



Food and Drug Administration
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April 26, 2016

CO-INNOVATION BIOTECH CO., LTD
HONG FENG
PRODUCT MANAGER
NO. 13, YANYUAN ROAD, TIANHE DISTRICT,
GUANGZHOU 510507, CHINA

Re: K153050

Trade/Device Name: Rapid Single/multi-drug Test Cup, Rapid Single/multi-drug Test
Dipcard

Regulation Number: 21 CFR 862.3650

Regulation Name: Opiate test system

Regulatory Class: II

Product Code: DJG, DKZ, LFG, DIO, LDJ, DNK, LAF, LCM, JXM, DIS, DJC, DJR, JXN

Dated: March 28, 2016

Received: March 28, 2016

Dear Hong Feng:

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 (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. 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.

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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153050

Device Name

Rapid Single/Multi-drug test Cup Rapid Single/Multi-drug test Dipcard

Indications for Use (Describe)

Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard is a rapid drug screening test designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylcegonine	300 ng/mL
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 2000 (MOP)	Morphine	2000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Buprenorphine(BUP)	Buprenorphine	10ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL
Morphine(MOP300)	Morphine	300 ng/mL
Propoxyphene(PPX)	Propoxyphene	300 ng/mL
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL

The tests contain two formats: 1) Test Cup and 2) Test Dipcard. The tests may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 15 analytes. Only one cutoff concentration will be included per analyte per device. The tests are intended for in vitro diagnostics use. They are intended for prescription use including point of care sites and over-the-counter use.

The tests will yield preliminary positive results when prescription drugs Barbiturates, Buprenorphine, Benzodiazepine, Methadone, Propoxyphene or Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturates, Buprenorphine, Benzodiazepine, Propoxyphene and Tricyclic Antidepressants in urine.

This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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Co-Innovation Biotech Co.,Ltd.

Section 5 - 510(k) Summary

Date of Summary Preparation: 26/4/2016

1. Submitter's Identifications

Submitter: Co-Innovation Biotech Co.,Ltd.

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2. Correspondent's Identifications

Correspondent's Name: Co-Innovation Biotech Co.,Ltd.

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3. Name of the Device

Recommended classification regulation:

21 CFR 862.3100 Amphetamine test system

21 CFR 862.3150 Barbiturate test system

21 CFR 862.3650 Opiate test system

21 CFR 862.3170 Benzodiazepine test system

21 CFR 862.3250 Cocaine test system

21 CFR 862.3620 Methadone test system

21 CFR 862.3610 Methamphetamine test system

21 CFR 862.3640 Morphine test system

Unclassified, Enzyme immunoassay, phencyclidine test system

21 CFR 862.3700 Propoxyphene test system

21 CFR 862.3910 Tri-cyclic Antidepressants drug test system

21 CFR 862.3870 Cannabinoid test system

Device class: Class II

Panel: Toxicology (91)

Product code: DKZ,DJC,DIO,LDJ,DNK,DIS,JXM,DJR,DJG,LCM,JXN,LFG

Common Name:

Amphetamine (AMP) Test System

Barbiturates (BAR) Test System

Buprenorphine(BUP) Test System

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Benzodiazepines (BZO) Test System
Cocaine (COC) Test System
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP) Test System
Methylenedioxymethamphetamine (MDMA) Test System
Methamphetamine (MET) Test System
Morphine (MOP300) Test System
Morphine(MOP2000) Test System
Methadone (MTD) Test System
Oxycodone (OXY) Test System
Phencyclidine (PCP) Test System
Propoxyphene(PPX) Test System
Tri-cyclic Antidepressants (TCA)Test System
Cannabinoid (THC) Test System

Proprietary names:

Rapid Single/Multi-drug Test Cup
Rapid Single/Multi-drug Test Dipcard

4. The Predicate Devices

K140748 One Step Single/Multi-drug Test Cup
 One Step Single/Multi-drug Test Dipcard
K142800 Rapid Single/Multi-drug Test Cup
 Rapid Single/Multi-drug Test Dipcard

5. Device Description

Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaines, 2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine, Methylenedioxymethamphetamine, Methamphetamine, Morphine300, Morphine2000, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Tri-cyclic Antidepressants, Marijuana and their metabolites (specifically THC) at or above the cut-off levels as indicated. The tests can be performed without the use of an instrument.

Test Cup and Test Dipcard use identical test strips made with same chemical formulation and manufacturing procedures.

6. Intended Use of Device

Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard is a rapid drug screening test for the qualitatively detection of drugs and drug metabolites in human urine. Drug test cut-off concentrations are listed below:

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Test	Calibrator	Cut-off level
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Buprenorphine(BUP)	Buprenorphine	10ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylcegonine	300 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300 ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine300(MOP300)	Morphine	300 ng/mL
Morphine2000(MOP2000)	Morphine	2000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene(PPX)	Propoxyphene	300 ng/mL
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL

The tests contain two formats: 1) Test Cup and 2) Test Dipcard. The tests may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 15 analytes. Only one cutoff concentration will be included per analyte per device. The tests are intended for in vitro diagnostics use. They are intended for prescription use including point of care sites and over-the-counter use.

The tests will yield preliminary positive results when prescription drugs Barbiturates, Buprenorphine, Benzodiazepine, Methadone, Propoxyphene or Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturates, Buprenorphine, Benzodiazepine, Propoxyphene and Tricyclic Antidepressants in urine.

This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

7. Comparison to Predicate Devices:

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Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard are a modified product format derived from the previously FDA-cleared Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard, One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard. A summary comparison of features of the Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard and the predicate devices is provided in the following Table.

Item	Device	Predicate (K140748, K142800)
Indication for use	Qualitative detection of drugs-of-abuse in 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, Marijuana)	Same (but the number of drugs detected different)
Intended Users	Over the Counter (OTC) Use and Prescription Use	Same
Specimen	Urine	Same
Cutoff	Amphetamine:1000 ng/mL Barbiturates:300 ng/mL Buprenorphine:10 ng/mL Benzodiazepines:300 ng/mL Cocaine:300 ng/mL EDDP:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methamphetamine:1000 ng/mL Morphine:300 ng/mL Morphine:2000 ng/mL Methadone:300 ng/mL Oxycodone:100 ng/mL Phencyclidine:25 ng/mL Propoxyphene:300 ng/mL Tri-cyclic Antidepressants:1000 ng/mL Marijuana:50 ng/mL	Same
Read time	5 minutes	Same
Storage	4 ~ 30 °C	Same
Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow	Same

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	immunochemical assay based on the principle of antigen antibody immunochemistry	
Configuration	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.

8. Performance Data:

8.1 Cross-reactivity with structurally similar compounds

To test the cross reactivity of the test, 2 lots of test Dipcard and one lot of test Cup was used to test with drug metabolites and drug structurally similar compounds in urine. All the components were added to drug-free normal human urine. Each sample was tested in 5 replicates using 3 lots of Test Cup and Test Dipcard. If any positive result was observed, the compounds were further diluted with known drug-free urine specimen sequentially to different concentrations and tested in quintuplicate, until the highest concentration that generates a negative result was identified. The cross reacting substances with the lowest concentration that produced a positive result was identified and is listed in the table below.

Amphetamine (AMP)	Lowest Concentration (ng/mL)	% Cross-reactivity	Methamphetamine (MET)	Lowest Concentration (ng/mL)	% Cross-reactivity
d-Amphetamine	1,000	100%	3,4- Methyleneoxyethyl amphetamine(MDEA)	50,000	2%
d,l-Amphetamine	2,500	40%	d-Amphetamine	> 100,000	Not detected
l-Amphetamine	50,000	2%	l-Amphetamine	> 100,000	Not detected
3,4-Methyleneoxyamphetamine (MDA)	2,000	50%	3,4-methyleneoxyamphetamine (MDA)	> 100,000	Not detected
d-methamphetamine	> 100,000	Not detected	Morphine300(MOP300)		
l-methamphetamine	> 100,000	Not detected	Morphine	300	100%
3,4-Methyleneoxyamphetamine (MDMA)	> 100,000	Not detected	Codeine	300	100%
Methyleneoxyethylamphetamine (MDEA)	> 100,000	Not detected	Hydrocodone	2000	15%
Barbiturates (BAR)			Hydromorphone	1500	20%
Secobarbital	300	100%	6-Monoacetylmorphine (6-MAM)	750	40%
Amobarbital	500	60%	Morphine 3-b-D-glucuronide	300	100%
Alphenal	150	200%	Ethylmorphine	3500	8.6%
Aprobarbital	200	150%	Levorphanol	5000	6%
Butobarbital	75	400%	Heroin	300	100%
Butalbital	1,500	20%	Norcodeine	7500	4%
Butethal	100	300%	Oxycodone	100000	0.3%
Cyclopentobarbital	600	50%	Thebain	8000	3.8%
Pentobarbital	700	42.9%	Morphine2000(MOP2000)		
Phenobarbital	300	100%	Morphine	2,000	100%
Buprenorphine(BUP)			Codeine	2,000	100%
Buprenorphine	10	100%	Hydrocodone	15,000	13.3%
Norbuprenorphine	20	50%	Hydromorphone	10,000	20%
Buprenorphine 3-D-glucuronide	15	66.7%	6-Monoacetylmorphine	5,000	40%

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Norbuprenorphine 3-D-glucuronide	200	5%	Morphine 3-b-D-glucuronide	2,000	100%
Benzodiazepines (BZO)			Oxycodone	>100000	2%
Oxazepam	300	100%	Methadone (MTD)		
Alprazolam	200	150%	Methadone	300	100%
α-Hydroxyalprazolam	1100	27.3%	(±)2-Ethy 1-1,5-dimethy 1-3,3-diphenylpyrrolinium	50000	0.6%
Bromazepam	1000	30%	Doxylamine	50000	0.6%
Chlordiazepoxide	2000	15%	Oxycodone (OXY)		
Clobazam	100	300%	Oxycodone	100	100%
Clonazepam	800	37.5%	Naloxone	50000	0.2%
Clorazepate	200	150%	Naltrexone	50000	0.2%
Delorazepam	1600	18.8%	Morphine 3-β-D-glucuronide	50000	0.2%
Desalkylflurazepam	400	75%	Hydrocodone	3000	3.3%
Diazepam	200	150%	Hydromorphone	75000	0.1%
Estazolam	1000	30%	Oxymorphone	1000	10%
Flunitrazepam	350	85.7%	Phencyclidine (PCP)		
Lorazepam	1200	25%	Phencyclidine	25	100%
Midazolam	2500	12%	4-Hydroxyphencyclidine	15000	0.2%
Nitrazepam	100	300%	Propoxyphene(PPX)		
Nordiazepam	400	75%	d-Propoxyphene	300	100%
Temazepam	120	250%	d-Norpropoxyphene	300	100%
Triazolam	1000	30%	Tri-cyclic Antidepressants (TCA)		
Cocaine (COC)			Nortriptyline	1000	100%
Benzoylcegonine	300	100%	Nordoxepin	1000	100%
Cocaine	800	37.5%	Trimipramine	5000	20%
Cocaethylene	12,500	2.4%	Promazine	3000	33.3%
Ecgonine HCl	35,000	0.9%	Desipramine	1000	100%
2-ethylidene-1, 5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			Imipramine	1000	100%
EDDP	300	100%	Clomipramine	12500	8%
Methylenedioxyamphetamine (MDMA)			Doxepin	2000	50%
(+/-)3,4-Methylenedioxyamphetamin (MDMA)	500	100%	Maprotiline	2000	50%
3,4-Methylenedioxyamphetamine (MDA)	2200	22.7%	Amitriptyline	1000	100%
3,4-Methylenedioxyethylamphetamine (MDEA)	240	208%	Promethazine	25000	4%
D-methamphetamine(MAMP)	100000	0.5%	Cannabinoids (THC)		
D-Amphetamine	>100000	Not detected	11-nor-Δ9-THC-9-COOH	50	100%
L-Amphetamine	>100000	Not detected	11-nor-Δ8-THC-9-COOH	50	100%
L-Methamphetamine	>100000	Not detected	Δ8- Tetrahydrocannabinol	10,000	0.5%
Methamphetamine (MET)			Δ9- Tetrahydrocannabinol	15,000	0.3%
3,4- Methylenedioxyethylamphetamine(MDEA)	50,000	2%	Cannabinol	20,000	0.3%
L(-)-Methamphetamine	8,000	12.5%	Cannabidiol	> 100,000	Not detected
(+/-)3,4-Methylenedioxyamphetamin(MDMA)	2,000	50%			
p-hydroxymethamphetamine	30,000	3.3%			

8.2 Interference

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine or drug positive urine containing AMP, BAR, BUP, BZO, COC, EDDP, MDMA, MET, MOP, MTD, OXY, PCP, PPX, TCA or THC with the concentration 50% below the cutoff and the concentration 50% above the cutoff, respectively. All potential interfering substances were added at a concentration of 100µg/mL (All concentrations of the drugs were confirmed with GC/MS, or LC/MS,HPLC). The urine specimens were tested with two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard.

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None of the compounds listed below were shown to interfere.

Acetaminophen	Estrone-3-sulfate	d,l-Octopamine
Acetophenetidin	Ethyl-p-aminobenzoate	Oxalic acid
Amoxicillin	Erythromycin	Oxolinic acid
Ampicillin	Fenoprofen	Oxymetazoline
Aspirin	Flucloxacillin	Oxytetracycline
Atenolol	Fluoxetine	Papaverine
Atorvastatin	Furosemide	Penicillin-G
Azlocillin	Gentisic acid	Pentazocine
Benzilic acid	Hemoglobin	Perphenazine
Benzylpenicillin	Hydralazine	Phenelzine
Benzoic acid	Hydrochlorothiazide	Prednisolone
Bilirubin	Hydrocortisone	Prednisone
Benzydamine	o-Hydroxyhippuric acid	d,l-Propranolol
Caffeine	p-Hydroxytyramine	d-Pseudoephedrine
Carbamazepine	Ibuprofen	Quinacrine
Cephalexin	Indomethacin	Quinine
Chloralhydrate	Iproniazid	Quinidine
Chloramphenicol	d,l-Isoproterenol	Ranitidine
Chlorothiazide	Isoxsuprine	Salicylic acid
Chlorpheniramine	Ketamine	Serotonin
d,l-Chlorpromazine	Ketoprofen	Sulfamethazine
Cholesterol	Labetalol	Sulindac
Clonidine	Lisinopril	Tetracycline
Cimetidine	Loperamide	Tetrahydrozoline
Citalopram	Meperidine	Thiamine
Cortisone	Meprobamate	Thioridazine
Creatinine	Methoxyphenamine	d, l-Thyroxine
Deoxycorticosterone	Methylphenidate	Tolbutamine
Dexamethasone	Nadolol	Tolbutamide
Dextromethorphan	Nalidixic acid	Trifluoperazine
Diclofenac	Naproxen	Tryptamine
Diflunisal	Niacinamide	Uric acid
Digoxin	Nicotine	Verapamil
Diphenhydramine	Nifedipine	Zomepirac
Ephedrine	Norethindrone	
β -Estradiol	Noscapine	

8.3 Effect of urinary pH

The pH of an aliquot negative urine pool is adjusted to a pH range of 3 to 9 in 1 pH unit increments and spiked with each drug at 50% below and 50% above cutoff levels (All concentrations were confirmed with GC/MS, or LC/MS, HPLC). Each sample was tested by two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard. The results

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demonstrate that varying ranges of pH do not interfere with the performance of the test.

8.4 Effect of Urinary specific gravity

The specific gravity studies were conducted on different specific gravity including 1.002,1.010, 1.020, 1.030, 1.040 specimens with drug free urine containing AMP, BAR, BUP, BZO, COC, EDDP, MDMA, MET, MOP, MTD, OXY, PCP, PPX, TCA or THC at 50% below and 50% above cutoff level (All concentrations were confirmed with GC/MS, or LC/MS, HPLC). Each sample was tested by two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

8.5 Precision

Precision studies were performed using the multi-drug test formats. Drug free specimens were spiked with analytes at 0, $\pm 75\%$ cutoff, $\pm 50\%$ cutoff, $\pm 25\%$ cutoff and $+100\%$ cutoff of drug. The concentrations of the target drugs were confirmed with GC/MS, or LC/MS, HPLC. Each concentration of the urine specimen was then divided into aliquots. Each aliquot was blindly labeled by a nonparticipant. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Two operators per location tested 3 aliquots at each concentration for each lot per day (3 runs/day) for 10 non-consecutive days using one device lot per location. One operator tested the test dipcard format and the second operator tested the test cup format. There were 1620 observations by 3 sites at 9 concentrations.

Multi-drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
AMP	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75% cutoff	60	0	60	0	60	0	60
	500ng/ml	-50% cutoff	60	0	60	0	60	0	60
	750ng/ml	-25% cutoff	60	8	52	8	52	10	50
	1000ng/ml	cutoff	60	34	26	34	26	32	28
	1250ng/ml	+25% cutoff	60	52	8	50	10	54	6
	1500ng/ml	+50% cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75% cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100% cutoff	60	60	0	60	0	60	0
BAR	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75% cutoff	60	0	60	0	60	0	60
	150ng/ml	-50% cutoff	60	0	60	0	60	0	60

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	225ng/ml	-25%cutoff	60	8	52	6	54	10	50
	300ng/ml	cutoff	60	38	22	36	24	38	22
	375ng/ml	+25%cutoff	60	56	4	56	4	54	6
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
BUP	0ng/ml	Negative	60	0	60	0	60	0	60
	2.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	5ng/ml	-50%cutoff	60	0	60	0	60	0	60
	7.5ng/ml	-25%cutoff	60	8	52	6	54	6	54
	10ng/ml	cutoff	60	34	26	32	28	34	26
	12.5ng/ml	+25%cutoff	60	50	10	48	12	50	10
	15ng/ml	+50%cutoff	60	60	0	60	0	60	0
	17.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	20ng/ml	+100%cutoff	60	60	0	60	0	60	0
BZO	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	4	56	6	54	8	52
	300ng/ml	cutoff	60	36	24	34	26	34	26
	375ng/ml	+25%cutoff	60	52	8	54	6	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	6	54	8	52	6	54
	300ng/ml	cutoff	60	38	22	36	24	38	22
	375ng/ml	+25%cutoff	60	54	6	56	4	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
EDDP	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	4	56	4	56	6	54
	300ng/ml	cutoff	60	36	24	36	24	38	22
	375ng/ml	+25%cutoff	60	54	6	56	4	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60

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	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	8	52	6	54	4	56
	500ng/ml	cutoff	60	32	28	34	26	34	26
	625ng/ml	+25%cutoff	60	52	8	48	12	50	10
	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	8	52	10	50	8	52
	1000ng/ml	cutoff	60	36	24	34	26	38	22
	1250ng/ml	+25%cutoff	60	54	6	52	8	50	10
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 300	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	10	50	10	50	12	48
	300ng/ml	cutoff	60	38	22	40	20	38	22
	375ng/ml	+25%cutoff	60	56	4	54	6	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
		600ng/ml	+100%cutoff	60	60	0	60	0	60
MOP 2000	0ng/ml	Negative	60	0	60	0	60	0	60
	500ng/ml	-75%cutoff	60	0	60	0	60	0	60
	1000ng/ml	-50%cutoff	60	0	60	0	60	0	60
	1500ng/ml	-25%cutoff	60	6	54	8	52	4	56
	2000ng/ml	cutoff	60	36	24	34	26	32	28
	2500ng/ml	+25%cutoff	60	56	4	54	6	54	6
	3000ng/ml	+50%cutoff	60	60	0	60	0	60	0
	3500ng/ml	+75%cutoff	60	60	0	60	0	60	0
		4000ng/ml	+100%cutoff	60	60	0	60	0	60
MTD	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	8	52	4	56	6	54
	300ng/ml	cutoff	60	38	22	36	24	36	24
	375ng/ml	+25%cutoff	60	56	4	54	6	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
		525ng/ml	+75%cutoff	60	60	0	60	0	60

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	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
OXY	0ng/ml	Negative	60	0	60	0	60	0	60
	25ng/ml	-75%cutoff	60	0	60	0	60	0	60
	50ng/ml	-50%cutoff	60	0	60	0	60	0	60
	75ng/ml	-25%cutoff	60	4	56	6	54	6	54
	100ng/ml	cutoff	60	36	24	38	22	36	24
	125ng/ml	+25%cutoff	60	54	6	58	2	56	4
	150ng/ml	+50%cutoff	60	60	0	60	0	60	0
	175ng/ml	+75%cutoff	60	60	0	60	0	60	0
	200ng/ml	+100%cutoff	60	60	0	60	0	60	0
PCP	0ng/ml	Negative	60	0	60	0	60	0	60
	6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
	12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
	18.8ng/ml	-25%cutoff	60	4	56	4	56	6	54
	25ng/ml	cutoff	60	38	22	34	26	34	26
	31.3ng/ml	+25%cutoff	60	56	4	54	6	56	4
	37.5ng/ml	+50%cutoff	60	60	0	60	0	60	0
	43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
	50ng/ml	+100%cutoff	60	60	0	60	0	60	0
PPX	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	4	56	6	54	6	54
	300ng/ml	cutoff	60	34	26	32	28	32	28
	375ng/ml	+25%cutoff	60	54	6	52	8	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
TCA	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	8	52	6	54	4	56
	1000ng/ml	cutoff	60	34	26	36	24	36	24
	1250ng/ml	+25%cutoff	60	52	8	50	10	54	6
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	4	56	6	54	6	54
	50ng/ml	cutoff	60	38	22	38	22	36	24
	62.5ng/ml	+25%cutoff	60	54	6	56	4	54	6

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	75ng/ml	+50%cutoff	60	60	0	60	0	60	0
	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	100ng/ml	+100%cutoff	60	60	0	60	0	60	0

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot 1		Lot 2		Lot 3	
				Positive	Negative	Positive	Negative	Positive	Negative
AMP	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	8	52	6	54	6	54
	1000ng/ml	cutoff	60	32	28	34	26	36	24
	1250ng/ml	+25%cutoff	60	50	10	52	8	50	10
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
BAR	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	10	50	8	52	10	50
	300ng/ml	cutoff	60	36	24	38	22	36	24
	375ng/ml	+25%cutoff	60	52	8	54	6	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
BUP	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
	0ng/ml	Negative	60	0	60	0	60	0	60
	2.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	5ng/ml	-50%cutoff	60	0	60	0	60	0	60
	7.5ng/ml	-25%cutoff	60	4	56	8	52	6	54
	10ng/ml	cutoff	60	32	28	32	28	34	26
	12.5ng/ml	+25%cutoff	60	52	8	50	10	48	12
BZO	15ng/ml	+50%cutoff	60	60	0	60	0	60	0
	17.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
	20ng/ml	+100%cutoff	60	60	0	60	0	60	0
	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	6	54	8	52	4	56
	300ng/ml	cutoff	60	34	26	36	24	32	28
375ng/ml	+25%cutoff	60	54	6	50	10	52	8	
450ng/ml	+50%cutoff	60	60	0	60	0	60	0	

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	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
COC	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	4	56	4	56	8	52
	300ng/ml	cutoff	60	36	24	38	22	34	26
	375ng/ml	+25%cutoff	60	54	6	52	8	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
EDDP	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	6	54	4	56	6	54
	300ng/ml	cutoff	60	38	22	38	22	36	24
	375ng/ml	+25%cutoff	60	56	4	54	6	54	6
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MDMA	0ng/ml	Negative	60	0	60	0	60	0	60
	125ng/ml	-75%cutoff	60	0	60	0	60	0	60
	250ng/ml	-50%cutoff	60	0	60	0	60	0	60
	375ng/ml	-25%cutoff	60	6	54	4	56	8	52
	500ng/ml	cutoff	60	34	26	32	28	32	28
	625ng/ml	+25%cutoff	60	50	10	48	12	52	8
	750ng/ml	+50%cutoff	60	60	0	60	0	60	0
	875ng/ml	+75%cutoff	60	60	0	60	0	60	0
	1000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MET	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	10	50	8	52	6	54
	1000ng/ml	cutoff	60	36	24	34	26	36	24
	1250ng/ml	+25%cutoff	60	52	8	52	8	54	6
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 300	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	12	48	10	50	8	52
	300ng/ml	cutoff	60	36	24	38	22	40	20

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	375ng/ml	+25%cutoff	60	54	6	54	6	56	4
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
MOP 2000	0ng/ml	Negative	60	0	60	0	60	0	60
	500ng/ml	-75%cutoff	60	0	60	0	60	0	60
	1000ng/ml	-50%cutoff	60	0	60	0	60	0	60
	1500ng/ml	-25%cutoff	60	8	52	8	52	6	54
	2000ng/ml	cutoff	60	34	26	32	28	34	26
	2500ng/ml	+25%cutoff	60	54	6	52	8	56	4
	3000ng/ml	+50%cutoff	60	60	0	60	0	60	0
	3500ng/ml	+75%cutoff	60	60	0	60	0	60	0
	4000ng/ml	+100%cutoff	60	60	0	60	0	60	0
MTD	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60
	225ng/ml	-25%cutoff	60	6	54	4	56	8	52
	300ng/ml	cutoff	60	36	24	34	26	38	22
	375ng/ml	+25%cutoff	60	56	4	56	4	54	6
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
OXY	0ng/ml	Negative	60	0	60	0	60	0	60
	25ng/ml	-75%cutoff	60	0	60	0	60	0	60
	50ng/ml	-50%cutoff	60	0	60	0	60	0	60
	75ng/ml	-25%cutoff	60	6	54	4	56	4	56
	100ng/ml	cutoff	60	38	22	36	24	38	22
	125ng/ml	+25%cutoff	60	54	6	54	6	56	4
	150ng/ml	+50%cutoff	60	60	0	60	0	60	0
	175ng/ml	+75%cutoff	60	60	0	60	0	60	0
	200ng/ml	+100%cutoff	60	60	0	60	0	60	0
PCP	0ng/ml	Negative	60	0	60	0	60	0	60
	6.3ng/ml	-75%cutoff	60	0	60	0	60	0	60
	12.5ng/ml	-50%cutoff	60	0	60	0	60	0	60
	18.8ng/ml	-25%cutoff	60	4	56	6	54	2	58
	25ng/ml	cutoff	60	36	24	38	22	34	26
	31.3ng/ml	+25%cutoff	60	54	6	56	4	52	8
	37.5ng/ml	+50%cutoff	60	60	0	60	0	60	0
	43.8ng/ml	+75%cutoff	60	60	0	60	0	60	0
	50ng/ml	+100%cutoff	60	60	0	60	0	60	0
PPX	0ng/ml	Negative	60	0	60	0	60	0	60
	75ng/ml	-75%cutoff	60	0	60	0	60	0	60
	150ng/ml	-50%cutoff	60	0	60	0	60	0	60

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	225ng/ml	-25%cutoff	60	6	54	4	56	8	52
	300ng/ml	cutoff	60	34	26	36	24	32	28
	375ng/ml	+25%cutoff	60	56	4	52	8	52	8
	450ng/ml	+50%cutoff	60	60	0	60	0	60	0
	525ng/ml	+75%cutoff	60	60	0	60	0	60	0
	600ng/ml	+100%cutoff	60	60	0	60	0	60	0
TCA	0ng/ml	Negative	60	0	60	0	60	0	60
	250ng/ml	-75%cutoff	60	0	60	0	60	0	60
	500ng/ml	-50%cutoff	60	0	60	0	60	0	60
	750ng/ml	-25%cutoff	60	6	54	4	56	6	54
	1000ng/ml	cutoff	60	32	28	34	26	36	24
	1250ng/ml	+25%cutoff	60	50	10	52	8	54	6
	1500ng/ml	+50%cutoff	60	60	0	60	0	60	0
	1750ng/ml	+75%cutoff	60	60	0	60	0	60	0
	2000ng/ml	+100%cutoff	60	60	0	60	0	60	0
THC	0ng/ml	Negative	60	0	60	0	60	0	60
	12.5ng/ml	-75%cutoff	60	0	60	0	60	0	60
	25ng/ml	-50%cutoff	60	0	60	0	60	0	60
	37.5ng/ml	-25%cutoff	60	6	54	8	52	4	56
	50ng/ml	cutoff	60	34	26	36	24	38	22
	62.5ng/ml	+25%cutoff	60	52	8	54	6	56	4
	75ng/ml	+50%cutoff	60	60	0	60	0	60	0
	87.5ng/ml	+75%cutoff	60	60	0	60	0	60	0
		100ng/ml	+100%cutoff	60	60	0	60	0	60

8.6 Accuracy

Multi-drug Test Cup:

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding Rapid Multi-drug Test Cup. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	0	6	34	80
	-	33	2	5	0	0	
BAR	+	0	0	0	7	33	80
	-	34	1	5	0	0	
BUP	+	0	0	0	6	33	80
	-	34	0	6	1	0	

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BZO	+	0	0	1	6	34	80
	-	31	2	6	0	0	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
EDDP	+	0	0	0	5	35	80
	-	35	0	5	0	0	
MDMA	+	0	0	0	7	33	80
	-	35	0	5	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP300	+	0	0	0	5	34	80
	-	33	2	5	1	0	
MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
MTD	+	0	0	0	7	32	80
	-	35	0	5	1	0	
OXY	+	0	0	0	5	34	80
	-	33	2	5	1	0	
PCP	+	0	0	0	5	35	80
	-	34	0	6	0	0	
PPX	+	0	0	1	5	35	80
	-	33	0	6	0	0	
TCA	+	0	0	1	5	35	80
	-	33	1	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	

Analysis of Discordant Results with Rapid Multi-drug Test Cup

Rapid Multi-drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Negative	11.7	Buprenorphine
BZO	300	Positive	286	Oxazepam
MET	1000	Positive	867	Methamphetamine
MOP300	300	Negative	356	Morphine
MOP2000	2000	Positive	1742	Morphine
MTD	300	Negative	328	Methadone
OXY	100	Negative	122	Oxycodone
PPX	300	Positive	248	Propoxyphene
TCA*	1000	Positive	861	Nortriptyline
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

Multi-drug Test Dipcard

Co-Innovation Biotech Co.,Ltd.

80 clinical urine specimens for each drug were analyzed by GC/MS, LC/MS, or HPLC and by one lot of the corresponding Rapid Multi-drug Test Dipcard. Samples were divided by concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	0	6	34	80
	-	33	2	5	0	0	
BAR	+	0	0	0	7	33	80
	-	34	1	5	0	0	
BUP	+	0	0	0	6	33	80
	-	34	0	6	1	0	
BZO	+	0	0	1	6	34	80
	-	31	2	6	0	0	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
EDDP	+	0	0	0	5	35	80
	-	35	0	5	0	0	
MDMA	+	0	0	0	7	33	80
	-	35	0	5	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP300	+	0	0	0	5	34	80
	-	33	2	5	1	0	
MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
MTD	+	0	0	0	7	32	80
	-	35	0	5	1	0	
OXY	+	0	0	0	5	34	80
	-	33	2	5	1	0	
PCP	+	0	0	0	5	35	80
	-	34	0	6	0	0	
PPX	+	0	0	1	5	35	80
	-	33	0	6	0	0	
TCA	+	0	0	1	5	35	80
	-	33	1	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	

Analysis of Discordant Results with Rapid Multi-drug Test Dipcard

Rapid Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
BUP**	10	Negative	11.7	Buprenorphine
BZO	300	Positive	286	Oxazepam
MET	1000	Positive	867	Methamphetamine

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MOP300	300	Negative	356	Morphine
MOP2000	2000	Positive	1742	Morphine
MTD	300	Negative	328	Methadone
OXY	100	Negative	122	Oxycodone
PPX	300	Positive	248	Propoxyphene
TCA*	1000	Positive	861	Nortriptyline
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH

(TCA*:TCA was based on HPLC data.BUP**:BUP was based on LC/MS data.)

8.7 Lay User Study

1720 lay users from age 18 to 65 years participated in the study. Urine samples were prepared at the following concentrations: 0, +/- 50% cutoff,+/- 25% cutoff and +100% cutoff by spiking drug into drug free urine specimens. Each sample contain different drugs and the different concentrations. The concentrations of target drugs were confirmed with GC/MS, or LC/MS, HPLC. Each participant performed only 1 test on provided specimen with one format of Rapid Multi- drug Test (Dipcard, Cup) using the English package insert as guide to perform the test. They were asked to fill out an English questionnaire after finishing the test. Results were as follows:

Multi-drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results				Agreement (%)
				Lot1		Lot2		
				Positive	Negative	Positive	Negative	
AMP	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%
	750ng/ml	-25%cutoff	10	1	9	2	8	85%
	1250ng/ml	+25%cutoff	10	8	2	9	1	85%
	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
BAR	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	1	9	90%
	375ng/ml	+25%cutoff	10	10	0	9	1	95%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
BUP	0ng/ml	Negative	360	0	360	0	360	100%
	5ng/ml	-50%cutoff	10	0	10	0	10	100%
	7.5ng/ml	-25%cutoff	10	1	9	2	8	85%
	12.5ng/ml	+25%cutoff	10	9	1	9	1	90%
	15ng/ml	+50%cutoff	30	30	0	30	0	100%
	20ng/ml	+100%cutoff	10	10	0	10	0	100%
BZO	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%

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	225ng/ml	-25%cutoff	10	0	10	1	9	95%
	375ng/ml	+25%cutoff	10	9	1	9	1	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
COC	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	0	10	1	9	95%
	375ng/ml	+25%cutoff	10	10	0	8	2	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
EDDP	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	0	10	95%
	375ng/ml	+25%cutoff	10	8	2	9	1	85%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
MDM A	0ng/ml	Negative	360	0	360	0	360	100%
	250ng/ml	-50%cutoff	10	0	10	0	10	100%
	375ng/ml	-25%cutoff	10	1	9	1	9	90%
	625ng/ml	+25%cutoff	10	8	2	9	1	85%
	750ng/ml	+50%cutoff	30	30	0	30	0	100%
	1000ng/ml	+100%cutoff	10	10	0	10	0	100%
MET	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%
	750ng/ml	-25%cutoff	10	2	8	1	9	85%
	1250ng/ml	+25%cutoff	10	8	2	10	0	90%
	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
MOP 300	0ng/ml	Negative	310	0	310			100%
	150ng/ml	-50%cutoff	10	0	10			100%
	225ng/ml	-25%cutoff	60	1	9			90%
	375ng/ml	+25%cutoff	60	9	1			90%
	450ng/ml	+50%cutoff	30	30	0			100%
	600ng/ml	+100%cutoff	10	10	0			100%
MOP 2000	0ng/ml	Negative	310			0	310	100%
	1000ng/ml	-50%cutoff	10			0	10	100%
	1500ng/ml	-25%cutoff	60			1	9	90%
	2500ng/ml	+25%cutoff	60			9	1	90%
	3000ng/ml	+50%cutoff	30			30	0	100%
	4000ng/ml	+100%cutoff	10			10	0	100%
MTD	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	2	8	85%

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	375ng/ml	+25%cutoff	10	8	2	9	1	85%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
OXY	0ng/ml	Negative	360	0	360	0	360	100%
	50ng/ml	-50%cutoff	10	0	10	0	10	100%
	75ng/ml	-25%cutoff	10	1	9	1	9	90%
	125ng/ml	+25%cutoff	10	8	2	10	0	90%
	150ng/ml	+50%cutoff	30	30	0	30	0	100%
	200ng/ml	+100%cutoff	10	10	0	10	0	100%
PCP	0ng/ml	Negative	360	0	360	0	360	100%
	12.5ng/ml	-50%cutoff	10	0	10	0	10	100%
	18.8ng/ml	-25%cutoff	10	2	8	1	9	85%
	31.3ng/ml	+25%cutoff	10	9	1	9	1	90%
	37.5ng/ml	+50%cutoff	30	30	0	30	0	100%
	50ng/ml	+100%cutoff	10	10	0	10	0	100%
PPX	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	0	10	95%
	375ng/ml	+25%cutoff	10	9	1	9	1	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
TCA	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%
	750ng/ml	-25%cutoff	10	0	10	2	8	90%
	1250ng/ml	+25%cutoff	10	8	2	10	0	90%
	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
THC	0ng/ml	Negative	360	0	360	0	360	100%
	25ng/ml	-50%cutoff	10	0	10	0	10	100%
	37.5ng/ml	-25%cutoff	10	1	9	2	8	85%
	62.5ng/ml	+25%cutoff	10	8	2	10	0	90%
	75ng/ml	+50%cutoff	30	30	0	30	0	100%
	100ng/ml	+100%cutoff	10	10	0	10	0	100%

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Layer user Results				Agreement(%)
				Lot1		Lot2		
				Positive	Negative	Positive	Negative	
AMP	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%

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	750ng/ml	-25%cutoff	10	1	9	1	9	90%
	1250ng/ml	+25%cutoff	10	9	1	10	0	95%
	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
BAR	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	0	10	1	9	95%
	375ng/ml	+25%cutoff	10	9	1	9	1	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
BUP	0ng/ml	Negative	360	0	360	0	360	100%
	5ng/ml	-50%cutoff	10	0	10	0	10	100%
	7.5ng/ml	-25%cutoff	10	1	9	2	8	85%
	12.5ng/ml	+25%cutoff	10	10	0	9	1	95%
	15ng/ml	+50%cutoff	30	10	0	9	0	100%
	20ng/ml	+100%cutoff	10	10	0	10	0	100%
BZO	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	1	9	90%
	375ng/ml	+25%cutoff	10	8	2	10	0	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
COC	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	1	9	90%
	375ng/ml	+25%cutoff	10	9	1	9	1	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
EDDP	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	2	8	1	9	85%
	375ng/ml	+25%cutoff	10	9	1	9	1	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
MDMA	0ng/ml	Negative	360	0	360	0	360	100%
	250ng/ml	-50%cutoff	10	0	10	0	10	100%
	375ng/ml	-25%cutoff	10	1	9	2	8	85%
	625ng/ml	+25%cutoff	10	10	0	9	1	95%
	750ng/ml	+50%cutoff	30	30	0	30	0	100%
	1000ng/ml	+100%cutoff	10	10	0	10	0	100%
MET	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%
	750ng/ml	-25%cutoff	10	1	9	0	10	95%

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	1250ng/ml	+25%cutoff	10	10	0	9	1	95%
	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
MOP300	0ng/ml	Negative	310	0	310			100%
	150ng/ml	-50%cutoff	10	0	10			100%
	225ng/ml	-25%cutoff	60	0	10			100%
	375ng/ml	+25%cutoff	60	9	1			90%
	450ng/ml	+50%cutoff	30	30	0			100%
	600ng/ml	+100%cutoff	10	10	0			100%
MOP2000	0ng/ml	Negative	310			0	310	100%
	1000ng/ml	-50%cutoff	10			0	10	100%
	1500ng/ml	-25%cutoff	60			1	9	90%
	2500ng/ml	+25%cutoff	60			9	1	90%
	3000ng/ml	+50%cutoff	30			30	0	100%
	4000ng/ml	+100%cutoff	10			10	0	100%
MTD	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	2	8	0	10	90%
	375ng/ml	+25%cutoff	10	10	0	8	2	90%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
OXY	0ng/ml	Negative	360	0	360	0	360	100%
	50ng/ml	-50%cutoff	10	0	10	0	10	100%
	75ng/ml	-25%cutoff	10	2	8	1	9	85%
	125ng/ml	+25%cutoff	10	9	1	9	1	90%
	150ng/ml	+50%cutoff	30	30	0	30	0	100%
	200ng/ml	+100%cutoff	10	10	0	10	0	100%
PCP	0ng/ml	Negative	360	0	360	0	360	100%
	12.5ng/ml	-50%cutoff	10	0	10	0	10	100%
	18.8ng/ml	-25%cutoff	10	0	10	2	8	90%
	31.3ng/ml	+25%cutoff	10	8	2	9	1	85%
	37.5ng/ml	+50%cutoff	30	30	0	30	0	100%
	50ng/ml	+100%cutoff	10	10	0	10	0	100%
PPX	0ng/ml	Negative	360	0	360	0	360	100%
	150ng/ml	-50%cutoff	10	0	10	0	10	100%
	225ng/ml	-25%cutoff	10	1	9	2	8	85%
	375ng/ml	+25%cutoff	10	8	2	9	1	85%
	450ng/ml	+50%cutoff	30	30	0	30	0	100%
	600ng/ml	+100%cutoff	10	10	0	10	0	100%
TCA	0ng/ml	Negative	360	0	360	0	360	100%
	500ng/ml	-50%cutoff	10	0	10	0	10	100%
	750ng/ml	-25%cutoff	10	2	8	1	9	85%
	1250ng/ml	+25%cutoff	10	9	1	9	1	90%

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	1500ng/ml	+50%cutoff	30	30	0	30	0	100%
	2000ng/ml	+100%cutoff	10	10	0	10	0	100%
THC	0ng/ml	Negative	360	0	360	0	360	100%
	25ng/ml	-50%cutoff	10	0	10	0	10	100%
	37.5ng/ml	-25%cutoff	10	0	10	2	8	90%
	62.5ng/ml	+25%cutoff	10	9	1	8	2	85%
	75ng/ml	+50%cutoff	30	30	0	30	0	100%
	100ng/ml	+100%cutoff	10	10	0	10	0	100%

1720 questionnaires were distributed collected. The results show that the test is easy to be used and the instruction insert is clear.

Evaluation of the readability of the labeling

The entire package insert readability was assessed. We choose 30 chain sentences from Instructions Insert at OTC user read. According to SMOG Conversion Table of Appendix B the SMOG Readability Formula of "Labeling of Home-Use In Vitro Testing Products: Approved Guideline: GP-14A5", the reading level belong to 7th degree.

8.7 Interference study

Interference studies were performed using the multi-drug test formats. Drug free specimens were spiked with single drug at 0, $\pm 50\%$ cutoff and +100% cutoff of drug. The concentrations of the target drugs were confirmed with GC/MS, or LC/MS, HPLC. Each concentration of the urine specimen was divided into aliquots. Each aliquot was blindly labeled by a nonparticipant. Separate sets of blinded coded samples were assigned and randomized prior to testing. The study was conducted by 6 operators at 3 Point-of-Care sites. Operators tested 3 aliquots at each concentration for each lot per day (3runs/day) and lasted for 5 non-consecutive days. A total of 15 determinations were made by each site at each concentration. There were 180 observations by 3 sites at 4 concentrations.

Multi-drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot1		Lot2		Lot3	
				Positive	Negative	Positive	Negative	Positive	Negative
AMP	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
BAR	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
BUP	0ng/ml	Negative	15	0	15	0	15	0	15
	5ng/ml	-50%cutoff	15	0	15	0	15	0	15

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	15ng/ml	+50%cutoff	15	15	0	15	0	15	0
	20ng/ml	+100%cutoff	15	15	0	15	0	15	0
BZO	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
COC	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
EDD P	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
MD MA	0ng/ml	Negative	15	0	15	0	15	0	15
	250ng/ml	-50%cutoff	15	0	15	0	15	0	15
	750ng/ml	+50%cutoff	15	15	0	15	0	15	0
	1000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MET	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MOP 300	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
MOP 2000	0ng/ml	Negative	15	0	15	0	15	0	15
	1000ng/ml	-50%cutoff	15	0	15	0	15	0	15
	3000ng/ml	+50%cutoff	15	15	0	15	0	15	0
	4000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MTD	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
OXY	0ng/ml	Negative	15	0	15	0	15	0	15
	50ng/ml	-50%cutoff	15	0	15	0	15	0	15
	150ng/ml	+50%cutoff	15	15	0	15	0	15	0
	200ng/ml	+100%cutoff	15	15	0	15	0	15	0
PCP	0ng/ml	Negative	15	0	15	0	15	0	15
	12.5ng/ml	-50%cutoff	15	0	15	0	15	0	15
	37.5ng/ml	+50%cutoff	15	15	0	15	0	15	0
	50ng/ml	+100%cutoff	15	15	0	15	0	15	0
PPX	0ng/ml	Negative	15	0	15	0	15	0	15

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	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
TCA	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
THC	0ng/ml	Negative	15	0	15	0	15	0	15
	25ng/ml	-50%cutoff	15	0	15	0	15	0	15
	75ng/ml	+50%cutoff	15	15	0	15	0	15	0
	100ng/ml	+100%cutoff	15	15	0	15	0	15	0

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations per lot	Result					
				Lot1		Lot2		Lot3	
				Positive	Negative	Positive	Negative	Positive	Negative
AMP	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
BAR	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
BUP	0ng/ml	Negative	15	0	15	0	15	0	15
	5ng/ml	-50%cutoff	15	0	15	0	15	0	15
	15ng/ml	+50%cutoff	15	15	0	15	0	15	0
	20ng/ml	+100%cutoff	15	15	0	15	0	15	0
BZO	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
COC	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
EDD P	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
MD	0ng/ml	Negative	15	0	15	0	15	0	15

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MA	250ng/ml	-50%cutoff	15	0	15	0	15	0	15
	750ng/ml	+50%cutoff	15	15	0	15	0	15	0
	1000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MET	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MOP 300	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
MOP 2000	0ng/ml	Negative	15	0	15	0	15	0	15
	1000ng/ml	-50%cutoff	15	0	15	0	15	0	15
	3000ng/ml	+50%cutoff	15	15	0	15	0	15	0
	4000ng/ml	+100%cutoff	15	15	0	15	0	15	0
MTD	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
OXY	0ng/ml	Negative	15	0	15	0	15	0	15
	50ng/ml	-50%cutoff	15	0	15	0	15	0	15
	150ng/ml	+50%cutoff	15	15	0	15	0	15	0
	200ng/ml	+100%cutoff	15	15	0	15	0	15	0
PCP	0ng/ml	Negative	15	0	15	0	15	0	15
	12.5ng/ml	-50%cutoff	15	0	15	0	15	0	15
	37.5ng/ml	+50%cutoff	15	15	0	15	0	15	0
	50ng/ml	+100%cutoff	15	15	0	15	0	15	0
PPX	0ng/ml	Negative	15	0	15	0	15	0	15
	150ng/ml	-50%cutoff	15	0	15	0	15	0	15
	450ng/ml	+50%cutoff	15	15	0	15	0	15	0
	600ng/ml	+100%cutoff	15	15	0	15	0	15	0
TCA	0ng/ml	Negative	15	0	15	0	15	0	15
	500ng/ml	-50%cutoff	15	0	15	0	15	0	15
	1500ng/ml	+50%cutoff	15	15	0	15	0	15	0
	2000ng/ml	+100%cutoff	15	15	0	15	0	15	0
THC	0ng/ml	Negative	15	0	15	0	15	0	15
	25ng/ml	-50%cutoff	15	0	15	0	15	0	15
	75ng/ml	+50%cutoff	15	15	0	15	0	15	0
	100ng/ml	+100%cutoff	15	15	0	15	0	15	0

9. Conclusion:

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The data collected in the performance and accuracy studies demonstrate that the Rapid Single/Multi Drug test cup and dipcard are substantially equivalent to the predicate device.

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