 |
| Methadone (MTD) | Methadone | 300 |
| 6-Monoacetylmorphine (6-MAM) | 6-Monoacetylmorphine | 10 |
| Fentanyl (FYL) | Fentanyl | 1 |

The single or multi-test cups can consist of any combination of the above listed drug analytes, but only one cut off concentration under same drug condition will be included per device.

This test provides only preliminary result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Evaluate preliminary positive results carefully. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

The CLUNGENE Multi-Drug Home Test Easy Cup is a lateral flow immunoassay for the qualitative detection of Morphine, Methamphetamine, Cocaine, Marijuana, Methylenedioxymethamphetamine, Buprenorphine, Propoxyphene, Amphetamine, Phencyclidine, EDDP (Methadone metabolite), Oxycodone, Oxazepam, Nortriptyline, Secobarbital, Methadone, 6-Monoacetylmorphine and Fentanyl in human urine at the following cut off concentrations:

| Drug (Identifier) | Cut-off (ng/mL) |
|---|---|
| Morphine (MOP/OPI2000) | 300 or 2000 |
| Methamphetamine (mAMP/MET) | 500 or 1,000 |
| Cocaine (COC) | 150 or 300 |
| Marijuana (THC) | 50 |
| Methylenedioxymethamphetamine (MDMA) | 500 |
| Buprenorphine (BUP) | 10 |
| Propoxyphene (PPX) | 300 |
| Amphetamine (AMP) | 500 or 1,000 |
| Phencyclidine (PCP) | 25 |
| Methadone metabolite (EDDP) | 300 |
| Oxycodone (OXY) | 100 |
| Oxazepam (BZO) | 300 |
| Nortriptyline (TCA) | 1,000 |
| Secobarbital (BAR) | 300 |
| Methadone (MTD) | 300 |
| 6-Monoacetylmorphine (6-MAM) | 10 |
| Fentanyl (FYL) | 1 |

The single or multi-test cup offers any combination from above 1 to 17 drugs, but only one cut off concentration under same drug condition will be included per device.

The test provides only preliminary test results. To obtain a confirmed analytical result, a more specific alternative chemical method must be used. GC/MS or LC-MS/MS is the preferred confirmatory method.

It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only

## 8. Device Description

CLUNGENE Multi-Drug Test Easy Cup and CLUNGENE Multi-Drug Home Test Easy Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine.

The device is a cup format. Each test device is sealed with two sachets of desiccant in an aluminum pouch. The device is in a ready-to-use format and no longer requires assembly before use.

## 9. Substantial Equivalence Information

| Item | Device | | Predicate (K250727) |
|---|---|---|---|
| **Intended use** | Qualitative detection of drugs of abuse in urine. For over-the-counter use. | | Same |
| **Methodology** | Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction | | Same |
| **Type of Test** | Qualitative | | Same |
| **Specimen Type** | Human urine | | Same |
| **Target Drug and Cut Off Values** | **Target Drugs** | **Cutoff (ng/mL)** | Same except for the TRA |
| | Amphetamine(AMP) | 1000 or 500 | |
| | Secobarbital (BAR) | 300 | |
| | Buprenorphine (BUP) | 10 | |
| | Oxazepam (BZO) | 300 | |
| | Cocaine (COC) | 150 or 300 | |
| | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 | |
| | Methylenedioxymethamphetamine (MDMA) | 500 | |
| | Methamphetamine (MET) | 1000 or 500 | |
| | Morphine (MOP300/OPI2000) | 300 or 2000 | |
| | Methadone (MTD) | 300 | |
| | Oxycodone (OXY) | 100 | |
| | Phencyclidine (PCP) | 25 | |
| | Propoxyphene(PPX) | 300 | |
| | Nortriptyline (TCA) | 1000 | |
| | Cannabinoids (THC) | 50 | |
| | 6-Monoacetylmorphine(6-MAM) | 10 | |
| | Fentanyl (FYL) | 1 | |
| **Configurations** | Test cup | | Same |

## 10. Standard/Guidance Document Reference (if applicable)

None referenced.

## 11. Test Principle

CLUNGENE Multi-Drug Test Easy Cup or CLUNGENE Multi-Drug Home Test Easy Cup is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

## 12. Performance Characteristics

### A. Analytical performance

### a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Other samples were prepared by spiked target drug in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test cups. The results obtained are summarized in the following tables:

| Drug | Lot Number | +100% cut off | +75% cut off | +50% cut off | +25% cut off | cut off | -25% cut off | -50% cut off | -75% cut off | -100% cut off |
|---|---|---|---|---|---|---|---|---|---|---|
| MOP300 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 23-/27+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 27-/23+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MET1000 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| COC300 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |

| Drug | Lot Number | +100% cut off | +75% cut off | +50% cut off | +25% cut off | cut off | -25% cut off | -50% cut off | -75% cut off | -100% cut off |
|---|---|---|---|---|---|---|---|---|---|---|
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| THC | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 24-/26+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MDMA | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BUP | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 27-/23+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| PPX | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| AMP1000 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 24-/26+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 22-/28+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| PCP | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 26-/24+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| EDDP | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 26-/24+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 22-/28+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| OXY | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BZO | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 23-/27+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| TCA | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 21-/29+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| BAR | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 24-/26+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MTD | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 24-/26+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| 6-MAM | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 27-/23+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 22-/28+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| FYL | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 22-/28+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |

| Drug | Lot Number | +100% cut off | +75% cut off | +50% cut off | +25% cut off | cut off | -25% cut off | -50% cut off | -75% cut off | -100% cut off |
|---|---|---|---|---|---|---|---|---|---|---|
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 24-/26+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| MET500 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 26-/24+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 25-/25+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| COC150 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 26-/24+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 25-/25+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 22-/28+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |
| OPI2000 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 0-/50+ | 25-/25+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| AMP500 | Lot1 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 26-/24+ | 49-/1+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot2 | 0-/50+ | 0-/50+ | 0-/50+ | 2-/48+ | 26-/24+ | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ |
| | Lot3 | 0-/50+ | 0-/50+ | 0-/50+ | 1-/49+ | 23-/27+ | 48-/2+ | 50-/0+ | 50-/0+ | 50-/0+ |

**b. Linearity/assay reportable range:**
Not applicable. This device is intended for qualitative use only.

**c. Stability:**
The device is stable at 4-30℃ for 24 months based on the accelerated stability study.

**d. Analytical specificity/Interference:**
To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of the device.
Percent cross-reactivity, provided in the below table, was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100.

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| MOP 300 | Morphine | 300 | 100% |
| | 6-Monoacetylmorphine (6-MAM) | 300 | 100% |
| | Codeine | 300 | 100% |
| | Dihydrocodeine | 1,000 | 30% |
| | Ethylmorphine | 1,000 | 30% |
| | Codeine-6-β-D-glucuronide | 500 | 60% |
| | Heroin | 300 | 100% |
| | Hydrocodone | 50,000 | 0.6% |
| | Hydromorphone | 1,000 | 30% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Levorphanol tartrate | 1,500 | 20% |
| | Nalorphine HCl | 1,000 | 30% |
| | Norcodeine | 2,000 | 15% |
| | Normorphine | 3,000 | 10% |
| | Oxymorphone | 10,000 | 3% |
| | Morphine-6-β-D-glucuronide | 1,000 | 30% |
| | Morphine-3-β-D-glucuronide | 1,000 | 30% |
| | Thebaine | 3,000 | 10% |
| | 6-Acetylcodeine | 8,000 | 3.8% |
| | Oxycodone | 100,000 (Negative) | Not detected |
| | Procaine | 100,000 (Negative) | Not detected |
| | Norpropoxyphene | 100,000 (Negative) | Not detected |
| MET 1000 | D-Methamphetamine | 1,000 | 100% |
| | (+/-)3,4-Methylenedioxy-nethylamphetamine (MDEA) | 20,000 | 5% |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 3,000 | 33.3% |
| | L-Methamphetamine | 20,000 | 5% |
| | p-Hydroxymethamphetamine | 30,000 | 3.3% |
| | D,L-Methamphetamine | 1,000 | 100% |
| | β-Phenylethylamine | 50,000 | 2% |
| | Mephentermine | 50,000 | 2% |
| | Methoxyphenamine HCl | 50,000 | 2% |
| | L-Amphetamine | 75,000 | 1.3% |
| | D-Amphetamine | 50,000 | 2% |
| | D,L-Amphetamine | 100,000 (negative) | Not detected |
| | Chloroquine | 100,000 (negative) | Not detected |
| | L-Ephedrine | 100,000 (negative) | Not detected |
| | D-Pseudoephedrine | 100,000 (negative) | Not detected |
| | (+/-)3,4-Methylenedioxyamphetamine (MDA) | 100,000 (negative) | Not detected |
| | Trimethobenzamide | 100,000 (negative) | Not detected |
| | L-Phenylephrine | 100,000 (negative) | Not detected |
| | Procaine | 100,000 (negative) | Not detected |
| | Phentermine | 100,000 (negative) | Not detected |
| | Fenflurmaine | 50,000 | 2% |
| COC300 | Benzoylecogonine | 300 | 100% |
| | Cocaethylene | 12,500 | 2.4% |
| | Cocaine HCl | 780 | 38.5% |
| | Ecgonine | 32,000 | 0.9% |
| | Norcocaine | 100,000 (Negative) | Not detected |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Ecgonine methyl ester | 100,000 (Negative) | Not detected |
| THC 50 | 11-nor-$\Delta^9$-THC-9-COOH | 50 | 100% |
| | 11-nor-$\Delta^8$-THC -9-COOH | 30 | 166.7% |
| | (±)-11-nor-9-carboxy-$\Delta^9$-THC | 100 | 50% |
| | 11-nor-$\Delta^9$-THC -carboxy glucuronide | 100 | 50% |
| | (±)-11-Hydroxy-$\Delta^9$-THC | 5,000 | 1% |
| | $\Delta^8$-Tetrahydrocannabinol | 1,500 | 3.3% |
| | $\Delta^9$-Tetrahydrocannabinol | 5,000 | 1% |
| | Cannabinol | 20,000 | 0.3% |
| | Cannabidiol | 100,000 (Negative) | Not detected |
| MDMA 500 | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 500 | 100% |
| | (+/-)3,4-Methylenedioxyamphetamine (MDA) | 3,000 | 16.7% |
| | (+/-)3,4-Methylenedioxy-nethylamphetamine (MDEA) | 300 | 166.7% |
| | L-Methamphetamine | 100,000 (Negative) | Not detected |
| | D-Methamphetamine | 100,000 (Negative) | Not detected |
| | D,L-Methamphetamine | 100,000 (Negative) | Not detected |
| | D-Amphetamine | 100,000 (Negative) | Not detected |
| | L-Amphetamine | 100,000 (Negative) | Not detected |
| | D,L-Amphetamine | 100,000 (Negative) | Not detected |
| | L-Ephedrine | 100,000 (Negative) | Not detected |
| | D-Pseudoephedrine | 100,000 (Negative) | Not detected |
| | Phentermine | 100,000 (Negative) | Not detected |
| | L-Phenylephrine | 100,000 (Negative) | Not detected |
| BUP 10 | Buprenorphine | 10 | 100% |
| | Buprenorphine -3-D-glucuronide | 160 | 6.3% |
| | Norbuprenorphine | 10 | 100% |
| | Norbuprenorphine-3-D-glucuronide | 200 | 5% |
| | Morphine | 100,000 (Negative) | Not detected |
| | Oxymorphone | 100,000 (Negative) | Not detected |
| | Hydromorphone | 100,000 (Negative) | Not detected |
| | Codeine | 100,000 (Negative) | Not detected |
| | Nalorphine HCl | 100,000 (Negative) | Not detected |
| PPX 300 | D-Propoxyphene | 300 | 100% |
| | D-Norpropoxyphene | 300 | 100% |
| AMP 1000 | D-Amphetamine | 1,000 | 100% |
| | L-Amphetamine | 50,000 | 2% |
| | D,L-Amphetamine | 3,000 | 33.3% |
| | Hydroxyamphetamine | 5,000 | 20% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | (+/-)3,4-Methylenedioxyamphetamine (MDA) | 5,000 | 20% |
| | Diethylstilbestrol | 4,000 | 25% |
| | Phentermine | 3,000 | 33.3% |
| | β-Phenylethylamine | 100,000 | 1% |
| | Tyramine | 100,000 | 1% |
| | D,L-Norephedrine | 100,000 | 1% |
| | p-Hydroxynorephedrine | 100,000 | 1% |
| | p-Hydroxyamphetamine | 100,000 | 1% |
| | D-Methamphetamine | 100,000 (Negative) | Not detected |
| | L-Methamphetamine | 100,000 (Negative) | Not detected |
| | D,L-Methamphetamine | 100,000 (Negative) | Not detected |
| | L-Ephedrine | 100,000 (Negative) | Not detected |
| | D-Pseudoephedrine | 100,000 (Negative) | Not detected |
| | Phenylpropanolamine | 100,000 (Negative) | Not detected |
| | L-Phenylephrine | 100,000 (Negative) | Not detected |
| | L-Epinephrine | 100,000 (Negative) | Not detected |
| | D,L-Epinephrine | 100,000 (Negative) | Not detected |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 100,000 (Negative) | Not detected |
| | (+/-)3,4-Methylenedioxy-nethylamphetamine (MDEA) | 100,000 (Negative) | Not detected |
| PCP 25 | Phencyclidine | 25 | 100% |
| | 4-Hydroxy phencyclidine | 12,500 | 0.2% |
| | Pheniramine | 40,000 | 0.06% |
| EDDP 300 | 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 | 100% |
| | Methadone | 100,000 (Negative) | Not detected |
| | EMDP | 100,000 (Negative) | Not detected |
| | Doxylamine | 100,000 (Negative) | Not detected |
| | Levacetylmethadol (LAAM) | 100,000 (Negative) | Not detected |
| | Disopyramide | 100,000 (Negative) | Not detected |
| | Alphamethadol | 100,000 (Negative) | Not detected |
| OXY 100 | Oxycodone | 100 | 100% |
| | Hydrocodone | 10,000 | 1% |
| | Hydromorphone | 12,500 | 0.8% |
| | Levorphanol tartrate | 20,000 | 0.5% |
| | Naloxone HCl | 15,000 | 0.7% |
| | Naltrexone HCl | 50,000 | 0.2% |
| | Oxymorphone | 1,500 | 6.7% |
| | Oxymorphone-3-β-D-glucuronide | 1,000 | 10% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Noroxycodone | 2,000 | 5% |
| | Noroxymorphone | 1,000 | 10% |
| | Dihydrocodeine | 20,000 | 0.5% |
| | Codeine | 100,000 (Negative) | Not detected |
| | Morphine | 100,000 (Negative) | Not detected |
| | Buprenorphine | 100,000 (Negative) | Not detected |
| | Ethylmorphine | 100,000 (Negative) | Not detected |
| | Thebaine | 100,000 (Negative) | Not detected |
| | 6-Monoacetylmorphine (6-MAM) | 100,000 (Negative) | Not detected |
| BZO 300 | Oxazepam | 300 | 100% |
| | α-Hydroxyalprazolam | 1,500 | 20% |
| | Alprazolam | 200 | 150% |
| | Bromazepam | 500 | 60% |
| | Chlordiazepoxide | 1,500 | 20% |
| | Clobazam | 100 | 300% |
| | Clonazepam | 800 | 37.5% |
| | Clorazepate dipotassium | 200 | 150% |
| | Desalkylflurazepam | 400 | 75% |
| | Diazepam | 200 | 150% |
| | Estazolam | 2,500 | 12% |
| | Flunitrazepam | 400 | 75% |
| | D,L-Lorazepam | 1,500 | 20% |
| | Midazolam | 12,500 | 2.4% |
| | Nitrazepam | 100 | 300% |
| | Norchlordiazepoxide | 200 | 150% |
| | Nordiazepam | 400 | 75% |
| | R,S-Lorazepam glucuronide | 200 | 150% |
| | Temazepam | 100 | 300% |
| | Triazolam | 2,500 | 12% |
| | Demoxepam | 2,000 | 15% |
| | Flurazepam | 500 | 60% |
| | Delorazepam | 2,000 | 15% |
| | Lormetazepam | 150 | 200% |
| TCA 1000 | Nortriptyline | 1,000 | 100% |
| | Amitriptyline | 1,500 | 66.7% |
| | Chlorpheniramine | 30,000 | 3.3% |
| | Clomipramine | 12,500 | 8% |
| | Cyclobenzaprine HCl | 5,000 | 20% |
| | Desipramine | 200 | 500% |
| | Doxepin | 2,000 | 50% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Duloxetine | 80,000 | 1.3% |
| | Imipramine | 750 | 133.3% |
| | Norclomipramine | 12,500 | 8% |
| | Nordoxepine | 1,000 | 100% |
| | Promazine | 1,500 | 66.7% |
| | Trimipramine | 5,000 | 20% |
| | Maprotiline | 2,000 | 50% |
| | Promethazine | 25,000 | 4% |
| BAR 300 | Secobarbital | 300 | 100% |
| | Alphenal | 150 | 200% |
| | Amobarbital | 300 | 100% |
| | Aprobarbital | 200 | 150% |
| | Butabarbital | 100 | 300% |
| | Butethal | 100 | 300% |
| | Cyclopentobarbital | 600 | 50% |
| | Pentobarbital | 250 | 120% |
| | Phenobarbital | 250 | 120% |
| | Butalbital | 2,500 | 12% |
| | Barbital | 300 | 100% |
| MTD 300 | Methadone | 300 | 100% |
| | Doxylamine | 5,000 | 6% |
| | EDDP | 100,000 (Negative) | Not detected |
| | Levacetylmethadol (LAAM) | 100,000 (Negative) | Not detected |
| | EMDP | 100,000 (Negative) | Not detected |
| | Alphamethadol | 100,000 (Negative) | Not detected |
| | Pheniramine | 100,000 (Negative) | Not detected |
| | Disopyramide | 100,000 (Negative) | Not detected |
| | Esomeprazole | 100,000 (Negative) | Not detected |
| 6-MAM 10 | 6-Monoacetylmorphine (6-MAM) | 10 | 100% |
| | Heroin | 10 | 100% |
| | Morphine | 100,000 | 0.01% |
| | Nalorphine HCl | 5,000 | 0.2% |
| | Hydrocodone | 50,000 | 0.02% |
| | Hydromorphone | 10,000 | 0.1% |
| | Oxymorphone | 50,000 | 0.02% |
| | Procaine | 50,000 | 0.02% |
| | Thebaine | 10,000 | 0.1% |
| | Normorphine | 100,000 (Negative) | Not detected |
| | Chlordiazepoxide | 100,000 (Negative) | Not detected |
| | Clobazam | 100,000 (Negative) | Not detected |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | D-Amphetamine | 100,000 (Negative) | Not detected |
| | D,L-Amphetamine | 100,000 (Negative) | Not detected |
| | Levorphanol tartrate | 100,000 (Negative) | Not detected |
| | Codeine | 100,000 (Negative) | Not detected |
| | Ethylmorphine | 100,000 (Negative) | Not detected |
| | Morphine-3-β-D-glucuronide | 100,000 (Negative) | Not detected |
| | Norcodeine | 100,000 (Negative) | Not detected |
| | Oxycodone | 100,000 (Negative) | Not detected |
| | 6-Acetylcodeine | 100,000 (Negative) | Not detected |
| | Buprenorphine | 100,000 (Negative) | Not detected |
| | Dihydrocodeine | 100,000 (Negative) | Not detected |
| | Dextromethorphan | 100,000 (Negative) | Not detected |
| | Imipramine | 100,000 (Negative) | Not detected |
| | Meperidine | 100,000 (Negative) | Not detected |
| | (±)-Methadone | 100,000 (Negative) | Not detected |
| | Mitragynine (Kratom) | 100,000 (Negative) | Not detected |
| | Morphine-6-β-D-glucuronide | 100,000 (Negative) | Not detected |
| | Naloxone HCl | 100,000 (Negative) | Not detected |
| | Naltrexone HCl | 100,000 (Negative) | Not detected |
| | Naproxen | 100,000 (Negative) | Not detected |
| | Norbuprenorphine | 100,000 (Negative) | Not detected |
| | Norbuprenorphine-3-D-glucuronide | 100,000 (Negative) | Not detected |
| | Noroxycodone HCl | 100,000 (Negative) | Not detected |
| | Noroxymorphone HCl | 100,000 (Negative) | Not detected |
| | (+)-Norpropoxyphene maleate | 100,000 (Negative) | Not detected |
| | Oxymorphone-3-β-D-glucuronide | 100,000 (Negative) | Not detected |
| | Tapentadol HCl | 100,000 (Negative) | Not detected |
| | Tramadol HCl | 100,000 (Negative) | Not detected |
| | Levacetylmethadol (LAAM) | 100,000 (Negative) | Not detected |
| FYL 1 | Fentanyl | 1 | 100% |
| | Acetyl fentanyl | 1 | 100% |
| | Acrylfentanyl | 1 | 100% |
| | Isobutyryl fentanyl | 2.5 | 40% |
| | Ocfentanil | 5 | 20% |
| | Butyryl fentanyl | 5 | 20% |
| | Furanyl fentanyl | 10 | 10% |
| | Valeryl fentanyl | 5 | 20% |
| | (±) β-Hydroxythiofentanyl | 2.5 | 40% |
| | 4-Fluoro-isobutyrylfentanyl | 10 | 10% |
| | Para-fluorobutyryl fentanyl | 5 | 20% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Para-fluoro fentanyl | 2.5 | 40% |
| | Carfentanil | 50 | 2% |
| | Sufentanil | 25 | 4% |
| | Alfentanil | 7500 | 0.01% |
| | ω-1-Hydroxy fentanyl | 2500 | 0.04% |
| | (±)-3-cis-methyl fentanyl | 75 | 1.3% |
| | Despropionyl fentanyl (4-ANPP) | 2000 | 0.05% |
| | β-hydroxyfentanyl | 100 | 1% |
| | Thiofentanyl | 50 | 2% |
| | Cyclopropyl fentanyl | 10 | 10% |
| | Trazodone | 1000 | 0.1% |
| | Remifentanil | 100,000 (Negative) | Not detected |
| | Norcarfentanil | 100,000 (Negative) | Not detected |
| | Norfentanyl | 100,000 (Negative) | Not detected |
| | Acetyl norfentanyl | 100,000 (Negative) | Not detected |
| | 6-Acetyl morphine | 100,000 (Negative) | Not detected |
| | Amphetamine | 100,000 (Negative) | Not detected |
| | Buprenorphine | 100,000 (Negative) | Not detected |
| | Buprenorphine-3-D-glucuronide | 100,000 (Negative) | Not detected |
| | Codeine | 100,000 (Negative) | Not detected |
| | Dextromethorphan | 100,000 (Negative) | Not detected |
| | Dihydrocodeine | 100,000 (Negative) | Not detected |
| | EDDP | 100,000 (Negative) | Not detected |
| | EMDP | 100,000 (Negative) | Not detected |
| | Fluoxetine | 100,000 (Negative) | Not detected |
| | Heroin | 100,000 (Negative) | Not detected |
| | Hydrocodone | 100,000 (Negative) | Not detected |
| | Hydromorphone | 100,000 (Negative) | Not detected |
| | Ketamine | 100,000 (Negative) | Not detected |
| | Levorphanol | 100,000 (Negative) | Not detected |
| | Meperidine | 100,000 (Negative) | Not detected |
| | Methadone | 100,000 (Negative) | Not detected |
| | Morphine | 100,000 (Negative) | Not detected |
| | Morphine-3-β-D-glucuronide | 100,000 (Negative) | Not detected |
| | Naloxone | 100,000 (Negative) | Not detected |
| | Naltrexone | 100,000 (Negative) | Not detected |
| | Norbuprenorphine | 100,000 (Negative) | Not detected |
| | Norcodeine | 100,000 (Negative) | Not detected |
| | Norketamine | 100,000 (Negative) | Not detected |
| | Normeperidine | 100,000 (Negative) | Not detected |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Normorphine | 100,000 (Negative) | Not detected |
| | Noroxycodone | 100,000 (Negative) | Not detected |
| | Oxycodone | 100,000 (Negative) | Not detected |
| | Oxymorphone | 100,000 (Negative) | Not detected |
| | Pentazocine (Talwin) | 100,000 (Negative) | Not detected |
| | Pipamperone | 100,000 (Negative) | Not detected |
| | Risperidone | 100,000 (Negative) | Not detected |
| | Tapentadol | 100,000 (Negative) | Not detected |
| | Thioridazine | 100,000 (Negative) | Not detected |
| | Tilidine | 100,000 (Negative) | Not detected |
| | Tramadol | 100,000 (Negative) | Not detected |
| | Tramadol-N-Desmethyl | 100,000 (Negative) | Not detected |
| | Tramadol-O-Desmethyl | 100,000 (Negative) | Not detected |
| | Isotonitaze | 100,000 (Negative) | Not detected |
| | AH-7921 HCl | 100,000 (Negative) | Not detected |
| MET 500 | D-Methamphetamine | 500 | 100% |
| | (+/-)3,4-Methylenedioxy-nethylamphetamine (MDEA) | 10,000 | 5% |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 1,500 | 33.3% |
| | L-Methamphetamine | 10,000 | 5% |
| | p-Hydroxymethamphetamine | 15,000 | 3.3% |
| | D,L-Methamphetamine | 500 | 100% |
| | β-Phenylethylamine | 25,000 | 2% |
| | Mephentermine | 25,000 | 2% |
| | Methoxyphenamine HCl | 25,000 | 2% |
| | L-Amphetamine | 37,500 | 1.3% |
| | D-Amphetamine | 25,000 | 2% |
| | D,L-Amphetamine | 100,000 (negative) | Not detected |
| | Chloroquine | 100,000 (negative) | Not detected |
| | L-Ephedrine | 100,000 (negative) | Not detected |
| | D-Pseudoephedrine | 100,000 (negative) | Not detected |
| | (+/-)3,4-Methylenedioxyamphetamine (MDA) | 100,000 (negative) | Not detected |
| | Trimethobenzamide | 100,000 (negative) | Not detected |
| | L-Phenylephrine | 100,000 (negative) | Not detected |
| | Procaine | 100,000 (negative) | Not detected |
| | Phentermine | 100,000 (negative) | Not detected |
| | Fenflurmaine | 25,000 | 2% |
| COC 150 | Benzoylecogonine | 150 | 100% |
| | Cocaethylene | 6,250 | 2.4% |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | Cocaine HCl | 340 | 44.1% |
| | Ecgonine | 16,000 | 0.9% |
| | Norcocaine | 100,000 (Negative) | Not detected |
| | Ecgonine methyl ester | 100,000 (Negative) | Not detected |
| OPI 2000 | Morphine | 2000 | 100% |
| | 6-Monoacetylmorphine (6-MAM) | 2,000 | 100% |
| | Codeine | 2,000 | 100% |
| | Dihydrocodeine | 1,500 | 133.3% |
| | Ethylmorphine | 3,000 | 66.7% |
| | Codeine-6-β-D-glucuronide | 3,000 | 66.7% |
| | Heroin | 2,000 | 100% |
| | Hydrocodone | 12,500 | 16% |
| | Hydromorphone | 5,000 | 40% |
| | Levorphanol tartrate | 75,000 | 2.7% |
| | Nalorphine HCl | 5,000 | 40% |
| | Norcodeine | 8,000 | 25% |
| | Normorphine | 50,000 | 4% |
| | Oxymorphone | 25,000 | 8% |
| | Morphine-6-β-D-glucuronide | 2,000 | 100% |
| | Morphine-3-β-D-glucuronide | 2,000 | 100% |
| | Thebaine | 5,000 | 40% |
| | 6-Acetylcodeine | 50,000 | 4% |
| | Oxycodone | 100,000 (Negative) | Not detected |
| | Procaine | 100,000 (Negative) | Not detected |
| | Norpropoxyphene | 100,000 (Negative) | Not detected |
| AMP 500 | D-Amphetamine | 500 | 100% |
| | L-Amphetamine | 25,000 | 2% |
| | D,L-Amphetamine | 1,500 | 33.3% |
| | Hydroxyamphetamine | 2,500 | 20% |
| | (+/-)3,4-Methylenedioxyamphetamine (MDA) | 2,500 | 20% |
| | Diethylstilbestrol | 2,000 | 25% |
| | Phentermine | 1,500 | 33.3% |
| | β-Phenylethylamine | 50,000 | 1% |
| | Tyramine | 50,000 | 1% |
| | D,L-Norephedrine | 50,000 | 1% |
| | p-Hydroxynorephedrine | 50,000 | 1% |
| | p-Hydroxyamphetamine | 50,000 | 1% |
| | D-Methamphetamine | 100,000 (Negative) | Not detected |
| | L-Methamphetamine | 100,000 (Negative) | Not detected |
| | D,L-Methamphetamine | 100,000 (Negative) | Not detected |

| Drug/Cut off | Compound | Minimum concentration required to obtain a positive result (ng/mL) | % Cross-Reactivity |
|---|---|---|---|
| | L-Ephedrine | 100,000 (Negative) | Not detected |
| | D-Pseudoephedrine | 100,000 (Negative) | Not detected |
| | Phenylpropanolamine | 100,000 (Negative) | Not detected |
| | L-Phenylephrine | 100,000 (Negative) | Not detected |
| | L-Epinephrine | 100,000 (Negative) | Not detected |
| | D,L-Epinephrine | 100,000 (Negative) | Not detected |
| | (+/-)3,4-Methylenedioxymethamphetamine (MDMA) | 100,000 (Negative) | Not detected |
| | (+/-)3,4-Methylenedioxy-nethylamphetamine (MDEA) | 100,000 (Negative) | Not detected |
| | Benzphetamine | 100,000 (Negative) | Not detected |

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff.

Compounds that show no interference at a concentration of 100µg/mL or specified concentrations are summarized in the following table.

| | | |
|---|---|---|
| Acetaminophen | Doxylamine (except MTD test) | Octopamine |
| Acetone (1000 mg/dL) | D-Pseudoephedrine | O-Hydroxyhippuric acid |
| Acetophenetidin | Duloxetine (except TCA test) | Olanzapine |
| Acetylsalicylic acid (Aspirin) | Ecgonine methyl ester | Omeprazole |
| Acyclovir | EMDP | Oxalic acid (100 mg/dL) |
| Albumin (100 mg/dL ) | Erythromycin | Oxolinic acid |
| Albuterol sulfate (Proair HFA) | Esomeprazole magnesium | Oxymetazoline |
| Alphamethadol | Estrone | Paliperidone |
| Aminophylline | Ethanol (1%) | Papaverine |
| Aminopyrine | Fenofibrate | Penicillin G |
| Amitriptyline | Fenoprofen | Penicillin V potassium |
| Amoxicillin | Fentanyl (except FYL test) | Perphenazine |
| Ampicillin | Fluoxetine HCl | Phenacetin |
| Aripiprazole | Fluphenazine | Phenelzine |
| Aspartame | Fotemustine | Phenylpropanolamine |
| Atomoxetine | Furosemide | Prednisone |
| Atorvastatin Calcium | Gabapentin | Pregablin |
| Atropine | Galactose (10 mg/dL) | Procaine (except 6-MAM test) |
| Azithromycin | Gamma globulin (500 mg/dL) | Promazine (except TCA test) |

| | | |
|---|---|---|
| Baclofen | Gatifloxacin | Promethazine (except TCA test) |
| Benzilic acid | Gemfibrozil | Propoxyphene (except PPX test) |
| Benzocaine | Gentisic acid | Propranolol |
| Benzoic acid | Glibenclamide | Propylthiouracil |
| Benzoylecgonine | Gliclazide | Pyridoxine |
| Benzphetamine | Glucose (3000 mg/dL) | Pyrilamine |
| Bilirubin | Guaiacol glyceryl ether | Pyrogallol |
| Boric acid (1%) | Hemoglobin | Quetiapine |
| Bupropion | Hydralazine | Quinine |
| Caffeine | Hydrochlorothiazide | Quinolinic acid |
| Cannabidiol | Hydrocortisone | R-(-)-Apomorphine |
| Captopril | Ibuprofen | Ranitidine |
| Carbamazepine | Imipramine (except TCA test) | Ribavirin |
| Carfentanil (except FYL test) | Isoxsuprine | Rifampicin |
| Carisoprodol | Ketamine | Risperidone |
| Cefradine | Ketoprofen | Salicylic acid |
| Cephalexin | LAAM HCl | Serotonin (5-Hydroxytyramine) |
| Chloral hydrate | Labetalol | Sertraline |
| Chloramphenicol | L-Ephedrine | Sildenafil citrate |
| Chlordiazepoxide (except BZO test) | L-Epinephrine | Simvastatin |
| Chloroquine | Levofloxacin HCl | Sulfamethazine |
| Chlorothiazide | Levonorgestrel | Sulindac |
| Chlorpheniramine (except TCA test) | Levothyroxine Sodium | Telmisartan |
| Chlorpromazine | Lidocaine HCl | Tetracycline |
| Cholesterol | Lisinopril | Tetrahydrocortisone 3-(β-Dglucuronide) |
| Ciprofloxacin HCl | Loperamide | Tetrahydrocortisone 3-acetate |
| Citalopram | Loratadine | Tetrahydrozoline |
| Clarithromycin | L-Phenylephrine | Theophylline |
| Clonidine | Magnesium | Thiamine |
| Clozapine | Maprotiline (except TCA test) | Thioridazine |
| Conjugated Estrogens | Meperidine | Tramadol |
| Cortisone | Meprobamate | Trazodone (except FYL test) |
| Creatine Hydrate | Methapyrilene | Triamterene |
| Creatinine | Methaqualone | Trifluoperazine |

| | | |
|---|---|---|
| Cyclobenzaprine HCl (except TCA test) | Methoxyphenamine (except MET test) | Trimethobenzamide |
| Cyclodextrin | Methylphenidate | Trimethoprim |
| D,L-Epinephrine | Metoprolol tartrate | Tryptamine |
| D,L-Isoproterenol | Metronidazole (300 µg/mL) | Tyramine (except AMP test) |
| D,L-Octopamine | Mifepristone | Urea (2000 mg/dL) |
| D,L-Propranolol | Montelukast sodium | Uric acid |
| D,L-Tryptophan | N-Acetylprocainamide | Valproic acid (250 µg/mL) |
| D,L-Tyrosine | NaCl (4000 mg/dL) | Venlafaxine HCl |
| Delorazepam (except BZO test) | Nalidixic acid | Verapamil |
| Deoxycorticosterone | Naloxone HCl (except OXY test) | Vitamin B2 (Riboflavin) |
| Desloratadine | Naltrexone HCl (except OXY test) | Vitamin C (Ascorbic acid) |
| Dextromethorphan | Niacinamide | Zaleplon |
| Diclofenac | Nicotine | Zomepirac sodium salt |
| Diclofenac sodium | Nicotinic acid | β-Estradiol |
| Diflunisal | Nifedipine | β-Phenylethylamine (except MET/AMP test) |
| Digoxin | Nitroglycerin | (-)-Cotinine |
| Diphenhydramine HCl | Nordoxepin (except TCA test) | (+)-Naproxen |
| Disopyramide | Norethindrone | 3-Hydroxytyramine |
| Dopamine HCl | Norfentanyl | 4-Dimethyl-aminoantipyrine |
| Doxepin (except TCA test) | Noscapine | 5, 5-Diphenylhydantoin |

Interference by pH and specific gravity were also evaluated using pooled urine specimens with drug concentrations 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.

**B. Method comparison study**

The method comparison studies for the device were performed in-house with three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The results are presented in the table below:

| Drug Test | Operator | Test Result | Drug-Free | Low Negative by LC-MS/MS (less than -50% cut off) | Near cut off Negative by LC-MS/MS (Between -50%cut off and cut off) | Near cut off Positive by LC-MS/MS (Between cut off and +50% cut off) | High Positive by LC-MS/MS (greater than +50%cut off) |
|---|---|---|---|---|---|---|---|
| MOP300 | Operator 1 | + | 0 | 0 | 1 | 18 | 21 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 18 | 21 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 19 | 21 |
| | | - | 10 | 15 | 14 | 0 | 0 |
| MET1000 | Operator 1 | + | 0 | 0 | 1 | 22 | 18 |
| | | - | 10 | 14 | 15 | 0 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| COC300 | Operator 1 | + | 0 | 0 | 1 | 18 | 21 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 18 | 21 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 19 | 21 |
| | | - | 10 | 15 | 14 | 0 | 0 |
| THC | Operator 1 | + | 0 | 0 | 0 | 22 | 18 |
| | | - | 10 | 14 | 16 | 0 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| MDMA | Operator 1 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| BUP | Operator 1 | + | 0 | 0 | 1 | 22 | 18 |
| | | - | 10 | 14 | 15 | 0 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |

| Drug Test | Operator | Test Result | Drug-Free | Low Negative by LC-MS/MS (less than -50% cut off) | Near cut off Negative by LC-MS/MS (Between -50%cut off and cut off) | Near cut off Positive by LC-MS/MS (Between cut off and +50% cut off) | High Positive by LC-MS/MS (greater than +50%cut off) |
|---|---|---|---|---|---|---|---|
| | Operator 3 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| PPX | Operator 1 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| AMP1000 | Operator 1 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 20 | 20 |
| | | - | 10 | 15 | 15 | 0 | 0 |
| PCP | Operator 1 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| EDDP | Operator 1 | + | 0 | 0 | 1 | 21 | 19 |
| | | - | 10 | 14 | 15 | 0 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 19 |
| | | - | 10 | 14 | 16 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 20 | 19 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| OXY | Operator 1 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 20 | 20 |
| | | - | 10 | 15 | 14 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| BZO | Operator 1 | + | 0 | 0 | 1 | 19 | 20 |
| | | - | 10 | 15 | 14 | 1 | 0 |

| Drug Test | Operator | Test Result | Drug-Free | Low Negative by LC-MS/MS (less than -50% cut off) | Near cut off Negative by LC-MS/MS (Between -50%cut off and cut off) | Near cut off Positive by LC-MS/MS (Between cut off and +50% cut off) | High Positive by LC-MS/MS (greater than +50%cut off) |
|---|---|---|---|---|---|---|---|
| | Operator 2 | + | 0 | 0 | 1 | 20 | 20 |
| | | - | 10 | 15 | 14 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| TCA | Operator 1 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 20 | 20 |
| | | - | 10 | 14 | 15 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 19 | 20 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| BAR | Operator 1 | + | 0 | 0 | 2 | 22 | 18 |
| | | - | 10 | 14 | 14 | 0 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| MTD | Operator 1 | + | 0 | 0 | 1 | 20 | 19 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 21 | 19 |
| | | - | 10 | 14 | 15 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 20 | 19 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| 6-MAM | Operator 1 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| FYL | Operator 1 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 2 | 22 | 18 |
| | | - | 10 | 15 | 13 | 0 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 20 | 18 |
| | | - | 10 | 15 | 14 | 2 | 0 |

| Drug Test | Operator | Test Result | Drug-Free | Low Negative by LC-MS/MS (less than -50% cut off) | Near cut off Negative by LC-MS/MS (Between -50%cut off and cut off) | Near cut off Positive by LC-MS/MS (Between cut off and +50% cut off) | High Positive by LC-MS/MS (greater than +50%cut off) |
|---|---|---|---|---|---|---|---|
| MET500 | Operator 1 | + | 0 | 0 | 1 | 20 | 19 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 20 | 19 |
| | | - | 10 | 14 | 16 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 20 | 19 |
| | | - | 10 | 14 | 15 | 1 | 0 |
| COC150 | Operator 1 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 21 | 18 |
| | | - | 10 | 15 | 15 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| OPI2000 | Operator 1 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 0 | 20 | 18 |
| | | - | 10 | 15 | 15 | 2 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 22 | 18 |
| | | - | 10 | 15 | 14 | 0 | 0 |
| AMP500 | Operator 1 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 2 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |
| | Operator 3 | + | 0 | 0 | 1 | 21 | 18 |
| | | - | 10 | 15 | 14 | 1 | 0 |

Discordant Results are summarized below.

| Drug Test | Operator | Sample Number | LC-MS/MS Result (ng/mL) | Test Result |
|---|---|---|---|---|
| MOP300 | Operator 1 | 1-08 | 269.32 | Positive |
| | Operator 3 | 1-33 | 289.66 | Positive |
| | Operator 1 | 1-60 | 336.93 | Negative |
| | Operator 2 | 1-17 | 310.02 | Negative |
| MET1000 | Operator 1 | 4-79 | 992.48 | Positive |
| | Operator 3 | 4-38 | 897.14 | Positive |
| | Operator 2 | 4-63 | 1018.46 | Negative |

| Drug Test | Operator | Sample Number | LC-MS/MS Result (ng/mL) | Test Result |
|---|---|---|---|---|
| | Operator 3 | 4-74 | 1007.84 | Negative |
| COC300 | Operator 1 | 6-32 | 296.35 | Positive |
| | Operator 2 | 6-63 | 295.68 | Positive |
| | Operator 3 | 6-79 | 272.56 | Positive |
| | Operator 1 | 6-51 | 306.47 | Negative |
| | Operator 2 | 6-68 | 300.47 | Negative |
| THC | Operator 2 | 7-04 | 53.73 | Negative |
| | Operator 3 | 7-32 | 57.78 | Negative |
| MDMA | Operator 2 | 8-07 | 496.27 | Positive |
| | Operator 1 | 8-48 | 508.66 | Negative |
| | Operator 2 | 8-20 | 547.97 | Negative |
| | Operator 3 | 8-42 | 511.26 | Negative |
| BUP | Operator 1,2 | 9-45 | 9.86 | Positive |
| | Operator 3 | 9-20 | 9.66 | Positive |
| | Operator 2 | 9-72 | 10.23 | Negative |
| | Operator 3 | 9-50 | 10.66 | Negative |
| PPX | Operator 1,3 | 11-21 | 297.14 | Positive |
| | Operator 2 | 11-11 | 293.10 | Positive |
| | Operator 1 | 11-02 | 302.98 | Negative |
| | Operator 3 | 11-65 | 322.25 | Negative |
| | Operator 2 | 11-71 | 309.47 | Negative |
| AMP1000 | Operator 1 | 13-08 | 870.13 | Positive |
| | Operator 1 | 13-07 | 1070.87 | Negative |
| | Operator 2 | 13-23 | 1013.55 | Negative |
| PCP | Operator 2 | 14-31 | 24.88 | Positive |
| | Operator 1 | 14-69 | 25.58 | Negative |
| | Operator 2 | 14-49 | 28.12 | Negative |
| | Operator 3 | 14-27 | 25.47 | Negative |
| EDDP | Operator 1 | 15-21 | 296.15 | Positive |
| | Operator 3 | 15-51 | 305.99 | Negative |
| OXY | Operator 1 | 16-28 | 91.36 | Positive |
| | Operator 2 | 16-51 | 99.55 | Positive |
| | Operator 3 | 16-77 | 96.15 | Positive |
| | Operator 1 | 16-74 | 110.47 | Negative |
| | Operator 3 | 16-75 | 104.20 | Negative |
| BZO | Operator 1 | 17-61 | 273.48 | Positive |
| | Operator 2 | 17-04 | 293.44 | Positive |
| | Operator 1 | 17-37 | 307.46 | Negative |
| | Operator 3 | 17-69 | 319.25 | Negative |
| TCA | Operator 2 | 18-65 | 886.47 | Positive |
| | Operator 1,3 | 18-26 | 1003.13 | Negative |

| Drug Test | Operator | Sample Number | LC-MS/MS Result (ng/mL) | Test Result |
|---|---|---|---|---|
| BAR | Operator 1 | 19-48 | 288.49 | Positive |
| | Operator 3 | 19-76 | 298.54 | Positive |
| | Operator 1 | 19-39 | 294.45 | Positive |
| | Operator 2 | 19-33 | 303.65 | Negative |
| | Operator 3 | 19-62 | 315.16 | Negative |
| MTD | Operator 1 | 20-65 | 292.16 | Positive |
| | Operator 2 | 20-79 | 289.43 | Positive |
| | Operator 1,3 | 20-27 | 303.66 | Negative |
| 6-MAM | Operator 1 | 21-56 | 8.94 | Positive |
| | Operator 1 | 21-06 | 10.55 | Negative |
| | Operator 2 | 21-23 | 10.55 | Negative |
| | Operator 3 | 21-08 | 11.46 | Negative |
| FYL | Operator 2 | 10-69 | 0.95 | Positive |
| | Operator 2 | 10-17 | 0.87 | Positive |
| | Operator 3 | 10-68 | 0.96 | Positive |
| | Operator 1 | 10-21 | 1.04 | Negative |
| | Operator 3 | 10-07 | 1.12 | Negative |
| | Operator 3 | 10-20 | 1.02 | Negative |
| MET500 | Operator 1 | 3-58 | 458.22 | Positive |
| | Operator 3 | 3-68 | 493.26 | Positive |
| | Operator 1 | 3-35 | 515.17 | Negative |
| | Operator 2 | 3-71 | 539.96 | Negative |
| | Operator 3 | 3-78 | 503.12 | Negative |
| COC150 | Operator 1,3 | 5-38 | 145.59 | Positive |
| | Operator 1 | 5-07 | 156.87 | Negative |
| | Operator 2 | 5-71 | 151.49 | Negative |
| | Operator 3 | 5-61 | 164.90 | Negative |
| OPI2000 | Operator 1 | 2-67 | 1834.41 | Positive |
| | Operator 3 | 2-04 | 1976.54 | Positive |
| | Operator 1 | 2-50 | 2179.28 | Negative |
| | Operator 2 | 2-10 | 2039.78 | Negative |
| | Operator 2 | 2-77 | 2034.78 | Negative |
| AMP500 | Operator 1 | 12-75 | 491.37 | Positive |
| | Operator 2 | 12-04 | 473.85 | Positive |
| | Operator 3 | 12-70 | 489.38 | Positive |
| | Operator 1 | 12-55 | 510.94 | Negative |
| | Operator 3 | 12-79 | 553.25 | Negative |
| | Operator 2 | 12-68 | 506.47 | Negative |

**C. Lay person study**

A lay user study was performed at three intended user sites with 280 lay persons. 176 male and 104 female participated the study. They had diverse educational and professional backgrounds and their age range from 21 to > 50. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC-MS/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. The results are summarized below.

Result of CLUNGENE Multi-Drug Test Easy Cup Configuration 1:

| **Drug** | **Cut off (ng/mL)** | **Results** | **Concentration** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **-100% cutoff** | **-75% cutoff** | **-50% cutoff** | **-25% cutoff** | **+25% cutoff** | **+50% cutoff** | **+75% cutoff** |
| **MOP** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **MET** | **1000** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **COC** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **THC** | **50** | Negative | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **MDMA** | **500** | Negative | 20 | 20 | 20 | 19 | 2 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 18 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 90% | 100% | 100% |
| **BUP** | **10** | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| **PPX** | **300** | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **AMP** | **1000** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **PCP** | **25** | Negative | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 100% | 100% | 100% |
| **EDDP** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **OXY** | **100** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **BZO** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **TCA** | **1000** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **BAR** | **300** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **MTD** | **300** | Negative | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **6-MAM** | **10** | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| **FYL** | **1** | Negative | 20 | 20 | 20 | 20 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Result of CLUNGENE Multi-Drug Test Easy Cup Configuration 2:

| **Drug** | **Cut off (ng/mL)** | **Results** | **Concentration** | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | **-100% cutoff** | **-75% cutoff** | **-50% cutoff** | **-25% cutoff** | **+25% cutoff** | **+50% cutoff** | **+75% cutoff** |
| **MET** | **500** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **COC** | **150** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **THC** | **50** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **OPI** | **2000** | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| **MDMA** | **500** | Negative | 20 | 20 | 20 | 18 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 95% | 100% | 100% |
| **BUP** | **10** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **PPX** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **AMP** | **500** | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **PCP** | **25** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |
| **EDDP** | **300** | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **OXY** | **100** | Negative | 20 | 20 | 20 | 20 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 0 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 100% | 95% | 100% | 100% |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **BZO** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **TCA** | **1000** | Negative | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **BAR** | **300** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |
| **MTD** | **300** | Negative | 20 | 20 | 20 | 18 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 2 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 90% | 100% | 100% | 100% |
| **6-MAM** | **10** | Negative | 20 | 20 | 20 | 19 | 0 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 20 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 100% | 100% | 100% |
| **FYL** | **1** | Negative | 20 | 20 | 20 | 19 | 1 | 0 | 0 |
| | | Positive | 0 | 0 | 0 | 1 | 19 | 20 | 20 |
| | | Total | 20 | 20 | 20 | 20 | 20 | 20 | 20 |
| | | Agreement (%) | 100% | 100% | 100% | 95% | 95% | 100% | 100% |

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 8.

Clinical Studies:
Not applicable.

## 13. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that CLUNGENE Multi-Drug Test Easy Cup and CLUNGENE Multi-Drug Home Test Easy Cup are substantially equivalent to the predicate devices.