October 9, 2025

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

Re: K252867
Trade/Device Name: VINScreen Urine Drug Test Cup; VINScreen Urine Drug Home Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, PTH, NGL, NFV, NFY, PTG, NGG, NGM, QBF, QAW, NFW
Dated: September 9, 2025
Received: September 9, 2025

Dear Jenny Xia:

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

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

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

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

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

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

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

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

Sincerely,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2025.10.09 08:08:29 -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

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.

510(k) Number *(if known)*
K252867

Device Name
VINScreen Urine Drug Test Cup;
VINScreen Urine Drug Home Test Cup

Indications for Use *(Describe)*
The VINScreen Urine Drug Test Cup is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

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

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device.
This in vitro diagnostic device provides only a preliminary test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory method.

The VINScreen Urine Drug Home Test Cup is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

Drug	Cut-off (ng/mL)	Abbreviation
6-monoacetylmorphine	10	6AM
Amphetamine	500 / 1000	AMP
Secobarbital	300	BAR
Buprenorphine	10	BUP
Oxazepam	300	BZO
Cocaine	150 / 300	COC
EDDP	300	EDDP
Fentanyl	1	FEN
Norfentanyl	5	FEN
Ecstasy	500	MDMA
Methamphetamine	500 / 1000	MET

Methadone	300	MTD
Opiates	300 / 2000	MOR/OPI
Oxycodone	100	OXY
Phencyclidine	25	PCP
Propoxyphene	300	PPX
Nortriptyline	1000	TCA
Marijuana	20 / 50	THC

The single or multi-test cup can include any combination of the analytes listed above, with and without on-board adulteration tests. However, only one cut-off concentration can be included per analyte per device.
This device provides only a preliminary test result. A more specific alternate method must be used in order to obtain a confirmed analytical test result. GC/MS or LC/MS is the preferred confirmatory method.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

K252867

1. Date: October 5, 2025

2. Submitter:
Advin Biotech, Inc.
10140 Mesa Rim Rd Unit 1
San Diego, CA 92121

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: VINScreen Urine Drug Test Cup
VINScreen Urine Drug Home 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) Fentanyl (FEN) Morphine (MOP/OPI) Oxycodone (OXY) 6-Monoacetylmorphine(6-AM) Norfentanyl (FEN)	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 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
QBF Propoxyphene(PPX)	862.3700 Propoxyphene test system.	Toxicology

NGM Phencyclidine (PCP)	Unclassified	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids (THC)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Devices:

AllTest Multi-Drug Rapid Test Cup (K244043)

7. Intended Use

The VINScreen Urine Drug Home Test Cup is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

Drug	**Cut-off (ng/mL)**	**Abbreviation**
6-monoacetylmorphine	10	6AM
Amphetamine	500 / 1000	AMP
Secobarbital	300	BAR
Buprenorphine	10	BUP
Oxazepam	300	BZO
Cocaine	150 / 300	COC
EDDP	300	EDDP
Fentanyl	1	FEN
Norfentanyl	5	FEN
Ecstasy	500	MDMA
Methamphetamine	500 / 1000	MET
Methadone	300	MTD
Opiates	300 / 2000	MOR/OPI
Oxycodone	100	OXY
Phencyclidine	25	PCP
Propoxyphene	300	PPX
Nortriptyline	1000	TCA
Marijuana	20 / 50	THC

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

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

The VINScreen Urine Drug Test Cup is lateral flow immunoassays for rapid detection of multiple commonly abused drugs in human urine. The detectable drugs and their cutoff concentrations are listed below:

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

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

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

8. Device Description

VINScreen Urine Drug Test Cup and VINScreen Urine Drug Home 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

Similarities		
Item	**Device**	**Predicate (K244043)**
Intended use	Qualitative detection of drugs of abuse in urine. For over-the-counter use	Same.
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction	Same

Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
Target Drug and Cut Off Values	**Target Drugs**	**Cutoff (ng/mL)**	Same except that no Norfentanyl THC20
	Amphetamine(AMP)	1000 or 500	
	Secobarbital (BAR)	300	
	Buprenorphine (BUP)	10	
	Oxazepam (BZO)	300	
	Cocaine (COC)	150 or 300	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methylenedioxymethamphetamine (MDMA)	500	
	Methamphetamine (MET)	1000 or 500	
	Morphine (MOP300/OPI2000)	300 or 2000	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene(PPX)	300	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC)	20 or 50	
	6-Monoacetylmorphine(6-AM)	10	
	Fentanyl (FEN)	1	
	Norfentanyl (FEN)	5	
Configurations	Test cup		Same

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

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

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized

in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.
When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

12. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiked target drug in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test cups with one operator per lot. 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
6AM 10	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
AMP 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
BUP 10	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
BZO 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
COC 150	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+

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

	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
MET 1000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
OPI 2000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
THC 50	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+

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

c. Stability:
The device is stable at 2-30℃ 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. The results obtained are summarized in the following table. 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.

6-AM (6-Acetylmorphine) (6-Acetylmorphine, Cutoff=10ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
6-Acetylmorphine	10	100%
Heroin	25	40%
Morphine	>100,000	<0.01%
Normorphine	>100,000	<0.01%
Nalorphine	>100,000	<0.01%
Hydrocodone	>100,000	<0.01%
Hydromorphone	>100,000	<0.01%
Chlordiazepoxide	>100,000	<0.01%
Clobazam	>100,000	<0.01%
D-Amphetamine	>100,000	<0.01%
(±)-Amphetamine	>100,000	<0.01%
Levorphanol	>100,000	<0.01%
Codeine	>100,000	<0.01%
Ethylmorphine	>100,000	<0.01%
Morphine3-β-D-glucuronide	>100,000	<0.01%

Norcodeine	>100,000	<0.01%
Oxycodone	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%
Procaine	>100,000	<0.01%
Thebaine	>100,000	<0.01%
6-Acetylcodeine	50,000	0.02%
Buprenorphine	>10,000	<0.1%
Dihydrocodeine	>100,000	<0.01%
Dextromethorphan	>100,000	<0.01%
Imipramine	>100,000	<0.01%
Meperidine	>100,000	<0.01%
(±)-Methadone	>100,000	<0.01%
Mitragynine(Kratom)	>10,000	<0.1%
Morphine-6-β-D-glucuronide	>10,000	<0.1%
Naloxone	>100,000	<0.01%
Naltrexone	>100,000	<0.01%
Naproxen	>100,000	<0.01%
Norbuprenorphine	>10,000	<0.1%
Norbuprenorphine-3-D-Glucuronide	10,000	0.1%
Noroxycodone	>100,000	<0.01%
Noroxymorphone	>10,000	<0.1%
Norpropoxyphene	>100,000	<0.01%
Oxymorphone-3β-D-glucuronide	>10,000	<0.1%
Tapentadol	>100,000	<0.01%
cis-Tramadol	>100,000	<0.01%

AMP(Amphetamine) (Amphetamine, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-3,4-Methylenedioxyamphetamine (MDA)	2,000	25%
(±)-Amphetamine	1,000	50%
D-Amphetamine	500	100%
Diethylstilbestrol	>10,000	<5%
L-Amphetamine	50,000	1%
Phentermine	15,000	3.33%
β-Phenylethylamine	>100,000	<0.5%
Tyramine	>100,000	<0.5%
p-Hydroxynorephedrine	>100,000	<0.5%
p-Hydroxyamphetamine	5,000	10%
D-Methamphetamine	>100,000	<0.5%
L-Methamphetamine	>100,000	<0.5%
Ephedrine	>100,000	<0.5%

(±)-3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	<0.5%
Phenylpropanolamine (Norephedrine)	>100,000	<0.5%
Benzphetamine	>100,000	<0.5%
(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
L-Epinephrine	>100,000	<0.5%
D,L-Epinephrine	>100,000	<0.5%
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<0.5%

AMP(Amphetamine) (Amphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	20%
(±)-Amphetamine	2,000	50%
D-Amphetamine	1,000	100%
Diethylstilbestrol	>10,000	<10%
L-Amphetamine	>100,000	<1%
Phentermine	25,000	4%
β-Phenylethylamine	>100,000	<1%
Tyramine	>100,000	<1%
p-Hydroxynorephedrine	>100,000	<1%
p-Hydroxyamphetamine	10,000	10%
D-Methamphetamine	>100,000	<1%
L-Methamphetamine	>100,000	<1%
Ephedrine	>100,000	<1%
(±)-3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	<1%
Phenylpropanolamine (Norephedrine)	>100,000	<1%
Benzphetamine	>100,000	<1%
(1R,2S)-(-)-Ephedrine	>100,000	<1%
L-Epinephrine	>100,000	<1%
D,L-Epinephrine	>100,000	<1%
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	>100,000	<1%

BAR(Secobarbital) (Secobarbital, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Alphenal	400	75%
Amobarbital	500	60%
Aprobarbital	150	200%

Barbital	1,000	30%
Butabarbital	70	428.57%
Butethal	20	1500%
Cyclopentobarbital	1,000	30%
Pentobarbital	200	150%
Phenobarbital	250	120%
Secobarbital	300	100%
Butalbital	10,000	3%

BUP(Buprenorphine) (Buprenorphine, Cutoff=10ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	20	50%
Norbuprenorphine	150	6.67%
Norbuprenorphine glucuronide	500	2%
Codeine	>100,000	<0.01%
Nalorphine	>100,000	<0.01%
Morphine	>100,000	<0.01%
Oxymorphone	>100,000	<0.01%
Hydromorphone	>100,000	<0.01%

BZO(Oxazepam) (Oxazepam, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
a-Hydroxyalprazolam	5,000	6%
Alprazolam	250	120%
Bromazepam	600	50%
Chlordiazepoxide	500	60%
Clobazam	300	100%
Clonazepam	>100,000	<0.3%
Clorazepate	500	60%
Desalkylflurazepam	500	60%
Diazepam	1,000	30%
Estazolam	>100,000	<0.3%
Flunitrazepam	1,000	30%
Lorazepam	1,000	30%
Lormetazepam	>100,000	<0.3%
Midazolam	>100,000	<0.3%
Nitrazepam	250	120%
Norchlordiazepoxide	70	428.57%
Nordiazepam	1,000	30%

Oxazepam	300	100%
Oxazepam glucuronide	30	1000%
Lorazepam glucuronide	100	300%
Temazepam	200	150%
Triazolam	5,000	6%
Demoxepam	25	1200%
Flurazepam	>100,000	<0.3%
Delorazepam	>10,000	<3%

COC(Benzoylecgonine) (Benzoylecgonine, Cutoff=150ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Benzoylecgonine	150	100%
Cocaethylene	2,000	7.5%
Cocaine	>100,000	<0.15%
Ecgonine	>100,000	<0.15%
Norcocaine	>100,000	<0.15%
Ecgonine methyl ester	>100,000	<0.15%

COC(Benzoylecgonine) (Benzoylecgonine, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Benzoylecgonine	300	100%
Cocaethylene	3,000	10%
Cocaine	>100,000	<0.3%
Ecgonine	>100,000	<0.3%
Norcocaine	>100,000	<0.3%
Ecgonine methyl ester	>100,000	<0.3%

EDDP (EDDP, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
EDDP	300	100%
Methadone	>100,000	<0.3%
EMDP	>100,000	<0.3%
Doxylamine	>100,000	<0.3%
Disopyramide	>100,000	<0.3%
LAAM(Levo-alpha-acetylmethadol) hydrochloride	>100,000	<0.3%
Alpha Methadol	>100,000	<0.3%

FEN(Fentanyl) (Fentanyl, Cutoff=1ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Norfentanyl	25,000	0.004%
Fentanyl	1	100%
Acetyl fentanyl	3	33.33%
Acetyl norfentanyl	20,000	0.005%
(±)-β-Hydroxythiofentanyl	5	20%
Acryl fentanyl	4	25%
Butyryl fentanyl	5	20%
(±)-cis-3-methyl Fentanyl	1	100 %
Furanyl fentanyl	10	10%
para-Fluorobutyryl fentanyl (PFBF)	10	10%
para-Fluorofentanyl	5	20%
9-Hydroxyrisperidone	>100,000	<0.001%
Alfentanil	>100,000	<0.001%
Isobutyryl fentanyl	10	10%
4-Fluoro-isobutyryl fentanyl	5	20%
Norcarfentanil	>10,000	<0.01%
Remifentanil	500	0.2%
Valeryl fentanyl	10	10%
Thienyl Fentanyl	30	3.33%
(±)-trans-3-methyl Fentanyl	5	20%
Despropionyl fentanyl (4-ANPP)	250	0.4%
MT-45	50	2%
Ocfentanil	2	50%
Isotonitazene	>100,000	<0.001%
Cyclopropylfentanyl	10	10%
AH-7921 HCL	2500	0.04%
Risperidone	>100,000	<0.001%
Sufentanil	20	5%
Carfentanil	5	20%
Labetalol	>100,000	<0.001%
Trazodone	>100,000	<0.001%
U-47700	>100,000	<0.001%
ω-1-Hydroxyfentanyl	2	50.00%
6-Acetylmorphine	>100,000	<0.001%
Amphetamine	>100,000	<0.001%
Buprenorphine	>100,000	<0.001%
Buprenorphine -3-D-Glucuronide	>100,000	<0.001%
Codeine	>100,000	<0.001%
Dextromethorphan	>100,000	<0.001%

Dihydrocodeine	>100,000	<0.001%
EDDP	>100,000	<0.001%
EMDP	>100,000	<0.001%
Fluoxetine	>100,000	<0.001%
Heroin	>100,000	<0.001%
Hydrocodone	>100,000	<0.001%
Hydromorphone	>100,000	<0.001%
Ketamine	>100,000	<0.001%
Levorphanol	>100,000	<0.001%
Meperidine	>100,000	<0.001%
Methadone	>100,000	<0.001%
Morphine	>100,000	<0.001%
Morphine-3-β-D-glucuronide	>100,000	<0.001%
Naloxone	>100,000	<0.001%
Naltrexone	>100,000	<0.001%
Norbuprenorphine	5,000	0.02%
Norcodeine	>100,000	<0.001%
Norketamine	>100,000	<0.001%
Normeperidine	>100,000	<0.001%
Normorphine	>100,000	<0.001%
Noroxycodone	>100,000	<0.001%
Oxycodone	>100,000	<0.001%
Oxymorphone	>100,000	<0.001%
Pentazocine (Talwin)	80,000	0.00125%
Pipamperone	5,000	0.02%
Tapentadol	>100,000	<0.001%
Thioridazine	>100,000	<0.001%
Tilidine	>100,000	<0.001%
cis-Tramadol	>100,000	<0.001%
O-Desmethyl-cis-tramadol	80,000	0.00125%
N-Desmethyl-cis-tramadol	>100,000	<0.001%

NFEN(Norfentanyl) (Norfentanyl, Cutoff=5ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Norfentanyl	5	100 %
Fentanyl	10,000	0.05%
Acetyl fentanyl	>10,000	<0.05%
Acetyl norfentanyl	200	2.5%
(±)-β-Hydroxythiofentanyl	>10,000	<0.05%
Acryl fentanyl	>10,000	<0.05%
Butyryl fentanyl	>10,000	<0.05%

(±)-cis-3-methyl Fentanyl	>10,000	<0.05%
Furanyl fentanyl	>10,000	<0.05%
para-Fluorobutyryl fentanyl (PFBF)	10,000	0.05%
para-Fluorofentanyl	>10,000	<0.05%
9-Hydroxyrisperidone	>100,000	<0.005%
Alfentanil	5,000	0.1%
Isobutyryl fentanyl	>100,000	<0.005%
4-Fluoro-isobutyryl fentanyl	>100,000	<0.005%
Norcarfentail	>10,000	<0.05%
Remifentanil	>10,000	<0.05%
Valeryl fentanyl	>10,000	<0.05%
Thienyl Fentanyl	>100,000	<0.005%
(±)-trans-3-methyl Fentanyl	>10,000	<0.05%
Despropionyl fentanyl (4-ANPP)	>10,000	<0.05%
MT-45	>100,000	<0.005%
Ocfentanil	>10,000	<0.05%
Isotonitazene	>100,000	<0.005%
Cyclopropylfentanyl	>10,000	<0.05%
AH-7921 HCL	>100,000	<0.005%
Risperidone	>100,000	<0.005%
Sufentanil	>10,000	<0.05%
Carfentanil	>10,000	<0.05%
Labetalol	>100,000	<0.005%
Trazodone	>100,000	<0.005%
U-47700	>100,000	<0.005%
ω-1-Hydroxyfentanyl	>100,000	<0.005%
6-Acetylmorphine	>100,000	<0.005%
Amphetamine	>100,000	<0.005%
Buprenorphine	>100,000	<0.005%
Buprenorphine -3-D-Glucuronide	>100,000	<0.005%
Codeine	>100,000	<0.005%
Dextromethorphan	>100,000	<0.005%
Dihydrocodeine	>100,000	<0.005%
EDDP	>100,000	<0.005%
EMDP	>100,000	<0.005%
Fluoxetine	>100,000	<0.005%
Heroin	>100,000	<0.005%
Hydrocodone	>100,000	<0.005%
Hydromorphone	>100,000	<0.005%
Ketamine	>100,000	<0.005%
Levorphanol	>100,000	<0.005%
Meperidine	>100,000	<0.005%
Methadone	>100,000	<0.005%

Morphine	>100,000	<0.005%
Morphine-3-β-D-glucuronide	>100,000	<0.005%
Naloxone	>100,000	<0.005%
Naltrexone	>100,000	<0.005%
Norbuprenorphine	>100,000	<0.005%
Norcodeine	>100,000	<0.005%
Norketamine	>100,000	<0.005%
Normeperidine	>100,000	<0.005%
Normorphine	>100,000	<0.005%
Noroxycodone	>100,000	<0.005%
Oxycodone	>100,000	<0.005%
Oxymorphone	>100,000	<0.005%
Pentazocine (Talwin)	>100,000	<0.005%
Pipamperone	>100,000	<0.005%
Tapentadol	>100,000	<0.005%
Thioridazine	>100,000	<0.005%
Tilidine	>100,000	<0.005%
cis-Tramadol	>100,000	<0.005%
O-Desmethyl-cis-tramadol	>100,000	<0.005%
N-Desmethyl-cis-tramadol	>100,000	<0.005%

MDMA(Ecstasy) (Ecstasy, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	500	100%
(±)-3,4-Methylenedioxyamphetamine (MDA)	5,000	10%
(±)-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
L-Methamphetamine	>100,000	<0.5%
7-Aminoclonazepam	>100,000	<0.5%
D-Methamphetamine	>100,000	<0.5%
D-Amphetamine	>100,000	<0.5%
L-Amphetamine	>100,000	<0.5%

MET(Methamphetamine) (Methamphetamine, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-3,4-Methylenedioxyethylamphetamine (MDEA)	30,000	1.67%

(±)-3,4-Methylenedioxymethamphetamine (MDMA)	5,000	10%
D-Methamphetamine	500	100%
L-Methamphetamine	15,000	3.33%
Fenfluramine	>100,000	<0.5%
p-Hydroxymethamphetamine	3,000	16.67%
(±)-Methamphetamine	500	100%
β-Phenylethylamine	>100,000	<0.5%
Mephetermine	10,000	5 %
Methoxyphenamine	>100,000	<0.5%
L-Amphetamine	>100,000	<0.5%
D-Amphetamine	>100,000	<0.5%
(±)-Amphetamine	>100,000	<0.5%
Chloroquine	>100,000	<0.5%
Ephedrine	>100,000	<0.5%
(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<0.5%
Trimethobenzamide	>100,000	<0.5%
l-phenylephrine	>100,000	<0.5%
(1R,2S)-(-)-Ephedrine	>100,000	<0.5%
Procaine	>100,000	<0.5%

MET(Methamphetamine) (Methamphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-3,4-Methylenedioxyethylamphetamine	>100,000	<1%
(±)-3,4-Methylenedioxymethamphetamine (MDMA)	10,000	10%
D-Methamphetamine	1,000	100%
L-Methamphetamine	25,000	4%
Fenfluramine	>100,000	<1%
p-Hydroxymethamphetamine	5,000	20%
(±)-Methamphetamine	2,000	50%
β-Phenylethylamine	>100,000	<1%
Mephetermine	30,000	3.33%
Methoxyphenamine	>100,000	<1%
L-Amphetamine	>100,000	<1%
D-Amphetamine	>100,000	<1%
(±)-Amphetamine	>100,000	<1%
Chloroquine	>100,000	<1%
Ephedrine	>100,000	<1%
(±)-3,4-Methylenedioxyamphetamine (MDA)	>100,000	<1%
Trimethobenzamide	>100,000	<1%

l-phenylephrine	>100,000	<1%
(1R,2S)-(-)-Ephedrine	>100,000	<1%
Procaine	>100,000	<1%

MOR(Morphine) (Morphine, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
6-Acetylmorphine	500	60%
Codeine	250	120%
Dihydrocodeine	500	60%
Ethylmorphine	300	100%
Heroin	500	60%
Hydrocodone	500	60%
Hydromorphone	500	60%
Levorphanol	5,000	6%
Morphine	300	100%
Nalorphine	3,000	10%
Thebaine	>100,000	<0.3%
Morphine-3-β-d-glucuronide	300	100%
Codeine-6-β-D-glucuronide	250	120%
Morphine-6-β-D-glucuronide	5,000	6%
6-Acetylcodeine	1,000	30%
Normorphine	>100,000	<0.3%
Oxycodone	>100,000	<0.3%
Oxymorphone	50,000	0.6%
Norcodeine	>100,000	<0.3%
Procaine	>100,000	<0.3%
Norpropoxyphene	>100,000	<0.3%

OPI(Morphine) (Morphine, Cutoff=2000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
6-Acetylmorphine	10,000	20%
Codeine	10,000	20%
Dihydrocodeine	10,000	20%
Ethylmorphine	5,000	40%
Heroin	20,000	10%
Hydrocodone	25,000	8%
Hydromorphone	25,000	8%
Levorphanol	>100,000	<2%
Morphine	2,000	100%

Nalorphine	>100,000	<2%
Thebaine	>100,000	<2%
Morphine-3-β-d-glucuronide	50,000	4%
Codeine-6-β-D-glucuronide	2,500	80%
Morphine-6-β-D-glucuronide	500	400%
6-Acetylcodeine	10,000	20%
Normorphine	>100,000	<2%
Oxycodone	>100,000	<2%
Oxymorphone	>100,000	<2%
Norcodeine	>100,000	<2%
Procaine	>100,000	<2%
Norpropoxyphene	>100,000	<2%

MTD(Methadone) (Methadone, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(±)-Methadone	300	100%
EDDP	>100,000	<0.3%
EMDP	>100,000	<0.3%
LAAM (Levo-alpha-acetylmethadol)	10,000	3%
Alpha Methadol	100	300%
Doxylamine	50,000	0.6%

OXY(Oxycodone) (Oxycodone, Cutoff=100ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Hydrocodone	20,000	0.5%
Hydromorphone	25,000	0.4%
Levorphanol	50,000	0.2%
Naloxone	30,000	0.33%
Naltrexone	20,000	0.5%
Oxycodone	100	100%
Oxymorphone	200	50%
Oxymorphone-3β-D-glucuronide	750	13.33%
Noroxycodone	2,500	4%
Noroxymorphone	1,000	10%
Dihydrocodeine	>100,000	<0.1%
Codeine	>100,000	<0.1%
Morphine	>100,000	<0.1%
Buprenorphine	>10,000	<0.1%
Ethylmorphine	>100,000	<0.1%
Thebaine	>100,000	<0.1%

6-Acetylmorphine	>100,000	<0.1%

PCP(Phencyclidine) (Phencyclidine, Cutoff=25ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	>100,000	<0.025%

PPX(Propoxyphene) (Propoxyphene, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Norpropoxyphene	500	60%
Propoxyphene	300	100%

TCA(Nortriptyline) (Nortriptyline, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Amitriptyline	10,000	10%
Chlorpheniramine	>100,000	<1%
Clomipramine	50,000	2%
Cyclobenzaprine	>100,000	<1%
Desipramine	500	200%
Doxepine	10,000	10%
Duloxetine	>100,000	<1%
Imipramine	50,000	2%
Norclomipramine	>100,000	<1%
Nordoxepin	5,000	20%
Nortriptyline	1,000	100%
Promazine	10,000	10%
Trimipramine	10,000	10%
Maprotiline	5,000	20%
Promethazine	>100,000	<1%

THC(Marijuana) (Marijuana, Cutoff=20ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(-)-11-nor-Δ^8-THC -9-COOH	50	40%
(-)-11-nor-9-carboxy-Δ^9-THC	20	100%
(±)-11-nor-9-carboxy-Δ9-THC	50	40%
11-nor-Δ^9-THC-carboxy glucuronide	5,000	0.4%

Δ^8-THC	8,000	0.25%
Δ^9-THC	>10,000	<0.2%
Cannabinol	>10,000	<0.2%
Cannabidiol	>100,000	<0.02%
(±)-11-hydroxy-Δ^9-THC	8,000	0.25%

THC(Marijuana) (Marijuana, Cutoff=50ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(-)-11-nor-Δ^8-THC -9-COOH	70	71.43%
(-)-11-nor-9-carboxy-Δ^9-THC	50	100%
(±)-11-nor-9-carboxy-Δ9-THC	150	33.33%
11-nor-Δ^9-THC-carboxy glucuronide	7,500	66.67%
Δ^8-THC	10,000	0.5%
Δ^9-THC	>10,000	<0.5%
Cannabinol	>10,000	<0.5%
Cannabidiol	>100,000	<0.05%
(±)-11-hydroxy-Δ^9-THC	10,000	0.5%

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

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

(-) Cotinine	Diclofenac	Norfentanyl (except FEN and NFEN tests)
(-)-11-nor-9-carboxy-Δ^9-THC (except THC test)	Diclofenac sodium	Norethindrone
4-Bromo-2,5-dimethoxyphenethylamine	Diflunisal	Norpropoxyphene (except PPX test)
7-Aminoclonazepam	Digoxin	Norpseudoephedrine
7-Aminoflunitrazepam	Diphenhydramine	Nortriptyline(except TCA test)
7-Aminonitrazepam	Diphenylhydantoin	Noscapine
Acetaminophen	Disopyramide	O-Hydroxyhippuric acid
Acetone (1000 mg/dL)	Dopamine (3-Hydroxytyramine)	Olanzapine
Acetophenetidin	Doxepine (except TCA test)	Omeprazole
Acyclovir	Doxylamine(except MTD test)	Oxalic acid (100mg/dL)
Albumin (100mg/dL)	Duloxetine	Oxazepam (except BZO test)
Albuterol	Ecgonine methyl ester	Oxazepam Glucuronide (except BZO test)
Alpha Methadol (except MTD test)	EMDP	Oxolinic acid
Aminophylline	Ephedrine	Oxymetazoline
Aminopyrine (4-Dimethyl-aminoantipyrine)	Erythromycin	Paliperidone
Amitriptyline(except TCA test)	Esomeprazole Magnesium	Papaverine

Amlodipine	Estrone	Penicillin-G
Amobarbital(except BAR test)	Ethanol (1%)	PenicillinV Potassium
Amoxicillin	Fenfluramine	Perphenazine
Ampicillin	Fenofibrate	Phenacetin
Apomorphine	Fentanyl (except FEN and NFEN tests)	Phencyclidine (except PCP test)
Aripiprazole	Fenoprofen	Phenelzine
Ascorbic acid (Vitamin C)	Fluoxetine	Pheniramine
Aspartame	Fluphenazine	Phenobarbital (except BAR test)
Aspirin (Acetylsalicylic acid)	Fotemustine	Phentermine (except AMP test)
Atomoxetine	Furosemide	Phenylethylamine
Atorvastatin Calcium	Gabapentin	Phenylpropanolamine
Atropine	Galactose	Prednisone
Azithromycin	Gatifloxacin	Pregabalin
Baclofen	Gemfibrozil	Procaine
Benzilic acid	Gentisic acid	Promazine (except TCA test)
Benzocaine	Guaiacolglyceryl ether	Promethazine
Benzoic acid	Hemoglobin	Propoxyphene (except PPX test)
Benzoylecgonine (except COC test)	Hexobarbital	Propranolol
Benzphetamine	Hydralazine	Pseudoephedrine
Benzylpiperiazine	Hydrochlorothiazide	Pyridoxine
Bilirubin	Hydrocortisone	Pyrilamine
Boric Acid (1%)	Hydroxybutyric Acid	Pyrogallol
Brompheniramine	Ibuprofen	Quetiapine
Bupropion	Imipramine (except TCA test)	Quinidine
Caffeine	Isoxsuprine	Quinine
Cannabidiol	Ketamine	Quinolinic Acid
Captopril	Ketoprofen	Ranitidine
Carbamazepine	L-Ephedrine	Riboflavin
Carfentanil (10ug/mL) (except FEN1 test)	L-Epinephrine	Risperidone
Carisoprodol	L-phenylephrine	Rifampicin
Cefradine	L-thyroxine	Salicylic acid
Cephalexin	LAAM (except MTD test)	Secobarbital(except BAR test)
Cetirizine	Labetalol	Serotonin (5- Hydroxytyramine)
Chloral hydrate	Lamotrigine	Sertraline
Chloramphenicol	Levofloxacin	Sildenafil Citrate
Chlordiazepoxide (except BZO test)	Levonorgestrel	Simvastatin
Chloroquine	Levothyroxine sodium	Sodium Azide
Chlorothiazide	Lidocaine	Sulfamethazine
Chlorpheniramine	Lisinopril	Sulindac
Chlorpromazine	Loperamide	Telmisartan
Cholesterol	Loratidine	Tetracycline
Ciprofloxacin	Lorazepam Glucuronide (except BZO test)	Tetrahydrocortisone 3-(β-Dglucuronide)
Citalopram	LSD	Tetrahydrocortisone, 3-acetate
Clarithromycin	Magnesium Chloride	Tetrahydrozoline
Clofibrate	Maprotiline(except TCA test)	Theophylline
Clomipramine (except TCA test)	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine

Clozapine	Metformin	Tramadol
Conjugated Estrogens	Methapyrilene	Trazodone
Cortisone	Methaqualone	Triamterene
Creatine	Methoxyphenamine	Trifluoperazine
Creatinine	Methylphenidate	Trifluoromethylphenyl-piperazine
Cyclobenzaprine	Metoprolol	Trimethobenzamide
Cyproheptadine	Metronidazole	Trimethoprim
D-(+)-Glucose (Glucose (3000 mg/dL)	Mifepristone	Tryptamine
D,L-Epinephrine	N-Acetylprocainamide	Tyramine
D,L-Isoproterenol	N-desmethyl Tapentadol	Urea (2000 mg/dL)
D,L-Lorazepam (except BZO test)	NaCl(4000 mg/dL)	Uric acid
D,L-Octopamine (Octopamine)	Nalidixic acid	Valproic acid (250 µg/mL)
D,L-Propranolol	Naloxone (except OXY test)	Venlafaxine
D,L-Tryptophan	Naltrexone (except OXY test)	Verapamil
D,L-Tyrosine	Naproxen	Vitamin B2
Delorazepam (10ug/mL)	Nicotinamide (Niacinamide)	Zaleplon
Demoxepam (except BZO test)	Nicotine	Zolpidem
Deoxycorticosterone	Nicotinic Acid	Zomepirac
Desipramine (except TCA test)	Nifedipine	β-Estradiol (Estradiol)
Desloratadine	Nitroglycerin	γ-Cyclodextrin (Cyclodextrin)
Dextromethorphan	Nordoxepin (except TCA test)	γ-Globulin (500mg/dL)

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

B. Method comparison study

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

Drug test	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%)
6AM10	Operator A	-	12	16	11	1	0
		+	0	0	1	15	24
	Operator B	-	12	16	11	0	0
		+	0	0	1	16	24

	Operator C	-	12	16	11	0	0
		+	0	0	1	16	24
AMP500	Operator A	-	12	16	12	1	0
		+	0	0	0	12	27
	Operator B	-	12	16	12	2	0
		+	0	0	0	11	27
	Operator C	-	12	16	12	1	0
		+	0	0	0	12	27
AMP1000	Operator A	-	12	17	11	0	0
		+	0	0	0	15	25
	Operator B	-	12	17	11	1	0
		+	0	0	0	14	25
	Operator C	-	12	17	11	1	0
		+	0	0	0	14	25
BAR300	Operator A	-	8	13	18	0	0
		+	0	0	1	16	24
	Operator B	-	8	13	17	0	0
		+	0	0	2	16	24
	Operator C	-	8	13	17	0	0
		+	0	0	2	16	24
BUP10	Operator A	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator B	-	15	14	10	1	0
		+	0	0	1	17	22
	Operator C	-	15	14	10	1	0
		+	0	0	1	17	22
BZO300	Operator A	-	8	17	13	0	0
		+	0	0	2	12	28
	Operator B	-	8	17	14	0	0
		+	0	0	1	12	28
	Operator C	-	8	17	13	0	0
		+	0	0	2	12	28
COC150	Operator A	-	12	13	14	2	0
		+	0	0	1	13	25
	Operator B	-	12	13	14	1	0
		+	0	0	1	14	25
	Operator C	-	12	13	14	1	0
		+	0	0	1	14	25
COC300	Operator A	-	12	18	10	1	0
		+	0	0	0	15	24
	Operator B	-	12	18	9	1	0
		+	0	0	1	15	24

	Operator C	-	12	18	10	0	0
		+	0	0	0	16	24
EDDP300	Operator A	-	11	16	12	1	0
		+	0	0	1	13	26
	Operator B	-	11	16	13	1	0
		+	0	0	0	13	26
	Operator C	-	11	16	11	1	0
		+	0	0	2	13	26
FEN1	Operator A	-	9	15	14	0	0
		+	0	0	2	15	25
	Operator B	-	9	15	14	1	0
		+	0	0	2	14	25
	Operator C	-	9	15	13	0	0
		+	0	0	3	15	25
NFEN5	Operator A	-	10	16	11	0	0
		+	0	0	3	16	24
	Operator B	-	10	16	12	1	0
		+	0	0	2	15	24
	Operator C	-	10	16	11	0	0
		+	0	0	3	16	24
MDMA500	Operator A	-	10	20	10	0	0
		+	0	0	0	12	28
	Operator B	-	10	20	9	1	0
		+	0	0	1	11	28
	Operator C	-	10	20	9	0	0
		+	0	0	1	12	28
MET500	Operator A	-	13	14	13	1	0
		+	0	0	0	11	28
	Operator B	-	13	14	12	0	0
		+	0	0	1	12	28
	Operator C	-	13	14	11	1	0
		+	0	0	2	11	28
MET1000	Operator A	-	13	16	11	1	0
		+	0	0	0	14	25
	Operator B	-	13	16	11	1	0
		+	0	0	0	14	25
	Operator C	-	13	16	11	1	0
		+	0	0	0	14	25
MTD300	Operator A	-	11	14	15	1	0
		+	0	0	0	12	27
	Operator B	-	11	14	14	0	0
		+	0	0	1	13	27

	Operator C	-	11	14	15	1	0
		+	0	0	0	12	27
MOR300	Operator A	-	12	15	12	0	0
		+	0	0	1	14	26
	Operator B	-	12	15	13	1	0
		+	0	0	0	13	26
	Operator C	-	12	15	13	1	0
		+	0	0	0	13	26
OPI2000	Operator A	-	12	14	14	0	0
		+	0	0	0	18	22
	Operator B	-	12	14	14	1	0
		+	0	0	0	17	22
	Operator C	-	12	14	14	2	0
		+	0	0	0	16	22
OXY100	Operator A	-	11	15	13	1	0
		+	0	0	1	12	27
	Operator B	-	11	15	13	1	0
		+	0	0	1	12	27
	Operator C	-	11	15	12	1	0
		+	0	0	2	12	27
PCP25	Operator A	-	13	15	10	0	0
		+	0	0	2	14	26
	Operator B	-	13	15	11	0	0
		+	0	0	1	14	26
	Operator C	-	13	15	11	1	0
		+	0	0	1	13	26
PPX300	Operator A	-	11	15	13	0	0
		+	0	0	1	13	27
	Operator B	-	11	15	13	0	0
		+	0	0	1	13	27
	Operator C	-	11	15	13	0	0
		+	0	0	1	13	27
TCA1000	Operator A	-	9	16	14	0	0
		+	0	0	1	14	26
	Operator B	-	9	16	13	0	0
		+	0	0	2	14	26
	Operator C	-	9	16	14	0	0
		+	0	0	1	14	26
THC20	Operator A	-	13	15	12	2	0
		+	0	0	0	14	24
	Operator B	-	13	15	10	1	0
		+	0	0	2	15	24

	Operator C	-	13	15	11	1	0
		+	0	0	1	15	24
THC50	Operator A	-	11	17	12	0	0
		+	0	0	0	14	26
	Operator B	-	11	17	12	2	0
		+	0	0	0	12	26
	Operator C	-	11	17	12	1	0
		+	0	0	0	13	26

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Accurate Result
6AM	A	V63	12.050	-
	B	V404	9.847	+
	A, C	V927	8.340	+
AMP500	B, C	V157	521.19	-
	A	V269	535.83	-
	B	V326	578.93	-
AMP1000	C	V379	1148.25	-
	B	V675	1107.17	-
BAR300	A, B	V97	282.40	+
	B, C	V236	287.92	+
	C	V1080	291.50	+
BUP10	A, C	V4	7.940	+
	B, C	V597	11.440	-
	B	V1072	8.880	+
	A	V1267	11.620	-
BZO300	C	V430	252.97	+
	A	V532	288.67	+
	A, C	V599	296.95	+
	B	V1101	276.94	+
COC150	A	V42	185.78	-
	B	V147	177.26	-
	C	V206	141.23	+
	A	V272	172.68	-
	B	V1051	135.25	+
	A	V1208	126.14	+
	C	V1245	159.79	-
COC300	B	V31	308.60	-
	A	V51	319.05	-
	B	V498	268.11	+
EDDP300	A	V193	312.04	-
	C	V367	311.54	-

	B	V794	308.49	-
	C	V1176	281.27	+
	A, C	V1183	239.61	+
FEN1	B, C	V158	0.908	+
	A	V253	0.874	+
	B, C	V396	0.911	+
	B	V663	1.211	-
	C	V1214	0.936	+
	A	V1278	0.910	+
NFEN5	A, C	V312	4.929	+
	A, B, C	V319	4.995	+
	A, B, C	V1010	4.998	+
	B	V1271	5.208	-
MDMA500	B	V254	411.27	+
	C	V1275	433.84	+
	B	V1177	576.19	-
MET500	A, C	V464	603.62	-
	C	V713	451.20	+
	B, C	V949	395.63	+
MET1000	B	V610	1095.29	-
	A	V692	1094.78	-
	C	V1050	1139.22	-
MTD300	C	V72	327.41	-
	A	V1095	324.39	-
	B	V1205	235.96	+
MOR300	C	V329	345.89	-
	A	V742	251.00	+
	B	V899	361.11	-
OPI2000	B	V615	2073.55	-
	C	V1084	2016.19	-
	C	V1280	2099.08	-
OXY100	B	V504	88.02	+
	C	V731	98.20	+
	A	V764	93.25	+
	C	V842	91.44	+
	A, C	V1009	105.20	-
	B	V1071	119.87	-
PCP25	C	V67	30.01	-
	A	V484	22.14	+
	A, B	V745	24.06	+
	C	V1048	23.30	+
PPX300	B	V268	267.51	+
	A, C	V992	268.19	+

TCA100	A	V105	914.22	+
	C	V201	886.50	+
	B	V452	928.62	+
	B	V861	917.240	+
THC20	A, C	V124	21.11	-
	B	V133	22.19	-
	A	V271	22.55	-
	B	V826	18.33	+
	B, C	V943	18.76	+
	A, C	V124	21.11	-
THC50	B	V734	54.36	-
	B, C	V844	58.23	-

C. Lay person study

A lay user study was performed at three intended user sites with 280 lay persons. 126 male and 154 female tested the VINScreen Urine Drug Test Cup. They had diverse educational and professional 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 below.

Result of The VINScreen Urine Drug Test Cup: Configuration 1

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
6-MAM	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
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%	95.0%	95.0%	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%	95.0%	95.0%	100%	100%
BUP	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	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%	95.0%	100%	100%
COC	150	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	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%	95.0%	95.0%	100%	100%
FEN	1	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
NFEN	5	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
MDMA	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%	95.0%	95.0%	100%	100%
MET	500	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
MOP	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
MTD	300	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	100%	100%	100%
OXY	100	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	100%	100%	100%
PCP	25	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%	95.0%	95.0%	100%	100%
PPX	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
TCA	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%	95.0%	100%	100%
THC	20	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	90.0%	100%	100%

Result of The VINScreen Urine Drug Test Cup: Configuration 2

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
6-MAM	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%	95.0%	95.0%	100%	100%
AMP	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%	95.0%	95.0%	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%	95.0%	95.0%	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%	95.0%	95.0%	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%	95.0%	95.0%	100%	100%
COC	300	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	100%	100%	100%
EDDP	300	Negative	20	20	20	19	1	0	0

		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
FEN	1	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
NFEN	5	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%	95.0%	95.0%	100%	100%
MDMA	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%	95.0%	95.0%	100%	100%
MET	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%	95.0%	100%	100%	100%
MTD	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%	95.0%	100%	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%	95.0%	95.0%	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%	95.0%	95.0%	100%	100%
PCP	25	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
PPX	300	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
TCA	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%	95.0%	100%	100%

THC	50	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	90.0%	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 The VINScreen Urine Drug Test Cup and The VINScreen Urine Drug Home Test Cup are substantially equivalent to the predicate device.