Shanghai Accurature Diagnostics Co., Ltd.
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.,
Shanghai 200122, China

Re: K232228
Trade/Device Name: Multi-drug Urine Test Cup
Multi-drug Urine Test Dip Card
Accurature Multi-drug Urine Test Cup
Accurature Multi-drug Urine Test Dip Card
Regulation Number: 21 CFR 862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Code: DJG, DIO, LDJ, LCM, JXM, LAF, DKZ, DIS, DJR, JXN,
Dated: January 22, 2024
Received: January 22, 2024

Dear Eva Li:
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: 2024.02.23 17:32:56 -05'00'

Joseph Kotarek
Toxicology 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232228

Device Name
Accurature Multi-drug Urine Test Cup
AccuratureMulti-drug Urine Test Dip Card

Indications for Use *(Describe)*
Accurature Multi-drug Urine Test Cup and Accurature Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxy-methamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Marijuana in human urine at the cut off concentrations of:

Drug	Abbreviation	Cut-off
Amphetamine	AMP	1000ng/mL
Secobarbital	BAR	300 ng/mL
Buprenorphine	BUP	10 ng/mL
Opzaepam	BZO	300 ng/mL
Cocaine	COC	300 ng/mL
Methylenedioxy-methamphetamine	MDMA	500 ng/mL
Methamphetamine	MET	1000ng/mL
Morphine	MOR	300 ng/mL
Methadone	MTD	300 ng/mL
Oxycodone	OXY	100 ng/mL
Phencyclidine	PCP	25 ng/mL
Marijuana	THC	50 ng/mL

Configuration of the Accurature Multi-drug Urine Test Cup and Accurature Multi-drug UrineTest Dip Card can consist of any combination of the above listed drug analytes.
The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For over-the-counter use.

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.

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
PRAStaff@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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232228

Device Name
Multi-drug Urine Test Cup
Multi-drug Urine Test Dip Card

Indications for Use *(Describe)*
Multi-drug Urine Test Cup and Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxy-methamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Marijuana in human urine at the cut off concentrations of:

Drug	Abbreviation	Cut-off
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Methylenedioxy-methamphetamine	MDMA	500 ng/mL
Methamphetamine	MET	1000ng/mL
Morphine	MOR	300 ng/mL
Methadone	MTD	300 ng/mL
Oxycodone	OXY	100 ng/mL
Phencyclidine	PCP	25 ng/mL
Marijuana	THC	50 ng/mL

Configuration of the Multi-drug Urine Test Cup and Multi-drug Test Dip Card can consist of any combination of the above listed drug analytes.
The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For prescription use only.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510（K）Summary（K232228）

1. Prepared date:	Jan 14, 2024
2. Submitter:	Shanghai Accurature Diagnostics Co.,Ltd.
	Building 1,No.168 Banqiao East Road, Shanyang Town, Jinshan District, Shanghai 201508, P.R.China
3. Contact person:	Shuang He +86-21-33691818 hes@kangliyixue.com
4. Device Name*:	OTC use: Accurature Multi-drug Urine Test Dip Card Accurature Multi-drug Urine Test Cup Rx use: Multi-drug Urine Test Dip Card Multi-drug Urine Test Cup
5. Classification:	II

*The Device for OTC and Rx are exact same, only have different name.
Hereafter, Multi-drug Urine Test Dip card and Multi-drug Urine Test Cup represented both OTC and Rx use.

Product Code	Regulation Section	Panel
DKZ Amphetamine	21 CFR § 862.3100, Amphetamine Test System	Toxicology
LDJ Marijuana	21 CFR § 862.3870, Cannabinoids Test System	
DIO Cocaine	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	
LAF Methamphetamine	21 CFR § 862.3610, Methamphetamine Test System	
DJG Morphine	21 CFR § 862.3650, Opiate Test System	
JXM Oxazepam	21 CFR § 862.3170, Benzodiazepine Test System	
DJG Oxycodone	21 CFR § 862.3650, Opiate Test System	
DIS Secobarbital	21 CFR § 862.3150, Barbiturate Test System	
DJG Buprenorphine	21 CFR § 862.3650, Opiate Test System	
LAF Methylenedioxy-methamphetamine	21 CFR § 862.3610, Methamphetamine Test System	
LCM Phencyclidine	Enzyme Immunoassay Phencyclidine	
DJR Methadone	21 CFR § 862.3620, Methadone Test System	

6. Description of the device:

The subject device will be sold in two formats: Multi-drug Urine Test Dip Card and Multi-drug Urine Test Cup.

Multi-Drug Urine Test Cup and Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Marijuana, Cocaine, Methamphetamine, Morphine, Oxazepam, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine and Methadone in human urine samples. Multi-Drug Urine Test devices detect each of analytes on different strips. A positive urine sample will not generate a colored-line for the specific drug tested in the designated region. A negative urine specimen or a urine sample containing Amphetamine, Marijuana, Cocaine, Methamphetamine, Morphine, Oxazepam, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine and Methadone at the concentration below the designated cutoff levels will generate a colored line in the designated test region for the drug. To serve as a test control, a color line will always appear at the control region.

7. The Predicate Devices:
K153050
Device name: Rapid Single/Multi-drug test Cup
Rapid Single/Multi-drug test Dipcard
Co-Innovation Biotech Co.,Ltd.

8. Indication for use:
Multi-drug Urine Test Cup and Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxy-methamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Marijuana in human urine at the cut off concentrations of:

Drug	**Abbreviation**	**Cut-off**
Amphetamine	AMP	1000ng/mL
Secobarbital	BAR	300 ng/mL
Buprenorphine	BUP	10 ng/mL
Oxazepam	BZO	300 ng/mL
Cocaine	COC	300 ng/mL
Methylenedioxy-methamphetamine	MDMA	500 ng/mL
Methamphetamine	MET	1000ng/mL
Morphine	MOR	300 ng/mL
Methadone	MTD	300 ng/mL
Oxycodone	OXY	100 ng/mL
Phencyclidine	PCP	25 ng/mL
Marijuana	THC	50 ng/mL

Configuration of the Multi-drug Urine Test Cup and Multi-drug Urine Test Dip Card can consist of any combination of the above listed drug analytes.
The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For prescription use only.

Accurature Multi-drug Urine Test Cup and Accurature Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxy-methamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Marijuana in human urine at the cut off concentrations of:

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Methamphetamine	MET	1000ng/mL
Morphine	MOR	300 ng/mL
Methadone	MTD	300 ng/mL
Oxycodone	OXY	100 ng/mL
Phencyclidine	PCP	25 ng/mL
Marijuana	THC	50 ng/mL

Configuration of the **Accurature** Multi-drug Urine Test Cup and **Accurature** Multi-drug urineTest Dip Card can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For over-the-counter use.

9. Substantial Equivalence Information

A summary comparison of features of the subject device and the predicate devices is provided in the following Table

Item	Subject device	Predicate device K153050	Comparison
Indication(s) for use	Qualitative detection of drugs-of-abuse in human urine (Amphetamine, Secobarbital , Buprenorphine, Oxazepam 、 Cocaine, Methylenedioxy-methamphetamine, Methamphetamine 、 Morphine, Methadone, Oxycodone 、 Phencyclidine, Marijuana)	Qualitative detection of drugs-of-abuse in human urine (Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Methylenedioxymethamphetamine, Methamphetamine, Morphine300, Morphine2000, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Tri-cyclic Antidepressants, Marijuan)	Same（but the number of drugs detected different)
Intended Users	Over the Counter (OTC) Use and Prescription Use	Over the Counter (OTC) Use and Prescription Use	Same

Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen	Human Urine	Human Urine	Same
Cutoff	Amphetamine:1000ng/mL Secobarbital:300ng/mL Buprenorphine:10ng/mL Oxazepam:300ng/mL Cocaine:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methamphetamine:1000ng/mL Morphine:300ng/mL Methadone:300ng/mL Oxycodone:100ng/mL Phencyclidine:25ng/mL Marijuana:50 ng/mL	Amphetamine:1000ng/mL Barbiturates:300ng/mL Buprenorphine:10ng/mL Benzodiazepines:300ng/mL Cocaine:300 ng/mL EDDP:300ng/mL Methylenedioxymethamphetamine:500 ng/mL Methamphetamine:1000ng/mL Morphine:300ng/mL Morphine:2000ng/mL Methadone:300ng/mL Oxycodone:100ng/mL Phencyclidine:25ng/mL Propoxyphene:300 ng/mL Tri-cyclic Antidepressants:1000 ng/mL Marijuana:50 ng/mL	Same
Configurations	Dipcard and Cup	Dipcard and Cup	Same

Remark:
The subject devices have all features of the predicate device except the number of drugs detected. These differences do not affect the performance characteristics of the subject devices.

10. performance Data
10. 1 Comparison Study

Different operators to test the same sample, the results are consistent. The Multi-drug Urine Test Cup/ Test Dip Card has good comparison. The Summarize/results are as follows:

	Cup		Card	
	Amphetamine	**Result**	**Amphetamine**	**Result**
% agreement among positives:	98.3%	Qualified	98.3%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Secobarbital	**Result**	**Secobarbital**	**Result**
% agreement among positives:	98.3%	Qualified	100.0%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Buprenorphine	**Result**	**Buprenorphine**	**Result**
% agreement among positives:	98.3%	Qualified	100.0%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Oxazepam	**Result**	**Oxazepam**	**Result**
% agreement among positives:	98.3%	Qualified	98.3%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Cocaine	**Result**	**Cocaine**	**Result**

% agreement among positives:	97.5%	Qualified	98.3%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Methylenedioxy-methamphetamine	**Result**	**Methylenedioxy-methamphetamine**	**Result**
% agreement among positives:	95.8%	Qualified	98.3%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Methamphetamine	**Result**	**Methamphetamine**	**Result**
% agreement among positives:	95.8%	Qualified	99.2%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Morphine	**Result**	**Morphine**	**Result**
% agreement among positives:	97.5%	Qualified	99.2%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Methadone	**Result**	**Methadone**	**Result**
% agreement among positives:	97.5%	Qualified	97.5%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Oxycodone	**Result**	**Oxycodone**	**Result**
% agreement among positives:	99.2%	Qualified	96.7%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Phencyclidine	**Result**	**Oxycodone**	**Result**
% agreement among positives:	95.8%	Qualified	99.2%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified
	Marijuana	**Result**	**Marijuana**	**Result**
% agreement among positives:	99.2%	Qualified	99.2%	Qualified
% agreement among negatives :	100.0%	Qualified	100.0%	Qualified

10.2 Cross Reactivity

Cross reactivity study is complemented, the result showed when there are substances of the corresponding concentration in the urine, the Test Cup and Test Dip Card may produce false positive results.

Drug	concentration (ng/mL)
Amphetamine	
D-Amphetamine	1,000
D,L-Amphetamine (Amphetamine Sulfate)	1,000
Phentermine	1,300
(+/-)-4-Hydroxyamphetamine HCL	700
1-Amphetamine	50,000
Methylenedioxyethylamphetamine	100,000
Secobarbital	
Secobarbital	300
Amobarbital	300
Aprobarbital	300
Phenobarbital	300

Oxazepam	
Buprenorphine	10
Buprenorphine -3-D-Glucuronide	10
Chlordiazepoxide	2000
Clorazepate	200
Oxazepam	
Alprazolam	200
Bromazepam	1,500
Chlordiazepoxide HCL	1,500
Clobazam	100
Clonazepam	750
Clorazepate Dipotassium	200
Delorazepam	1,500
Desalkylflurazepam	400
Diazepam	200
Estazolam	2,500
Flunitrazepam	400
A-Hydroxyalprazolam	1260
(±) Lorazepam	1,500
RS-Lorazepam glucuronide	160
Midazolam	12,500
Nitrazepam	100
Norchlordiazepoxide	200
Nordiazepam	400
Oxazepam	300
Temazepam	100
Triazolam	2,500
Cocaine	
Benzoylecogonine	300
Cocaethylene	300
CocaineHCl	300
Ecgonine HCl	35000
Methylenedioxy-methamphetamine	
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
Methamphetamine	
D-Methamphetamine	1,000
Methamphetamine	1000
L(-)-Methamphetamine	8000

d-Amphetamine	100,000
3,4-methylenedioxyampheta mine (MDA)	100,000
Morphine	
Morphine	300
Codeine	300
Norcodeine	7500
Morphine 3-b-D-glucuronide	300
Methadone	
Methadone	300
(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000
Oxycodone	
Oxycodone	100
Naloxone	50000
Naltrexone	50000
Morphine 3- β-D-glucuronide	50000
Phencyclidine	
Phencyclidine	25
Marijuana	
11-nor-Δ9-THC-9-COOH	50
11-Nor-Δ9-Tetrahydrocannabinol	50
11-Nor-Δ8-Tetrahydrocannabinol	50
Cannabidiol	100,000
Δ8- Tetrahydrocannabinol	10,000

10.3 Interference

Potential interfering substances were added to drug-free urine sample and samples with target drugs of ±25% cutoff level.The substances in the table up did not affect the Test Dip Card/Test Cup at concentrations of 100ug/ml.All samples with a concentration of -25% cutoff and drug free test results are negative, and all samples with a concentration of+25% cutoff test results are positive.

10.4 Interference of Different pH

The results are all positive for samples at +50% cutoff and all negative for samples at -50% cutoff. The results show that when the pH of samples are in the range of 4-9, there is no effect on the test results.

10.5 Interference of Specific Gravity

The results all positive for samples at +50% cutoff and all negative for samples at -50% cutoff. The results show that when the gravity is in the range of 1.000-1.035, there is no effect on the test results.

10.6 Cut-off

The cut-off value is

Calibrator	Cut-off (ng/mL)
Amphetamine	1000
Secobarbital	300
Buprenorphine	10

Oxazepam	300
Cocaine	300
Methylenedioxy-methamphetamine	500
Methamphetamine	1000
Morphine	300
Methadone	300
Oxycodone	100
Phencyclidine	25
Marijuana	50

10.7 Precision

As the results ,all the results of drug free,-75%Cut off,-50%Cut off are negative, and all the results of +100% cutoff,+75%Cut off,+50%Cut off are positive, and cutoff coincidence rate of the test results is 79%(>55%),±25% cutoff coincidence rate of the test results is 88%(>84%),so the Precision of kit is qualified.

10.8 Lay User Study

A lay user study were performed at three intended user sites with 603 laypersons(303 laypersons for Test Cup and 300 laypersons for Test Dip Card).They should have diverse educational and professional backgrounds and ranged in age from 21 to 50. Urine samples are prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cut off by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/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. They will be asked to fill out an English questionnaire after finishing the test.

The results of the lay user method comparison (Test Cup)

Amphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	253.8674	0	20	100.0%
-50%Cut off	508.5452	0	161	100.0%
-25%Cut off	736.2487	0	20	100.0%
+25%Cut off	1197.5758	19	1	95.0%
+50%Cut off	1501.0527	42	0	100.0%
+75%Cut off	1678.9382	20	0	100.0%

Secobarbital

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	

0	0.00	0	20	100.0%
-75%Cut off	71.5804	0	20	100.0%
-50%Cut off	147.7771	0	161	100.0%
-25%Cut off	226.3641	0	20	100.0%
+25%Cut off	364.0221	20	0	100.0%
+50%Cut off	419.027	42	0	100.0%
+75%Cut off	515.8795	20	0	100.0%

Buprenorphine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	2.4489	0	20	100.0%
-50%Cut off	4.731	0	161	100.0%
-25%Cut off	7.2609	0	20	100.0%
+25%Cut off	11.7585	20	0	100.0%
+50%Cut off	14.2329	42	0	100.0%
+75%Cut off	16.8724	20	0	100.0%

Oxazepam

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	70.446	0	20	100.0%
-50%Cut off	151.3073	0	161	100.0%
-25%Cut off	220.6369	0	20	100.0%
+25%Cut off	389.9653	19	1	95.0%
+50%Cut off	461.6992	42	0	100.0%
+75%Cut off	502.0942	20	0	100.0%

Cocaine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	70.446	0	20	100.0%
-50%Cut off	151.3073	0	161	100.0%
-25%Cut off	220.6369	0	20	100.0%
+25%Cut off	389.9653	20	0	100.0%
+50%Cut off	461.6992	42	0	100.0%
+75%Cut off	502.0942	20	0	100.0%

Methylenedioxy-methamphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%

-75%Cut off	114.1879	0	20	100.0%
-50%Cut off	257.9109	0	161	100.0%
-25%Cut off	359.2816	0	20	100.0%
+25%Cut off	613.3061	20	0	100.0%
+50%Cut off	692.4385	42	0	100.0%
+75%Cut off	918.3664	20	0	100.0%

Methamphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	257.2811	0	20	100.0%
-50%Cut off	519.5908	0	161	100.0%
-25%Cut off	780.8035	0	20	100.0%
+25%Cut off	1127.6588	20	0	100.0%
+50%Cut off	1435.7586	42	0	100.0%
+75%Cut off	1795.7356	20	0	100.0%

Morphine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	74.9251	0	20	100.0%
-50%Cut off	148.7061	0	161	100.0%
-25%Cut off	210.2795	0	20	100.0%
+25%Cut off	354.7366	20	0	100.0%
+50%Cut off	420.8013	42	0	100.0%
+75%Cut off	476.5929	20	0	100.0%

Methadone

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	76.2488	0	20	100.0%
-50%Cut off	157.0163	0	161	100.0%
-25%Cut off	206.975	0	20	100.0%
+25%Cut off	356.5922	19	1	95.0%
+50%Cut off	454.0655	42	0	100.0%
+75%Cut off	519.0941	20	0	100.0%

Oxycodone

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	22.5121	0	20	100.0%
-50%Cut off	45.9304	0	161	100.0%

-25%Cut off	70.8923	0	20	100.0%
+25%Cut off	131.2278	20	0	100.0%
+50%Cut off	144.5957	42	0	100.0%
+75%Cut off	174.6656	20	0	100.0%

Phencyclidine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	5.6551	0	20	100.0%
-50%Cut off	11.8659	0	161	100.0%
-25%Cut off	19.3029	0	20	100.0%
+25%Cut off	29.5142	20	0	100.0%
+50%Cut off	38.0936	42	0	100.0%
+75%Cut off	41.2136	20	0	100.0%

Marijuana

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	12.9481	0	20	100.0%
-50%Cut off	23.5849	0	161	100.0%
-25%Cut off	36.2969	0	20	100.0%
+25%Cut off	59.5132	20	0	100.0%
+50%Cut off	74.5304	42	0	100.0%
+75%Cut off	90.3451	20	0	100.0%

The results of the lay user method comparison (Test Dip Card)

Amphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	253.8674	0	19	100.0%
-50%Cut off	508.5452	0	160	100.0%
-25%Cut off	736.2487	0	20	100.0%
+25%Cut off	1197.5758	20	0	100.0%
+50%Cut off	1501.0527	41	0	100.0%
+75%Cut off	1678.9382	20	0	100.0%

Secobarbital

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	71.5804	0	19	100.0%
-50%Cut off	147.7771	0	160	100.0%
-25%Cut off	226.3641	0	20	100.0%
+25%Cut off	364.0221	20	0	100.0%
+50%Cut off	419.027	41	0	100.0%
+75%Cut off	515.8795	20	0	100.0%

Buprenorphine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	2.4489	0	19	100.0%
-50%Cut off	4.731	0	160	100.0%
-25%Cut off	7.2609	0	20	100.0%
+25%Cut off	11.7585	19	1	95.0%
+50%Cut off	14.2329	41	0	100.0%
+75%Cut off	16.8724	20	0	100.0%

Oxazepam

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0.00	0	20	100.0%
-75%Cut off	70.446	0	19	100.0%
-50%Cut off	151.3073	0	160	100.0%
-25%Cut off	220.6369	0	20	100.0%

+25%Cut off	389. 9653	20	0	100. 0%
+50%Cut off	461. 6992	41	0	100. 0%
+75%Cut off	502. 0942	20	0	100. 0%

Cocaine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	70. 446	0	19	100. 0%
-50%Cut off	151. 3073	0	160	100. 0%
-25%Cut off	220. 6369	0	20	100. 0%
+25%Cut off	389. 9653	20	0	100. 0%
+50%Cut off	461. 6992	41	0	100. 0%
+75%Cut off	502. 0942	20	0	100. 0%

Methylenedioxy-methamphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	114. 1879	0	19	100. 0%
-50%Cut off	257. 9109	0	160	100. 0%
-25%Cut off	359. 2816	0	20	100. 0%
+25%Cut off	613. 3061	20	0	100. 0%
+50%Cut off	692. 4385	41	0	100. 0%
+75%Cut off	918. 3664	20	0	100. 0%

Methamphetamine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	257. 2811	0	19	100. 0%
-50%Cut off	519. 5908	0	160	100. 0%
-25%Cut off	780. 8035	0	20	100. 0%
+25%Cut off	1127. 6588	20	0	100. 0%
+50%Cut off	1435. 7586	41	0	100. 0%
+75%Cut off	1795. 7356	20	0	100. 0%

Morphine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	74. 9251	0	19	100. 0%

-50%Cut off	148. 7061	0	160	100. 0%
-25%Cut off	210. 2795	0	20	100. 0%
+25%Cut off	354. 7366	20	0	100. 0%
+50%Cut off	420. 8013	41	0	100. 0%
+75%Cut off	476. 5929	20	0	100. 0%

Methadone

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	76. 2488	0	19	100. 0%
-50%Cut off	157. 0163	0	160	100. 0%
-25%Cut off	206. 975	0	20	100. 0%
+25%Cut off	356. 5922	20	0	100. 0%
+50%Cut off	454. 0655	41	0	100. 0%
+75%Cut off	519. 0941	20	0	100. 0%

Oxycodone

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	22. 5121	0	19	100. 0%
-50%Cut off	45. 9304	0	160	100. 0%
-25%Cut off	70. 8923	0	20	100. 0%
+25%Cut off	131. 2278	20	0	100. 0%
+50%Cut off	144. 5957	41	0	100. 0%
+75%Cut off	174. 6656	20	0	100. 0%

Phencyclidine

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%
-75%Cut off	5. 6551	0	19	100. 0%
-50%Cut off	11. 8659	0	160	100. 0%
-25%Cut off	19. 3029	0	20	100. 0%
+25%Cut off	29. 5142	20	0	100. 0%
+50%Cut off	38. 0936	41	0	100. 0%
+75%Cut off	41. 2136	20	0	100. 0%

Marijuana

% of Cutoff	Concentration by LC/MS (ng/mL)	Lay person results		The percentage agreement (%)
		No. of Positive	No. of Negative	
0	0. 00	0	20	100. 0%

-75%Cut off	12. 9481	0	19	100. 0%
-50%Cut off	23. 5849	0	160	100. 0%
-25%Cut off	36. 2969	0	20	100. 0%
+25%Cut off	59. 5132	20	0	100. 0%
+50%Cut off	74. 5304	41	0	100. 0%
+75%Cut off	90. 3451	20	0	100. 0%

“Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.”

11. Conclusion

The data collected in the performance and comparison studies demonstrate that subject devices are substantially equivalent to the predicate.