



April 15, 2025

ANHUI Deepblue Medical Technological Co., Ltd.
% Jenny Xia
Director
LSI International, Inc.
504 East Diamond Ave, Suite H
Gaithersburg, Maryland 20877

Re: K250803

Trade/Device Name: Deepblue Multi-Drug Urine Test Cup; Deepblue Home Muti-Drug Urine Test Cup
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: NGL, PTH, NFT, NFV, NFY, PTG, NGG, NGM, QBF, QAW, NFW
Dated: March 16, 2025
Received: March 17, 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: 2025.04.15
15:16:37 -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

510(k) Number (if known)

K250803

Device Name

Deepblue Multi-Drug Urine Test Cup;

Deepblue Home Multi-Drug Urine Test Cup

Indications for Use (Describe)

The Deepblue Multi-Drug Urine Test Cup is a rapid lateral flow immunoassay for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoylcegonine, Buprenorphine, EDDP, fentanyl, Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrator	Cut-off(ng/mL)
6-MAM	6-Monoacetylmorphine	10
AMP	d-Amphetamine	500 or 1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylcegonine	150 or 300
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
FYL	Fentanyl	1
MDMA	Methylenedioxymethamphetamine	500
MET	d-Methamphetamine	500 or 1000
MTD	d/l-Methadone	300
MOP/OPI	Morphine	300 or 2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	d-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-COOH	50

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination with or without on-board adulteration/specimen validity tests (SVT).

The tests provide only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive 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.

The Deepblue Home Multi-Drug Urine Test Cup is a rapid qualitative immunoassay.

The device provides preliminary results for the detection of one or more of the following drugs.

Code	Substance	Cut-off(ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	EDDP	300

FYL	Fentanyl	1
MET	Methamphetamine	1000 or 500
MDMA	Ecstasy	500
OPI	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50
6-MAM	6-Monoacetylmorphine	10

This drug test cup may contain any combination of the drug tests listed in the table above.

This test provides only preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive 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.

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
K250803

- 1. Date:** March 9, 2025
- 2. Submitter:** ANHUI Deepblue Medical Technological Co., Ltd.
Pearl Industrial Park, 106 Innovation Ave.
Hefei, Anhui 230088
China
- 3. Contact person:** Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Email: jxia@lsi-consulting.org
- 4. Device Name:** Deepblue Multi-Drug Urine Test Cup
Deepblue Home Muti-Drug Urine Test Cup
- 5. Classification:** Class II

Product Code Target Drug	Regulation Section	Panel
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NGL Buprenorphine (BUP) Morphine (OPI) Oxycodone (OXY) 6-Monoacetylmorphine(6-MAM) Fentanyl (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
NGM	Unclassified	Toxicology

Phencyclidine (PCP)		
QBF Propoxyphene(PPX)	862.3700 Propoxyphene test system.	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids (THC 50)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Devices:

Healgen Accurate Urine Drug Screen Dip Card (K240686)

7. Intended Use

The Deepblue Multi-Drug Urine Test Cup is a rapid lateral flow immunoassay for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoylcegonine, Buprenorphine, EDDP, fentanyl, Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, and THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrator	Cut-off (ng/mL)
6-MAM	6-Monoacetylmorphine	10
AMP	d-Amphetamine	500 / 1000
BAR	Secobarbital	300
BUP	Buprenorphine	10
BZO	Oxazepam	300
COC	Benzoylcegonine	150 / 300
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
FYL	Fentanyl	1
MDMA	Methylenedioxymethamphetamine	500
MET	d-Methamphetamine	500 / 1000
MTD	d/l-Methadone	300
OPI	Morphine	300 / 2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	d-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- Δ^9 -THC-COOH	50

The single or multi-test cups can consist of up to seventeen (17) of the above listed analytes in any combination with or without on-board adulteration/specimen validity tests (SVT).

The tests provide only a preliminary result. A more specific alternative chemical method must be used to obtain a confirmed presumptive 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.

The Deepblue Home Multi-Drug Urine Test Cup is a rapid qualitative immunoassay.

The device provides preliminary results for the detection of one or more of the following drugs.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	EDDP	300
FYL	Fentanyl	1
MET	Methamphetamine	1000 or 500
MDMA	Ecstasy	500
OPI	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50
6-MAM	6-Monoacetylmorphine	10

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

8. Device Description

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

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

9. Substantial Equivalence Information

Similarities			
Item	Device		Predicate (K240686)
Intended use	Qualitative detection of drugs of abuse in urine. For prescription use or 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 no Fentanyl
	Amphetamine(AMP)	1000 or 500	
	Secobarbital (BAR)	300	
	Buprenorphine (BUP)	10	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Fentanyl	1	
	Methylenedioxymethamphetamine (MDMA)	500	
	Methamphetamine (MET)	1000 or 500	
	Morphine (MOP300/OPI2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene(PPX)	300	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC)	50	
	6-Monoacetylmorphine(6-MAM)	10	
Differences			
Configurations	Test cup		Test Dip Card

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

Deepblue Home Muti-Drug Urine Test Cup or Deepblue Muti-Drug Urine 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 conjugate binding sites.

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

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

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

12. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility:

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

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
AMP 1000	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	8-/42+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	4-/46+	11-/39+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	7-/43+	48-/2+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	4-/46+	17-/33+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	14-/36+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	15-/35+	48-/2+	50-/0+	50-/0+	50-/0+

BUP 10	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	19-/31+	46-/4+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	18-/32+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	18-/32+	47-/3+	50-/0+	50-/0+	50-/0+
BZO 300	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	15-/35+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	16-/34+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	14-/36+	47-/3+	50-/0+	50-/0+	50-/0+
COC 300	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	9-/41+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	8-/42+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	12-/38+	49-/1+	50-/0+	50-/0+	50-/0+
EDDP 300	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	10-/40+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	10-/40+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	10-/40+	47-/3+	50-/0+	50-/0+	50-/0+
FYL 1	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	18-/32+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	4-/46+	20-/30+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	18-/32+	46-/4+	50-/0+	50-/0+	50-/0+
MDM A 500	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	12-/38+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	14-/36+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	15-/35+	48-/2+	50-/0+	50-/0+	50-/0+
MET 1000	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	10-/40+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	8-/42+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	7-/43+	48-/2+	50-/0+	50-/0+	50-/0+
MOP 300	Lot 1	0-/50+	0-/50+	0-/50+	4-/46+	10-/40+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	12-/38+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	13-/37+	48-/2+	50-/0+	50-/0+	50-/0+
MTD 300	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	17-/33+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	19-/31+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	20-/30+	47-/3+	50-/0+	50-/0+	50-/0+
OXY 100	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	10-/40+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	9-/41+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	10-/40+	47-/3+	50-/0+	50-/0+	50-/0+
PCP 25	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	17-/33+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	20-/30+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	18-/32+	48-/2+	50-/0+	50-/0+	50-/0+
PPX 300	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	22-/28+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	47-/3+	50-/0+	50-/0+	50-/0+
TCA 1000	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	20-/30+	46-/4+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	18-/32+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	21-/29+	47-/3+	50-/0+	50-/0+	50-/0+
THC 50	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	4-/46+	26-/24+	49-/1+	50-/0+	50-/0+	50-/0+

	Lot 3	0-/50+	0-/50+	0-/50+	4-/46+	22-/28+	48-/2+	50-/0+	50-/0+	50-/0+
6-MAM 10	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	11-/39+	46-/4+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	14-/36+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	9-/41+	48-/2+	50-/0+	50-/0+	50-/0+
AMP 500	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	11-/39+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	12-/38+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	11-/39+	47-/3+	50-/0+	50-/0+	50-/0+
COC 150	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	12-/38+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	14-/36+	46-/4+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	3-/47+	10-/40+	48-/2+	50-/0+	50-/0+	50-/0+
MET 500	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	9-/41+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	4-/46+	10-/40+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	8-/42+	48-/2+	50-/0+	50-/0+	50-/0+
OPI 2000	Lot 1	0-/50+	0-/50+	0-/50+	3-/47+	12-/38+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	3-/47+	14-/36+	47-/3+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	4-/46+	15-/35+	47-/3+	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°C for 24 months based on real time stability study.

d. Analytical specificity/Interference:

To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of the device.

Percent cross-reactivity, provided in the below table, was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100. If no cross-reactivity was observed, the highest concentration tested is shown.

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
AMP 1000	Hydroxyamphetamine	8000	12.5%
	(+/-)-Methylenedioxyamphetamine (MDA)	10000	10%
	D,L-Amphetamine	1,000	100%
	D-Amphetamine	1,000	100%
	Diethylstilbestrol	>100000	<1%

	L-Amphetamine	50000	2%
	Phentermine	10000	10%
	β-Phenylethylamine	100000	1%
	Tyramine	100000	1%
	p-Hydroxynorephedrine	100000	1%
	D,L-Norephedrine	100000	1%
	p-Hydroxyamphetamine	100000	1%
	D-Methamphetamine	>100000	<1%
	L-Methamphetamine	>100000	<1%
	Ephedrine hydrochloride	>100000	<1%
	(+/-)3,4-Methylenedioxymethamphetamine(MDMA)	>100000	<1%
	Phenylpropanolamine	>100000	<1%
	Benzphetamine	>100000	<1%
	L-Ephedrine	>100000	<1%
	L-Epinephrine	>100000	<1%
	D,L-Epinephrine	>100000	<1%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	>100000	<1%
BAR 300	Alphenal	150	200%
	Amobarbital	300	100%
	Aprobarbital	300	100%
	Butabarbital	100	300%
	Butethal	100	300%
	Cyclopentobarbital	500	60%
	Pentobarbital	200	150%
	Phenobarbital	200	150%
	Secobarbital	300	100%
	Butalbital	2500	12%
BUP 10	Buprenorphine	10	100%
	Buprenorphine -3-D-Glucuronide	10	100%
	Norbuprenorphine	20	50%
	Norbuprenorphine-3-D-Glucuronide	200	5%
	Morphine	>100000	<0.01%

	Oxymorphone	>100000	<0.01%
	Hydromorphone	>100000	<0.01%
BZO 300	a-Hydroxyalprazolam	1000	30%
	Alprazolam	200	150%
	Bromazepam	1000	30%
	Chlordiazepoxide	1500	20%
	Clobazam	100	300%
	Clonazepam	2500	12%
	Clorazepate Dipotassium	200	150%
	Desalkylflurazepam	500	60%
	Diazepam	200	150%
	Estazolam	500	60%
	Flunitrazepam	400	75%
	D,L-Lorazepam	1000	30%
	Midazolam	10000	3%
	Nitrazepam	100	300%
	Norchlordiazepoxide	200	150%
	Nordiazepam	200	150%
	Oxazepam	300	100%
	R,S-Lorazepam glucuronide	200	150%
	Temazepam	100	300%
	Triazolam	2500	12%
	Demoxepam	2000	15%
	Flurazepam	500	60%
	Delorazepam	10000	3%
COC 300	Benzoyllecgonine	300	100%
	Cocaethylene	12500	2.4%
	Cocaine hydrochloride	200	150%
	Ecgonine	>100000	<0.3%
	Norcocaine	100000	0.3%
	Ecgonine methyl ester	>100000	<0.3%
EDDP 300	EDDP	300	100%
	Methadone	>100000	<0.3%
	EMDP	>100000	<0.3%

	Doxylamine	>100000	<0.3%
	Disopyramide	100000	0.3%
	LAAM (Levo-alpha-acetylmethadol) hydrochloride	>100000	<0.3%
	Alpha Methadol	>100000	<0.3%
FYL 1	Norfentanyl	>100000	<0.001%
	Fentanyl	1	100%
	Acetyl fentanyl	1	100%
	Acetyl Norfentanyl	>100000	<0.001%
	(±)-β-Hydroxythiofentanyl HCl	1	100%
	Acryl Fentanyl	1	100%
	Butyryl Fentanyl	2	50%
	Cis-d, I 3-Methylfentanyl	50	2%
	Furanyl Fentanyl	5	20%
	Para-fluoro butyrl Fentanyl (P-FBF)	3	33.3%
	Para-fluoro Fentanyl	3	33.3%
	9-Hydroxy Risperidone	10000	0.01%
	Alfentanil	5000	0.02%
	Isobutyryl Fentanyl	1	100%
	4-Fluoro-isobutyryl Fentanyl	50	2%
	Norcarfentail Oxalate	10000	0.01%
	Remifentanil	>100000	<0.001%
	Valeryl Fentanyl	10	10%
	Thienyl Fentanyl	1000	0.1%
	Trans-d, I 3-Methylfentanyl	1000	0.1%
	Despropionyl fentanyl (4-ANPP)	2500	0.04%
	MT-45	10000	0.01%
	Ocfentanil	2	50%
	Risperidone	>100000	<0.001%
	Sufentanil	10	10%
	Carfentanil Oxalate	500	0.2%
	Labetalol Hydrochloride	>100000	<0.001%
	Trazodone	>100000	<0.001%
	U-47700	>100000	<0.001%

	ω-1-Hydroxyfentanyl	20000	0.005
	6-Acetyl morphine	>100000	<0.001%
	Amphetamine	>100000	<0.001%
	Buprenorphine	>100000	<0.001%
	Buprenorphineglucuronide	>100000	<0.001%
	Codeine	>100000	<0.001%
	Dextromethorphan	>100000	<0.001%
	Dihydrocodeine	>100000	<0.001%
	EDDP	>100000	<0.001%
	EMDP	>100000	<0.001%
	Fluoxetine	>100000	<0.001%
	Heroin	>100000	<0.001%
	Hydrocodone	>100000	<0.001%
	Hydromorphone	>100000	<0.001%
	Ketamine	>100000	<0.001%
	Levorphanol	>100000	<0.001%
	Meperidine	>100000	<0.001%
	Methadone	>100000	<0.001%
	Morphine	>100000	<0.001%
	Morphine-3-glucuronide	>100000	<0.001%
	Naloxone	>100000	<0.001%
	Naltrexone	>100000	<0.001%
	Norbuprenorphine	>100000	<0.001%
	Norcodeine	>100000	<0.001%
	Norketamine	>100000	<0.001%
	Normeperidine	>100000	<0.001%
	Normorphine	>100000	<0.001%
	Noroxycodone	>100000	<0.001%
	Oxycodone	>100000	<0.001%
	Oxymorphone	>100000	<0.001%
	Pentazocine (Talwin)	>100000	<0.001%
	Pipamperone	>100000	<0.001%
	Tapentadol	>100000	<0.001%
	Thioridazine	>100000	<0.001%

	Tilidine	>100000	<0.001%
	Tramadol	>100000	<0.001%
	Tramadol-O-Desmethyl	>100000	<0.001%
	Tramadol-N-Desmethyl	>100000	<0.001%
MDMA 500	(+/-)3,4-Methylenedioxy-n-Ethylamphetamine (MDEA)	>100000	<0.5%
	(+/-)-Methylenedioxyamphetamine(MDA)	5000	10%
	(±)-MDMA	500	100%
	L-Methamphetamine	100000	0.5%
	d-methamphetamine	100000	0.5%
	d-amphetamine	>100000	<0.5%
	l-amphetamine	>100000	<0.5%
MET 1000	(+/-)3,4-Methylenedioxy-n-Ethylamphetamine (MDEA)	>100000	<1%
	(±)-MDMA	2000	50%
	D-Methamphetamine	1000	100%
	L-Methamphetamine	25000	4%
	Fenfluramine	50000	2%
	p-Hydroxymethamphetamine	10000	10%
	D,L-Methamphetamine	1000	100%
	β-Phenylethylamine	50000	2%
	Mephetermine	50000	2%
	Methoxyphenamine hydrochloride	10000	1%
	L-Amphetamine	75000	1.3%
	D-Amphetamine	>100000	<1%
	D,L-Amphetamine	>100000	<1%
	Chloroquine	100000	1%
	Ephedrine hydrochloride	50000	2%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	100000	1%
	Trimethobenzamide	100000	1%
	l-phenylephrine	50000	2%
	(1R,2S)-(-)-Ephedrine	100000	1%
	Procaine hydrochloride	>100000	<1%

MOP 300	6-acetylmorphine	100	300%
	Codeine	300	100%
	Dihydrocodeine	1000	30%
	EthylMorphine	300	100%
	Heroin	500	60%
	Hydrocodone	1000	30%
	Hydromorphone	10000	3%
	Levorphanol tartrate	1500	20%
	Morphine	300	100%
	Nalorphine hydrochloride	300	100%
	Thebaine	10000	3%
	s-Monoacetylmorphine	300	100%
	Morphine-3-β-d-glucuronide	300	100%
	6-Monoacetylmorphine	300	100%
	Codeine-6-β-D-glucuronide	25000	1.2%
	Morphine-6-β-D-glucuronide	1000	30%
	6-Acetylcodeine	25000	1.2%
	Normorphine	50000	0.6%
	Oxycodone	>100000	<0.3%
	Oxymorphone	>100000	<0.3%
	Norcodeine	25000	1.2%
	Procaine hydrochloride	>100000	<0.3%
	Norpropoxyphene	>100000	<0.3%
MTD 300	(±)-Methadone	300	100%
	EDDP	>100000	<0.3%
	EMDP	>100000	<0.3%
	LAAM	>100000	<0.3%
	Alpha Methadol	>100000	<0.3%
	Doxylamine	>100000	<0.3%
OXY 100	Ethyl Oxycodone	50000	0.2%
	Hydrocodone	5000	2%
	Hydromorphone	100000	0.1%
	Levorphanol tartrate	50000	0.2%
	Naloxone hydrochloride	50000	0.2%

	Naltrexone hydrochloride	50000	0.2%
	Oxycodone	100	100%
	Oxymorphone	200	50%
	Oxymorphone-3 β -D-glucuronide	500	20%
	Noroxycodone	1000	10%
	Noroxymorphone	2500	4%
	Dihydrocodeine	20000	0.5%
	Codeine	100000	0.1%
	Morphine	>100000	<0.1%
	Buprenorphine	>100000	<0.1%
	Ethylmorphine	>100000	<0.1%
	Thebaine	>100000	<0.1%
	6-acetylmorphine	>100000	<0.1%
PCP 25	Phencyclidine	25	100%
	4-Hydroxy Phencyclidine	12,500	0.2%
PPX 300	d-Propoxyphene	300	100%
	d-Norpropoxyphene	300	100%
TCA 1000	Amitriptyline	1000	100%
	Chlorpheniramine	50000	2%
	Clomipramine	1000	100%
	Cyclobenzaprine Hydrochloride	1000	100%
	Desipramine	300	333%
	Doxepine	1000	100%
	Duloxetine	>100000	<1%
	Imipramine	500	200%
	Norclomipramine	500	200%
	Nordoxepine	10000	10%
	Nortriptyline	1000	100%
	Promazine	2000	50%
	Trimipramine	3000	33.3%
	Maprotiline	>100000	<1%
	Promethazine hydrochloride	50000	2%
THC 50	11-nor- Δ 8-THC -9-COOH	30	166%
	(-)-11-nor-9-carboxy- Δ 9-THC	50	100%

	(±)-11-nor-9-Carboxy-Δ9-THC	50	100%
	11-nor-Δ9-THC -carboxy glucuronide	50	100%
	11-hydroxy-Δ9-Tetrahydrocannabinol	5000	1%
	Δ8- Tetrahydrocannabinol	5000	1%
	Δ9- Tetrahydrocannabinol	10000	0.5%
	Cannabinol	10000	0.5%
	Cannabidiol	>100000	<0.05%
	(±)-11-Hydroxy-Δ9-THC	>100000	<0.05%
6-MAM 10	6-acetylmorphine	10	100%
	Heroin	50	20%
	Morphine	10000	0.1%
	Normorphine	100000	0.01%
	Nalorphine HCl	100000	0.01%
	Hydrocodone	100000	0.01%
	Hydromorphone	100000	0.01%
	Chlordiazepoxide	100000	0.01%
	Clobazam	100000	0.01%
	D-Amphetamine	>100000	<0.01%
	(±)-Amphetamine	>100000	<0.01%
	Levorphanol tartrate	100000	0.01%
	Codeine	>100000	<0.01%
	Ethylmorphine	>100000	<0.01%
	Morphine3-β-D-glucuronide	100000	0.01%
	Norcodeine	100000	0.01%
	Oxycodone	>100000	<0.01%
	Oxymorphone	>100000	<0.01%
	Procaine hydrochloride	>100000	<0.01%
	Thebaine	>100000	<0.01%
	6-Acetylcodeine	100000	0.01%
	Buprenorphine	>100000	<0.01%
	Dihydrocodeine	>100000	<0.01%
	Dextromethorphan	>100000	<0.01%
	Imipramine hydrochloride	>100000	<0.01%

	Meperidine	>100000	<0.01%
	(±)-Methadone	>100000	<0.01%
	Mitragynine(kratom)	100000	0.01%
	Morphine-6-β-D-glucuronide	100000	0.01%
	Naloxone hydrochloride	>100000	<0.01%
	Naltrexone hydrochloride	>100000	<0.01%
	Naproxen	>100000	<0.01%
	Norbuprenorphine	>100000	<0.01%
	Norbuprenorphine-3-D-Glucuronide	100000	0.01%
	Noroxycodone HCL	>100000	<0.01%
	Noroxymorphone HCL	>100000	<0.01%
	Norpropoxyphene	>100000	<0.01%
	Oxymorphone-3β-D-glucuronide	>100000	<0.01%
	Tapentadol hydrochloride	>100000	<0.01%
	Tramadol hydrochloride	>100000	<0.01%
AMP 500	Hydroxyamphetamine	4000	12.5%
	(+/-)-Methylenedioxyamphetamine(MDA)	200	250%
	D,L-Amphetamine	500	100%
	D-Amphetamine	500	100%
	Diethylstilbestrol	>100000	<0.5%
	L-Amphetamine	10000	5%
	Phentermine	4000	12.5%
	β-Phenylethylamine	50000	1%
	Tyramine	10000	5%
	p-Hydroxynorephedrine	50000	1%
	p-Hydroxyamphetamine	50000	1%
	D,L-Norephedrine	50000	1%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	>100000	<0.5%
	d-Methamphetamine	>100000	<0.5%
	l-Methamphetamine	>100000	<0.5%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>10000	<5%
	Ephedrine hydrochloride	>100000	<0.5%

	Phenylpropanolamine	>100000	<0.5%
	Benzphetamine	>100000	<0.5%
	L-Ephedrine	>100000	<0.5%
	L-Epinephrine	>100000	<0.5%
	D,L-Epinephrine	>100000	<0.5%
COC 150	Benzoyllecgonine	150	100%
	Cocaethylene	150	100%
	Cocaine hydrochloride	100	150%
	Ecgonine	>100000	<0.15%
	Norcocaine	>100000	<0.15%
	Ecgonine methyl Ester	>100000	<0.15%
MET 500	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	>100000	<0.5%
	(±)-MDMA	1000	50%
	D-Methamphetamine	500	100%
	L-Methamphetamine	10000	5%
	Fenfluramine	25000	2%
	p-Hydroxymethamphetamine	5000	10%
	D,L-Methamphetamine	500	100%
	β-Phenylethylamine	10000	5%
	Mephetermine	25000	2%
	Methoxyphenamine hydrochloride	50000	1%
	L-Amphetamine	100000	0.5%
	Ephedrine hydrochloride	100000	0.5%
	(1R,2S)-(-)-Ephedrine	>100000	<0.5%
	D-Amphetamine	>100000	<0.5%
	Chloroquine	100000	0.5%
	(+/-)3,4-Methylenedioxymphetamine(MDA)	>100000	<0.5%
	L-Phenylephrine	100000	0.5%
	Trimethobenzamide	100000	0.1%
	Procaine hydrochloride	>100000	<0.5%
	d/l-Amphetamine	100000	0.5%

OPI 2000	6-acetylmorphine	10000	20%
	Codeine	1000	200%
	Dihydrocodeine	1500	133.3%
	EthylMorphine	2500	80%
	Codeine-6-β-D-glucuronide	2500	80%
	Heroin	5000	40%
	Hydrocodone	5000	40%
	Hydromorphone	2500	80%
	Levorphanol tartrate	10000	20%
	Morphine	2000	100%
	Nalorphine hydrochloride	5000	40%
	Norcodeine	4000	50%
	Normorphine	50000	4%
	Oxymorphone	25000	8%
	s-Monoacetylmorphine	5000	40%
	Morphine-6-β-D-glucuronide	2000	100%
	Thebaine	10000	20%
	Morphine 3-β-D-glucuronide	2000	100%
	6-Monoacetylmorphine (6-MAM)	1500	133.3%
	6-Acetylcodeine	10000	20%
	Oxycodone	>100000	<2%
	Procaine	>100000	<2%
	Norpropoxyphene	>100000	<2%

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 are summarized in the following table.

(-) Cotinine	Diflunisal	Norethindrone
3-Hydroxytyramine(except AMP test)	Digoxin	Norpropoxyphene
7-Aminoflunitrazepam(except MDMA test)	Dimethyl-aminoantipyrine	Norpseudoephedrine
7-Aminonitrazepam	Diphenhydramine HCl	Nortriptyline(except TCA test)
Acetaminophen	Diphenylhydantoin	Noscapine
Acetone (1000 mg/dL)	Disopyramide	Octopamine

Acetophenetidin	Dopamine HCl (except AMP TCA test)	O-Hydroxyhippuric acid
Acetylsalicylic acid	Doxepine(except TCA test)	Olanzapine
Acyclovir	Doxylamine	Omeprazole
Albumin(100mg/dL)	D-Pseudoephedrine	Oxalic acid
Albuterol	Duloxetine	Oxazepam (except BZO test)
Albuterol sulfate(Proair HFA)	Ecgonine methyl ester	Oxolinic acid
Alpha Methadol	EMDP	Oxymetazoline
Aminophylline	Ephedrine hydrochloride(except MET test)	Paliperidone
Aminopyrine	Erythromycin	Papaverine
Amitriptyline(except TCA test)	Esomeprazole Magnesium	Penicillin-G
Amlodipine besylate	Estradiol	Penicillin V Potassium
Amobarbital(except BAR test)	Estrone	Perphenazine(except TCA test)
Amoxicillin	Ethanol(1%)	Phenacetin
Ampicillin	Fenfluramine(except MET test)	Phencyclidine(except PCP test)
Apomorphine	Fenofibrate	Phenelzine
Aripiprazole	Fenoprofen	Phenethylamine(except AMP MDMA test)
Ascorbic acid	Fluoxetine Hydrochloride	Phenobarbital(except BAR test)
Aspartame	Fluphenazine	Phentermine(except AMP test)
Aspirin	Fotomustine	Phenylpropanolamine
Atomoxetine	Furosemide	Prednisone
Atorvastatin Calcium	Gabapentin	Pregablin
Atropine	Galactose	Procaine
Azithromycin	Gatifloxacin	Promazine(except TCA test)
Baclofen	Gemfibrozil	Promethazine
Benzilic acid	Gentisic acid	Propoxyphene(except PPX test)
Benzocaine	Glucose	Propranolol
Benzoic acid	Guaiacolglycerylether	Pseudoephedrine
Benzoyllecgonine(except COC test)	Hemoglobin	Pyridoxine
Benzphetamine	Hexobarbital	Pyrilamine
Benzylpiperiazine	Hydralazine	Pyrogallol
Bilirubin	Hydrochlorothiazide	Quetiapine
Boric Acid (1%)	Hydrocortisone	Quinidine
Bromo-2,5,Dimethoxyphenethylamine	Hydroxybutyric Acid	Quinine
Bupropion	Ibuprofen	Quinolinic Acid
Caffeine	Imipramine(except TCA test)	Ranitidine
Cannabidiol	Isoproterenol	Rifampicin
Captopril	Isoxsuprine	Salicylic acid
Carbamazepine	Ketamine	Secobarbital(except BAR test)
Carfentanil	Ketoprofen	Serotonin(except AMP test)

Carisoprodol	LAAM HCl	Serotonin (5-Hydroxytyramine)(except AMP test)
Cefradine	Labetalol	Sertraline
Cephalexin	Lamotrigine	Sildenafil Citrate
Cetirizine	L-Ephedrine	Simvastatin
Chloralhydrate	L-Epinephrine	Sodium Azide
Chloramphenicol	Levofloxacin Hydrochloride(except AMP test)	Sulfamethazine(except 6-MAM test)
Chlordiazepoxide(except BZO test)	Levonorgestrel	Sulindac(except BZO test)
Chloroquine	Levothyroxine Sodium	Telmisartan
Chlorothiazide	Lidocaine Hydrochloride	Tetracycline
Chlorpheniramine(except TCA test)	Lisinopril	Tetrahydrocortisone 3-(β -Dglucuronide)
Chlorpromazine(except TCA test)	Loperamide	Tetrahydrocortisone, 3-acetate
Cholesterol	Loratadine	Tetrahydrozoline
Ciprofloxacin Hydrochloride(except AMP test)	L-phenylephrine	THC (except THC test)
Citalopram(except TCA test)	LSD	Theophylline
Clarithromycin	L-thyroxine	Thiamine
Clofibrate	Magnesium	Thioridazine(except TCA test)
Clomipramine(except TCA test)	Maprotiline	Trazodone Hydrochloride
Clonidine	Meperidine	Triamteren
Clozapine	Meprobamate	Trifluoperazine
Conjugated Estrogens	Metformin	Trifluoromethylphenyl-piperazine
Cortisone	Methapyrilene	Trimethobenzamide(except AMP MET test)
Creatine Hydrate	Methaqualone	Trimethoprim
Creatinine	Methoxyphenamine (except MET test)	Tryptamine
Cyclobenzaprine(except TCA test)	Methylphenidate	Tyramine (except AMP test)
Cyproheptadine	Metoprolol Tartrate	Urea (2000 mg/dL)
D,L-Epinephrine	Metronidazole	Uric acid
D,L-Isoproterenol	Mifepristone	Valproic acid (250 μ g/mL)
D,L-Lorazepam (except BZO test)	N-Acetylprocainamide	Venlafaxine HCl
D,L-Octopamine	Nacl (4000 mg/dL)	Verapamil
D,L-Propranolol	Nalidixic acid	Vitamin B2
D,L-Tryptophan	Naloxone hydrochloride(except OXY test)	Vitamin C
D,L-Tyrosine	Naltrexone hydrochloride(except OXY test)	Zaleplon
Delorazepam	Naproxen	Zolpidem
Demoxepam(except BZO test)	N-desmethyl Tapentadol	Zomepirac

Deoxycorticosterone	Niacinamide	β -Estradiol
Desloratadine(except TCA test)	Nicotine	γ -Cyclodextrin
Dextromethorphan	Nicotinic Acid	γ -Globulin (500mg/dL)
Diclofenac	Nifedipine	
Diclofenac sodium	Nitroglycerin	

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 Result		Drug-Free	Low Negative by LC-MS/MS (less than - 50%)	Near Cutoff Negative by LC-MS/MS (Between - 50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
AMP (1000)	Operator A	+	0	0	0	15	22
		-	10	14	16	3	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	1	17	22
		-	10	14	15	1	0
AMP (500)	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator C	+	0	0	1	18	22
		-	10	14	15	0	0
BAR	Operator A	+	0	0	1	16	22
		-	10	14	15	2	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	2	17	22
		-	10	14	14	1	0
BUP	Operator	+	0	0	0	16	22

	A	-	10	14	16	2	0
	Operator	+	0	0	1	16	22
	B	-	10	14	15	2	0
	Operator	+	0	0	1	17	22
	C	-	10	14	15	1	0
	Operator	+	0	0	0	15	22
	A	-	10	14	16	3	0
	Operator	+	0	0	1	17	22
BZO	B	-	10	14	15	1	0
	Operator	+	0	0	2	18	22
	C	-	10	14	14	0	0
	Operator	+	0	0	1	15	22
COC (300)	A	-	10	14	15	3	0
	Operator	+	0	0	1	15	22
	B	-	10	14	15	3	0
	Operator	+	0	0	1	17	22
	C	-	10	14	15	1	0
	Operator	+	0	0	2	18	22
	A	-	10	14	14	0	0
	Operator	+	0	0	2	18	22
COC (150)	B	-	10	14	14	0	0
	Operator	+	0	0	3	18	22
	C	-	10	14	13	0	0
	Operator	+	0	0	2	17	22
EDDP	A	-	10	14	14	1	0
	Operator	+	0	0	2	18	22
	B	-	10	14	14	0	0
	Operator	+	0	0	3	18	22
	C	-	10	14	13	0	0
	Operator	+	0	0	2	16	22
	A	-	10	14	14	2	0
	Operator	+	0	0	2	16	22
FYL	B	-	10	14	14	2	0
	Operator	+	0	0	3	16	22
	C	-	10	14	13	2	0
	Operator	+	0	0	2	17	22
MDMA	A	-	10	14	14	1	0
	Operator	+	0	0	1	16	22
	B	-	10	14	15	2	0
	Operator	+	0	0	2	17	22
	C	-	10	14	14	1	0
	Operator	+	0	0	1	17	22
	MET	+	0	0	1	17	22
	Operator	+	0	0	1	17	22

(1000)	A	-	10	14	15	1	0
	Operator B	+	0	0	0	17	22
		-	10	14	16	1	0
	Operator C	+	0	0	2	18	22
		-	10	14	14	0	0
MET (500)	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	2	17	22
		-	10	14	14	1	0
MOP (300)	Operator A	+	0	0	0	16	22
		-	10	14	16	2	19
	Operator B	+	0	0	0	15	22
		-	10	14	16	3	0
	Operator C	+	0	0	1	17	22
		-	10	14	15	1	0
OPI (2000)	Operator A	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	2	17	22
		-	10	14	14	1	0
MTD	Operator A	+	0	0	0	15	22
		-	10	14	16	3	0
	Operator B	+	0	0	0	15	22
		-	10	14	16	3	0
	Operator C	+	0	0	1	17	22
		-	10	14	15	1	0
OXY	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator C	+	0	0	1	16	22
		-	10	14	15	2	0
PCP	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	1	17	22
		-	10	14	15	1	0
PPX	Operator	+	0	0	0	16	22

	A	-	10	14	16	2	0
	Operator B	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator C	+	0	0	0	17	22
		-	10	14	16	1	0
TCA	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator C	+	0	0	1	17	22
		-	10	14	15	1	0
THC	Operator A	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator B	+	0	0	0	16	22
		-	10	14	16	2	0
	Operator C	+	0	0	1	18	22
		-	10	14	15	0	0
6-MAM	Operator A	+	0	0	1	16	22
		-	10	14	15	2	0
	Operator B	+	0	0	1	16	22
		-	10	14	15	2	0
	Operator C	+	0	0	2	18	22
		-	10	14	14	0	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Accurate Result
6-MAM 10	Operator A、C	DBMC1307	8.77	Positive
	Operator B、C	DBMC0177	9.16	Positive
	Operator A、B	DBMC0604	10.82	Negative
	Operator A、B	DBMC0685	11.01	Negative
AMP 1000	Operator B、C	DBMC0242	998.95	Positive
	Operator A、B、C	DBMC1670	1017.86	Negative
	Operator A	DBMC1538	1033.17	Negative
	Operator A	DBMC0629	1039.9	Negative
BAR 300	Operator A、B、C	DBMC0762	298.98	Positive
	Operator C	DBMC0612	288.79	Positive
	Operator A、B、C	DBMC0103	314.09	Negative
	Operator A	DBMC0278	319.32	Negative
BUP 10	Operator B	DBMC0867	9.95	Positive
	Operator C	DBMC0498	9.97	Positive
	Operator A、B、C	DBMC0182	10.44	Negative

	Operator A、 B	DBMC0496	10.69	Negative
BZO 300	Operator C	DBMC1305	278.05	Positive
	Operator B、 C	DBMC0603	285.73	Positive
	Operator A	DBMC1300	310.58	Negative
	Operator A、 B	DBMC1022	305.35	Negative
	Operator A	DBMC0514	309.44	Negative
COC 300	Operator A、 B、 C	DBMC0058	295.45	Positive
	Operator A、 B	DBMC1107	305.07	Negative
	Operator A、 B、 C	DBMC0277	301.06	Negative
	Operator B	DBMC0815	311.63	Negative
	Operator A	DBMC0550	312.18	Negative
EDDP 300	Operator C	DBMC0495	268.37	Positive
	Operator A、 B、 C	DBMC0728	284.94	Positive
	Operator A、 B、 C	DBMC1634	288.76	Positive
	Operator A	DBMC0961	301.82	Negative
FYL	Operator C	DBMC1630	0.94	Positive
	Operator A、 B、 C	DBMC0260	0.97	Positive
	Operator A、 B、 C	DBMC0313	0.99	Positive
	Operator A、 B、 C	DBMC0622	1.03	Negative
	Operator A	DBMC1198	1.06	Negative
	Operator C	DBMC1514	1.1	Negative
	Operator B	DBMC1336	1.06	Negative
MDMA 500	Operator A、 C	DBMC0425	472.58	Positive
	Operator A、 B、 C	DBMC0522	471.3	Positive
	Operator A、 B、 C	DBMC0804	527.24	Negative
	Operator B	DBMC0464	540.66	Negative
MET 1000	Operator A、 C	DBMC0780	981.48	Positive
	Operator C	DBMC1290	978.54	Positive
	Operator A、 B	DBMC0723	1019.75	Negative
MOP 300	Operator C	DBMC0162	290.78	Positive
	Operator A、 B、 C	DBMC0424	301.43	Negative
	Operator A、 B	DBMC1121	303.18	Negative
	Operator B	DBMC0343	304.93	Negative
MTD 300	Operator C	DBMC0452	286.81	Positive
	Operator A、 B、 C	DBMC0668	310.22	Negative
	Operator A、 B	DBMC0750	316.65	Negative
	Operator A、 B	DBMC0553	327.95	Negative
OXY 100	Operator C	DBMC0525	92.84	Positive
	Operator A、 B、 C	DBMC0838	102.37	Negative
	Operator A、 B、 C	DBMC1006	101.84	Negative
PCP 25	Operator B、 C	DBMC1636	24.98	Positive
	Operator A、 B	DBMC1007	25.72	Negative
	Operator A、 C	DBMC0548	25.82	Negative

PPX 300	Operator A、 B	DBMC1533	313.94	Negative
	Operator A、 B、 C	DBMC1383	308.97	Negative
TCA 1000	Operator C	DBMC0768	988.94	Positive
	Operator A、 B、 C	DBMC1567	1029.78	Negative
	Operator A、 B	DBMC1439	1046.84	Negative
THC 50	Operator C	DBMC1146	45.12	Positive
	Operator A、 B	DBMC0105	50.68	Negative
	Operator A	DBMC1442	51.24	Negative
	Operator B	DBMC0884	52.32	Negative
AMP 500	Operator C	DBMC0523	466.77	Positive
	Operator A、 B	DBMC1578	505.67	Negative
	Operator B	DBMC1490	518.94	Negative
	Operator A	DBMC0050	517.74	Negative
COC 150	Operator A、 C	DBMC1580	148.45	Positive
	Operator B、 C	DBMC0561	148.38	Positive
	Operator A、 B、 C	DBMC1233	149.02	Positive
MET 500	Operator C	DBMC0398	473.25	Positive
	Operator B、 C	DBMC1029	482.02	Positive
	Operator A	DBMC0673	520.94	Negative
	Operator A、 B、 C	DBMC1667	508.23	Negative
OPI 2000	Operator A、 C	DBMC1103	1878.95	Positive
	Operator B、 C	DBMC0369	1875.61	Positive
	Operator A、 B、 C	DBMC1167	2029.55	Negative

C. Lay person study

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

Result of Deepblue Muti-Drug Urine Test Cup Configuration 1:

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	500	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BAR	300	Negative	20	20	20	19	1	0	0

		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BUP	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BZO	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%	95%	100%	100%
COC	150	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
EDDP	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%	95%	100%	100%
FTY	1	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
MDMA	500	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
MET	500	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MOP	300	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
MTD	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OXY	100	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%

PCP	25	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%	90%	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%	95%	100%	100%
TCA	1000	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
THC	50	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
6-MAM	10	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%

Result of Deepblue Multi-Drug Urine Test Cup Configuration 2:

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	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BAR	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BUP	10	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%	90%	100%	100%
BZO	300	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%	90%	100%	100%
COC	300	Negative	20	20	20	19	1	0	0

		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
		Negative	20	20	20	19	1	0	0
EDDP	300	Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
		Negative	20	20	20	19	1	0	0
FTY	1	Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
		Negative	20	20	20	18	1	0	0
MDMA	500	Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
		Negative	20	20	20	20	1	0	0
MET	1000	Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
		Negative	20	20	20	19	0	0	0
MOP	2000	Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	100%	100%	100%
		Negative	20	20	20	19	1	0	0
MTD	300	Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
		Negative	20	20	20	19	1	0	0
OXY	100	Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
		Negative	20	20	20	19	2	0	0
PCP	25	Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
		Negative	20	20	20	18	1	0	0
PPX	300	Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
		Negative	20	20	20	19	2	0	0
TCA	1000	Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
		Negative	20	20	20	19	2	0	0

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%	90%	100%	100%
6-MAM	10	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%

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 Deepblue Home Muti-Drug Urine Test Cup and Deepblue Muti-Drug Urine Test Cup are substantially equivalent to the predicate devices.