



December 17, 2024

Healgen Scientific LLC  
% Jenny Xia  
Director  
LSI International Inc  
504E Diamond Ave., Suite H  
Gaithersburg, Maryland 20877

Re: K243365

Trade/Device Name: Healgen® Accurate Multi-Drug Urine Drug Screen Cup; Healgen® Accurate Home Multi-Drug Urine Test Cup

Regulation Number: 21 CFR 862.3650

Regulation Name: Opiate test system

Regulatory Class: Class II

Product Code: NGL,NFT,PTH,NFY,NFV,PTG,NGG,NGM,QBF,QAW,NFW

Dated: October 26, 2024

Received: October 29, 2024

Dear Jenny Xia:

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

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

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

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

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

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Joseph A. Kotarek -S** Digitally signed by  
Joseph A. Kotarek -S  
Date: 2024.12.17  
10:21:47 -05'00'

Joseph Kotarek  
Branch Chief  
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)  
K243365

### Device Name

Healgen® Accurate Multi-Drug Urine Drug Screen Cup;  
Healgen® Accurate Home Multi-Drug Urine Test Cup

### Indications for Use (Describe)

The Healgen® Accurate Multi-Drug Urine Screening Cup is a rapid lateral flow immunoassay for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoyllecgonine, Buprenorphine, EDDP, Norfentanyl, Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, THC-COOH and Tramadol 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	Benzoyllecgonine	150 or 300
EDDP	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
FEN or FYL	Norfentanyl	5
MDMA	Methylenedioxymethamphetamine	500
MET	d-Methamphetamine	500 or 1000
MTD	Methadone	300
OPI	Morphine	300 or 2000
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	d-Propoxyphene	300
TCA	Nortriptyline	1000
THC	11-nor- $\Delta^9$ -THC-COOH	50
TRA or TML	Tramadol	100

The single or multi-test cups can consist of up to eighteen (18) 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 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 Healgen® Accurate 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	Norfentanyl	5
MET/mAMP	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
TML	Tramadol	100
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 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)

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**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) SUMMARY  
K243365**

- 1. Date:** October 29, 2024
- 2. Submitter:** Healgen Scientific LLC.  
3818 Fuqua Street  
Houston, TX 77047
- 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](mailto:jxia@lsi-consulting.org)
- 4. Device Name:** Healgen® Accurate Muti-Drug Urine Drug Screen Cup  
Healgen® Accurate Home Muti-Drug Urine Test Cup
- 5. Classification:** Class II

<b>Product Code Target Drug</b>	<b>Regulation Section</b>	<b>Panel</b>
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) Norfentanyl (FEN) Tramadol (TML)	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	862.3610, Methamphetamine Test System	Toxicology

Methylenedioxyamphetamine (MDMA) Methamphetamine (MET)		
NGM Phencyclidine (PCP)	Unclassified	Toxicology
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 Healgen® Accurate Multi-Drug Urine Screening Cup is a rapid lateral flow immunoassay for the qualitative detection of 6-Monoacetylmorphine, d-Amphetamine, Benzoylcegonine, Buprenorphine, EDDP, Norfentanyl, Methadone, d-Methamphetamine, d/l-Methylenedioxyamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, THC-COOH and Tramadol 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
FEN or FYL	Norfentanyl	5
MDMA	Methylenedioxyamphetamine	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- $\Delta^9$ -THC-COOH	50

TRA or TML	Tramadol	100
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The single or multi-test cups can consist of up to eighteen (18) 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 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 Healgen® Accurate 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	Norfentanyl	5
MET/mAMP	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
TML	Tramadol	100
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 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

Healgen® Accurate Home Muti-Drug Urine Test Cup and Healgen® Accurate Muti-Drug Urine



Drug Screen 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)
<b>Intended use</b>	Qualitative detection of drugs of abuse in urine. For prescription use or over-the-counter use		Same.
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
<b>Type of Test</b>	Qualitative		Same
<b>Specimen Type</b>	Human urine		Same
<b>Target Drug and Cut Off Values</b>	<b>Target Drugs</b>	<b>Cutoff (ng/mL)</b>	Same except no Norfentanyl and Tramadol
	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	
	Norfentanyl	5	
	Methylenedioxyamphetamine (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
	Tramadol	100
Differences		
<b>Configurations</b>	Test cup	Test Dip Card

## 10. Standard/Guidance Document Reference (if applicable)

None referenced.

## 11. Test Principle

Healgen® Accurate Home Multi-Drug Urine Test Cup or Healgen® Accurate Multi-Drug Urine Drug Screen 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 with one operator per lot. The results obtained are summarized in the following tables:

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
AMP 1000	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
BUP 10	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	26-/24+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	27-/23+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
BZO 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
COC 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
EDDP 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
FYL 5	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
MDMA 500	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
MET 1000	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
OPI 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
MTD 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
OXY 100	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
PCP 25	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+

	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
<b>PPX 300</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
<b>TCA 1000</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
<b>THC 50</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
<b>TML 100</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	2-/48+	25-/25+	48-/2+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	48-/2+	50-/0+	50-/0+	50-/0+
<b>6-MAM 10</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	2-/48+	26-/24+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
<b>AMP 500</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
<b>COC 150</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	2-/48+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	48-/2+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+
<b>MET 500</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	48-/2+	50-/0+	50-/0+	50-/0+
<b>OPI 2000</b>	<b>Lot 1</b>	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	<b>Lot 2</b>	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	<b>Lot 3</b>	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	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 36 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.

<b>Drug/Cutoff</b>	<b>Compound</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross-Reactivity</b>
AMP 1000	Hydroxyamphetamine	8000	12.5%
	(+/-)-Methylenedioxyamphetamine(MDA)	400	250%
	D,L-Amphetamine	1,000	100%
	D-Amphetamine	1,000	100%
	Diethylstilbestrol	5,000	20%
	L-Amphetamine	50,000	2%
	Phentermine	8,000	12.5%
	β-Phenylethylamine	100,000	1%
	Tyramine	100,000	1%
	p-Hydroxynorephedrine	100,000	1%
	D,L-Norephedrine	100,000	1%
	p-Hydroxyamphetamine	100,000	1%
	D-Methamphetamine	100,000(Negative)	Not detected
	L-Methamphetamine	100,000(Negative)	Not detected
	Ephedrine hydrochloride	100,000(Negative)	Not detected
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000(Negative)	Not detected
	Phenylpropanolamine	100,000(Negative)	Not detected
	Benzphetamine	100,000(Negative)	Not detected
	L-Ephedrine	100,000(Negative)	Not detected
	L-Epinephrine	100,000(Negative)	Not detected
D,L-Epinephrine	100,000(Negative)	Not detected	
(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100,000(Negative)	Not detected	
BAR 300	Alphenal	150	200%
	Amobarbital	300	100%

	Aprobarbital	250	120%
	Butabarbital	2,500	12%
	Butethal	100	300%
	Cyclopentobarbital	600	50%
	Pentobarbital	250	120%
	Phenobarbital	250	120%
	Secobarbital	300	100%
	Butalbital	2,500	12%
BUP 10	Buprenorphine	10	100%
	Buprenorphine -3-D-Glucuronide	160	6.25%
	Norbuprenorphine	10	100%
	Norbuprenorphine-3-D-Glucuronide	200	5%
	Morphine	100000 (Negative)	Not Detected
	Oxymorphone	100000 (Negative)	Not Detected
	Hydromorphone	100000 (Negative)	Not Detected
BZO 300	a-Hydroxyalprazolam	1,260	23.8%
	Alprazolam	200	150%
	Bromazepam	1,560	19.2%
	Chlordiazepoxide	1,560	19.2%
	Clobazam	100	300%
	Clonazepam	2,500	12%
	Clorazepate Dipotassium	200	150%
	Desalkylflurazepam	400	75%
	Diazepam	200	150%
	Estazolam	2,500	12%
	Flunitrazepam	400	75%
	D,L-Lorazepam	1,560	19.2%
	Midazolam	12,500	2.4%
	Nitrazepam	100	300%
	Norchlordiazepoxide	200	150%
	Nordiazepam	400	75%
	Oxazepam	300	100%
	Oxazepam glucuronide	500	60%
	R,S-Lorazepam glucuronide	160	187.5%

	Temazepam	100	300%
	Triazolam	2,500	12%
	Demoxepam	2,000	15%
	Flurazepam	500	60%
	Delorazepam	100,000(negative)	Not detected
COC 300	Benzoyllecgonine	300	100%
	Cocaethylene	300	100%
	Cocaine hydrochloride	300	100%
	Ecgonine	50,000	0.6%
	Norcocaine	100,000	0.3%
	Ecgonine methyl ester	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
FYL 5	Norfentanyl	5	100%
	Fentanyl	10	50%
	Acetyl fentanyl	150	3.3%
	Acetyl Norfentanyl	200	2.5%
	(±)-β-Hydroxythiofentanyl HCl	2,500	0.2%
	Acryl Fentanyl	2,500	0.2%
	Butyryl Fentanyl	5,000	0.1%
	Cis-d, I 3-Methylfentanyl	50,000	0.01%
	Furanyl Fentanyl	10,000	0.05%
	Para-fluoro butyryl Fentanyl (P-FBF)	80,000	0.01%
	Para-fluoro Fentanyl	40,000	0.005%
	9-HydroxyRisperidone	10,000	0.05%
	Alfentanil	20,000	0.03%
	Isobutyryl Fentanyl	5,000	0.1%
Trans-d, 1-3-Methylfentanyl	50	10%	

Norcarfentail Oxalate	50,000	0.01%
Remifentanyl	15,000	0.03%
Valeryl Fentanyl	20,000	0.03%
Thienyl Fentanyl	50	10%
4-Fluoro-isobutyryl Fentanyl	20,000(Negative)	Not detected
Despropionyl fentanyl (4-ANPP)	20,000(Negative)	Not detected
MT-45	100,000(Negative)	Not detected
Ocfentanyl	100,000(Negative)	Not detected
Risperidone	100,000(Negative)	Not detected
Sufentanyl	100,000(Negative)	Not detected
Carfentanyl Oxalate	100,000(Negative)	Not detected
Labetalol Hydrochloride	100,000(Negative)	Not detected
Trazodone	100,000(Negative)	Not detected
U-47700	100,000(Negative)	Not detected
$\omega$ -1-Hydroxyfentanyl	20,000(Negative)	Not detected
6-Acetyl morphine	100,000(Negative)	Not detected
Amphetamine	100,000(Negative)	Not detected
Buprenorphine	100,000(Negative)	Not detected
Buprenorphine -3-D-Glucuronide	100,000(Negative)	Not detected
Codeine	100,000(Negative)	Not detected
Dextromethorphan	100,000(Negative)	Not detected
Dihydrocodeine	100,000(Negative)	Not detected
EDDP	100,000(Negative)	Not detected
EMDP	100,000(Negative)	Not detected
Fluoxetine	100,000(Negative)	Not detected
Heroin	100,000(Negative)	Not detected
Hydrocodone	100,000(Negative)	Not detected
Hydromorphone	100,000(Negative)	Not detected
Ketamine	100,000(Negative)	Not detected
Levorphanol tartrate	100,000(Negative)	Not detected
Meperidine	100,000(Negative)	Not detected
Methadone	100,000(Negative)	Not detected
Morphine	100,000(Negative)	Not detected
Morphine-3- $\beta$ -D-glucuronide	100,000(Negative)	Not detected



	Naloxone hydrochloride	100,000(Negative)	Not detected
	Naltrexone hydrochloride	100,000(Negative)	Not detected
	Norbuprenorphine	100,000(Negative)	Not detected
	Norcodeine	100,000(Negative)	Not detected
	Norketamine	100,000(Negative)	Not detected
	Normeperidine	100,000(Negative)	Not detected
	Normorphine	100,000(Negative)	Not detected
	Noroxycodone	100,000(Negative)	Not detected
	Oxycodone	100,000(Negative)	Not detected
	Oxymorphone	100,000(Negative)	Not detected
	Pentazocine (Talwin)	100,000(Negative)	Not detected
	Pipamperone	100,000(Negative)	Not detected
	Tapentadol hydrochloride	100,000(Negative)	Not detected
	Thioridazine	100,000(Negative)	Not detected
	Tilidine	100,000(Negative)	Not detected
	Tramadol	100,000(Negative)	Not detected
	o-Desmethyl Tramadol	100,000(Negative)	Not detected
	n-Desmethyl Tramadol	100,000(Negative)	Not detected
MDMA 500	(+/-)3,4-Methylenedioxyamphetamine HCl(MDMA)	500	100%
	(+/-)3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	16.7%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
	L-Methamphetamine	50,000	1%
	7-Aminoclonazepam	100,000	0.5%
	d-methamphetamine	100,000(Negative)	Not detected
	d-amphetamine	100,000(Negative)	Not detected
	l-amphetamine	100,000(Negative)	Not detected
MET 1000	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000	5%
	(+/-)3,4-	2,500	40%

	Methylenedioxyamphetamine (MDMA)		
	D-Methamphetamine	1,000	100%
	L-Methamphetamine	25,000	4%
	Fenfluramine	50,000	2%
	p-Hydroxymethamphetamine	10,000	10%
	D,L-Methamphetamine	1,000	100%
	$\beta$ -Phenylethylamine	50,000	2%
	Mephetermine	50,000	2%
	Methoxyphenamine hydrochloride	50,000	2%
	L-Amphetamine	75,000	1.33%
	D-Amphetamine	100,000(Negative)	Not detected
	D,L-Amphetamine	100,000(Negative)	Not detected
	Chloroquine	100,000(Negative)	Not detected
	Ephedrine hydrochloride	100,000(Negative)	Not detected
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	100,000(Negative)	Not detected
	Trimethobenzamide	100,000(Negative)	Not detected
	l-phenylephrine	100,000(Negative)	Not detected
	(1R,2S)-(-)-Ephedrine	100,000(Negative)	Not detected
	Procaine hydrochloride	100,000(Negative)	Not detected
OPI 2000	6-acetylmorphine	2,500	80%
	Codeine	1,000	200%
	Dihydrocodeine	1,500	133.3%
	EthylMorphine	2,500	80%
	Codeine-6- $\beta$ -D-glucuronide	2,500	80%
	Heroin	5,000	40%
	Hydrocodone	5,000	40%
	Hydromorphone	2,500	80%
	Levorphanol tartrate	10,000	20%
	Morphine	2,000	100%
	Nalorphine hydrochloride	5,000	40%
	Norcodeine	4,000	50%
	Normorphine	5,000	40%

	Oxymorphone	75,000	2.7%
	s-Monoacetylmorphine	2,000	100%
	Morphine-6-β-D-glucuronide	2,000	100%
	Thebaine	13,000	15.4%
	Morphine 3-β-D-glucuronide	2,000	100%
	6-Monoacetylmorphine (6-MAM)	1,500	133%
	6-Acetylcodeine	10,000	20%
	Oxycodone	100,000(Negative)	Not detected
	Procaine	100,000(Negative)	Not detected
	Norpropoxyphene	100,000(Negative)	Not detected
MTD 300	EDDP	100,000(Negative)	Not detected
	Doxylamine	100,000(Negative)	Not detected
	Levacetylmethadol (LAAM)	100,000(Negative)	Not detected
	EMDP	100,000(Negative)	Not detected
	Alpha Methadol	100,000(Negative)	Not detected
OXY 100	Ethyl Oxycodone	75,000	0.13%
	Hydrocodone	5,000	2%
	Hydromorphone	25,000	0.4%
	Levorphanol tartrate	25,000	0.4%
	Naloxone hydrochloride	10,000	1%
	Naltrexone hydrochloride	50,000	0.2%
	Oxycodone	100	100%
	Oxymorphone	200	50%
	Oxymorphone-3β-D-glucuronide	500	20%
	Noroxycodone	1,500	6.7%
	Noroxymorphone	3,000	3.3%
	Dihydrocodeine	100,000(Negative)	Not detected
	Codeine	100,000(Negative)	Not detected
	Morphine	100,000(Negative)	Not detected
	Buprenorphine	100,000(Negative)	Not detected
	Ethylmorphine	100,000(Negative)	Not detected
	Thebaine	100,000(Negative)	Not detected
6-acetylmorphine	100,000(Negative)	Not detected	
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	1,500	66.7%
	Chlorpheniramine	50,000	2%
	Clomipramine	10,000	10%
	Cyclobenzaprine Hydrochloride	5,000	20%
	Desipramine	1,000	100%
	Doxepine	2,000	50%
	Duloxetine	10,000	10%
	Imipramine	1,000	100%
	Norclomipramine	12,500	8%
	Nordoxepine	1,000	100%
	Nortriptyline	1,000	100%
	Promazine	50,000	2%
	Trimipramine	10,000	10%
	Maprotiline	100,000(Negative)	Not detected
Promethazine hydrochloride	100,000(Negative)	Not detected	
THC 50	11-nor- $\Delta$ 8-THC -9-COOH	30	166.7%
	(-)-11-nor-9-carboxy- $\Delta$ 9-THC	50	100%
	( $\pm$ )-11-nor-9-Carboxy- $\Delta$ 9-THC	50	100%
	11-nor- $\Delta$ 9-THC -carboxy glucuronide	100	50%
	11-hydroxy- $\Delta$ 9-Tetrahydrocannabinol	5,000	1%
	$\Delta$ 8- Tetrahydrocannabinol	1,300	3.8%
	$\Delta$ 9- Tetrahydrocannabinol	5,000	1%
	Cannabinol	20,000	0.25%
	Cannabidiol	100,000(Negative)	Not detected
	( $\pm$ )-11-Hydroxy- $\Delta$ 9-THC	100,000(Negative)	Not detected
TML 100	Tramadol	100	100%
	n-Desmethyl Tramadol	400	25%
	o-Desmethyl Tramadol	1,000	10%
	o-Desmethyl Venlafaxine	10,000(Negative)	Not detected
	Venlafaxine HCl	100,000(Negative)	Not detected
6-MAM 10	6-acetylmorphine	10	100%

6-Monoacetylmorphine (6-MAM)	10	100%
Heroin	60	16.7%
Morphine	75,000	0.01%
s-Monoacetylmorphine	10	100%
Normorphine	100,000(Negative)	Not detected
Nalorphine HCl	100,000(Negative)	Not detected
Hydrocodone	100,000(Negative)	Not detected
Hydromorphone	100,000(Negative)	Not detected
Chlordiazepoxide	100,000(Negative)	Not detected
Clobazam	100,000(Negative)	Not detected
D-Amphetamine	100,000(Negative)	Not detected
(±)-Amphetamine	100,000(Negative)	Not detected
Levorphanol tartrate	100,000(Negative)	Not detected
Codeine	100,000(Negative)	Not detected
Ethylmorphine	100,000(Negative)	Not detected
Morphine-3-β-D-glucuronide	100,000(Negative)	Not detected
Norcodeine	100,000(Negative)	Not detected
Oxycodone	100,000(Negative)	Not detected
Oxymorphone	100,000(Negative)	Not detected
Procaine hydrochloride	100,000(Negative)	Not detected
Thebaine	100,000(Negative)	Not detected
6-Acetylcodeine	100,000(Negative)	Not detected
Buprenorphine	100,000(Negative)	Not detected
Dihydrocodeine	100,000(Negative)	Not detected
Dextromethorphan	100,000(Negative)	Not detected
Imipramine hydrochloride	100,000(Negative)	Not detected
Meperidine	100,000(Negative)	Not detected
(±)-Methadone	100,000(Negative)	Not detected
Mitragynine(kratom)	100,000(Negative)	Not detected
Morphine-6-β-D-glucuronide	100,000(Negative)	Not detected
Naloxone hydrochloride	100,000(Negative)	Not detected
Naltrexone hydrochloride	100,000(Negative)	Not detected
Naproxen	100,000(Negative)	Not detected
Norbuprenorphine	100,000(Negative)	Not detected

	Norbuprenorphine-3-D-Glucuronide	100,000(Negative)	Not detected
	Noroxycodone HCL	100,000(Negative)	Not detected
	Noroxymorphone HCL	100,000(Negative)	Not detected
	(+)-Norpropoxyphene maleate	100,000(Negative)	Not detected
	Oxymorphone-3 $\beta$ -D-glucuronide	100,000(Negative)	Not detected
	Tapentadol HCl	100,000(Negative)	Not detected
	Tramadol	100,000(Negative)	Not detected
AMP 500	Hydroxyamphetamine	4,000	12.5%
	(+/-)- Methylenedioxyamphetamine(MDA)	200	250%
	D,L-Amphetamine	500	100%
	D-Amphetamine	500	100%
	Diethylstilbestrol	2,500	20%
	L-Amphetamine	25,000	2%
	Phentermine	4,000	12.5%
	$\beta$ -Phenylethylamine	50,000	1%
	Tyramine	50,000	1%
	p-Hydroxynorephedrine	50,000	1%
	p-Hydroxyamphetamine	50,000	1%
	D,L-Norephedrine	50,000	1%
	(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	100,000	0.5%
	d-Methamphetamine	100,000(Negative)	Not detected
	l-Methamphetamine	100,000(Negative)	Not detected
	(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	100,000(Negative)	Not detected
	Ephedrine hydrochloride	100,000(Negative)	Not detected
	Phenylpropanolamine	100,000(Negative)	Not detected
	Benzphetamine	100,000(Negative)	Not detected
	L-Ephedrine	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%

	Cocaethylene	150	100%
	Cocaine hydrochloride	150	100%
	Ecgonine	25,000	0.6%
	Norcocaine	50,000	0.3%
	Ecgonine methyl Ester	100,000(negative)	Not detected
MET 500	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10,000	5%
	(+/-)3,4-methylenedioxyamphetamine (MDMA)	1,250	40%
	D-Methamphetamine	500	100%
	L-Methamphetamine	12,500	4%
	Fenfluramine	25,000	2%
	p-Hydroxymethamphetamine	5,000	10%
	D,L-Methamphetamine	500	100%
	β-Phenylethylamine	25,000	2%
	Mephetermine	25,000	2%
	Methoxyphenamine hydrochloride	25,000	2%
	L-Amphetamine	40,000	1.25%
	Ephedrine hydrochloride	100,000	0.5%
	(1R,2S)-(-)-Ephedrine	100,000	0.5%
	D-Amphetamine	100,000(negative)	Not detected
	Chloroquine	100,000(negative)	Not detected
	(+/-)3,4-Methylenedioxyamphetamine(MDA)	100,000(negative)	Not detected
	L-Phenylephrine	100,000(negative)	Not detected
	Trimethobenzamide	100,000(negative)	Not detected
Procaine hydrochloride	100,000(negative)	Not detected	
d/l-Amphetamine	100,000(negative)	Not detected	
OPI 300	6-acetylmorphine	400	75%
	Codeine	300	100%
	Dihydrocodeine	1,000	30%
	EthylMorphine	100	300%
	Heroin	600	50%

Hydrocodone	500	60%
Hydromorphone	1,000	30%
Levorphanol tartrate	10,000	3%
Morphine	300	100%
Nalorphine hydrochloride	50,000	0.6%
Thebaine	6,240	4.8%
s-Monoacetylmorphine	300	100%
Morphine-3-β-d-glucuronide	1,000	30%
6-Monoacetylmorphine (6-MAM)	150	200%
Codeine-6-β-D-glucuronide	150	200%
Morphine-6-β-D-glucuronide	150	200%
6-Acetylcodeine	900	33.3%
Normorphine	100,000(negative)	Not detected
Oxycodone	100,000(negative)	Not detected
Oxymorphone	100,000(negative)	Not detected
Norcodeine	100,000(negative)	Not detected
Procaine	100,000(negative)	Not detected
Norpropoxyphene	100,000(negative)	Not detected

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	Diclofenac sodium	Nitroglycerin
3-Hydroxytyramine	Diflunisal	Norethindrone
7-Aminoclonazepam (except MDMA test)	Digoxin	Norpropoxyphene
7-Aminoflunitrazepam	Dimethyl-aminoantipyrine	Norpseudoephedrine
7-Aminonitrazepam	Diphenhydramine HCl	Nortriptyline (except TCA test)
Acetaminophen	Diphenylhydantoin	Noscapine
Acetone (1000 mg/dL)	Disopyramide	Octopamine
Acetophenetidin	Dopamine HCl	O-Hydroxyhippuric acid
Acetylsalicylic acid	Doxepine (except TCA test)	Olanzapine
Acyclovir	Doxylamine	Omeprazole
Albumin(100mg/dL)	D-Pseudoephedrine	Oxalic acid (100mg/dL)
Albuterol	Duloxetine (except TCA test)	Oxazepam (except BZO test)



Albuterol sulfate(Proair HFA)	Ecgonine methyl ester	Oxazepam Glucuronide (except BZO test)
Alpha Methadol	EMDP	Oxalinic acid
Aminophylline	Ephedrine hydrochloride (except MET test)	Oxymetazoline
Aminopyrine	Erythromycin	Paliperidone
Amitriptyline(except TCA test)	Esomeprazole Magnesium	Papaverine
Amlodipine besylate	Estradiol	Penicillin-G
Amobarbital(except BAR test)	Estrone	PenicillinV Potassium
Amoxicillin	Ethanol(1%)	Perphenazine
Ampicillin	Fenfluramine(except MET test)	Phenacetin
Apomorphine	Fenofibrate	Phencyclidine (except PCP test)
Aripiprazole	Fenoprofen	Phenelzine
Ascorbic acid	Fluoxetine Hydrochloride	Phenylethylamine
Aspartame	Fluphenazine	Phenobarbital (except BAR test)
Aspirin	Fotemustine	Phentermine (except AMP test)
Atomoxetine	Furosemide	Phenylpropanolamine
Atorvastatin Calcium	Gabapentin	Prednisone
Atropine	Galactose	Pregablin
Azithromycin	Gatifloxacin	Procaine
Baclofen	Gemfibrozil	Promazine (except TCA test)
Benzilic acid	Gentisic acid	Promethazine
Benzocaine	Glucose (3000mg/dL)	Propoxyphene (except PPX test)
Benzoic acid	Guaiacolglyceryl ether	Propranolol
Benzoylcegonine (except COC test)	Hemoglobin	Pseudoephedrine
Benzphetamine	Hexobarbital	Pyridoxine
Benzylpiperiazine	Hydralazine	Pyrilamine
Bilirubin	Hydrochlorothiazide	Pyrogallol
Boric Acid (1%)	Hydrocortisone	Quetiapine
Bromo-2,5,Dimethoxyphenethylamine	Hydroxybutyric Acid	Quinidine
Bupropion	Ibuprofen	Quinine
Caffeine	Imipramine(except TCA test)	Quinolinic Acid
Cannabidiol	Isoproterenol	Ranitidine
Captopril	Isoxsuprine	Riboflavin
Carbamazepine	Ketamine	Rifampicin
Carfentanil	Ketoprofen	Salicylic acid
Carisoprodol	LAAM HCl	Secobarbital (except BAR test)
Cefradine	Labetalol	Serotonin
Cephalexin	Lamotrigine	Serotonin (5-Hydroxytyramine)
Cetirizine	L-Ephedrine	Sertraline
Chloral hydrate	L-Epinephrine	Sildenafil Citrate
Chloramphenicol	Levofloxacin Hydrochloride	Simvastatin
Chlordiazepoxide(except BZO test)	Levonorgestrel	Sodium Azide

Chloroquine	Levothyroxine Sodium	Sulfamethazine
Chlorothiazide	Lidocaine Hydrochloride	Sulindac
Chlorpheniramine(except TCA test)	Lisinopril	Telmisartan
Chlorpromazine	Loperamide	Tetracycline
Cholesterol	Loratadine	Tetrahydrocortisone 3-( $\beta$ -D-glucuronide)
Ciprofloxacin Hydrochloride	Lorazepam Glucuronide (except BZO test)	Tetrahydrocortisone, 3-acetate
Citalopram	L-phenylephrine	Tetrahydrozoline
Clarithromycin	LSD	THC (except THC test)
Clofibrate	L-thyroxine	Theophylline
Clomipramine(except TCA test)	Magnesium	Thiamine
Clonidine	Maprotiline	Thioridazine
Clozapine	Meperidine	Trazodone Hydrochloride
Conjugated Estrogens	Meprobamate	Triamterene
Cortisone	Metformin	Trifluoperazine
Creatine Hydrate	Methapyrilene	Trifluoromethylphenyl-piperazine
Creatinine	Methaqualone	Trimethobenzamide
Cyclobenzaprine(except TCA test)	Methoxyphenamine (except MET test)	Trimethoprim
Cyproheptadine	Methylphenidate	Tryptamine
D,L-Epinephrine	Metoprolol Tartrate	Tyramine (except AMP test)
D,L-Isoproterenol	Metronidazole	Urea (2000 mg/dL)
D,L-Lorazepam (except BZO test)	Mifepristone	Uric acid
D,L-Octopamine	N-Acetylprocainamide	Valproic acid (250 $\mu$ g/mL)
D,L-Propranolol	NaCl (4000 mg/dL)	Venlafaxine HCl
D,L-Tryptophan	Nalidixic acid	Verapamil
D,L-Tyrosine	Naloxone hydrochloride (except OXY test)	Vitamin B2
Delorazepam	Naltrexone hydrochloride(except OXY test)	Vitamin C
Demoxepam(except BZO test)	Naproxen	Zaleplon
Deoxycorticosterone	N-desmethyl Tapentadol	Zolpidem
Desloratadine	Niacinamide	Zomepirac
Desipramine(except TCA test)	Nicotine	$\beta$ -Estradiol
Dextromethorphan	Nicotinic Acid	$\gamma$ -Cyclodextrin
Diclofenac	Nifedipine	$\gamma$ -Globulin (500mg/dL)

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The

results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

**B. Method comparison study**

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

Drug test	Test 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	17	22
		-	10	14	16	1	0
	Operator B	+	0	0	1	17	22
		-	10	14	15	1	0
	Operator C	+	0	0	0	17	22
		-	10	14	16	1	0
AMP (500)	Operator A	+	0	0	1	18	21
		-	10	14	15	1	0
	Operator B	+	0	0	1	18	21
		-	10	14	15	1	0
	Operator C	+	0	0	1	18	21
		-	10	14	15	1	0
BAR	Operator A	+	0	0	1	11	28
		-	10	15	14	1	0
	Operator B	+	0	0	1	12	28
		-	10	15	14	0	0
	Operator C	+	0	0	1	11	28
		-	10	15	14	1	0
BUP	Operator A	+	0	0	2	18	20
		-	10	16	12	2	0
	Operator B	+	0	0	1	18	20
		-	10	16	13	2	0
	Operator C	+	0	0	2	18	20
		-	10	16	12	2	0
BZO	Operator A	+	0	0	1	22	16
		-	10	17	12	2	0

	Operator B	+	0	0	1	22	16
		-	10	17	12	2	0
	Operator C	+	0	0	1	22	16
		-	10	17	12	2	0
COC (300)	Operator A	+	0	0	1	16	23
		-	10	16	13	1	0
	Operator B	+	0	0	2	16	23
		-	10	16	12	1	0
	Operator C	+	0	0	1	16	23
		-	10	16	13	1	0
COC (150)	Operator A	+	0	0	1	21	18
		-	10	16	13	1	0
	Operator B	+	0	0	1	20	18
		-	10	16	13	2	0
	Operator C	+	0	0	1	21	18
		-	10	16	13	1	0
EDDP	Operator A	+	0	0	1	16	23
		-	10	16	13	1	0
	Operator B	+	0	0	1	15	23
		-	10	16	13	2	0
	Operator C	+	0	0	0	17	23
		-	10	16	14	0	0
FYL	Operator A	+	0	0	2	15	24
		-	10	16	12	1	0
	Operator B	+	0	0	1	14	24
		-	10	16	13	2	0
	Operator C	+	0	0	1	15	24
		-	10	16	13	1	0
MDMA	Operator A	+	0	0	2	16	23
		-	10	15	13	1	0
	Operator B	+	0	0	1	16	23
		-	10	15	14	1	0
	Operator C	+	0	0	1	16	23
		-	10	15	14	1	0
MET (1000)	Operator A	+	0	0	0	19	20
		-	10	17	13	1	0
	Operator B	+	0	0	1	19	20
		-	10	17	12	1	0
	Operator C	+	0	0	0	19	20
		-	10	17	13	1	0
MET (500)	Operator A	+	0	0	1	23	17
		-	10	15	14	0	0

	Operator B	+	0	0	1	22	17
		-	10	15	14	1	0
	Operator C	+	0	0	1	22	17
		-	10	15	14	1	0
OPI (300)	Operator A	+	0	0	1	20	19
		-	10	15	14	1	0
	Operator B	+	0	0	0	20	19
		-	10	15	15	1	0
	Operator C	+	0	0	1	20	19
		-	10	15	14	1	0
OPI (2000)	Operator A	+	0	0	0	18	22
		-	10	16	14	0	0
	Operator B	+	0	0	1	17	22
		-	10	16	13	1	0
	Operator C	+	0	0	0	17	22
		-	10	16	14	1	0
MTD	Operator A	+	0	0	1	15	24
		-	10	16	13	1	0
	Operator B	+	0	0	0	14	24
		-	10	16	14	2	0
	Operator C	+	0	0	0	15	24
		-	10	16	14	1	0
OXY	Operator A	+	0	0	1	13	25
		-	10	15	14	2	0
	Operator B	+	0	0	1	14	25
		-	10	15	14	1	0
	Operator C	+	0	0	1	13	25
		-	10	15	14	2	0
PCP	Operator A	+	0	0	1	13	25
		-	10	16	13	2	0
	Operator B	+	0	0	1	13	25
		-	10	16	13	2	0
	Operator C	+	0	0	1	14	25
		-	10	16	13	1	0
PPX	Operator A	+	0	0	0	15	24
		-	10	16	14	1	0
	Operator B	+	0	0	1	15	24
		-	10	16	13	1	0
	Operator C	+	0	0	0	15	24
		-	10	16	14	1	0
TCA	Operator A	+	0	0	1	19	20
		-	10	15	14	1	0

	Operator B	+	0	0	1	19	20
		-	10	15	14	1	0
	Operator C	+	0	0	0	19	20
		-	10	15	15	1	0
THC	Operator A	+	0	0	1	16	22
		-	10	16	13	2	0
	Operator B	+	0	0	2	16	22
		-	10	16	12	2	0
	Operator C	+	0	0	1	16	22
		-	10	16	13	2	0
TML	Operator A	+	0	0	1	14	24
		-	10	16	13	2	0
	Operator B	+	0	0	1	15	24
		-	10	16	13	1	0
	Operator C	+	0	0	1	15	24
		-	10	16	13	1	0
6-MAM	Operator A	+	0	0	1	18	20
		-	10	16	13	2	0
	Operator B	+	0	0	1	18	20
		-	10	16	13	2	0
	Operator C	+	0	0	2	19	20
		-	10	16	12	1	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Accurate Result
6-MAM 10	Operator A, C	TF-6-MAM06071	8.13	+
	Operator C	TF-6-MAM06001	8.54	+
	Operator B	TF-6-MAM06030	9.85	+
	Operator B	TF-6-MAM06018	10.84	-
	Operator A, B, C	TF-6-MAM06037	11.04	-
	Operator A	TF-6-MAM06060	11.31	-
AMP 1000	Operator B	TF-AMP06041	968.58	+
	Operator A, B	TF-AMP06035	1008.47	-
	Operator C	TF-AMP06027	1038.84	-
BAR 300	Operator A, C	TF-BAR06026	274.49	+
	Operator B	TF-BAR06024	291.27	+
	Operator A, C	TF-BAR06037	316.44	-
BUP 10	Operator A, C	TF-BUP06058	9.22	+
	Operator B, C	TF-BUP06065	9.58	+
	Operator A	TF-BUP06032	9.79	+
	Operator A	TF-BUP06071	10.18	-

	Operator B, C	TF-BUP06002	10.33	-
	Operator B	TF-BUP06059	10.77	-
	Operator C	TF-BUP06039	11.02	-
	Operator A	TF-BUP06057	11.22	-
BZO 300	Operator A, C	TF-BZO06049	276.48	+
	Operator B	TF-BZO06004	289.45	+
	Operator A, B	TF-BZO06014	302.46	-
	Operator A, C	TF-BZO06018	318.53	-
	Operator B	TF-BZO06006	322.77	-
	Operator C	TF-BZO06071	336.40	-
COC 300	Operator A	TF-COC06076	294.37	+
	Operator B	TF-COC06061	296.67	+
	Operator B	TF-COC06010	288.91	+
	Operator C	TF-COC06066	291.80	+
	Operator A	TF-COC06036	331.25	-
	Operator B	TF-COC06002	302.88	-
	Operator C	TF-COC06029	311.54	-
EDDP 300	Operator B	TF-EDDP06008	278.15	+
	Operator A	TF-EDDP06065	294.41	+
	Operator B	TF-EDDP06042	308.29	-
	Operator B	TF-EDDP06040	314.11	-
	Operator A	TF-EDDP06025	326.51	-
FYL	Operator A	TF-FYL06017	4.28	+
	Operator C	TF-FYL06062	4.54	+
	Operator B	TF-FYL06038	4.61	+
	Operator A	TF-FYL06078	4.83	+
	Operator B	TF-FYL06049	5.11	-
	Operator A	TF-FYL06063	5.48	-
	Operator C	TF-FYL06073	5.63	-
	Operator B	TF-FYL06022	5.77	-
MDMA 500	Operator A	TF-MDMA06047	434.68	+
	Operator C	TF-MDMA06080	443.57	+
	Operator B	TF-MDMA06072	483.40	+
	Operator A	TF-MDMA06046	491.32	+
	Operator C	TF-MDMA06006	505.64	-
	Operator A, B	TF-MDMA06002	519.63	-
MET 1000	Operator B	TF-MET06052	946.52	+
	Operator B	TF-MET06031	1064.20	-
	Operator A	TF-MET06007	1139.47	-
	Operator C	TF-MET06006	1162.76	-
OPI 300	Operator A, C	TF-MOP06065	291.05	+
	Operator B	TF-MOP06062	302.36	-
	Operator A	TF-MOP06031	317.77	-

	Operator C	TF-MOP06032	351.52	-
MTD 300	Operator A	TF-MTD06025	280.13	+
	Operator B	TF-MTD06078	306.14	-
	Operator C	TF-MTD06056	321.60	-
	Operator A	TF-MTD06006	336.27	-
	Operator B	TF-MTD06060	351.49	-
OXY 100	Operator A, C	TF-OXY06058	95.88	+
	Operator B	TF-OXY06003	97.96	+
	Operator A	TF-OXY06078	100.28	-
	Operator A, C	TF-OXY06073	100.77	-
	Operator B	TF-OXY06024	102.28	-
	Operator C	TF-OXY06060	115.34	-
PCP 25	Operator A, C	TF-PCP06039	20.19	+
	Operator B	TF-PCP06002	23.68	+
	Operator A, C	TF-PCP06018	25.19	-
	Operator A, B	TF-PCP06075	25.88	-
	Operator B	TF-PCP06043	28.42	-
PPX 300	Operator B	TF-PPX06066	277.71	+
	Operator B	TF-PPX06037	304.35	-
	Operator A	TF-PPX06012	321.47	-
	Operator C	TF-PPX06045	335.28	-
TCA 1000	Operator B	TF-TCA06015	892.55	+
	Operator A	TF-TCA06008	951.60	+
	Operator B	TF-TCA06020	1013.28	-
	Operator C	TF-TCA06068	1120.01	-
	Operator A	TF-TCA06080	1120.63	-
THC 50	Operator B	TF-THC06021	42.33	+
	Operator A	TF-THC06073	44.93	+
	Operator C	TF-THC06060	47.61	+
	Operator B	TF-THC06050	49.77	+
	Operator A, C	TF-THC06062	53.28	-
	Operator B	TF-THC06014	57.74	-
	Operator B	TF-THC06040	58.69	-
	Operator A, C	TF-THC06064	59.33	-
TML	Operator A	TF-TML06052	84.31	+
	Operator C	TF-TML06043	90.15	+
	Operator B	TF-TML06024	94.68	+
	Operator A	TF-TML06054	101.37	-
	Operator B, C	TF-TML06056	108.45	-
	Operator A	TF-TML06046	114.31	-
AMP 500	Operator B	TF-SAMP06031	447.35	+
	Operator C	TF-SAMP06034	465.44	+
	Operator A	TF-SAMP06006	479.87	+



	Operator B	TF-SAMP06055	502.90	-
	Operator A	TF-SAMP06075	541.26	-
	Operator C	TF-SAMP06054	577.15	-
COC 150	Operator A, B, C	TF-SCOC06030	133.67	+
	Operator B	TF-SCOC06062	155.27	-
	Operator A, C	TF-SCOC06053	160.33	-
	Operator B	TF-SCOC06019	165.57	-
MET 500	Operator B	TF-SMET06029	428.49	+
	Operator A, C	TF-SMET06042	481.16	+
	Operator B, C	TF-SMET06035	512.71	-
OPI 2000	Operator B	TF-SMOP06029	1972.07	+
	Operator B	TF-SMOP06014	2108.15	-
	Operator C	TF-SMOP06065	2194.62	-

### **C. Lay person study**

A lay user study was performed at three intended user sites with 280 lay persons. 76 male and 64 female tested Healgen® Accurate Muti-Drug Urine Drug Screen Cup Configuration 1; 73 male and 67 female tested Healgen® Accurate Muti-Drug Urine Drug Screen 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 Healgen® Accurate Muti-Drug Urine Drug Screen Cup Configuration 1:**

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	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%
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	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%
EDDP	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
FYL	5	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%
MDMA	500	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MET	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%
MOP	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MTD	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%
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
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
PCP	25	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%
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	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%
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
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
TML	100	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	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%

Result of Healgen® Accurate Multi-Drug Urine Drug Screen Cup Configuration 2:

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	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%
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	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%
COC	150	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%

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%
FYL	5	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	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%
MET	500	Negative	20	20	20	20	1	0	0
		Positive	0	0	0	0	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	100%	95%	100%	100%
MOP	2000	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%
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	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%
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	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%
TCA	1000	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
THC	50	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20

		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
TML	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%
6-MAM	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%

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 Healgen® Accurate Home Muti-Drug Urine Test Cup and Healgen® Accurate Muti-Drug Urine Drug Screen Cup are substantially equivalent to the predicate devices.