



Guangzhou Decheng Biotechnology Co., Ltd.
% Joe Shia
Director
LSI International
504 E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K232659

Trade/Device Name: Dochek® Multi-Drug Urine Test Cup Rx, Dochek® Multi-Drug Urine Test Cup
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate test system
Regulatory Class: Class II
Product Code: DJG, DKZ, PTH, NFT, NGL, DIS, NFV, JXM, DIO, NFY, PTG, DJR, NGG, DJC,
NGM, LCM, QBF, JXN, QAW, LFG, LDJ, NFW
Dated: November 6th, 2023
Received: November 6th, 2023

Dear Joe Shia:

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

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by
Joseph A. Kotarek -S
Date: 2023.12.13 14:33:39
-05'00'

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)

K232659

Device Name

Dochek® Multi-Drug Urine Test Cup

Indications for Use (Describe)

Dochek® Multi-Drug Urine Test Cup is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the cutoff concentrations of following table.

Drug(Identifier)	Cut-off level(ng/mL)
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
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

Dochek® Multi-Drug Urine Test Cup offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device .

It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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

☐

Prescription Use (Part 21 CFR 801 Subpart D)

☒

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

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

Indications for Use

510(k) Number (if known)

K232659

Device Name

DocheK® Multi-Drug Urine Test Cup Rx

Indications for Use (Describe)

DocheK® Multi-Drug Urine Test Cup Rx is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the cutoff concentrations of following table.

Drug(Identifier)	Cut-off level(ng/mL)
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
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

DocheK® Multi-Drug Urine Test Cup Rx offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device .

It is intended for prescription use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

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

510(k) SUMMARY

K232659

- 1. Date:** December 8, 2023
- 2. Submitter:** Guangzhou Decheng Biotechnology Co., Ltd.
Room 107/218/212/405, Building 2, No.68, Nanxiang
1st Road, Science City, Huangpu District, Guangzhou,
Guangdong, 510663, P.R. China
- 3. Contact person:** Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com
- 4. Device Name:** Docheck® Multi-Drug Urine Test Cup Rx
Docheck® Multi-Drug Urine Test Cup
- 5. Classification:** Class II

Product Code Target Drug	Regulation Section	Panel
DKZ, NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
DIS, PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
DJG, NGL Buprenorphine (BUP) Morphine (MOP/OPI) Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
JXM, NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
DIO, NFY Cocaine (COC)	862.3250, Cocaine and cocaine metabolite test system	Toxicology
DJR, PTG 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology
DJC, NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
LCM, NGM	Unclassified	Toxicology

Phencyclidine (PCP)		
JXN,QBF Propoxyphene(PPX)	862.3700 Propoxyphene test system.	Toxicology
LFG, QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
LDJ,NFW Cannabinoids (THC 50)	862.3870, Cannabinoids Test System	Toxicology
DJG 6-Monoacetylmorphine(6-MAM)	862.3650, Opiate Test System	Toxicology

6. Predicate Devices:

AssureTech DOA Dipstick Screen Panel Tests and AssureTech DOA Integrated Cup Tests(K201630)

7. Intended Use

DocheK® Multi-Drug Urine Test Cup Rx is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the cutoff concentrations of following table.

Drug(Identifier)	Cut-off level(ng/mL)
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
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

DocheK® Multi-Drug Urine Test Cup Rx offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device .

It is intended for prescription use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

Dochek® Multi-Drug Urine Test Cup is an immunoassay for the qualitative determination of single or multiple drugs in human urine at the cutoff concentrations of following table.

Drug(Identifier)	Cut-off level(ng/mL)
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
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

Dochek® Multi-Drug Urine Test Cup offers any combinations from 1 to 16 drugs but only one cutoff concentration under same drug condition will be included per device .

It is intended for over-the-counter (OTC) use. For in vitro diagnostic use only.

The test provides only preliminary results. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. GC/MS or LC/MS is the recommended confirmatory method.

8. Device Description

Dochek® Multi-Drug Urine Test Cup Rx and Dochek® 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. The test strips are integrated into the cup provided and the urine sample is collected directly into the cup containing the strips. Each cup 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 (K201630)
Intended use	Qualitative detection of drugs of abuse in urine. For prescription use or over-the-counter use		Same. Only for prescription use.
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
Differences			
Configurations	Test cup		Test panel and test cup
Target Drug and Cut Off Values	Target Drugs	Cutoff (ng/mL)	Same except of Amphetamine (AMP): 500 ng/mL Cocaine (COC): 150 ng/mL Methamphetamine (MET): 500 ng/mL Cannabinoids (THC): 20 ng/mL
	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	
	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	

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

Dochek® Multi-Drug Urine Test Cup Rx or Dochek® Multi-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 (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. 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 I	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
BAR 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
BUP 10	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	16-/34+	50-/0+	50-/0+	50-/0+	50-/0+
BZO 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
COC 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+

EDDP 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
MDM A 500	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
MET 1000	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
OPI 2000	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
MTD 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
OXY 100	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
PCP 25	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	16-/34+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
PPX 300	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
TCA 1000	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
THC 50	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
6- MAM	Lot I	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot II	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot III	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
AMP 500	Lot IV	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot V	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot VI	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
COC 150	Lot IV	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot V	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot VI	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
MET 500	Lot IV	0-/50+	0-/50+	0-/50+	0-/50+	13-/37+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot V	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+

	Lot VI	0-/50+	0-/50+	0-/50+	0-/50+	12-/38+	50-/0+	50-/0+	50-/0+	50-/0+
MOP 300	Lot IV	0-/50+	0-/50+	0-/50+	0-/50+	15-/35+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot V	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot VI	0-/50+	0-/50+	0-/50+	0-/50+	14-/36+	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°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.

Drug/Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
AMP 1000	d-Amphetamine	1,000	100%
	d/l-Amphetamine	3,000	33.3%
	l-Amphetamine	50,000	2%
	(+/-) 3,4- methylenedioxyamphetamine (MDA)	5,000	20%
	Phentermine	3,000	33.3%
	Hydroxyamphetamine	10,000	10%
	d-Methamphetamine	100,000(Negative)	Not detected
	l-Methamphetamine	100,000(Negative)	Not detected
	(+/-)3,4- Methylenedioxyethylamphetamine (MDEA)	100,000(Negative)	Not detected
	(+/-)3,4- Methylenedioxymethamphetamine	100,000(Negative)	Not detected

	(MDMA)		
	(1R,2S)-(-)-Ephedrine	100,000(Negative)	Not detected
	β -Phenylethylamine	100,000	1%
	Tyramine	100,000	1%
	p-Hydroxynorephedrine	100,000	1%
	Phenylpropanolamine	100,000(Negative)	Not detected
	($\pm$)Phenylpropanolamine	100,000(Negative)	Not detected
	p-Hydroxyamphetamine	100,000	1%
	d/l-Norephedrine	100,000	1%
	Benzphetamine	100,000(Negative)	Not detected
	l-Epinephrine	100,000(Negative)	Not detected
	d/l-Epinephrine	100,000(Negative)	Not detected
BAR 300	Secobarbital	300	100%
	Amobarbital	1,000	3%
	Alphenal	75	400%
	Aprobarbital	250	120%
	Butabarbital	100	300%
	Butalbital	5,000	6%
	Butethal	500	60%
	Cyclopentobarbital	500	60%
	Pentobarbital	200	150%
	Phenobarbital	300	100%
BUP 10	Buprenorphine	10	100%
	Norbuprenorphine	50	20%
	Buprenorphine 3-D-glucuronide	10	100%
	Norbuprenorphine 3-D-glucuronide	10	100%
	Morphine	100000 (Negative)	Not Detected
	Oxymorphone	100000 (Negative)	Not Detected
	Hydromorphone	100000 (Negative)	Not Detected
BZO 300	Oxazepam	300	100%
	Alprazolam	150	200%
	α -Hydroxyalprazolam	1,500	20%

	Bromazepam	100	300%
	Chlordiazepoxide	500	60%
	Clobazam	750	40%
	Clonazepam	1,500	20%
	Clorazepate dipotassium	100	300%
	Diazepam	500	60%
	Estazolam	500	60%
	Flunitrazepam	2,500	12%
	Midazolam	2,000	15%
	Nitrazepam	2,000	15%
	Nordiazepam	500	60%
	Temazepam	250	120%
	Triazolam	1,000	30%
	Desalkylflurazepam	500	60%
	Lorazepam	5,000	6%
	Norchlordiazepoxide	500	60%
	Nordazepam	1,000	30%
	Delorazepam	2,000	15%
	Demoxepam	5,000	6%
	Flurazepam	500	60%
COC 300	Benzoyllecgonine	300	100%
	Cocaine HCl	750	40%
	Cocaethylene	12,500	2.4%
	Ecgonine	30,000	1%
	Ecgonine methyl ester	100,000(negative)	Not detected
	Norcocaine	100,000(negative)	Not detected
EDDP 300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	100%
	Methadone	100,000(negative)	Not detected
	EMDP	100,000(negative)	Not detected
	Doxylamine	100,000(negative)	Not detected
	Levacetylmethadol (LAAM)	100,000(negative)	Not detected
	Disopyramide	100,000(negative)	Not detected
	Alpha Methadol	100,000(negative)	Not detected

MDMA 500	(+/-)3,4-Methylenedioxyamphetamine HCl(MDMA)	500	100%
	(+/-)3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
	d-Methamphetamine	100,000(Negative)	Not detected
	d-Amphetamine	100,000(Negative)	Not detected
	l-Methamphetamine	100,000(Negative)	Not detected
	l-Amphetamine	100,000(Negative)	Not detected
MET 1000	d-Methamphetamine	1,000	100%
	d-Amphetamine	50,000	2%
	Chloroquine	50,000	2%
	(1R,2S)-(-)-Ephedrine	50,000	2%
	(-)-Methamphetamine	25,000	4%
	(+/-)3,4-methylenedioxymethamphetamine (MDMA)	4,000	25%
	β-Phenylethylamine	50,000	2%
	Trimethobenzamide	10,000	10%
	l-Amphetamine	75,000	1.3%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	30,000	3.3%
	Mephentermine	50,000	2%
	Methoxyphenamine	50,000	2%
	Fenfluramine	75,000	1.3%
	Procaine	100,000(Negative)	Not detected
	d/l-Amphetamine	100,000(Negative)	Not detected
	p-Hydroxymethamphetamine	30,000	3.3%
	l-Phenylephrine	100,000(Negative)	Not detected

	d/l-Methamphetamine	1,000	100%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	100,000(Negative)	Not detected
OPI 2000	Morphine	2,000	100%
	Codeine	2,000	100%
	Hydrocodone	12,500	16%
	Hydromorphone	5,000	40%
	6-Monoacetylmorphine	1,500	133%
	Morphine 3-β-D-glucuronide	2,000	100%
	Ethylmorphine	1,500	133%
	Diacetylmorphine (heroin)	2,000	100%
	Levorphanol	75,000	2.7%
	Norcodeine	12,500	16%
	Oxycodone	100,000(Negative)	Not detected
	Thebaine	5,000	40%
	Normorphine	50,000	4%
	Oxymorphone	100,000(Negative)	Not detected
	Procaine	100,000(Negative)	Not detected
	Codeine-6-β-D-glucuronide	3,000	67%
	d-Norpropoxyphene hydrochloride	5,000	40%
MTD 300	Methadone	300	100%
	EDDP	100,000(Negative)	Not detected
	Doxylamine	50,000	0.6%
	Levacetylmethadol (LAAM)	100,000(negative)	Not detected
	EMDP	100,000(negative)	Not detected
	Alpha Methadol	100,000(negative)	Not detected
OXY 100	Oxycodone	100	100%
	Hydrocodone	5,000	2%
	Hydromorphone	50,000	0%
	Oxymorphone	1,000	10%
	Codeine	>100,000	Not detected
	Ethylmorphine	>100,000	Not detected
	Dihydrocodeine	20,000	0.5%

	Oxymorphone-3 β -D- glucuronide	5,000	2%
	Morphine	100,000(negative)	Not detected
	6-Monoacetylmorphine	100,000(negative)	Not detected
	Buprenorphine	100,000(negative)	Not detected
	Thebaine	100,000(negative)	Not detected
PCP 25	Phencyclidine	25	100%
	4-Hydroxy Phencyclidine	1500	1.7%
PPX 300	d-Propoxyphene	300	100%
	d-Norpropoxyphene	300	100%
TCA 1000	Notriptyline	1,000	100%
	Nordoxepin	1,000	100%
	Trimipramine	3,000	33.3%
	Promazine	1,500	66.7%
	Desipramine	200	500%
	Imipramine	750	133%
	Clomipramine	10,000	10%
	Doxepin	1,250	80%
	Maprotiline	2,000	50%
	Amitriptyline	1,500	66.7%
	Promethazine	25,000	4%
	Cyclobenzaprine	1,000	100%
	Norclomipramine	12,500	8%
THC 50	11-nor- Δ 9-THC-9-COOH	50	100%
	11-nor- Δ 8-THC-9-COOH	30	167%
	($\pm$)-11-Hydroxy- Δ 9-THC	2,500	2%
	Δ 8- Tetrahydrocannabinol	2,000	2.5%
	Δ 9- Tetrahydrocannabinol	5,000	1%
	Cannabinol	10,000	0.5%
	Cannabidiol(CBD)	100,000	0.05%
	($\pm$)-11-nor-9-carboxy- Δ 9-THC	100	50%
	11-nor- Δ 9-THC-carboxy glucuronide	100	50%
6-MAM 10	6-Monoacetylmorphine	10	100%
	Codeine	100,000(Negative)	Not detected

Ethylmorphine	100,000(Negative)	Not detected
Hydrocodone	50,000	0.02%
Hydromorphone	10,000	0.1%
Levorphanol	100,000(Negative)	Not detected
Morphine 3-β-D-glucuronide	100,000(Negative)	Not detected
Morphine	100,000	0.01%
Norcodeine	100,000(Negative)	Not detected
Normorphine	100,000(Negative)	Not detected
Oxycodone	100,000(Negative)	Not detected
Oxymorphone	10,000	0.1%
Procaine	50,000	0.02%
Thebaine	10,000	0.1%
Diacetylmorphine (heroin)	25	40%
Acetylcodeine	10,000(Negative)	<0.1%
Buprenorphine	10,000(Negative)	<0.1%
Dihydrocodeine	10,000(Negative)	<0.1%
Nalorphine	5,000	0.02%
Dextromethorphan	100,000(Negative)	Not detected
Imipramine	100,000(Negative)	Not detected
Levacetylmethadol (LAAM)	100,000(Negative)	Not detected
Meperidine	100,000(Negative)	Not detected
Methadone	100,000(Negative)	Not detected
Mitragynine (kratom)	20,000(Negative)	<0.05%
Morphine 6-D-glucuronide	100,000(Negative)	Not detected
Naloxone	100,000(Negative)	Not detected
Naltrexone	100,000(Negative)	Not detected
Naproxen	100,000(Negative)	Not detected
Norbuprenorphine	10,000(Negative)	<0.1%
Norbuprenorphine glucuronide	100,000(Negative)	Not detected
Norhydrocodone	100,000(Negative)	Not detected
Noroxycodone	100,000(Negative)	Not detected
Noroxymorphone	100,000(Negative)	Not detected
Norpropoxyphene	100,000(Negative)	Not detected
Oxymorphone-3β-D- glucuronide	100,000(Negative)	Not detected

	Tapentadol HCl	100,000(Negative)	Not detected
	Tramadol	100,000(Negative)	Not detected
AMP 500	d-Amphetamine	500	100%
	d/l-Amphetamine	1,500	33.3%
	l-Amphetamine	25,000	2%
	(+/-) 3,4-methylenedioxyamphetamine (MDA)	2,500	20%
	Phentermine	1,500	33.3%
	Hydroxyamphetamine	5,000	10%
	d-Methamphetamine	100,000(Negative)	Not detected
	l-Methamphetamine	100,000(Negative)	Not detected
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100,000(Negative)	Not detected
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000(Negative)	Not detected
	(1R,2S)-(-)-Ephedrine	100,000(Negative)	Not detected
	β-Phenylethylamine	100,000	0.5%
	Tyramine	100,000	0.5%
	p-Hydroxynorephedrine	100,000	0.5%
	Phenylpropanolamine	100,000(Negative)	Not detected
	(±)Phenylpropanolamine	100,000(Negative)	Not detected
	p-Hydroxyamphetamine	100,000	0.5%
	d/l-Norephedrine	100,000	0.5%
	Benzphetamine	100,000(Negative)	Not detected
	l-Epinephrine	100,000(Negative)	Not detected
	d/l-Epinephrine	100,000(Negative)	Not detected
COC 150	Benzoyllecgonine	150	100%
	Cocaine HCl	500	30%
	Cocaethylene	5,000	3%
	Ecgonine	15,000	1%
	Ecgonine methyl ester	100,000(negative)	Not detected

	Norcocaine	100,000(negative)	Not detected
MET 500	d-Methamphetamine	500	100%
	d-Amphetamine	25,000	2%
	Chloroquine	25,000	2%
	(1R,2S)-(-)-Ephedrine	25,000	2%
	(-)-Methamphetamine	12,500	4%
	(+/-)3,4-methylenedioxymethamphetamine (MDMA)	2,000	25%
	β -Phenylethylamine	25,000	2%
	Trimethobenzamide	5,000	10%
	l-Amphetamine	50,000	1%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	15,000	3.3%
	Mephentermine	25,000	2%
	Methoxyphenamine	25,000	2%
	Fenfluramine	37,500	1.3%
	Procaine	>100,000	Not detected
	d/l-Amphetamine	75,000	0.7%
	p-Hydroxymethamphetamine	15,000	3.3%
	l-Phenylephrine	>100,000	Not detected
	d/l-Methamphetamine	500	100%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	75,000	0.7%
MOP 300	Morphine	300	100%
	Codeine	300	100%
	Hydrocodone	5,000	6%
	Hydromorphone	1,000	30%
	6-Monoacetylmorphine	150	200%
	Morphine 3- β -D-glucuronide	1,000	30%
	Ethylmorphine	100	300%
	Diacetylmorphine (heroin)	300	100%

	Levorphanol	10,000	3%
	Norcodeine	5,000	6%
	Oxycodone	75,000	0.4%
	Thebaine	3,000	10%
	Normorphine	3,000	10%
	Oxymorphone	25,000	1.2%
	Procaine	100,000(Negative)	Not detected
	Codeine-6-β-D-glucuronide	500	60%
	d-Norpropoxyphene hydrochloride	300	100%

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

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

3-Hydroxytyramine	Diflunisal	Oxolinic Acid
Acetaminophen	Digoxin	Oxymetazoline
Acetylsalicylic Acid	Diphenhydramine	Paliperidone
Acyclovir	Dopamine HCl	Papaverine
Albumin (100mg/dL)	D-Pseudoephedrine	Penicillin-G
Albuterol sulfate(Proair HFA)	Duloxetine	Penicillin V Potassium
Aminophylline	Erythromycin	Phenacetin (Acetophenetidin)
Aminopyrine	Esomeprazole Magnesium	Phenelzine
Amoxicillin	Ethanol (1%)	Prednisone
Ampicillin	Fenoprofen	Pregablin
Apomorphine	Fluoxetine Hydrochloride	Quinine
Aripiprazole	Furosemide	Ranitidine
Aspartame	Gabapentin	Rifampicin
Atomoxetine	Gentisic Acid	Risperidone
Atorvastatin Calcium	Glucose	Salicylic Acid
Atropine	Hemoglobin	Serotonin
Azithromycin	Hydralazine	Sertraline Hydrochloride
Benzilic acid	Hydrochlorothiazide	Sildenafil Citrate
Benzocaine	Hydrocortisone	Simvastatin
Benzoic acid	Ibuprofen	Sulfamethazine

Bilirubin	Isoxsuprine	Sulindac
Bupropion	Ketamine	Tetrahydrozoline
Captopril	Ketoprofen	Theophylline
Carbamazepine	Labetalol	Thiamine
Cefradine	Levofloxacin Hydrochloride	Thioridazine
Cephalexin	Levonorgestrel	Tramadol Hydrochloride
Chloral Hydrate	Levothyroxine Sodium	Trazodone Hydrochloride
Chloramphenicol	Lidocaine Hydrochloride	Triamterene
Chlorothiazide	Lisinopril	Trifluoperazine
chlorpheniramine	Loperamide	Trimethoprim
Cholesterol	Loratadine	Uric Acid
Ciprofloxacin Hydrochloride	Magnesium	Venlafaxine HCl
Citalopram	Meperidine	Verapamil
Clarithromycin	Meprobamate	Vitamin B2
Clonidine	Metoprolol Tartrate	Vitamin C (Ascorbic acid)
Clozapine	Mifepristone	Zomepirac
Conjugated Estrogens	N-Acetylprocainamide	β-Estradiol
Cortisone	Nalidixic Acid	Chlorpromazine
Cotinine	Naproxen	Perphenazine
Creatinine	Niacinamide	Tetrahydrocortisone 3-(β-D-glucuronide)
D,L- Isoproterenol	Nicotine	Tetrahydrocortisone 3-acetate
D,L-Octopamine	Nifedipine	Ecgonine methyl ester
D,L-Propranolol	Nitroglycerin	Methoxyphenamine (except MET test)
D,L-Tryptophan	Norethindrone	Naloxone
D,L-Tyrosine	Noscapine	Naltrexone
Deoxycorticosterone	O-Hydroxyhippuric Acid	Tyramine (except AMP test)
Dextromethorphan	Omeprazole	
Diclofenac	Oxalic Acid	

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 25% below and 25% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.003 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%)
AMP (AMP 1000)	Viewer A	+	0	0	0	6	31
		-	15	8	17	3	0
	Viewer B	+	0	0	0	6	31
		-	15	8	17	3	0
	Viewer C	+	0	0	0	7	31
		-	15	8	17	2	0
AMP (AMP 500)	Viewer A	+	0	0	0	8	30
		-	15	12	13	2	0
	Viewer B	+	0	0	0	8	30
		-	15	12	13	2	0
	Viewer C	+	0	0	0	8	30
		-	15	12	13	2	0
BAR	Viewer A	+	0	0	0	16	22
		-	15	18	7	2	0
	Viewer B	+	0	0	0	15	22
		-	15	18	7	3	0
	Viewer C	+	0	0	0	16	22
		-	15	18	7	2	0
BUP	Viewer A	+	0	0	2	29	10
		-	15	13	10	1	0
	Viewer B	+	0	0	1	29	10
		-	15	13	11	1	0
	Viewer C	+	0	0	2	29	10
		-	15	13	10	1	0
BZO	Viewer A	+	0	0	2	7	31
		-	15	11	12	2	0
	Viewer B	+	0	0	1	7	31
		-	15	11	13	2	0
	Viewer	+	0	0	1	8	31

	C	-	15	11	13	1	0
COC(C OC 300)	Viewer A	+	0	0	1	11	27
		-	15	13	11	2	0
	Viewer B	+	0	0	2	11	27
		-	15	13	10	2	0
	Viewer C	+	0	0	2	11	27
		-	15	13	10	2	0
COC(C OC 150)	Viewer A	+	0	0	1	13	25
		-	15	12	12	2	0
	Viewer B	+	0	0	1	13	25
		-	15	12	12	2	0
	Viewer C	+	0	0	1	13	25
		-	15	12	12	2	0
EDDP	Viewer A	+	0	0	0	11	29
		-	15	6	19	0	0
	Viewer B	+	0	0	1	11	29
		-	15	6	18	0	0
	Viewer C	+	0	0	1	11	29
		-	15	6	18	0	0
MDMA	Viewer A	+	0	0	0	9	30
		-	15	14	11	1	0
	Viewer B	+	0	0	1	9	30
		-	15	14	10	1	0
	Viewer C	+	0	0	1	9	30
		-	15	14	10	1	0
MET(M ET 1000)	Viewer A	+	0	0	0	8	30
		-	15	8	17	2	0
	Viewer B	+	0	0	0	8	30
		-	15	8	17	2	0
	Viewer C	+	0	0	0	8	30
		-	15	8	17	2	0
MET (MET 500)	Viewer A	+	0	0	0	9	30
		-	15	14	11	1	0
	Viewer B	+	0	0	0	9	30
		-	15	14	11	1	0
	Viewer C	+	0	0	0	10	30
		-	15	14	11	0	0
OPI (MOP 2000)	Viewer A	+	0	0	2	9	29
		-	15	9	14	2	0
	Viewer B	+	0	0	2	9	29
		-	15	9	14	2	0
	Viewer	+	0	0	2	9	29
		-	15	9	14	2	0

	C	-	15	9	14	2	0
MOP(M OP 300)	Viewer A	+	0	0	2	19	21
		-	15	12	11	0	0
	Viewer B	+	0	0	2	18	21
		-	15	12	11	1	0
	Viewer C	+	0	0	2	18	21
		-	15	12	11	1	0
MTD	Viewer A	+	0	0	2	8	30
		-	15	12	11	2	0
	Viewer B	+	0	0	2	9	30
		-	15	12	11	1	0
	Viewer C	+	0	0	2	9	30
		-	15	12	11	1	0
OXY	Viewer A	+	0	0	2	9	29
		-	15	12	11	2	0
	Viewer B	+	0	0	2	10	29
		-	15	12	11	1	0
	Viewer C	+	0	0	2	10	29
		-	15	12	11	1	0
PCP	Viewer A	+	0	0	0	28	12
		-	15	13	12	0	0
	Viewer B	+	0	0	0	27	12
		-	15	13	12	1	0
	Viewer C	+	0	0	0	27	12
		-	15	13	12	1	0
PPX	Viewer A	+	0	0	1	12	28
		-	15	13	11	0	0
	Viewer B	+	0	0	1	10	28
		-	15	13	11	2	0
	Viewer C	+	0	0	2	11	28
		-	15	13	10	1	0
TCA	Viewer A	+	0	0	0	6	32
		-	15	13	12	2	0
	Viewer B	+	0	0	0	6	32
		-	15	13	12	2	0
	Viewer C	+	0	0	0	6	32
		-	15	13	12	2	0
THC	Viewer A	+	0	0	1	9	30
		-	15	13	11	1	0
	Viewer B	+	0	0	1	9	30
		-	15	13	11	1	0
	Viewer	+	0	0	2	9	30

	C	-	15	13	10	1	0
6-MAM	Viewer A	+	0	0	3	28	10
		-	15	13	9	2	0
	Viewer B	+	0	0	3	28	10
		-	15	13	9	2	0
	Viewer C	+	0	0	3	28	10
		-	15	13	9	2	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Docheck Result
6-MEM 10	Viewer A, B, C	1091	9.006	+
	Viewer A, B, C	1081	9.465	+
	Viewer A, B, C	1053	9.967	+
	Viewer A, B, C	1048	10.237	-
	Viewer A, B, C	1052	10.257	-
AMP 1000	Viewer A, B, C	0955	1014.625	-
	Viewer A, B, C	0936	1056.71	-
	Viewer A, B	0903	1141.794	-
BAR 300	Viewer A, B, C	0221	302.963	-
	Viewer B	0238	304.207	-
	Viewer A, B, C	0173	312.828	-
BUP 10	Viewer A, B, C	0136	8.76	+
	Viewer A, C	0137	8.785	+
	Viewer A, B, C	0141	10.761	-
BZO 300	Viewer A	0405	269.424	+
	Viewer A, B, C	0428	290.449	+
	Viewer A, B	0422	301.512	-
	Viewer A, B, C	0409	301.586	-
COC 300	Viewer A, B, C	0632	284.614	+
	Viewer B, C	0602	295.071	+
	Viewer A, B, C	0620	307.773	-
	Viewer A, B, C	0630	308.012	-
EDDP 300	Viewer B, C	1591	296.944	+
MDMA 500	Viewer B, C	0762	458.975	+
	Viewer A, B, C	0750	565.340	-
MET 1000	Viewer A, B, C	972	1002.105	-
	Viewer A, B, C	1025	1026.596	-
OPI 2000	Viewer A, B, C	0817	1872.771	+
	Viewer A, B, C	0855	1996.034	+
	Viewer A, B, C	0879	2022.484	-
	Viewer A, B, C	0880	2137.854	-
MTD 300	Viewer A, B, C	1159	271.186	+

	Viewer A, B, C	1185	273.035	+
	Viewer A, B, C	1129	308.556	-
	Viewer A	1123	324.733	-
OXY 100	Viewer A, B, C	0379	85.212	+
	Viewer A, B, C	0375	87.649	+
	Viewer A	0397	106.706	-
	Viewer A, B, C	0340	108.7	-
PCP 25	Viewer B, C	0053	25.901	-
PPX 300	Viewer A, B, C	0504	285.846	+
	Viewer C	0487	295.988	+
	Viewer B, C	0536	347.008	-
	Viewer B	0551	355.750	-
TCA 1000	Viewer A, B, C	0688	1,051.49	-
	Viewer A, B, C	0653	1,135.56	-
THC 50	Viewer B, C	0300	41.179	+
	Viewer A, C	0317	49.391	+
	Viewer A, B, C	0312	55.644	-
AMP 500	Viewer A, B, C	1345	512.815	-
	Viewer A, B, C	1297	545.751	-
COC 150	Viewer A, B, C	1446	138.861	+
	Viewer A, B, C	1512	156.470	-
	Viewer A, B, C	1505	162.099	-
MET 500	Viewer A, B	1403	507.553	-
MOP 300	Viewer A, B, C	1279	248.796	+
	Viewer A, B, C	1259	249.557	+
	Viewer B, C	1264	308.896	-

C. Lay person study

78 male and 62 female tested DocheK® Multi-Drug Urine Test Cup Configuration 1; 89 male and 51 female tested DocheK® Multi-Drug Urine Test Cup Configuration 2. 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 DocheK® Multi-Drug Urine Test Cup Configuration 1:

Drug	Cutoff (ng/mL)	Results	Drug Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff

AMP	1000	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
BAR	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
BZO	300	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	90%	100%	100%
COC	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
		Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
EDDP	300	Negative	20	20	20	20	0	0	0
		Positive	0	0	0	0	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MDMA	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

		Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%
MET	1000	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
OPI	2000	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
MTD	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
OXY	100	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	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
		Percentage of correct results (%)	100%	100%	100%	90%	95%	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
		Percentage of correct results (%)	100%	100%	100%	95%	90%	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
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%
THC	50	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
6-MAM	10	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	100%	100%

Result of Dochek® Multi-Drug Urine Test Cup Configuration 2:

Drug	Cutoff (ng/mL)	Results	Drug Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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
		Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
BAR	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
BUP	10	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	95%	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
COC	150	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	90%	100%	100%	100%
EDDP	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
		Percentage of correct results (%)	100%	100%	100%	90%	100%	100%	100%
MDM A	500	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	90%	100%	100%	100%
MET	500	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	90%	100%	100%
MOP	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
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
MTD	300	Negative	20	20	20	20	2	0	0
		Positive	0	0	0	0	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	100%	90%	100%	100%
OXY	100	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of	100%	100%	100%	90%	90%	100%	100%

		correct results (%)							
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
		Percentage of correct results (%)	100%	100%	100%	95%	95%	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
		Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%
TCA	1000	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
THC	50	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
6-MAM	10	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

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 Docheck® Multi-Drug Urine Test Cup Rx and Docheck® Multi-Drug Urine Test Cup are substantially equivalent to the predicate devices.