March 31, 2023

Shenzhen Bioeasy Biotechnology Co., Ltd.
% Joe Shia
Director
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K230238
Trade/Device Name: BIOEASY™ U-Catch MAX Multi-Drug Test Cup, BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, NFT, NFW, NFY, NGG, NGL, NFV, PTG, PTH, NGM, QAW, QBF
Dated: January 27, 2023
Received: January 30, 2023

Dear Joe Shia:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Paula V. Caposino -S

Digitally signed by Paula V. Caposino -S
Date: 2023.03.31 20:52:54 -04'00'

Paula Caposino, Ph.D.
Acting Deputy Director
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
k230238

Device Name
BIOEASY™ U-Catch MAX Multi-Drug Test Cup

Indications for Use *(Describe)*
BIOEASY™ U-Catch MAX Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Morphine (MOP 300) | 300 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| d-Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Marijuana (THC) | 50 ng/mL |

BIOEASY™ U-Catch MAX Multi-Drug Test Cup offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

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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Department of Health and Human Services
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K230238

Device Name

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx

Indications for Use *(Describe)*

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline Cannabinoids and 6-Acetylmorphine in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Morphine (MOP 300) | 300 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| d-Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Acetylmorphine | 10 ng/mL |

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

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.**

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Department of Health and Human Services
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*PRAStaff@fda.hhs.gov*

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510(k) SUMMARY

K230238

The purpose of this submission is to add analytes Amphetamine 500, Cocaine 150, Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM) to previously cleared devices (k182530). These five new analytes were evaluated in this submission. For other analytes, please refer to k182530 for Buprenorphine, Secobarbital, Oxazepam, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids. In this submission the performance results are presented for the five new analytes, but the lay user study was conducted using the entire panel except of 6-AM.

1. Date: March 31, 2023

2. Submitter: Shenzhen Bioeasy Biotechnology Co., Ltd.
No.2-1 Liuxian 1st Road, Xin'an Sub-District
Shenzhen 518101, China

3. Contact person: Joe Shia
LSI International Inc
504E Diamond Ave., Suite I
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com.

4. Device Name: BIOEASY™ U-Catch MAX Multi-Drug Test Cup
BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx

Classification: Class 2

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| DJG Monoacetylmorphine | II | 21 CFR § 862.3650, Morphine Test System | Toxicology (91) |
| DKZ Amphetamine | II | 21 CFR § 862.3100, Amphetamine Test System | Toxicology (91) |
| LDJ Cannabinoids | II | 21 CFR § 862.3870, Cannabinoids Test System | Toxicology (91) |
| DIO Cocaine | II | 21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System | Toxicology (91) |
| LAF Methamphetamine | II | 21 CFR § 862.3610, Methamphetamine Test System | Toxicology (91) |
| DJG Morphine | II | 21 CFR § 862.3650, Morphine Test System | Toxicology (91) |
| JXM Oxazepam | II | 21 CFR § 862.3170, Benzodiazepine Test System | Toxicology (91) |
| DJG Oxycodone | II | 21 CFR § 862.3650, Opiate Test System | Toxicology (91) |
| DIS Secobarbital | II | 21 CFR § 862.3150, Barbiturate Test System | Toxicology (91) |
| DJG Buprenorphine | II | 21 CFR § 862.3650, Opiate Test System | Toxicology (91) |

| | | | |
|---|---|---|---|
| LAF<br>Methylenedioxy-methamphetamine | II | 21 CFR § 862.3610, Methamphetamine Test System | Toxicology (91) |
| LCM<br>Phencyclidine | unclassified | Enzyme Immunoassay Phencyclidine | Toxicology (91) |
| DJR<br>Methadone | II | 21 CFR § 862.3620, Methadone Test System | Toxicology (91) |
| DJR<br>2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) | II | 21 CFR § 862.3620, Methadone Test System | Toxicology (91) |
| LFG<br>Nortriptyline | II | 21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System | Toxicology (91) |
| JXN<br>Propoxyphene | II | 21 CFR, 862.3700 Propoxyphene Test System | Toxicology (91) |

5. Predicate Devices: K201630

   The Assure Tech Panel Dip Tests/AssureTech Quick Cup Tests

6. Intended Use

   BIOEASY™ U-Catch MAX Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Morphine (MOP 300) | 300 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| d-Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Marijuana (THC) | 50 ng/mL |

   BIOEASY™ U-Catch MAX Multi-Drug Test Cup offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

   The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

   The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline Cannabinoids and 6-Acetylmorphine in human urine at the cutoff concentrations of:

| **Drug (Identifier)** | **Cut-off level** |
|---|---|
| Amphetamine (AMP) | 500 ng/mL |
| Buprenorphine (BUP) | 10 ng/mL |
| Secobarbital (BAR) | 300 ng/mL |
| Oxazepam (BZO) | 300 ng/mL |
| Cocaine (COC) | 150 ng/mL |
| 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| Methamphetamine (MET) | 500 ng/mL |
| Methylenedioxymethamphetamine (MDMA) | 500 ng/mL |
| Morphine (MOP 300) | 300 ng/mL |
| Methadone (MTD) | 300 ng/mL |
| Oxycodone (OXY) | 100 ng/mL |
| Phencyclidine (PCP) | 25 ng/mL |
| d-Propoxyphene (PPX) | 300 ng/mL |
| Nortriptyline (TCA) | 1000 ng/mL |
| Cannabinoids (THC) | 50 ng/mL |
| 6-Acetylmorphine | 10 ng/mL |

BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, d-Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

7. Device Description

The BIOEASY™ U-Catch MAX Multi-Drug Test Cup and BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx are immunochromatographic assays that use a lateral flow system for the qualitative detection of target drug or drug metabolites in human urine. The products are single-use in vitro diagnostic devices. The BIOEASY™ U-Catch MAX Multi-Drug Test Cup kit contains a Cup device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the BIOEASY™ U-Catch MAX Multi-Drug Test Cup and the predicate devices is provided in following tables.

**Table 1: Features Comparison of BIOEASY™ U-Catch MAX Multi-Drug Test Cup and the Predicate Devices**

| Item | Device | Predicate – K201630 |
|---|---|---|
| **Indication(s)** | For the qualitative determination of drugs of | Same (but the number of |

| | | |
|---|---|---|
| **for Use** | abuse in human urine. | drugs detected is different) |
| **Calibrator and Cut-Off Values** | Amphetamine (AMP): 500 ng/ml<br>Oxazepam (BZO):300 ng/ml<br>Cocaine (COC): 150 ng/ml<br>11-Nor-$\Delta^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml<br>Methamphetamine (MET): 500 ng/ml<br>Morphine (MOR): 300 ng/mL<br>Oxycodone(OXY) : 100 ng/ml<br>Secobarbital (BAR): 300 ng/ml<br>Methadone (MTD): 300 ng/ml<br>Buprenorphine (BUP): 10 ng/ml<br>D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml<br>Phencyclidine (PCP): 25 ng/ml<br>Nortriptyline (TCA): 1000 ng/ml<br>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/ml<br>d-Propoxyphene (PPX): 300 ng/ml | Same except<br>THC at 20 ng/mL |
| **Methodology** | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same |
| **Type of Test** | Qualitative | Same |
| **Specimen Type** | Human Urine | Same |
| **Intended Use** | For over-the-counter | For prescription use |
| **Configurations** | Cup | Same |

**Table 2: Features Comparison of BIOEASY™ U-Catch MAX Multi-Drug Test Cup Rx and the Predicate Devices**

| Item | Device | Predicate – K201630 |
|---|---|---|
| **Indication(s) for Use** | For the qualitative determination of drugs of abuse in human urine. | Same |
| **Calibrator and Cut-Off Values** | Amphetamine (AMP): 500 ng/ml<br>Oxazepam (BZO):300 ng/ml<br>Cocaine(COC): 150 ng/ml<br>11-Nor-$\Delta^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml<br>Methamphetamine (MET): 500 ng/ml<br>Morphine (MOR): 300ng/mL<br>Oxycodone(OXY) : 100 ng/ml<br>Secobarbital (BAR): 300 ng/ml<br>Methadone (MTD): 300 ng/ml | Same except<br>THC at 20 ng/mL |

| | | |
|---|---|---|
| | Buprenorphine (BUP): 10 ng/ml<br>D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml<br>Phencyclidine (PCP): 25 ng/ml<br>Nortriptyline (TCA): 1000 ng/ml<br>2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/ml<br>d-Propoxyphene (PPX): 300 ng/ml<br>6-Acetylmorphine (6-AM): 10 ng/mL | |
| **Methodology** | Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry. | Same |
| **Type of Test** | Qualitative | Same |
| **Specimen Type** | Human Urine | Same |
| **Intended Use** | For prescription use | Same |
| **Configurations** | Cup | Cup |

9. Test Principle

The BIOEASY™ U-Catch MAX Multi-Drug Test Cup tests are rapid tests for the qualitative detection of target drug or drug metabolites in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results obtained are summarized in the following tables for Amphetamine 500, Cocaine 150, Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene,

Nortriptyline and Cannabinoids were reported in k182530.

**AMP500**

| Concentration by LC/MS (ng/mL) / Lot Number | -100% Cut-off | -75% Cut-off | -50% Cut-off | -25% Cut-off | Cut-off | Cut-off +25% | Cut-off +50% | Cut-off +75% | Cut-off +100% |
|---|---|---|---|---|---|---|---|---|---|
| | 0 | 127 | 250 | 374 | 480 | 590 | 695 | 825 | 915 |
| **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 22-/28+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 26-/24+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 26-/24+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

**COC150**

| Concentration by LC/ MS (ng/mL) / Lot Number | -100% Cut-off | -75% Cut-off | -50% Cut-off | -25% Cut-off | Cut-off | Cut-off +25% | Cut-off +50% | Cut-off +75% | Cut-off +100% |
|---|---|---|---|---|---|---|---|---|---|
| | 0 | 38.2 | 77.8 | 113 | 154 | 191 | 230 | 262 | 302 |
| **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 28-/22+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 29-/21+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 22-/28+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

**MET500**

| Concentration by LC/MS (ng/mL) / 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 |
|---|---|---|---|---|---|---|---|---|---|
| | 0 | 129 | 240 | 368 | 476 | 605 | 705 | 860 | 1010 |
| **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 27-/23+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 23-/27+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 25-/25+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

**EDDP**

| Concentration by LC/MS (ng/mL) / 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 |
|---|---|---|---|---|---|---|---|---|---|
| | 0 | 72.0 | 146 | 216 | 293 | 360 | 426 | 507 | 582 |
| **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 24-/26+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 26-/24+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 25-/25+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

**6-AM**

| Concentration by LC/MS (ng/mL) / 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 |
|---|---|---|---|---|---|---|---|---|---|
| | 0 | 2.46 | 4.88 | 7.42 | 9.98 | 12.3 | 14.6 | 16.8 | 20.1 |
| **Lot 1** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 26-/24+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 2** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 24-/26+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |
| **Lot 3** | 50-/0+ | 50-/0+ | 50-/0+ | 50-/0+ | 23-/27+ | 50+/0- | 50+/0- | 50+/0- | 50+/0- |

The following cut-off values are verified.

| Drug (Identifier) | Cut-off level |
|---|---|
| | |

| | |
|---|---|
| Amphetamine (AMP) | 500 ng/mL |
| Cocaine (COC) | 150 ng/mL |
| Methamphetamine (MET) | 500 ng/mL |
| 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP) | 300 ng/mL |
| 6-acetylmorphine (6-AM) | 10 ng/mL |

b. Linearity

Not applicable.

c. Stability and Traceability

The devices are stable at 4-30 °C for 24 months based on real time stability studies. All drug calibrators of the device are traceable to available commercial reference materials.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100µg/mL are summarized in the following tables.

| | | | |
|---|---|---|---|
| Acetaminophen | Creatinine | Ketamine | Prednisone |
| Acetophenetidin | Deoxycorticosterone | Ketoprofen | (±)-Propranolol |
| N-Acetylprocainamide | Dextromethorphan | Labetalol | Pseudoephedrine |
| Acetylsalicylic acid | Diclofenac | Loperamide | Quinine |
| Albumin (100mg/dL) | Diflunisal | Meperidine | Ranitidine |
| Aminopyrine | Digoxin | Meprobamate | Salicylic acid |
| Amoxicillin | Diphenhydramine | Methoxyphenamine | Serotonin (5- Hydroxytyramine) |
| Ampicillin | 1% Ethanol | Nalidixic acid | Sulfamethazine |
| Apomorphine | Ecgonine methyl ester | Naloxone | Sulindac |
| Ascorbic acid | β-Estradiol | Naltrexone | Tetrahydrocortisone 3-(β-Dglucuronide) |
| Aspartame | Erythromycin | Naproxen | Tetrahydrocortisone 3-acetate |
| Atropine | Fenoprofen | Niacinamide | Tetrahydrozoline |
| Benzilic acid | Furosemide | Nifedipine | Thiamine |
| Benzoic acid | Gentisic acid | Norethindrone | Thioridazine |
| Bilirubin | Hemoglobin | Noscapine | Triamterene |
| Chloral hydrate | Hydralazine | (±)-Octopamine | Trifluoperazine |
| Chloramphenicol | Hydrochlorothiazide | Oxalic acid | Trimethoprim |
| Chlorothiazide | Hydrocortisone | Oxolinic acid | DL-Tryptophan |
| Chlorpromazine | O-Hydroxyhippuric acid | Oxymetazoline | Tyramine |
| Cholesterol | 3-Hydroxytyramine | Papaverine | DL-Tyrosine |
| Clonidine | Ibuprofen | Penicillin G | Uric acid |
| Cortisone | Isoproterenol | Perphenazine | Verapamil |
| (-)-Cotinine | Isoxsuprine | Phenelzine | Zomepirac |

e. Specificity

To test specificity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Amphetamine 500, Cocaine 150,

Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids were reported in k182530.

| **AMP500 (Cut-off=500 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| D - Amphetamine | 500 | 100% |
| L - Amphetamine | 10000 | 5% |
| DL - Amphetamine | 1500 | 33% |
| Phentermine | 15000 | 3.3% |
| Hydroxyamphetamine | 4000 | 12.5% |
| Methylenedioxyamphetamine (MDA) | 10000 | 5% |
| d-Methamphetamine | ＞100000 | ＜0.5% |
| 1-Methamphetamine | ＞100000 | ＜0.5% |
| Ephedrine | ＞100000 | ＜0.5% |
| Methylenedioxyethylamphetamine (MDE) | ＞100000 | ＜0.5% |
| 3,4-methylenedioxy-methamphetamine (MDMA) | ＞100000 | ＜0.5% |

| **COC150 (Cut-off=150 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| Benzoylecgonine | 150 | 100% |
| Cocaine HCl | 375 | 40% |
| Cocaethylene | 6250 | 2.4% |
| Ecgonine | 16000 | 0.9% |
| Norcocaine | 50000 | 0.3% |

| **MET500 (Cut-off=500 ng/mL)** | **Result Positive at (ng/ml)** | **%Cross-Reactivity** |
|---|---|---|
| D(+)-Methamphetamine | 500 | 100% |
| (+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA) | 5000 | 10% |
| D/L-Methamphetamine | 500 | 100% |
| p-Hydroxymethamphetamine | 5000 | 10% |
| D-Amphetamine | ＞100000 | ＜0.5% |
| L-Amphetamine | ＞100000 | ＜0.5% |
| Chloroquine | 25000 | 2% |
| (+/-)-Ephedrine | 2000 | 25% |
| L-Methamphetamine | 5000 | 10% |
| (+/-)3,4-Methylenedioxyamphetamine (MDA) | ＞100000 | ＜0.5% |
| β-Phenylethylamine | 3750 | 13.3% |
| Trimethobenzamide | 10000 | 5% |
| (+/-)3,4-methylenedioxymethamphetamine(MDMA) | 5000 | 10% |

| **EDDP (Cut-off=300 ng/mL)** | **Result Positive at (ng/ml)** | **% Cross-Reactivity** |
|---|---|---|

| | | |
|---|---|---|
| EDDP | 300 | 100% |
| Methadone | 300000 | 0.1% |
| Doxylamine | ＞100000 | ＜0.3% |
| LAAM HCl | ＞100000 | ＜0.3% |
| Alpha Methadol | ＞100000 | ＜0.3% |
| EMDP | ＞100000 | ＜0.3% |
| Disopyramide | ＞100000 | ＜0.3% |

| **6-AM (Cut-off=10 ng/mL)** | **Result Positive at (ng/ml)** | **% Cross-Reactivity** |
|---|---|---|
| 6-acetylmorphine | 10 | 100% |
| Acetylcodeine | >10000 | <0.1% |
| Buprenorphine | >10000 | <0.1% |
| Codeine | >10000 | <0.1% |
| Diacetylmorphine | 1000 | 0.01% |
| Dihydrocodeine | >10000 | <0.1% |
| Ethylmorphine | >10000 | <0.1% |
| Hydrocodone | >10000 | <0.1% |
| Hydromorphone | 5000 | 0.002% |
| Morphine | 10000 | 0.001% |
| Morphine-3-glucuronide | >10000 | <0.1% |
| Nalorphine | 5000 | 0.002% |
| Thebaine | >20000 | <0.05% |
| Dextromethorphan | >100,000 | <0.01% |
| Heroin | 100000 | 0.0001% |
| Imipramine | >100,000 | <0.01% |
| LAAM (Levacetylmethadol) | >100,000 | <0.01% |
| Levorphanol | >100,000 | <0.01% |
| Meperidine | >100,000 | <0.01% |
| Methadone | >100,000 | <0.01% |
| Mitragynine (kratom) | >20,000 | <0.05% |
| Morphine 6-D-glucuronide | >100,000 | <0.01% |
| Naloxone | >100,000 | <0.01% |
| Naltrexone | >100,000 | <0.01% |
| Naproxen | >100,000 | <0.01% |
| Norbuprenorphine | >10,000 | <0.1% |
| Norbuprenorphine glucuronide | >100,000 | <0.01% |
| Norcodeine | >100,000 | <0.01% |
| Norhydrocodone | >100,000 | <0.01% |
| Normorphine | >100,000 | <0.01% |
| Noroxycodone | >100,000 | <0.01% |
| Noroxymorphone | >100,000 | <0.01% |
| Norpropoxyphene | >100,000 | <0.01% |
| Oxycodone | >100,000 | <0.01% |
| Oxymorphone | >100,000 | <0.01% |
| Oxymorphone-3β-D-glucuronide | >100,000 | <0.01% |
| Tapentadol HCl | >100,000 | <0.01% |

| | | |
|---|---|---|
| Tramadol | >100,000 | <0.01% |

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off.

2. Comparison Studies

Method comparison studies for the BIOEASY™ U-Catch MAX Multi-Drug Test Cup were performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Amphetamine 500, Cocaine 150, Methamphetamine 500, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDP), and 6-acetylmorphine (6-AM). The data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Oxazepam, Morphine, Methadone, Oxycodone, Phencyclidine, d-Propoxyphene, Nortriptyline and Cannabinoids were reported in k182530.

**AMP500**

| U-Catch MAX Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 3 | 17 | 20 |
| | Negative | 7 | 16 | 14 | 3 | 0 |
| Viewer B | Positive | 0 | 0 | 2 | 18 | 20 |
| | Negative | 7 | 16 | 15 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 3 | 18 | 20 |
| | Negative | 7 | 16 | 14 | 2 | 0 |

**Discordant Results**

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|---|---|---|---|
| **Viewer A** | AMPLC063 | 473 | Positive |
| **Viewer C** | AMPLC063 | 473 | Positive |
| **Viewer B** | AMPLC040 | 477 | Positive |
| **Viewer A** | AMPLC039 | 490 | Positive |
| **Viewer B** | AMPLC039 | 490 | Positive |
| **Viewer C** | AMPLC039 | 490 | Positive |
| **Viewer A** | AMPLC004 | 494 | Positive |
| **Viewer C** | AMPLC004 | 494 | Positive |
| **Viewer A** | AMPLC018 | 520 | Negative |
| **Viewer B** | AMPLC018 | 520 | Negative |
| **Viewer A** | AMPLC064 | 525 | Negative |
| **Viewer B** | AMPLC064 | 525 | Negative |
| **Viewer C** | AMPLC064 | 525 | Negative |

| | | | |
|---|---|---|---|
| **Viewer A** | AMPLC009 | 540 | Negative |
| **Viewer C** | AMPLC014 | 570 | Negative |

**COC150**

| U-Catch MAX Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 2 | 19 | 19 |
| | Negative | 7 | 16 | 15 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 2 | 18 | 19 |
| | Negative | 7 | 16 | 15 | 3 | 0 |
| Viewer C | Positive | 0 | 0 | 2 | 19 | 19 |
| | Negative | 7 | 16 | 15 | 2 | 0 |

**Discordant Results**

| Viewer | Sample Number | LC/MS Result | Easy Cup Viewer Results |
|---|---|---|---|
| **Viewer B** | COCLC046 | 139 | Positive |
| **Viewer A** | COCLC019 | 142 | Positive |
| **Viewer C** | COCLC019 | 142 | Positive |
| **Viewer B** | COCLC026 | 142 | Positive |
| **Viewer A** | COCLC060 | 145 | Positive |
| **Viewer C** | COCLC060 | 145 | Positive |
| **Viewer A** | COCLC049 | 154 | Negative |
| **Viewer B** | COCLC049 | 154 | Negative |
| **Viewer C** | COCLC049 | 154 | Negative |
| **Viewer A** | COCLC024 | 157 | Negative |
| **Viewer B** | COCLC062 | 157 | Negative |
| **Viewer C** | COCLC062 | 157 | Negative |
| **Viewer B** | COCLC029 | 159 | Negative |

**MET500**

| U-Catch MAX Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 2 | 17 | 20 |
| | Negative | 7 | 16 | 15 | 3 | 0 |
| Viewer B | Positive | 0 | 0 | 3 | 18 | 20 |
| | Negative | 7 | 16 | 14 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 2 | 17 | 20 |
| | Negative | 7 | 16 | 15 | 3 | 0 |

**Discordant Results**

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|---|---|---|---|
| **Viewer B** | METL055 | 427 | Positive |
| **Viewer B** | METL005 | 447 | Positive |
| **Viewer C** | METL005 | 447 | Positive |
| **Viewer A** | METL020 | 465 | Positive |
| **Viewer B** | METL020 | 465 | Positive |
| **Viewer A** | METL063 | 486 | Positive |
| **Viewer C** | METL063 | 486 | Positive |
| **Viewer B** | METL053 | 525 | Negative |
| **Viewer C** | METL053 | 525 | Negative |
| **Viewer A** | METL060 | 530 | Negative |
| **Viewer C** | METL060 | 530 | Negative |
| **Viewer A** | METL036 | 540 | Negative |
| **Viewer B** | METL036 | 540 | Negative |
| **Viewer A** | METL059 | 555 | Negative |
| **Viewer C** | METL059 | 555 | Negative |

**EDDP**

| U-Catch MAX Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 2 | 18 | 20 |
| | Negative | 6 | 18 | 14 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 2 | 18 | 20 |
| | Negative | 6 | 18 | 14 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 3 | 18 | 20 |
| | Negative | 6 | 18 | 13 | 2 | 0 |

**Discordant Results**

| Viewer | Sample Number | LC/MS Result | Easy Cup Viewer Results |
|---|---|---|---|
| **Viewer A** | EDDPLC042 | 244 | Positive |
| **Viewer C** | EDDPLC042 | 244 | Positive |
| **Viewer B** | EDDPLC004 | 291 | Positive |
| **Viewer C** | EDDPLC004 | 291 | Positive |
| **Viewer A** | EDDPLC051 | 294 | Positive |
| **Viewer B** | EDDPLC051 | 294 | Positive |
| **Viewer C** | EDDPLC051 | 294 | Positive |
| **Viewer A** | EDDPLC074 | 303 | Negative |
| **Viewer B** | EDDPLC074 | 303 | Negative |
| **Viewer C** | EDDPLC074 | 303 | Negative |
| **Viewer B** | EDDPLC052 | 327 | Negative |
| **Viewer A** | EDDPLC018 | 330 | Negative |

| | | | |
|---|---|---|---|
| **Viewer C** | EDDPLC018 | 330 | Negative |

**6-AM**

| U-Catch MAX Multi-Drug Test Cup | | Negative | Low Negative by LC/MS (less than -50%) | Near Cutoff Negative by LC/MS (Between -50% and cutoff) | Near Cutoff Positive by LC/MS (Between the cutoff and +50%) | High Positive by LC/MS (greater than +50%) |
|---|---|---|---|---|---|---|
| Viewer A | Positive | 0 | 0 | 2 | 16 | 22 |
| | Negative | 6 | 17 | 15 | 2 | 0 |
| Viewer B | Positive | 0 | 0 | 2 | 16 | 22 |
| | Negative | 6 | 17 | 15 | 2 | 0 |
| Viewer C | Positive | 0 | 0 | 2 | 15 | 22 |
| | Negative | 6 | 17 | 15 | 3 | 0 |

**Discordant Results**

| Viewer | Sample Number | LC/MS Result | Dip Card Viewer Results |
|---|---|---|---|
| **Viewer B** | 6-AMLC016 | 9.23 | Positive |
| **Viewer A** | 6-AMLC074 | 9.68 | Positive |
| **Viewer C** | 6-AMLC074 | 9.68 | Positive |
| **Viewer B** | 6-AMLC026 | 9.93 | Positive |
| **Viewer A** | 6-AMLC037 | 9.95 | Positive |
| **Viewer C** | 6-AMLC037 | 9.95 | Positive |
| **Viewer A** | 6-AMLC009 | 10.3 | Negative |
| **Viewer C** | 6-AMLC009 | 10.3 | Negative |
| **Viewer B** | 6-AMLC027 | 11.1 | Negative |
| **Viewer C** | 6-AMLC027 | 11.1 | Negative |
| **Viewer A** | 6-AMLC038 | 11.4 | Negative |
| **Viewer B** | 6-AMLC038 | 11.4 | Negative |
| **Viewer C** | 6-AMLC035 | 11.8 | Negative |

Lay-user study

A lay user study was performed at three intended user sites with 140 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/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. Each device was tested. Results are shown below.

| Drugs | % of Cut-off | Number of samples | Concentration by LC/MS (ng/mL) | Lay person results | | The percentage of correct results (%) |
|---|---|---|---|---|---|---|
| | | | | No. of Positive | No. of Negative | |
| AMP | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 130 | 0 | 20 | 100 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | -50% Cut-off | 20 | 251 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 383 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 635 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 755 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 885 | 20 | 0 | 100 |
| BAR | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 75.9 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 150 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 220 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 360 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 429 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 501 | 20 | 0 | 100 |
| COC | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 37.6 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 74.8 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 110 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 183 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 224 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 248 | 20 | 0 | 100 |
| BZO | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 70.8 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 148 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 224 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 390 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 452 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 504 | 20 | 0 | 100 |
| MET | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 124 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 242 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 367 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 610 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 705 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 825 | 20 | 0 | 100 |
| MTD | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 76.8 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 147 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 226 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 375 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 441 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 504 | 20 | 0 | 100 |
| MOP | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 79 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 158 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 246 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 389 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 469 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 530 | 20 | 0 | 100 |
| OXY | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 24.5 | 0 | 20 | 100 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | -50% Cut-off | 20 | 49.3 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 71.1 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 118 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 147 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 169 | 20 | 0 | 100 |
| THC | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 13 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 25.3 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 41 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 65 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 79 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 93 | 20 | 0 | 100 |
| TCA | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 273 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 509 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 809 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 1190 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 1510 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 1680 | 20 | 0 | 100 |
| BUP | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 2.57 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 5.14 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 6.76 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 12.8 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 15.1 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 17.2 | 20 | 0 | 100 |
| PCP | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 6.27 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 12.5 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 17.9 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 30.8 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 36.4 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 42.8 | 20 | 0 | 100 |
| MDMA | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 137 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 250 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 351 | 0 | 20 | 100 |
| | +25% Cut-off | 20 | 600 | 19 | 1 | 95 |
| | +50% Cut-off | 20 | 745 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 925 | 20 | 0 | 100 |
| EDDP | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 76.2 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 141 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 224 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 375 | 20 | 0 | 100 |
| | +50% Cut-off | 20 | 447 | 20 | 0 | 100 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | +75% Cut-off | 20 | 522 | 20 | 0 | 100 |
| PPX | -100% Cut-off | 20 | 0 | 0 | 20 | 100 |
| | -75% Cut-off | 20 | 77.4 | 0 | 20 | 100 |
| | -50% Cut-off | 20 | 150 | 0 | 20 | 100 |
| | -25% Cut-off | 20 | 227 | 1 | 19 | 95 |
| | +25% Cut-off | 20 | 351 | 20 | 0 | 100 |
| | +50% Cut-off | 20 | 420 | 20 | 0 | 100 |
| | +75% Cut-off | 20 | 492 | 20 | 0 | 100 |

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the U-Catch MAX Multi-Drug Test Cup is substantially equivalent to the predicate.