Aicheck Biotech, Inc.
% Dylan Wu
IVD Senior Consultant
Shanghai Sungo Management Consulting Co., Ltd.
14th Floor, 1500# Century Avenue
Shanghai, 200122, China

Re: K242498
Trade/Device Name: Pocguide Multi-Drug Test Panel, Pocguide Multi-Drug Test Panel OTC
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NGL, PTH, NFV, NFY, PTG, NGG, NGM, QAW, NFW
Dated: August 22, 2024
Received: August 22, 2024

Dear Dylan Wu:

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.

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: 2024.10.01 10:15:07 -04'00'

Joseph Kotarek
Branch Chief for Toxicology
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242498

Device Name
Pocguide Multi-Drug Test Panel OTC
Pocguide Multi-Drug Test Panel

Indications for Use *(Describe)*
Pocguide Multi-Drug Test Panel OTC is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, 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
Benzoylecognine (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 panels can consist of up to the above listed analytes in any combination.
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.
For over-the-counter use. For in vitro diagnostic use only

Pocguide Multi-Drug Test Panel is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, 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
Benzoylecognine (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 panels 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.
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.

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510(K) Summary

K242498

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement by 21 CFR 807.92

Date prepared: 15th, Aug 2024

1 Submitter's Information

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3 Subject Device

3.1 Trade Name and Regulatory Information

Pocguide™ Multi-Drug Test Panel
Pocguide™ Multi-Drug Test Panel OTC

3.2 Regulatory Information

Drug (Identifier)	Code (s)	Classification	Regulation Section	Panel
Amphetamine (AMP)	NFT	Class II	21 CFR § 862.3100 Amphetamine Test System	Clinical Toxicology
Buprenorphine (BUP)	NGL	Class II	21 CFR § 862.3650 Opiate Test System	Clinical Toxicology
Secobarbital (BAR)	PTH	Class II	21 CFR § 862.3150 Barbiturate test system	Clinical Toxicology
Oxazepam (BZO)	NFV	Class II	21 CFR § 862.3170 Benzodiazepine test system	Clinical Toxicology
Benzoylecognine (COC)	NFY	Class II	21 CFR § 862.3250 Cocaine and Cocaine Metabolites Test System	Clinical Toxicology
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	PTG	Class II	21CFR § 862.3620 Methadone Test System	Clinical Toxicology
Methamphetamine (MET)	NGG	Class II	21 CFR § 862.3610 Methamphetamine Test System	Clinical Toxicology

Drug (Identifier)	Code (s)	Classification	Regulation Section	Panel
Methylenedioxymethamphetamine (MDMA)	NGG	Class II	21 CFR § 862.3610 Methamphetamine Test System	Clinical Toxicology
Morphine (OPI/MOP)	NGL	Class II	21 CFR § 862.3650 Opiate Test System	Clinical Toxicology
Methadone (MTD)	PTG	Class II	21CFR § 862.3620 Methadone Test System	Clinical Toxicology
Oxycodone (OXY)	NGL	Class II	21 CFR § 862.3650 Opiate Test System	Clinical Toxicology
Phencyclidine (PCP)	NGM	Unclassified		
Nortriptyline (TCA)	QAW	Class II	21 CFR § 862.3910 Tricyclic antidepressant drugs test system	Clinical Toxicology
Marijuana (THC)	NFW	Class II	21 CFR § 862.3870 Cannabinoid test system	Clinical Toxicology

4 Predicate device

K202567

Wondfo T-Dip® Multi-Drug Urine Test Panel

Wondfo T-Dip® Multi-Drug Urine Test Panel Rx

5 Indications for use/Intended use

Pocguide™ Multi-Drug Test Panel is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, 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
Benzoylecognine (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 panels 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.

For in vitro diagnostic use only.

Pocguide™ Multi-Drug Test Panel OTC is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, 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
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Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Benzoylecognine (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 panels can consist of up to the above listed analytes in any combination.

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.

For over-the-counter (OTC) use. For in vitro diagnostic use only.

6 Device Description

Pocguide™ Multi-Drug Test Panel and Pocguide™ Multi-Drug Test Panel OTC are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine at or above the cut-off levels as indicated. The products are single use in vitro diagnostic devices.

This device is a dipcard format in which the test strips are integrated into the plastic dipcard. After removing the cap of the dipcard, the absorbent end of the test strips is exposed and can be in direct contact with the urine sample. The device is in a ready-to-use format and no longer requires assembly before use.

7 Principle of Operation

Pocguide™ Multi-Drug Test Panel 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.

8 Substantial Equivalence Information

8.1 Technological characteristics

Table 1 Comparison of Technological characteristics

Device	**Proposed Device**		**Predicate Device**
510K number	K242498		K202567
Device name	Pocguide™ Multi-Drug Test Panel Pocguide™ Multi-Drug Test Panel OTC		Wondfo T-Dip® Multi-Drug Urine Test Panel Wondfo T-Dip® Multi-Drug Urine Test Panel Rx
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, Propoxyphene, Nortriptyline and Marijuana in human urine.		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 Cutoff Value	**Target Drug**	**Cutoff (ng/mL)**	The number of drugs detected are different, the predicate device also includes Propoxyphene (PPX) 300 ng/mL
	Amphetamine (AMP)	1000 or 500	
	Buprenorphine (BUP)	10	
	Secobarbital (BAR)	300	
	Oxazepam (BZO)	300	
	Benzoylecognine (COC)	300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methamphetamine (MET)	1000 or 500	
	Methylenedioxymethamphetamine (MDMA)	500	
	Morphine (OPI2000/MOP300)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Nortriptyline (TCA)	1000	
	Marijuana (THC)	50	
Configurations	Test Panel		Same

9 Summary of Non-Clinical Testing

9.1 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% cutoff and +100% cutoff. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking target drug in drug-free urines samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were tested in a blinded fashion. For each concentration, tests were performed in 2 runs per day for 25 days using 3 lots of test panels. The results obtained are summarized in Table 2.

Table 2 Precision / Reproducibility results of Pocguide™ Multi-Drug Test Panel

Drug tested Claimed Cutoff	%cutoff	Lot 1		Lot 2		Lot 3		Total Result		%Positive	%Negative
		+	-	+	-	+	-	+	-		
AMP 500	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	41	9	42	8	40	10	123	27	82.0%	18.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
AMP 1000	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	43	7	43	7	128	22	85.3%	14.7%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
BUP 10	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	41	9	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	Negative	0	50	0	50	0	50	0	150	0.0%	100.0%
BAR 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	41	9	41	9	124	26	82.7%	17.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
BZO 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	41	9	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
COC 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	42	8	41	9	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%

Drug tested Claimed Cutoff	%cutoff	Lot 1		Lot 2		Lot 3		Total Result		%Positive	%Negative
		+	-	+	-	+	-	+	-		
COC 150	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	41	9	41	9	42	8	124	26	82.7%	17.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
EDDP 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	43	7	43	7	128	22	85.3%	14.7%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
MET 1000	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	40	10	41	9	41	9	122	28	81.3%	18.7%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
MET 500	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	41	9	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	Negative	0	50	0	50	0	50	0	150	0.0%	100.0%
MDMA 500	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	41	9	43	7	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
OPI 2000	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	41	9	43	7	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
MOP 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	42	8	40	10	124	26	82.7%	17.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%

Drug tested Claimed Cutoff	%cutoff	Lot 1		Lot 2		Lot 3		Total Result		%Positive	%Negative
		+	-	+	-	+	-	+	-		
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
MTD 300	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	42	8	43	7	127	23	84.7%	15.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
OXY 100	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	44	6	43	7	130	20	86.7%	13.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
PCP 25	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	43	7	42	8	127	23	84.7%	15.3%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
TCA 1000	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	43	7	41	9	42	8	126	24	84.0%	16.0%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
THC 50	+100% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+75% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+50% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	+25% cutoff	50	0	50	0	50	0	150	0	100.0%	0.0%
	cutoff	42	8	43	7	43	7	128	22	85.3%	14.7%
	-25% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-50% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-75% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%
	-100% cutoff	0	50	0	50	0	50	0	150	0.0%	100.0%

b Linearity/assay reportable range

Linearity is not applicable since this is a qualitative test.

c Analytical specificity/Interference

c.1 Cross-Reactivity

To test cross-reactivity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into drug-free urine sample and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound is listed below along with the corresponding % cross-reactivity. The highest concentration tested is shown if no cross reactivity was observed.

Table 3 Cross-Reactivity results of Pocguide™ Multi-Drug Test Panel

Drug (Cutoff)	Substances	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
AMP 500	d-Amphetamine	500	100%
	l-Amphetamine	15000	3.30%
	dl- Amphetamine	1500	33.30%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	5000	10%

Drug (Cutoff)	Substances	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Phentermine	1500	33.30%
	Hydroxyamphetamine	8000	6.25%
	d-Methamphetamine	>100000	--
	l-Methamphetamine	>100000	--
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	>100000	--
	(+/-) 3,4-Methylenedioxymethamphetamine (MDMA)	>100000	--
	Ephedrine	>100000	--
	β-Phenylethylamine	100000	0.50%
	Tyramine	100000	0.50%
	p-Hydroxynorephedrine	100000	0.50%
	Phenylpropanolamine	>100000	--
	(±) Phenylpropanolamine	>100000	--
	p-Hydroxyamphetamine	100000	0.50%
	d/l-Norephedrine	100000	0.50%
	Benzphetamine	>100000	--
	l-Ephedrine	>100000	--
	l-Epinephrine	>100000	--
	d/l-Epinephrine	>100000	--
AMP 1000	d-Amphetamine	1000	100%
	l-Amphetamine	30000	3.30%
	dl- Amphetamine	3000	33.30%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	5000	20%
	Phentermine	3000	33.30%
	Hydroxyamphetamine	8000	12.50%
	d-Methamphetamine	> 100000	--
	l-Methamphetamine	> 100000	--
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	> 100000	--
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	> 100000	--
	Ephedrine	>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	--
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	-
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%
BZO 300	Oxazepam	300	100%
	Alprazolam	200	150%
	a-Hydroxyalprazolam	1000	30%
	Bromazepam	500	60%
	Chlordiazepoxide	1500	20%

Drug (Cutoff)	Substances	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	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 300	Benzoylecgonine	300	100%
	Cocaine	1000	30%
	Cocaethylene	15000	2%
	Ecgonine	30000	1%
	Ecgonine methyl ester	＞100000	--
	Norcocaine	＞100000	--
COC 150	Benzoylecgonine	150	100%
	Cocaine	500	30%
	Cocaethylene	6250	2.40%
	Ecgonine	16000	0.94%
	Ecgonine methyl ester	> 100000	--
	Norcocaine	> 100000	--
EDDP 300	2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine	300	100%
	Methadone	200000	0.15%
	EMDP	300000	0.10%
	Doxylamine	> 100000	--
	Disopyramide	> 100000	--
	LAAM (Levo-alpha-acetylmethadol) HCl	> 100000	--
	Alpha Methadol	> 100000	--
MET 1000	D (+)-Methamphetamine	1000	100%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	2000	50%
	D/L-Methamphetamine	1000	100%
	p-Hydroxymethamphetamine	30000	3.30%
	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%
MET 500	D (+) -Methamphetamine	500	100%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	2000	25%
	D/L-Methamphetamine	500	100%
	p-Hydroxymethamphetamine	15000	3.33%
	D-Amphetamine	50000	1%
	L-Amphetamine	100000	0.50%
	Chloroquine	10000	5%
	(+/-)-Ephedrine	25000	2%

Drug (Cutoff)	Substances	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	(-)-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	0.50%
	L-Methamphetamine	10000	5%
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	--
OPI 2000	Morphine	2000	100%
	Normorphine	50000	4%
	Codeine	2000	100%
	s-Monoacetylmorphine	2000	100%
	Ethyl Morphine	1500	133.30%
	Heroin	2000	100%
	Hydrocodone	12500	16%
	Hydromorphone	3500	57.10%
	Morphinie-3-β-d-glucuronide	2000	100%
	Oxycodone	25000	8%
	Oxymorphone	25000	8%
	Thebaine	5000	40%
	Levorphanol	75000	2.70%
	6-Monoacetylmorphine (6-MAM)	1500	133.30%
	Norcodeine	12500	16%
	Procaine	150000	1.30%
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	0.30%
	Thebaine	3000	10%
	Levorphanol	5000	6%
	6-Monoacetylmorphine (6-MAM)	150	200%
	Norcodeine	6500	4.60%
	Procaine	100000	0.30%
MTD 300	Methadone	300	100%
	Doxylamine	3000	10%
	EDDP	> 100000	--
	EMDP	> 100000	--
	LAAM	> 100000	--
	Alpha Methadol	> 100000	--
OXY 100	Oxycodone	100	100%
	Dihydrocodeine	20000	0.50%
	Hydrocodone	10000	1%
	Oxymorphone	1000	10%
	Codeine	100000	0.10%
	Hydromorphone	32000	0.30%
	Morphine	＞100000	--

Drug (Cutoff)	Substances	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
	Acetylmorphine	＞100000	--
	Buprenorphine	＞100000	--
	Ethylmorphine	＞100000	--
	Thebaine	＞100000	--
	Phencyclidine	25	100%
PCP 25	4-Hydroxyphencyclidine	12500	0.20%
	Nortriptyline	1000	100%
	Nordoxepine	1000	100%
	Trimipramine	2000	50%
	Amitriptyline	1500	66.70%
	Promazine	1500	66.70%
	Desipramine	400	250%
TCA 1000	Imipramine	400	250%
	Clomipramine	12500	8%
	Doxepin	1000	100%
	Maprotiline	2000	50%
	Promethazine	25000	4%
	Cyclobenzaprine	1500	66.70%
	Norclomipramine	10000	10%
	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%
THC 50	Cannabinol	20000	0.25%
	Cannabidiol	100000	0.05%
	Δ8- Tetrahydrocannabinol	1300	3.80%
	Δ9- Tetrahydrocannabinol	5000	1%
	511-hydroxy-Δ9-Tetrahydrocannabinol	5000	1%

c.2 Interference Study

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and urine samples with concentrations of the target drugs at 25% below and 25% above Cutoff levels. These urine samples were tested using three lots of each device. The compounds were tested at 100 μg/mL (unless otherwise noted in the table). No interference was observed for any of the compounds tested, and the list of compounds is provided in the following table.

Table 4 Interfering substances

Acetaminophen	Ciprofloxacin Hydrochloride	1% Ethanol	Lidocaine Hydrochloride	Ondansetran
Acetophenetidin	Citalopram	Fenofibrate	Lisinopril	Paliperidone
Acetylsalicylic Acid	Clarithromycin	Fenoprofen	Lithium Carbonate	Pantoprazole
Acyclovir	Clonidine	Fentanyl Citrate	Liverite	Papaverine
Afrin	Clopidogrel Hydrogen Sulphate	Fluoxetine Hydrochloride	Loperamide	Paroxetine Hydrochloride
Albumin(100mg/dL)	Clozapine	Fluvoxamine	Loratadine	Penfluridol
Aminophylline	Conjugated Estrogens	Furosemide	Magnesium	PenicillinV Potassium
Aminopyrine	Cortisone	Gabapentin	Meperidine	Penicillin-G
Amiodarone Hydrochloride	Creatinine	Gentisic Acid	Meprobamate	Phenelzine
Amlodipine Mesylate	(-) Cotinine	Glibenclamide	Metoprolol Tartrate	Pioglitazone Hydrochloride
Amoxicillin	chlorpheniramine	Gliclazide	Mifepristone	Piracetam
Ampicillin	D, L-Octopamine	Glipizide	Mirtazapine	Pravastatin Sodium
Apomorphine	D, L-Propranolol	Glucose	Montelukast Sodium	Prednisone
Aripiprazole	D, L-Tyrosine	Haloperidol	Mosapride Citrate	Propylthiouracil
Aspartame	Deoxy- corticosterone	Hemoglobin	Minocycline	Quetiapine Fumarate
Atomoxetine	Dextromethorphan	Hydrochlorothiazide	Nalidixic Acid	Quinine
Atorvastatin Calcium	Diclofenac	Hydrocortisone	Naproxen	Ranitidine
Atropine	Diflunisal	3-Hydroxytyramine	Niacinamide	Rifampicin
Benzilic Acid	Digoxin	Isosorbide Dinitrate	Nifedipine	Risperidone
Benzoic Acid	Diphenhydramine	Isoxsuprine	Nikethamide	Salicylic Acid
Bilirubin	Dirithromycin	Ibuprofen	Nimodipine	Serotonin
Bupropion	Domperidone	Ketoconazole	Nitroglycerin	Sertraline Hydrochloride
Captopril	D-Pseudoephedrine	Ketoprofen	Norethindrone	Sildenafil Citrate
Carbamazepine	Duloxetine	Ketamine	N-Acetylprocain-amide	Simvastatin
Cefradine	Dicyclomine	Kratom powder	O-Hydroxyhippuric Acid	Sodium Valproate
Cephalexin	Effexor	Labetalol	Olanzapine	Spironolactone
Chloral Hydrate	Enalapril Maleate	Lamotrigine	Omeprazole	Sulfamethazine
Chloramphenicol	Erythromycin	Levofloxacin Hydrochloride	Oxalic Acid	Sulindac

Chlorothiazide	Esomeprazole Magnesium	Levonorgestrel	Oxolinic Acid	Tetracycline
Cholesterol	β-Estradiol	Levothyroxine Sodium	Oxymetazoline	Tetrahydrocortsone 3 -acetate
Tetrahydrocortisone 3-(β-D glucuronide)	Thioridazine	Trazodone Hydrochloride	Trimethoprim	Verapamil
Tetrahydrozoline	Topiramate	Triamterene	Uric Acid	Vitamin B2
Thiamine	Tramadol Hydrochloride	Trifluoperazine	Valproate	Vitamin C
Chloroquine	Ecgonine Methyl Ester	Doxylamine	Epinephrine Hydrochloride	Maprotiline
Promethazine				

c.3 Effect of urine specific gravity and pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with specific gravity ranging from 1.000 to 1.035 or urine samples with pH ranging from 4 to 9 were spiked with the target drugs to concentrations at -25% Cutoff and +25% Cutoff levels. These samples were tested using three lots of each device. Results were all positive for samples at +25% Cutoff and all negative for samples at -25% Cutoff. The results demonstrated that urine specific gravity levels of 1.000 to 1.035 and urine pH levels of 4 to 9 do not affect the results of the assays.

d Traceability, Stability, Expected values (controls, calibrators, or methods):

d.1 Traceability

The device is traceable to commercially available materials.

d.2 Stability

The stability data supports that the products have the shelf life of 24 months when stored at 4-30℃.

Real time Stability

A 27-month real time stability test is planned to verify the shelf-life stability of the device as 24 months. Three batches for each configuration in sealed foil pouch are currently stable for 21 months at 4℃ and 30℃, and the real time stability study is still on-going.

Accelerated Stability

Stable at 4-30℃ for 24 months based on the accelerated stability study at 55℃ for 31 days and real time stability determination at both 4℃ and 30℃.

e Detection limit

Not Applicable.

f Assay Cut-off

Refer to section 9.1.a.

9.2 Comparison Studies

a Method comparison studies

Method comparison studies were performed by three operators. Eighty (80) unaltered clinical samples (40 negative and 40 positive) were run for each target drug. The samples were tested in a blinded fashion and compared to LC/MS results. The results are presented in Table 5 below, and the discordant results are summarized in below.

Table 5 The Results of Method comparison with predicate device

Drug cutoff	Candidate Device Result		Drug-Free	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
AMP 1000	Viewer A	Positive	0	0	1	14	25
		Negative	7	15	17	1	0
	Viewer B	Positive	0	0	1	15	25
		Negative	7	15	17	0	0
	Viewer C	Positive	0	0	1	14	25
		Negative	7	15	17	1	0
AMP 500	Viewer A	Positive	0	0	2	15	23
		Negative	13	7	18	2	0
	Viewer B	Positive	0	0	2	16	23
		Negative	13	7	18	1	0
	Viewer C	Positive	0	0	1	15	23
		Negative	13	7	19	2	0
BAR 300	Viewer A	Positive	0	0	1	19	19
		Negative	10	15	14	2	0
	Viewer B	Positive	0	0	1	19	19
		Negative	10	15	14	2	0
	Viewer C	Positive	0	0	1	19	19
		Negative	10	15	14	2	0
BUP 10	Viewer A	Positive	0	0	3	20	18
		Negative	10	15	12	2	0
	Viewer B	Positive	0	0	3	20	18
		Negative	10	15	12	2	0
	Viewer C	Positive	0	0	2	20	18
		Negative	10	15	13	2	0
BZO 300	Viewer A	Positive	0	0	2	18	20
		Negative	10	15	13	2	0
	Viewer B	Positive	0	0	2	18	20
		Negative	10	15	13	2	0
	Viewer C	Positive	0	0	3	18	20
		Negative	10	15	12	2	0
COC 300	Viewer A	Positive	0	0	0	18	21
		Negative	9	16	15	1	0
	Viewer B	Positive	0	0	0	17	21
		Negative	9	16	15	2	0
	Viewer C	Positive	0	0	1	19	21
		Negative	9	16	14	0	0
COC 150	Viewer A	Positive	0	0	0	21	15
		Negative	10	15	15	4	0
	Viewer B	Positive	0	0	1	23	15
		Negative	10	15	14	2	0

Drug cutoff	Candidate Device Result		Drug-Free	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 cutoff and +50%)	High Positive by LC/MS (greater than +50%)
	Viewer C	Positive	0	0	0	21	15
		Negative	10	15	15	4	0
EDDP 300	Viewer A	Positive	0	0	2	19	20
		Negative	10	14	14	1	0
	Viewer B	Positive	0	0	3	19	20
		Negative	10	14	13	1	0
	Viewer C	Positive	0	0	2	20	20
		Negative	10	14	14	0	0
MET 1000	Viewer A	Positive	0	0	1	16	22
		Negative	8	13	18	2	0
	Viewer B	Positive	0	0	2	17	22
		Negative	8	13	17	1	0
	Viewer C	Positive	0	0	2	17	22
		Negative	8	13	17	1	0
MET 500	Viewer A	Positive	0	0	1	21	16
		Negative	8	20	11	3	0
	Viewer B	Positive	0	0	2	23	16
		Negative	8	20	10	1	0
	Viewer C	Positive	0	0	0	21	16
		Negative	8	20	12	3	0
OPI 2000	Viewer A	Positive	0	0	1	22	18
		Negative	10	15	14	0	0
	Viewer B	Positive	0	0	1	20	18
		Negative	10	15	14	2	0
	Viewer C	Positive	0	0	2	20	18
		Negative	10	15	13	2	0
MOP 300	Viewer A	Positive	0	0	1	23	15
		Negative	10	14	15	2	0
	Viewer B	Positive	0	0	2	23	15
		Negative	10	14	14	2	0
	Viewer C	Positive	0	0	1	23	15
		Negative	10	14	15	2	0
MTD 300	Viewer A	Positive	0	0	1	14	24
		Negative	10	18	11	2	0
	Viewer B	Positive	0	0	1	15	24
		Negative	10	18	11	1	0
	Viewer C	Positive	0	0	0	14	24
		Negative	10	18	12	2	0
OXY 100	Viewer A	Positive	0	0	2	23	15
		Negative	10	15	13	2	0
	Viewer B	Positive	0	0	2	23	15
		Negative	10	15	13	2	0
	Viewer C	Positive	0	0	1	22	15
		Negative	10	15	14	3	0
PCP 25	Viewer A	Positive	0	0	1	20	18
		Negative	9	16	14	2	0
	Viewer B	Positive	0	0	1	20	18
		Negative	9	16	14	2	0
	Viewer C	Positive	0	0	0	20	18
		Negative	9	16	15	2	0
TCA 1000	Viewer A	Positive	0	0	2	20	18
		Negative	10	15	13	2	0
	Viewer B	Positive	0	0	1	19	18
		Negative	10	15	14	3	0
	Viewer C	Positive	0	0	2	20	18
		Negative	10	15	13	2	0
THC 50	Viewer A	Positive	0	0	1	18	20
		Negative	10	15	14	2	0
	Viewer B	Positive	0	0	2	19	20
		Negative	10	15	13	1	0
	Viewer C	Positive	0	0	1	17	20
		Negative	10	15	14	3	0
MDMA 500	Viewer A	Positive	0	0	1	20	18
		Negative	10	15	14	2	0
	Viewer B	Positive	0	0	1	21	18
		Negative	10	15	14	1	0
	Viewer C	Positive	0	0	1	20	18
		Negative	10	15	14	2	0

Table 6 Discordant results

Drug cutoff	Operator	Sample ID	LC/MS Results (ng/mL)	Test Result
AMP 1000	Viewer C	AH621	968.6	Positive
	Viewer A, B	AH618	970.1	Positive
	Viewer A, C	AH562	1101	Negative
AMP 500	Viewer B	AL554	472.6	Positive
	Viewer A	AL486	475.7	Positive
	Viewer A, B, C	AL546	489	Positive
	Viewer A, C	AL491	501.2	Negative
	Viewer B, C	AL551	508.9	Negative
	Viewer A	AL483	536.2	Negative
BAR 300	Viewer A, B, C	BA436	296	Positive
	Viewer A, C	BA445	302.1	Negative
	Viewer A, B, C	BA474	307.2	Negative
	Viewer B	BA403	319.83	Negative
BUP 10	Viewer A, B	BU001	8.36	Positive
	Viewer A, B, C	BU052	9.21	Positive
	Viewer A, B, C	BU053	9.42	Positive
	Viewer A, B, C	BU007	10.2	Negative
	Viewer A, B, C	BU003	10.5	Negative
BZO 300	Viewer B, C	BZ100	282	Positive
	Viewer A, C	BZ112	291.2	Positive
	Viewer A, B, C	BZ149	298	Positive
	Viewer C	BZ103	301	Negative
	Viewer A, B, C	BZ096	305	Negative
	Viewer B	BZ108	309	Negative
	Viewer A	BZ155	317.6	Negative
COC 300	Viewer C	CH945	294.8	Positive
	Viewer A, B	CH948	328.5	Negative
	Viewer B	CH893	338.5	Negative
COC 150	Viewer B	CL801	145	Positive
	Viewer B	CL827	154	Negative
	Viewer A, C	CL806	156	Negative
	Viewer A, B, C	CL839	159	Negative
	Viewer A, C	CL830	160.1	Negative
	Viewer A, C	CL858	163.5	Negative
EDDP 300	Viewer B	ED366	280.8	Positive
	Viewer A, B, C	ED350	281	Positive
	Viewer A, B, C	ED335	284.1	Positive
	Viewer A	ED331	325	Negative
	Viewer B	ED358	335.7	Negative
MET 1000	Viewer A, B, C	MH307	981.1	Positive
	Viewer B, C	MH291	995.8	Positive
	Viewer A, B	MH246	1039.7	Negative
	Viewer A, C	MH302	1098	Negative
MTD 300	Viewer A, B	MT464	278.8	Positive
	Viewer A, B, C	MT424	326.5	Negative
	Viewer A, C	MT475	329.8	Negative
MET 500	Viewer B	ML217	457.3	Positive
	Viewer A, B	ML177	491	Positive
	Viewer A, C	ML224	506	Negative
	Viewer B, C	ML216	512	Negative
	Viewer A, C	ML168	518	Negative
	Viewer A	ML233	523	Negative
OPI 2000	Viewer A, C	OP094	1869.3	Positive
	Viewer B, C	OP084	1983	Positive
	Viewer B, C	OP149	2045	Negative
	Viewer B, C	OP087	2080	Negative
MOP 300	Viewer B	MO033	287.5	Positive
	Viewer A, B, C	MO039	298	Positive
	Viewer A, B, C	MO028	301	Negative
	Viewer A, C	MO009	301.6	Negative
	Viewer B	MO071	319.5	Negative
OXY 100	Viewer C	OX236	87	Positive
	Viewer B	OX228	92.3	Positive
	Viewer A, B	OX204	95	Positive
	Viewer A	OX185	96	Positive
	Viewer A, B, C	OX199	100	Negative
	Viewer A, C	OX209	102	Negative
	Viewer B, C	OX195	103	Negative
PCP 25	Viewer A	PC252	23.16	Positive
	Viewer B	PC260	23.97	Positive
	Viewer A, B, C	PC286	25.39	Negative
	Viewer A, B, C	PC297	25.9	Negative
TCA 1000	Viewer C	TA752	849	Positive
	Viewer A, C	TA776	892	Positive
	Viewer A, B	TA724	934	Positive
	Viewer A	TA774	1025	Negative
	Viewer B, C	TA761	1058	Negative
	Viewer B, C	TA767	1069	Negative
	Viewer A, B	TA799	1079	Negative
THC 50	Viewer B, C	TH334	48	Positive
	Viewer A, B	TH375	48.8	Positive
	Viewer A, C	TH374	50.35	Negative
	Viewer A, C	TH339	53.46	Negative
	Viewer B, C	TH398	54.45	Negative
MDMA 500	Viewer B	MD642	476.1	Positive
	Viewer A, C	MD708	482.34	Positive
	Viewer A, C	MD706	502	Negative
	Viewer B, C	MD681	527.89	Negative
	Viewer A	MD710	532	Negative

b Matrix comparison

Not applicable. This device is for testing with human urine only.

10 Clinical studies

a Clinical Sensitivity

Not applicable

b Clinical specificity

Not applicable

c Other clinical supportive data (when a. and b. are not applicable)

c.1 Lay-User Study

The lay-user study was performed at three intended use sites. 58 male and 82 female tested Pocguide™ Multi-Drug Test Panel Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150); 56 male and 84 female tested Pocguide™ Multi-Drug Test Panel Configuration 2 (including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300). They had diverse educational and occupational backgrounds and their age range from 18 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 in below.

Table 7 Result of Pocguide™ Multi-Drug Test Panel Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150)

Drug	Cutoff	Results	Concentration						
	(ng/mL)		-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	1	0	0
		Positive	0	0	0	0	19	20	20

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95.00%	100%	100%
BZO	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%
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	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%
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%	95.00%	100%	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	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%
THC	50	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%

Table 8 Result of Pocguide™ Multi-Drug Test Panel Configuration 2 (including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300)

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%	100.00%	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%	95.00%	95.00%	100%	100%

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
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%	100.00%	95.00%	100%	100%
COC	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%	100.00%	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	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%	100.00%	95.00%	100%	100%
OPI	2000	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%
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	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100.00%	95.00%	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%	100.00%	95.00%	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	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%

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.

d Clinical Cut-off

Not applicable

11 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 Panel and Pocguide™ Multi-Drug Test Panel OTC are substantially equivalent to the predicate devices.
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.