Aicheck Biotech, Inc.
% Jenny Xia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K242077
Trade/Device Name: Pocguide™ Multi-Drug Test Cup OTC, Pocguide™ Multi-Drug Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: NFT
Dated: July 12, 2024
Received: July 16, 2024

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.

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: 2024.08.14 10:57:33 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistryand 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242077

Device Name

PocguideTM Multi-Drug Test Cup OTC;
PocguideTM Multi-Drug Test Cup

Indications for Use *(Describe)*

PocguideTM Multi-Drug Test Cup OTC is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Benzoylecgonine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (OPI2000/MOP300)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to the above listed analytes in any combination.
For over-the-counter use.
The tests provide only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

PocguideTM Multi-Drug Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

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Benzoylecgonine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (OPI2000/MOP300)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

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The tests may yield positive results for the prescription drugs 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.

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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.

510(k) SUMMARY
K242077

1. **Date:** July 11, 2024
2. **Submitter:** Aicheck Biotech, Inc.
   17701 Cowan, Ste 230
   Irvine, CA 92614
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:** Pocguide™ Multi-Drug Test Cup OTC
   Pocguide™ Multi-Drug Test Cup
5. **Classification:** Class II

Product Code **Target Drug**	**Regulation Section**	**Panel**
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NGL Buprenorphine (BUP) Morphine (MOP/OPI) Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine and cocaine metabolite test system	Toxicology
PTG Methadone (MTD) 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	862.3620, Methadone Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGM Phencyclidine (PCP)	Unclassified	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW	862.3870, Cannabinoids Test System	Toxicology

Cannabinoids (THC)		

6. Predicate Devices:

Wondfo T-Cup® Multi-Drug Urine Test Cup (K182701)

7. Intended Use

Pocguide™ Multi-Drug Test Cup OTC is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
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Oxazepam (BZO)	300 ng/mL
Benzoylecgonine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (OPI2000/MOP300)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to the above listed analytes in any combination. For over-the-counter use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

Pocguide™ Multi-Drug Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxy-methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

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Benzoylecgonine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (OPI2000/MOP300)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

The single or multi-test cups can consist of up to the above listed analytes in any combination.

The tests may yield positive results for the prescription drugs 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 a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed positive result. Gas Chromatography-Mass Spectrometry (GC-MS), Liquid Chromatography-Mass Spectrometry (LC-MS), and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

8. Device Description

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

The devices are a cup format. Each test device is sealed with 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	Proposed Device		Predicate (K182701)
Indication(s) for use	For the qualitative determination of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine.		Same (but the number of drugs detected is different)
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 Drug**	**Cutoff (ng/mL)**	Same (but the number of drugs detected is different)
	Amphetamine (AMP)	1000 or 500	
	Buprenorphine (BUP)	10	
	Secobarbital (BAR)	300	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methamphetamine (MET)	1000 or 500	
	Methylenedioxymethamphetamine (MDMA)	500	
	Morphine (MOP 300/OPI 2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Nortriptyline (TCA)	1000	
	Marijuana (THC 50)	50	
Configurations	Test cup		Same
Intended Use	For over-the-counter use		Same

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

Pocguide™ Multi-Drug Test Cup OTC or Pocguide™ Multi-Drug Test Cup is a competitive immunoassay that is used to screen for the presence of drugs of abuse in urine. It is chromatographic absorbent device in which drugs or drug metabolites in a sample competitively combined to a limited number of antibody-dye conjugate binding sites. When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane.

When sample drug levels are at or above the target cutoff (the detection sensitivity of the test), the drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein pre-coated in the test region (T). This prevents the development of a distinct colored band in the test region indicating a potentially positive result.

When sample drug levels are zero or below the target cutoff, antibody-dye conjugate binds to the drug-protein pre-coated in the test region (T) of the device. This produces a colored test line that, regardless of its intensity, indicates a negative result.

To serve as a procedural control, a colored line will always appear at the control region (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

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. Samples with concentration of -100% cutoff were drug-free urine samples. Other samples were prepared by spiking 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% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
AMP 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
AMP 1000	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+

BUP 10	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
BZO 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
MDMA 500	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
MET 500	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
MET 1000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
MOP 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
OPI 2000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
MTD 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
OXY 100	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
PCP 25	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
TCA 1000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
THC 50	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
COC 150	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	16-/34+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	17-/33+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
COC 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
EDDP 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

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 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/Cutoff	**Compound**	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
AMP 500	d-Amphetamine	500	100%
	l-Amphetamine	15000	3.3%
	dl- Amphetamine	1500	33.3%
	（+/-）3,4-Methylenedioxyamphetamine (MDA)	5000	10%
	Phentermine	1500	33.3%
	Hydroxyamphetamine	8000	6.25%
	d-Methamphetamine	>100000	-
	l-Methamphetamine	>100000	-
	（+/-）3,4-Methylenedioxyethylamphetamine (MDE)	>100000	-

	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100000	-
	β-Phenylethylamine	100000	0.5%
	Tyramine	100000	0.5%
	p-Hydroxynorephedrine	100000	0.5%
	Phenylpropanolamine	>100000	-
	(±)Phenylpropanolamine	>100000	-
	p-Hydroxyamphetamine	100000	0.5%
	d/l-Norephedrine	100000	0.5%
	Benzphetamine	>100000	-
	l-Ephedrine	>100000	-
	l-Epinephrine	>100000	-
	d/l-Epinephrine	>100000	-
AMP 1000	d-Amphetamine	1000	100%
	l-Amphetamine	30000	3.3%
	dl- Amphetamine	3000	33.3%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	5000	20%
	Phentermine	3000	33.3%
	Hydroxyamphetamine	8000	12.5%
	d-Methamphetamine	＞100000	-
	l-Methamphetamine	＞100000	-
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	＞100000	-
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	＞100000	-
	β-Phenylethylamine	100000	1%
	Tyramine	100000	1%
	p-Hydroxynorephedrine	100000	1%
	Phenylpropanolamine	＞100000	-

	(±)Phenylpropanolamine	＞100000	--
	p-Hydroxyamphetamine	100000	1%
	d/l-Norephedrine	100000	1%
	Benzphetamine	＞100000	-
	l-Ephedrine	＞100000	-
	l-Epinephrine	＞100000	-
	d/l-Epinephrine	＞100000	-
BAR 300	Secobarbital	300	100%
	Amobarbital	5000	6%
	Alphenol	150	200%
	Aprobarbital	200	150%
	Butabarbital	150	200%
	Butethal	50	600%
	Butalbital	2500	12%
	Cyclopentobarbital	600	50%
	Pentobarbital	2000	15%
	Phenobarbital	5000	6%
BUP 10	Buprenorphine	10	100%
	Buprenorphine -3-D-Glucuronide	15	66.67%
	Norbuprenorphine	20	50%
	Norbuprenorphine-3-D-Glucuronide	100	10%
	Morphine	> 100000	-
	Oxymorphone	> 100000	-
	Hydromorphone	> 100000	-
BZO 300	Oxazepam	300	100%
	Alprazolam	200	150%
	a-Hydroxyalprazolam	1000	30%
	Bromazepam	500	60%
	Chlordiazepoxide	1500	20%
	Clobazam	100	300%
	Clonazepam	3000	10%
	Clorazepate dipotassium	200	150%
	Delorazepam	1500	20%

	Desalkylflurazepam	400	75%
	Diazepam	200	150%
	Estazolam	500	60%
	Flunitrazepam	1000	30%
	Midazolam	5000	6%
	Nitrazepam	1000	30%
	Norchlordiazepoxide	200	150%
	Nordiazepam	500	60%
	Temazepam	250	120%
	Triazolam	1200	25%
	Demoxepam	2000	15%
	Flurazepam	500	60%
	D,L-Lorazepam	1500	20%
COC 150	Benzoylecgonine	150	100%
	Cocaine	500	30%
	Cocaethylene	6250	2.4%
	Ecgonine	16000	0.94%
	Ecgonine methyl ester	＞100000	-
	Norcocaine	＞100000	-
COC 300	Benzoylecgonine	300	100%
	Cocaine	1000	30%
	Cocaethylene	15000	2%
	Ecgonine	30000	1%
	Ecgonine methyl ester	＞100000	-
	Norcocaine	＞100000	-
MDMA 500	3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
	3,4-Methylenedioxyamphetamine HCl (MDA)	3000	16.67%
	3,4-Methylenedioxyethylamphetamine (MDEA)	500	100%
	d-methamphetamine	> 100000	-

	d-amphetamine	> 100000	-
	l-methamphetamine	50000	1%
	l-amphetamine	> 100000	-
MET 500	D(+)-Methamphetamine	500	100%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	2000	25% 5%
	D/L-Methamphetamine	500	100%
	p-Hydroxymethamphetamine	15000	3.33%
	D-Amphetamine	50000	1%
	L-Amphetamine	100000	0.5%
	Chloroquine	10000	5%
	(+/-)-Ephedrine	25000	2%
	(-)-Methamphetamine	12500	4%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	2000	25%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2000	25%
	β-Phenylethylamine	25000	2%
	Trimethobenzamide	5000	10%
	d,l-Amphetamine	75000	0.67%
	Mephetermine	25000	2%
	(1R,2S)-(-)-Ephedrine	50000	1%
	l-phenylephrine	100000	0.5%
	L-Methamphetamine	10000	5%
MET 1000	D(+)-Methamphetamine	1000	100%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	2000	50%
	D/L-Methamphetamine	1000	100%
	p-Hydroxymethamphetamine	30000	3.3%
	D-Amphetamine	> 100000	-
	L-Amphetamine	100000	1%
	Chloroquine	20000	5%

	(+/-)-Ephedrine	50000	2%
	(-)-Methamphetamine	25000	4%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	2500	40%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4000	25%
	β-Phenylethylamine	50000	2%
	Trimethobenzamide	10000	10%
	d,l-Amphetamine	100000	1%
	Mephetermine	50000	2%
	(1R,2S)-(-)-Ephedrine	> 100000	-
	l-phenylephrine	> 100000	-
	L-Methamphetamine	20000	5%
MOP 300	Morphine	300	100%
	Normorphine	250	120%
	Codeine	300	100%
	s-Monoacetylmorphine	300	100%
	Ethyl Morphine	100	300%
	Heroin	300	100%
	Hydrocodone	5000	6%
	Hydromorphone	2000	15%
	Morphinie-3-β-d-glucuronide	1000	30%
	Oxycodone	＞100000	--
	Oxymorphone	100000	0.3%
	Thebaine	3000	10%
	Levorphanol	5000	6%
	6-Monoacetylmorphine (6-MAM)	150	200%
	Norcodeine	6500	4.6%
	Procaine	100000	0.3%
OPI 2000	Morphine	2000	100%
	Normorphine	50000	4%
	Codeine	2000	100%

	s-Monoacetylmorphine	2000	100%
	Ethyl Morphine	1500	133.3%
	Heroin	2000	100%
	Hydrocodone	12500	16%
	Hydromorphone	3500	57.1%
	Morphinie-3-β-d-glucuronide	2000	100%
	Oxycodone	25000	8%
	Oxymorphone	25000	8%
	Thebaine	5000	40%
	Levorphanol	75000	2.7%
	6-Monoacetylmorphine (6-MAM)	1500	133.3%
	Norcodeine	12500	16%
	Procaine	150000	1.3%
MTD 300	Methadone	300	100%
	Doxylamine	3000	10%
	EDDP	＞100000	-
	EMDP	＞100000	-
	LAAM	＞100000	-
	Alpha Methadol	＞100000	-
OXY 100	Oxycodone	100	100%
	Dihydrocodeine	20000	0.5%
	Hydrocodone	10000	1%
	Oxymorphone	1000	10%
	Codeine	100000	0.1%
	Hydromorphone	32000	0.3%
	Morphine	＞100000	-
	Acetylmorphine	＞100000	-
	Buprenorphine	＞100000	-
	Ethylmorphine	＞100000	-
	Thebaine	＞100000	-
PCP 25	Phencyclidine	25	100%
	4-Hydroxyphencyclidine	12500	0.2%
TCA 1000	Nortriptyline	1000	100%
	Nordoxepine	1000	100%

	Trimipramine	2000	50%
	Amitriptyline	1500	66.7%
	Promazine	1500	66.7%
	Desipramine	400	250%
	Imipramine	400	250%
	Clomipramine	12500	8%
	Doxepin	1000	100%
	Maprotiline	2000	50%
	Promethazine	25000	4%
	Cyclobenzaprine	1500	66.7%
	Norclomipramine	10000	10%
THC 50	11-nor-Δ9-THC-9-COOH	50	100%
	(-)-11-nor-9-carboxy-Δ9-THC	50	100%
	11-nor-Δ8-THC-9-COOH	30	166.67%
	11-nor-Δ9-THC-carboxy glucuronide	100	50%
	Cannabinol	20000	0.25%
	Cannabidiol	100000	0.05%
	Δ8- Tetrahydrocannabinol	1300	3.8%
	Δ9- Tetrahydrocannabinol	5000	1%
	11-hydroxy-Δ9-Tetrahydrocannabinol	5000	1%
EDDP 300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	100%
	Methadone	200000	0.15%
	EMDP	300000	0.1%
	Doxylamine	＞100000	-
	Disopyramide	＞100000	-
	LAAM (Levo-alpha-acetylmethadol) HCl	＞100000	-
	Alpha Methadol	＞100000	-

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 25% below and 25% above each corresponding cutoff.

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

(-) Cotinine	Duloxetine	Nimodipine
3-Hydroxytyramine	Effexor	Nitroglycerin
Acetaminophen	Enalapril Maleate	Norethindrone
Acetophenetidin	Erythromycin	O-Hydroxyhippuric Acid
Acetylsalicylic Acid	Esomeprazole Magnesium	Olanzapine
Acyclovir	Ethanol (1%)	Omeprazole
Afrin	Fenofibrate	Ondansetran
Albumin (100mg/dL)	Fenoprofen	Oxalic Acid
Aminophylline	Fentanyl Citrate	Oxolinic Acid
Aminopyrine	Fluoxetine Hydrochloride	Oxymetazoline
Amiodarone Hydrochloride	Fluvoxamine	Paliperidone
Amlodipine Mesylate	Furosemide	Pantoprazole
Amoxicillin	Gabapentin	Papaverine
Ampicillin	Gentisic Acid	Paroxetine Hydrochloride
Apomorphine	Glibenclamide	Penfluridol
Aripiprazole	Gliclazide	Penicillin-G
Aspartame	Glipizide	PenicillinV Potassium
Atomoxetine	Glucose	Phenelzine
Atorvastatin Calcium	Haloperidol	Pioglitazone Hydrochloride
Atropine	Hemoglobin	Piracetam
Benzilic Acid	Hydrochlorothiazide	Pravastatin Sodium
Benzoic Acid	Hydrocortisone	Prednisone
Bilirubin	Ibuprofen	Propylthiouracil
Bupropion	Isosorbide Dinitrate	Quetiapine Fumarate
Captopril	Isoxsuprine	Quinine
Carbamazepine	Ketamine	Ranitidine
Cefradine	Ketoconazole	Rifampicin
Cephalexin	Ketoprofen	Risperidone
Chloral Hydrate	Kratom powder	Salicylic Acid
Chloramphenicol	Labetalol	Serotonin
Chlorothiazide	Lamotrigine	Sertraline Hydrochloride
chlorpheniramine	Levofloxacin Hydrochloride	Sildenafil Citrate
Cholesterol	Levonorgestrel	Simvastatin
Ciprofloxacin Hydrochloride	Levothyroxine Sodium	Sodium Valproate
Citalopram	Lidocaine Hydrochloride	Spironolactone
Clarithromycin	Lisinopril	Sulfamethazine
Clonidine	Lithium Carbonate	Sulindac
Clopidogrel Hydrogen Sulphate	Liverite	Tetracycline

Clozapine	Loperamide	Tetrahydrocortisone 3-(β-D glucuronide)
Conjugated Estrogens	Loratadine	Tetrahydrocortsone 3 -acetate
Cortisone	Magnesium	Tetrahydrozoline
Creatinine	Meperidine	Thiamine
D,L-Octopamine	Meprobamate	Thioridazine
D,L-Propranolol	Metoprolol Tartrate	Topiramate
D,L-Tyrosine	Mifepristone	Tramadol Hydrochloride
Deoxy- corticosterone	Minocycline	Trazodone Hydrochloride
Dextromethorphan	Mirtazapine	Triamterene
Diclofenac	Montelukast Sodium	Trifluoperazine
Dicyclomine	Mosapride Citrate	Trimethoprim
Diflunisal	N-Acetylprocain-amide	Uric Acid
Digoxin	Nalidixic Acid	Valproate
Diphenhydramine	Naproxen	Verapamil
Dirithromycin	Niacinamide	Vitamin B2
Domperidone	Nifedipine	Vitamin C
D-Pseudoephedrine	Nikethamide	β-Estradiol

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations at 25% below and 25% 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 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	Test Cup Result		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
AMP 500	Operator A	+	0	0	3	16	23
		-	13	7	17	1	0
	Operator B	+	0	0	4	16	23
		-	13	7	16	1	0
	Operator C	+	0	0	1	15	23
		-	13	7	19	2	0
	Operator	+	0	0	1	15	25

AMP 1000	A	-	7	15	17	0	0
	Operator B	+	0	0	1	14	25
		-	7	15	17	1	0
	Operator C	+	0	0	1	14	25
		-	7	15	17	1	0
BAR	Operator A	+	0	0	1	18	19
		-	10	15	14	3	0
	Operator B	+	0	0	0	18	19
		-	10	15	15	3	0
	Operator C	+	0	0	2	19	19
		-	10	15	13	2	0
BUP	Operator A	+	0	0	3	20	18
		-	10	15	12	2	0
	Operator B	+	0	0	4	20	18
		-	10	15	11	2	0
	Operator C	+	0	0	3	20	18
		-	10	15	12	2	0
BZO	Operator A	+	0	0	2	18	20
		-	10	15	13	2	0
	Operator B	+	0	0	2	18	20
		-	10	15	13	2	0
	Operator C	+	0	0	3	18	20
		-	10	15	12	2	0
COC 150	Operator A	+	0	0	0	21	15
		-	10	15	15	4	0
	Operator B	+	0	0	0	22	15
		-	10	15	15	3	0
	Operator C	+	0	0	0	21	15
		-	10	15	15	4	0
COC 300	Operator A	+	0	0	0	18	21
		-	9	16	15	1	0
	Operator B	+	0	0	0	17	21
		-	9	16	15	2	0
	Operator C	+	0	0	0	17	21
		-	9	16	15	2	0
MDMA	Operator A	+	0	0	0	20	18
		-	10	15	15	2	0
	Operator B	+	0	0	2	21	18
		-	10	15	13	1	0
	Operator C	+	0	0	0	19	18
		-	10	15	15	3	0
	Operator	+	0	0	0	20	16

MET 500	Operator A	-	8	20	12	4	0
		+	0	0	0	20	16
	Operator B	-	8	20	12	4	0
		+	0	0	1	22	16
	Operator C	-	8	20	11	2	0
MET 1000	Operator A	+	0	0	3	18	22
		-	8	13	16	0	0
	Operator B	+	0	0	2	17	22
		-	8	13	17	1	0
	Operator C	+	0	0	2	16	22
		-	8	13	17	2	0
MOP	Operator A	+	0	0	1	23	15
		-	10	14	15	2	0
	Operator B	+	0	0	1	22	15
		-	10	14	15	3	0
	Operator C	+	0	0	3	23	15
		-	10	14	13	2	0
OPI	Operator A	+	0	0	1	21	18
		-	10	15	14	1	0
	Operator B	+	0	0	2	21	18
		-	10	15	13	1	0
	Operator C	+	0	0	2	20	18
		-	10	15	13	2	0
MTD	Operator A	+	0	0	1	14	24
		-	10	18	11	2	0
	Operator B	+	0	0	0	14	24
		-	10	18	12	2	0
	Operator C	+	0	0	1	14	24
		-	10	18	11	2	0
OXY	Operator A	+	0	0	4	25	15
		-	10	15	11	0	0
	Operator B	+	0	0	3	24	15
		-	10	15	12	1	0
	Operator C	+	0	0	2	23	15
		-	10	15	13	2	0
PCP	Operator A	+	0	0	1	19	18
		-	9	16	14	3	0
	Operator B	+	0	0	0	19	18
		-	9	16	15	3	0
	Operator C	+	0	0	2	18	18
		-	9	16	13	4	0
TCA	Operator	+	0	0	3	20	18

	A	-	10	15	12	2	0
	Operator B	+	0	0	3	21	18
		-	10	15	12	1	0
	Operator C	+	0	0	3	20	18
		-	10	15	12	2	0
THC	Operator A	+	0	0	1	18	20
		-	10	15	14	2	0
	Operator B	+	0	0	0	17	20
		-	10	15	15	3	0
	Operator C	+	0	0	2	18	20
		-	10	15	13	2	0
EDDP	Operator A	+	0	0	3	20	20
		-	10	14	13	0	0
	Operator B	+	0	0	2	18	20
		-	10	14	14	2	0
	Operator C	+	0	0	3	19	20
		-	10	14	13	1	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Discordant Result
AMP 500	Operator B	AL243	441.6	Positive
	Operator A, B, C	AL073	443.7	Positive
	Operator A, B	AL251	457	Positive
	Operator B	AL022	475.7	Positive
	Operator A	AL143	489	Positive
	Operator C	AL036	501.2	Negative
	Operator A, B, C	AL212	508.9	Negative
AMP 1000	Operator C	AH051	910.3	Positive
	Operator B	AH070	968.6	Positive
	Operator A	AH066	970.1	Positive
	Operator B, C	AH002	1101	Negative
BAR	Operator C	BR328	279.6	Positive
	Operator A, C	BR311	296	Positive
	Operator A, B	BR321	302.1	Negative
	Operator A, B, C	BR440	307.2	Negative
	Operator B	BR226	319.83	Negative
	Operator A, C	BR227	323	Negative
BUP	Operator A, B, C	BP449	7.73	Positive
	Operator A, B	BP306	8.02	Positive
	Operator A, B, C	BP329	9.21	Positive
	Operator B, C	BP330	9.42	Positive

	Operator A, B, C	BP277	10.5	Negative
	Operator A, B, C	BP450	11.3	Negative
BZO	Operator A, B, C	BZ201	282	Positive
	Operator A, B, C	BZ213	291.2	Positive
	Operator C	BZ257	298	Positive
	Operator B	BZ204	301	Negative
	Operator C	BZ197	305	Negative
	Operator A, B	BZ356	317.6	Negative
	Operator A, C	BZ200	346	Negative
COC 150	Operator A, B	CL534	154	Negative
	Operator A, B, C	CL530	156.5	Negative
	Operator C	CL537	160.1	Negative
	Operator C	CL573	161.4	Negative
	Operator A	CL565	163.5	Negative
	Operator A, B, C	CL575	166.9	Negative
COC 300	Operator A, B, C	CH513	338.5	Negative
	Operator B	CH572	346.4	Negative
	Operator C	CH553	356.8	Negative
MDMA	Operator B	MM238	476.1	Positive
	Operator B	MM305	482.34	Positive
	Operator A, C	MM303	502	Negative
	Operator A	MM278	527.89	Negative
	Operator C	MM284	536.21	Negative
	Operator B	MM263	543.6	Negative
	Operator C	MM266	605	Negative
MET 500	Operator C	ML648	456.2	Positive
	Operator B	ML665	506	Negative
	Operator A, B, C	ML652	511	Negative
	Operator B	ML657	512	Negative
	Operator A, B, C	ML671	534	Negative
	Operator A	ML662	543	Negative
	Operator A	ML668	564.2	Negative
MET 1000	Operator A, C	MH623	962.6	Positive
	Operator A, B, C	MH667	981.1	Positive
	Operator A, B	MH651	995.8	Positive
	Operator C	MH767	1009.7	Negative
	Operator B, C	MH625	1083.2	Negative
MOP	Operator C	MO484	246	Positive
	Operator C	MO488	272.3	Positive
	Operator A, B, C	MO431	298	Positive
	Operator A, B, C	MO420	301	Negative
	Operator A, B, C	MO374	301.6	Negative
	Operator B	MO424	313.3	Negative

OPI	Operator A, B, C	OP384	1869.3	Positive
	Operator B, C	OP379	1984	Positive
	Operator C	OP472	2028	Negative
	Operator A, B, C	OP373	2080	Negative
MTD	Operator A, C	MT753	278.8	Positive
	Operator A, B, C	MT709	326.5	Negative
	Operator A, B, C	MT872	329.8	Negative
OXY	Operator A	OX286	77	Positive
	Operator A, B	OX296	92.3	Positive
	Operator A, B, C	OX272	95	Positive
	Operator A, B, C	OX253	96	Positive
	Operator C	OX267	100	Negative
	Operator B	OX277	102	Negative
	Operator C	OX263	103	Negative
PCP	Operator A, C	PC380	22.257	Positive
	Operator C	PC341	23.97	Positive
	Operator A, B, C	PC371	25.39	Negative
	Operator A, B, C	PC425	26.4	Negative
	Operator A, B, C	PC340	27.2	Negative
	Operator C	PC376	27.5	Negative
TCA	Operator A, C	TA419	817	Positive
	Operator B	TA407	849	Positive
	Operator A, B, C	TA431	892	Positive
	Operator A, B, C	TA379	934	Positive
	Operator A, B	TA429	1025	Negative
	Operator C	TA422	1069	Negative
	Operator A, C	TA391	1117	Negative
THC	Operator A, C	TH360	47.7	Positive
	Operator C	TH374	48.8	Positive
	Operator B	TH373	50.35	Negative
	Operator A, B, C	TH338	53.46	Negative
	Operator A, B, C	TH332	57.1	Negative
EDDP	Operator A, B, C	ED725	280.8	Positive
	Operator A, B, C	ED709	281	Positive
	Operator A, C	ED694	281.4	Positive
	Operator B	ED690	325	Negative
	Operator C	ED724	335	Negative
	Operator B	ED717	335.7	Negative

C. Lay person study

A lay user study was performed at three intended user sites with 280 lay persons. 114 males and 166 females tested Pocguide™ Multi-Drug Test Cup. They had diverse educational and professional backgrounds and their ages ranged from 18 to > 50. The 280 lay persons were split

into two groups of 140 whereby group 1 tested configuration 1 of the cup and group 2 tested configuration 2 of the cup. 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.

Results of Pocguide™ Multi-Drug Test Cup:

Sample Group 1 for Configuration 1 Cup:

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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%	95.00%	95.00%	100%	100%
BAR	300	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90.00%	100%	100%
BZO	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%	95.00%	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%	95.00%	95.00%	100%	100%
COC	150	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%	95.00%	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%	95.00%	95.00%	100%	100%
MDMA	500	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%	95.00%	100%	100%
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%	95.00%	95.00%	100%	100%
MOP	**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%	95.00%	100%	100%	100%
MTD	**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%	95.00%	100%	100%
OXY	**100**	**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%	95.00%	95.00%	100%	100%
PCP	**25**	**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%	95.00%	100%	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%	95.00%	95.00%	100%	100%
THC	**50**	**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%	95.00%	100%	100%

Sample Group 2 for Configuration 2 Cup:

Drug	**Cutoff (ng/mL)**	**Results**	**Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP	**1000**	**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%	95.00%	100%	100%	100%
BAR	**300**	**Negative**	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90.00%	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%	95.00%	95.00%	100%	100%
BUP	**10**	**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%	95.00%	100%	100%
COC	**300**	**Negative**	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90.00%	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%	95.00%	95.00%	100%	100%
MDMA	**500**	**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%	95.00%	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%	95.00%	100%	100%
OPI	**2000**	**Negative**	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	90.00%	100%	100%
MTD	**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%	95.00%	100%	100%
OXY	**100**	**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%	95.00%	95.00%	100%	100%
PCP	**25**	**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%	95.00%	100%	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%	95.00%	95.00%	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%	95.00%	95.00%	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 7.

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 Pocguide™ Multi-Drug Test Cup OTC and Pocguide™ Multi-Drug Test Cup are substantially equivalent to the predicate device.