



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

December 11, 2014

Re: K142800
Trade/Device Name: Rapid Single/Multi-drug Test Cup
Rapid Single/Multi-drug Test Dipcard
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, DJC, DIS, DIO, JXM, LDJ, DJR, DJG, LCM, DNK
Dated: September 26, 2014
Received: September 29, 2014

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,


Katherine Serrano -S

For : 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)
k142800

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 are lateral flow chromatographic immunoassays 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	50ng/mL
Cocaine (COC)	Benzolecgonine	300ng/mL
Amphetamine (AMP)	D-Amphetamine	1000ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000ng/mL
Morphine 2000 (MOP)	Morphine	2000ng/mL
Barbiturates (BAR)	Secobarbital	300ng/mL
Benzodiazepines (BZO)	Oxazepam	300ng/mL
Methylenedioxymethamphetamine (MDMA)	3,4-Methylenedioxymethamphetamine	500ng/mL
Methadone (MTD)	Methadone	300ng/mL
Oxycodone (OXY)	Oxycodone	100ng/mL
Phencyclidine (PCP)	Phencyclidine	25ng/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. These 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, Benzodiazepine, and Methadone are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturates and Benzodiazepine in urine.

The assays provide 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 - 510(k) Summary

Date of Summary Preparation: 12/05/2014

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

Proprietary names:

Rapid Single/Multi-drug Test Cup

Rapid Single/Multi-drug Test Dipcard

Recommended classification regulation:

21 CFR 862.3100 Amphetamine test system

21 CFR 862.3610 Methamphetamine test system

21 CFR 862.3250 Cocaine test system

21 CFR 862.3640 Morphine test system

21 CFR 862.3870 Cannabinoid test system

21 CFR 862.3150 Barbiturate test system

21 CFR 862.3170 Benzodiazepine test system

21 CFR 862.3620 Methadone test system

21 CFR 862.3650 Opiate test system

Unclassified, Enzyme immunoassay, phencyclidine test system

Device class: Class II

Panel: Toxicology (91)

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

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4. The Predicate Devices

K122809 Advin Multi-Drug Screen Test Dip Card
 Advin Multi-Drug Screen Test Cup
 Advin Multi-Drug Screen Test Cassette

5. Device Description

Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Methamphetamine, Morphine, Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone, Oxycodone, Phencyclidine and their metabolites (specifically THC) at or above the cut-off levels as indicated. The tests are performed without the use of an instrument.

The test cup and test dipcard formats use identical test strips made with the same chemical formulation and manufacturing procedures.

6. Indications for Use

Rapid Single/Multi-drug Test Cup and Rapid Single/Multi-drug Test Dipcard are lateral flow chromatographic immunoassays 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)	Benzoyllecgonine	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

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. The tests are intended for in vitro diagnostics use. They are intended for

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prescription use including point of care sites and over-the-counter use.

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

The assays provide 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:

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 (K122809)
Indication for use	Qualitative detection of drugs-of-abuse in urine (Cocaine, Morphine, Methamphetamine, Amphetamine, Marijuana, Barbiturates, Benzodiazepines, Methylenedioxymethamphetamine, Methadone, Oxycodone, Phencyclidine)	Same (but the number of drugs detected different)
Intended Users	Over the Counter (OTC) Use and Prescription Use	Same
Specimen	Urine	Same
Cutoff	Cocaine:300 ng/mL Methamphetamine:1000 ng/mL Amphetamine:1000 ng/mL Morphine:2000 ng/mL Marijuana:50 ng/mL Barbiturates:300 ng/mL Benzodiazepines:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methadone:300 ng/mL Oxycodone:100 ng/mL Phencyclidine:25 ng/mL	Cocaine:150 ng/mL Methamphetamine:500 ng/mL Amphetamine:500 ng/mL Morphine:300 ng/mL Marijuana:50 ng/mL Barbiturates:300 ng/mL Benzodiazepines:300 ng/mL Methylenedioxymethamphetamine:500 ng/mL Methadone:300 ng/mL Oxycodone:100 ng/mL Phencyclidine:25 ng/mL
Read time	5 minutes	Same

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Results	Qualitative	Same
Methodology	Competitive binding, Lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Configuration	Dipcard and Cup	Cassette,Dip Card and Cup

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	Benzodiazepines (BZO)	Lowest Concentration (ng/mL)	% Cross-reactivity
d-Amphetamine	1,000	100%	Oxazepam	300	100%
d,l-Amphetamine	2,500	40%	Alprazolam	200	150%
l-Amphetamine	50,000	2%	α -Hydroxyalprazolam	1100	27.3%
3,4-Methylenedioxyamphetamine (MDA)	2,000	50%	Bromazepam	1000	30%
d-methamphetamine	>100,000	Not detected	Chlordiazepoxide	2000	15%
l-methamphetamine	>100,000	Not detected	Clobazam	100	300%
3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	Not detected	Clonazepam	800	37.5%
Methylenedioxyethylamphetamine (MDEA)	>100,000	Not detected	Clorazepate	200	150%
Cannabinoids (THC)			Delorazepam	1600	18.8%
11-nor- Δ 9-THC-9-COOH	50	100%	Desalkylflurazepam	400	75%
11-nor- Δ 8-THC-9-COOH	50	100%	Diazepam	200	150%
Δ 8- Tetrahydrocannabinol	10,000	0.5%	Estazolam	1000	30%
Δ 9- Tetrahydrocannabinol	15,000	0.3%	Flunitrazepam	350	85.7%
Cannabinol	20,000	0.3%	Lorazepam	1200	25%
Cannabidiol	>100,000	Not detected	Midazolam	2500	12%
Cocaine (COC)			Nitrazepam	100	300%
Benzoylcegonine	300	100%	Nordiazepam	400	75%
Cocaine	800	37.5%	Temazepam	120	250%
Cocaethylene	12,500	2.4%	Triazolam	1000	30%
Ecgonine HCl	35,000	0.9%	Methylenedioxymethamphetamine (MDMA)		
Methamphetamine (MET)			D-Amphetamine	>100000	Not

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					detected
D(+)-Methamphetamine	1,000	100%	(+/-)3,4-Methylenedioxyamphetamine (MDMA)	500	60%
L(-)-Methamphetamine	8,000	12.5%	3,4-Methylenedioxyamphetamine (MDA)	2200	13.6%
(+/-)3,4-Methylenedioxyamphetamine(MDMA)	2,000	50%	3,4-Methylenedioxyethylamphetamine (MDEA)	240	125%
p-hydroxymethamphetamine	30,000	3.3%	D-methamphetamine(MAMP)	100000	0.3%
3,4-Methylenedioxyethylamphetamine(MDEA)	50,000	2%	L-Amphetamine	>100000	Not detected
d-Amphetamine	>100,000	Not detected	L-Methamphetamine	>100000	Not detected
l-Amphetamine	>100,000	Not detected	Methadone (MTD)		
3,4-methylenedioxyamphetamine (MDA)	>100,000	Not detected	Methadone	300	100%
Morphine 2000 (MOP)			(±)2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Morphine	2,000	100%	Doxylamine	50000	0.6%
Codeine	2,000	100%	Oxycodone (OXY)		
Hydrocodone	15,000	13.3%	Oxycodone	100	100%
Hydromorphone	10,000	20%	Naloxone	50000	0.2%
6-Monoacetylmorphine	5,000	40%	Naltrexone	50000	0.2%
Morphine 3-b-D-glucuronide	2,000	100%	Morphine 3-β-D-glucuronide	50000	0.2%
Oxycodone	>100000	2%	Hydrocodone	3000	3.3%
Hydromorphone	10,000	20%	Hydromorphone	75000	0.1%
Barbiturates (BAR)			Oxymorphone	1000	10%
Secobarbital	300	100%	Phencyclidine (PCP)		
Amobarbital	500	60%	Phencyclidine	25	100%
Alphenol	150	200%	4-Hydroxyphencyclidine	15000	0.2%
Aprobarbital	200	150%			
Butobarbital	75	400%			
Butalbital	1,500	20%			
Butethal	100	300%			
Cyclopentobarbital	600	50%			
Pentobarbital	700	42.9%			
Phenobarbital	300	100%			

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, THC, COC, MET, MOP, BAR, BZO, MDMA, MTD, OXY, or PCP 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). The urine specimens were tested with two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard. None of the compounds listed below were shown to interfere.

Acetaminophen
Acetophenetidin

Estrone-3-sulfate
Ethyl-p-aminobenzoate

d,l-Octopamine
Oxalic acid

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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	Quindine
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). 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 pH do not interfere with the performance of the test.

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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, THC, COC, MET, MOP, BAR, BZO, MDMA, MTD, OXY, or PCP at 50% below and 50% above cutoff level (All concentrations were confirmed with GC/MS). 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 single drug and 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. In both the single drug test and multi-drug test precision studies 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. 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.

Single 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	6	54	8	52	8	52
	1000ng/ml	cutoff	60	34	26	36	24	32	28
	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	
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	8	52	6	54	4	56
	300ng/ml	cutoff	60	36	24	34	26	38	22
	375ng/ml	+25% cutoff	60	56	4	54	6	52	8

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	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
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	4	56	8	52	6	54
	1000ng/ml	cutoff	60	34	26	36	24	38	22
	1250ng/ml	+25% cutoff	60	54	6	56	4	58	2
	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	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	10	50	8	52
	2000ng/ml	cutoff	60	42	18	44	16	44	16
	2500ng/ml	+25% cutoff	60	54	6	56	4	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	
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	8	52	6	54	6	54
	50ng/ml	cutoff	60	36	24	38	22	36	24
	62.5ng/ml	+25% cutoff	60	52	8	56	4	54	6
	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
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
	225ng/ml	-25% cutoff	60	4	56	6	54	4	56
	300ng/ml	cutoff	60	38	22	38	22	36	24
	375ng/ml	+25% cutoff	60	54	6	56	4	58	2
	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
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	6	54	4	56	6	54

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	300ng/ml	cutoff	60	38	22	36	24	34	26
	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	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	8	52	6	54	6	54
	500ng/ml	cutoff	60	36	24	34	26	36	24
	625ng/ml	+25% cutoff	60	52	8	54	6	56	4
	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
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	4	56
	300ng/ml	cutoff	60	34	26	38	22	36	24
	375ng/ml	+25% cutoff	60	54	6	58	2	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
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	8	52
	100ng/ml	cutoff	60	36	24	38	22	34	26
	125ng/ml	+25% cutoff	60	56	4	56	4	58	2
	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	36	24	38	22	34	26
	31.3ng/ml	+25% cutoff	60	54	6	56	4	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

Multi-drug Test Cup:

Co-Innovation Biotech Co.,Ltd.

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	6	54	6	54	8	52
	1000ng/ml	cutoff	60	34	26	38	22	36	24
	1250ng/ml	+25% cutoff	60	54	6	58	2	56	4
	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
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	4	56	6	54
	300ng/ml	cutoff	60	34	26	36	24	34	26
	375ng/ml	+25% cutoff	60	54	6	56	4	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
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	4	56	6	54	6	54
	1000ng/ml	cutoff	60	34	26	38	22	36	24
	1250ng/ml	+25% cutoff	60	56	4	58	2	58	2
	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	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	10	50
	2000ng/ml	cutoff	60	40	20	44	16	42	18
	2500ng/ml	+25% cutoff	60	56	4	54	6	54	6
	3000ng/ml	+50% cutoff	60	60	0	60	0	60	0

Co-Innovation Biotech Co.,Ltd.

	3500ng/ml	+75% cutoff	60	60	0	60	0	60	0
	4000ng/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	38	22	36	24	36	24
	62.5ng/ml	+25% cutoff	60	52	8	56	4	54	6
	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
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
	225ng/ml	-25% cutoff	60	6	54	2	58	4	56
	300ng/ml	cutoff	60	38	22	36	24	34	26
	375ng/ml	+25% cutoff	60	58	2	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
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	8	52	4	56	6	54
	300ng/ml	cutoff	60	36	24	36	24	38	22
	375ng/ml	+25% cutoff	60	52	8	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
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	8	52	10	50	6	54
	500ng/ml	cutoff	60	32	28	34	26	36	24
	625ng/ml	+25% cutoff	60	56	4	54	6	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

Co-Innovation Biotech Co.,Ltd.

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	2	58	4	56	4	56
	300ng/ml	cutoff	60	38	22	34	26	36	24
	375ng/ml	+25% cutoff	60	58	2	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
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	8	52	4	56
	100ng/ml	cutoff	60	34	26	36	24	38	22
	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	36	24	34	26
	31.3ng/ml	+25% cutoff	60	56	4	54	6	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

Single 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	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	10	50
	1000ng/ml	cutoff	60	36	24	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

Co-Innovation Biotech Co.,Ltd.

	1750ng/ml	+75% cutoff	60	60	0	60	0	60	0
	2000ng/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	4	56	8	52
	300ng/ml	cutoff	60	34	26	36	24	34	26
	375ng/ml	+25% cutoff	60	54	6	56	4	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
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	4	56	4	56	6	54
	1000ng/ml	cutoff	60	36	24	34	26	34	26
	1250ng/ml	+25% cutoff	60	56	4	56	4	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	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	10	50	8	52	6	54
	2000ng/ml	cutoff	60	44	16	42	18	40	20
	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	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	4	56	8	52
	50ng/ml	cutoff	60	34	26	38	22	36	24
	62.5ng/ml	+25% cutoff	60	50	10	52	8	54	6
	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
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
	225ng/ml	-25% cutoff	60	6	54	4	56	4	56
	300ng/ml	cutoff	60	38	22	36	24	34	26

Co-Innovation Biotech Co.,Ltd.

	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	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	8	52	6	54	4	56
	300ng/ml	cutoff	60	36	24	38	22	36	24
	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
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	8	52	10	50
	500ng/ml	cutoff	60	34	26	36	24	32	28
	625ng/ml	+25% cutoff	60	54	6	56	4	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
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	4	56	2	58	6	54
	300ng/ml	cutoff	60	32	28	36	24	34	26
	375ng/ml	+25% cutoff	60	56	4	54	6	58	2
	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	2	58	6	54	4	56
	100ng/ml	cutoff	60	34	26	36	24	34	26
	125ng/ml	+25% cutoff	60	54	6	56	4	58	2
	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

Co-Innovation Biotech Co.,Ltd.

18.8ng/ml	-25% cutoff	60	6	54	6	54	4	56
25ng/ml	cutoff	60	38	22	36	24	38	22
31.3ng/ml	+25% cutoff	60	56	4	56	4	58	2
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

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	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	32	28	34	26
	1250ng/ml	+25% cutoff	60	56	4	54	6	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	
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	8	52	6	54	4	56
	300ng/ml	cutoff	60	34	26	36	24	32	28
	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	0
600ng/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	6	54	8	52	4	56
	1000ng/ml	cutoff	60	38	22	36	24	36	24
	1250ng/ml	+25% cutoff	60	54	6	56	4	56	4
	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	

Co-Innovation Biotech Co.,Ltd.

MOP	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	10	50	8	52
	2000ng/ml	cutoff	60	42	18	40	20	44	16
	2500ng/ml	+25% cutoff	60	54	6	56	4	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
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	8	52	4	56	6	54
	50ng/ml	cutoff	60	36	24	34	26	38	22
	62.5ng/ml	+25% cutoff	60	50	10	52	8	54	6
	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
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
	225ng/ml	-25% cutoff	60	4	56	6	54	8	52
	300ng/ml	cutoff	60	36	24	34	26	38	22
	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
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	6	54	4	56	6	54
	300ng/ml	cutoff	60	38	22	34	26	36	24
	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	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

Co-Innovation Biotech Co.,Ltd.

	375ng/ml	-25% cutoff	60	10	50	6	54	8	52
	500ng/ml	cutoff	60	36	24	34	26	34	26
	625ng/ml	+25% cutoff	60	52	8	56	4	54	6
	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
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	2	58
	300ng/ml	cutoff	60	36	24	34	26	36	24
	375ng/ml	+25% cutoff	60	56	4	58	2	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
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	8	52	4	56	6	54
	100ng/ml	cutoff	60	38	22	36	24	34	26
	125ng/ml	+25% cutoff	60	56	4	58	2	54	6
	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	2	58	4	56	6	54
	25ng/ml	cutoff	60	36	24	38	22	34	26
	31.3ng/ml	+25% cutoff	60	58	2	56	4	54	6
	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

8.6 Accuracy

80 clinical urine specimens for each drug were analyzed by GC/MS and by two lots of the corresponding Rapid Single/Multi-drug Test Cup and Test Dipcard. Samples were divided by

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concentration into five categories: drug free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. All samples were blindly labeled by a nonparticipant. Separate sets of the blind coded were assigned. Samples were also randomized prior to testing. The study was conducted by 4 nurses at two Point-of-Care sites. The test dipcard format was performed at one site and the test cup format at the second site. Each operator only performed one test format and different nurses tested each format. Results were as follows:

Single drug Test Cup:

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	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	
BAR	+	0	0	0	6	34	80
	-	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	-	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	-	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	-	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	-	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	-	35	0	4	0	0	

Analysis of Discordant Results with Rapid Single drug Test Cup

Rapid Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MOP2000	2000	Positive	1742	Morphine
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Metadone
PCP	25	Positive	23	Phencyclidine

Co-Innovation Biotech Co.,Ltd.

Multi-drug Test Cup:

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	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	
BAR	+	0	0	0	6	34	80
	-	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	-	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	-	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	-	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	-	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	-	35	0	4	0	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
MET	1000	Positive	867	Methamphetamine
MOP2000	2000	Positive	1742	Morphine
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methodone
PCP	25	Positive	23	Phencyclidine

Single drug Test Dipcard:

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	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	

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MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	
BAR	+	0	0	0	6	34	80
	-	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	-	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	-	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	-	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	-	35	0	5	0	0	
PCP	+	0	0	1	5	35	80
	-	35	0	4	0	0	

Analysis of Discordant Results with Rapid Single drug Test Dipcard

Rapid Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
MET	1000	Positive	867	Methamphetamine
MOP2000	2000	Positive	1742	Morphine
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

Multi-drug Test Dipcard:

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	
COC	+	0	0	0	5	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP2000	+	0	0	1	6	34	80
	-	30	4	5	0	0	
THC	+	0	0	0	6	33	80
	-	34	1	5	1	0	
BAR	+	0	0	0	6	34	80
	-	33	0	7	0	0	
BZO	+	0	0	1	7	33	80
	-	31	0	8	0	0	
MDMA	+	0	0	0	5	34	80
	-	32	3	5	1	0	
MTD	+	0	0	1	5	35	80
	-	32	2	5	0	0	
OXY	+	0	0	0	6	34	80
	-	35	0	5	0	0	

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PCP	+	0	0	1	5	35	80
	-	35	0	4	0	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
MET	1000	Positive	867	Methamphetamine
MOP2000	2000	Positive	1742	Morphine
THC	50	Negative	61	11-nor- Δ^9 -THC-9-COOH
BZO	300	Positive	188	Oxazepam
MDMA	500	Negative	715	3,4-Methylenedioxymethamphetamine
MTD	300	Positive	209	Methadone
PCP	25	Positive	23	Phencyclidine

8.7 Home Use Consumer Study

360 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. The concentrations of target drugs were confirmed with GC/MS. Each participant performed only 1 test on provided specimen with one format of Rapid Single/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:

Single drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations	Layer user Results		Agreement (%)
				Positive	Negative	
AMP	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	7	53	88%
	1250ng/ml	+25% cutoff	60	50	10	83%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
COC	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	6	54	90%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%

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MET	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	4	56	93%
	1250ng/ml	+25% cutoff	60	55	5	92%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
MOP2000	0ng/ml	Negative	60	0	60	100%
	1000ng/ml	-50% cutoff	60	0	60	100%
	1500ng/ml	-25% cutoff	60	8	52	87%
	2500ng/ml	+25% cutoff	60	58	2	97%
	3000ng/ml	+50% cutoff	60	60	0	100%
	4000ng/ml	+100% cutoff	60	60	0	100%
THC	0ng/ml	Negative	60	0	60	100%
	25ng/ml	-50% cutoff	60	0	60	100%
	37.5ng/ml	-25% cutoff	60	6	54	90%
	62.5ng/ml	+25% cutoff	60	52	8	87%
	75ng/ml	+50% cutoff	60	60	0	100%
	100ng/ml	+100% cutoff	60	60	0	100%
BAR	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	6	54	90%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
BZO	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	8	52	87%
	375ng/ml	+25% cutoff	60	55	5	92%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MDMA	0ng/ml	Negative	60	0	60	100%
	250ng/ml	-50% cutoff	60	0	60	100%
	375ng/ml	-25% cutoff	60	5	55	92%
	625ng/ml	+25% cutoff	60	56	4	93%
	750ng/ml	+50% cutoff	60	60	0	100%
	1000ng/ml	+100% cutoff	60	60	0	100%
MTD	0ng/ml	Negative	60	0	60	100%

Co-Innovation Biotech Co.,Ltd.

	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	6	54	90%
	375ng/ml	+25% cutoff	60	57	3	95%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
OXY	0ng/ml	Negative	60	0	60	100%
	50ng/ml	-50% cutoff	60	0	60	100%
	75ng/ml	-25% cutoff	60	5	55	92%
	125ng/ml	+25% cutoff	60	56	4	93%
	150ng/ml	+50% cutoff	60	60	0	100%
	200ng/ml	+100% cutoff	60	60	0	100%
PCP	0ng/ml	Negative	60	0	60	100%
	12.5ng/ml	-50% cutoff	60	0	60	100%
	18.8ng/ml	-25% cutoff	60	4	56	93%
	31.3ng/ml	+25% cutoff	60	56	4	93%
	37.5ng/ml	+50% cutoff	60	60	0	100%
	50ng/ml	+100% cutoff	60	60	0	100%

Multi-drug Test Cup:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations	Layer user Results		Agreement (%)
				Positive	Negative	
AMP	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	9	51	85%
	1250ng/ml	+25% cutoff	60	54	6	90%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
COC	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	6	54	90%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MET	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%

Co-Innovation Biotech Co.,Ltd.

	750ng/ml	-25% cutoff	60	4	56	93%
	1250ng/ml	+25% cutoff	60	58	2	97%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
MOP2000	0ng/ml	Negative	60	0	60	100%
	1000ng/ml	-50% cutoff	60	0	60	100%
	1500ng/ml	-25% cutoff	60	6	54	90%
	2500ng/ml	+25% cutoff	60	55	5	92%
	3000ng/ml	+50% cutoff	60	60	0	100%
	4000ng/ml	+100% cutoff	60	60	0	100%
THC	0ng/ml	Negative	60	0	60	100%
	25ng/ml	-50% cutoff	60	0	60	100%
	37.5ng/ml	-25% cutoff	60	4	56	93%
	62.5ng/ml	+25% cutoff	60	54	6	90%
	75ng/ml	+50% cutoff	60	60	0	100%
	100ng/ml	+100% cutoff	60	60	0	100%
BAR	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	5	55	92%
	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
BZO	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	5	55	92%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MDMA	0ng/ml	Negative	60	0	60	100%
	250ng/ml	-50% cutoff	60	0	60	100%
	375ng/ml	-25% cutoff	60	6	54	90%
	625ng/ml	+25% cutoff	60	54	6	90%
	750ng/ml	+50% cutoff	60	60	0	100%
	1000ng/ml	+100% cutoff	60	60	0	100%
MTD	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	5	55	92%

Co-Innovation Biotech Co.,Ltd.

	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
OXY	0ng/ml	Negative	60	0	60	100%
	50ng/ml	-50% cutoff	60	0	60	100%
	75ng/ml	-25% cutoff	60	4	56	93%
	125ng/ml	+25% cutoff	60	56	4	93%
	150ng/ml	+50% cutoff	60	60	0	100%
	200ng/ml	+100% cutoff	60	60	0	100%
PCP	0ng/ml	Negative	60	0	60	100%
	12.5ng/ml	-50% cutoff	60	0	60	100%
	18.8ng/ml	-25% cutoff	60	5	55	92%
	31.3ng/ml	+25% cutoff	60	54	6	90%
	37.5ng/ml	+50% cutoff	60	60	0	100%
	50ng/ml	+100% cutoff	60	60	0	100%

Single drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations	Layer user Results		Agreement (%)
				Positive	Negative	
AMP	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	8	52	87%
	1250ng/ml	+25% cutoff	60	51	9	85%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
COC	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	5	55	92%
	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MET	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	6	54	90%
	1250ng/ml	+25% cutoff	60	53	7	88%

Co-Innovation Biotech Co.,Ltd.

	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
MOP2000	0ng/ml	Negative	60	0	60	100%
	1000ng/ml	-50% cutoff	60	0	60	100%
	1500ng/ml	-25% cutoff	60	9	51	85%
	2500ng/ml	+25% cutoff	60	56	4	93%
	3000ng/ml	+50% cutoff	60	60	0	100%
	4000ng/ml	+100% cutoff	60	60	0	100%
THC	0ng/ml	Negative	60	0	60	100%
	25ng/ml	-50% cutoff	60	0	60	100%
	37.5ng/ml	-25% cutoff	60	7	53	88%
	62.5ng/ml	+25% cutoff	60	50	10	83%
	75ng/ml	+50% cutoff	60	60	0	100%
	100ng/ml	+100% cutoff	60	60	0	100%
BAR	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	5	55	92%
	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
BZO	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	7	53	88%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MDMA	0ng/ml	Negative	60	0	60	100%
	250ng/ml	-50% cutoff	60	0	60	100%
	375ng/ml	-25% cutoff	60	6	54	90%
	625ng/ml	+25% cutoff	60	53	7	88%
	750ng/ml	+50% cutoff	60	60	0	100%
	1000ng/ml	+100% cutoff	60	60	0	100%
MTD	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	4	56	93%
	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%

Co-Innovation Biotech Co.,Ltd.

OXY	0ng/ml	Negative	60	0	60	100%
	50ng/ml	-50% cutoff	60	0	60	100%
	75ng/ml	-25% cutoff	60	4	56	93%
	125ng/ml	+25% cutoff	60	57	3	95%
	150ng/ml	+50% cutoff	60	60	0	100%
	200ng/ml	+100% cutoff	60	60	0	100%
PCP	0ng/ml	Negative	60	0	60	100%
	12.5ng/ml	-50% cutoff	60	0	60	100%
	18.8ng/ml	-25% cutoff	60	3	57	95%
	31.3ng/ml	+25% cutoff	60	54	6	90%
	37.5ng/ml	+50% cutoff	60	60	0	100%
	50ng/ml	+100% cutoff	60	60	0	100%

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample	% of cutoff	Number of determinations	Layer user Results		Agreement (%)
				Positive	Negative	
AMP	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	6	54	90%
	1250ng/ml	+25% cutoff	60	53	7	88%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
COC	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	4	56	93%
	375ng/ml	+25% cutoff	60	53	7	88%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MET	0ng/ml	Negative	60	0	60	100%
	500ng/ml	-50% cutoff	60	0	60	100%
	750ng/ml	-25% cutoff	60	5	55	92%
	1250ng/ml	+25% cutoff	60	54	6	90%
	1500ng/ml	+50% cutoff	60	60	0	100%
	2000ng/ml	+100% cutoff	60	60	0	100%
MOP2000	0ng/ml	Negative	60	0	60	100%

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	1000ng/ml	-50% cutoff	60	0	60	100%
	1500ng/ml	-25% cutoff	60	7	53	88%
	2500ng/ml	+25% cutoff	60	57	3	95%
	3000ng/ml	+50% cutoff	60	60	0	100%
	4000ng/ml	+100% cutoff	60	60	0	100%
THC	0ng/ml	Negative	60	0	60	100%
	25ng/ml	-50% cutoff	60	0	60	100%
	37.5ng/ml	-25% cutoff	60	8	52	87%
	62.5ng/ml	+25% cutoff	60	53	7	88%
	75ng/ml	+50% cutoff	60	60	0	100%
	100ng/ml	+100% cutoff	60	60	0	100%
BAR	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	4	56	93%
	375ng/ml	+25% cutoff	60	57	3	95%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
BZO	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	6	54	90%
	375ng/ml	+25% cutoff	60	54	6	90%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
MDMA	0ng/ml	Negative	60	0	60	100%
	250ng/ml	-50% cutoff	60	0	60	100%
	375ng/ml	-25% cutoff	60	4	56	93%
	625ng/ml	+25% cutoff	60	55	5	92%
	750ng/ml	+50% cutoff	60	60	0	100%
	1000ng/ml	+100% cutoff	60	60	0	100%
MTD	0ng/ml	Negative	60	0	60	100%
	150ng/ml	-50% cutoff	60	0	60	100%
	225ng/ml	-25% cutoff	60	3	57	95%
	375ng/ml	+25% cutoff	60	56	4	93%
	450ng/ml	+50% cutoff	60	60	0	100%
	600ng/ml	+100% cutoff	60	60	0	100%
OXY	0ng/ml	Negative	60	0	60	100%
	50ng/ml	-50% cutoff	60	0	60	100%
	75ng/ml	-25% cutoff	60	6	54	90%

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	125ng/ml	+25% cutoff	60	55	5	92%
	150ng/ml	+50% cutoff	60	60	0	100%
	200ng/ml	+100% cutoff	60	60	0	100%
PCP	0ng/ml	Negative	60	0	60	100%
	12.5ng/ml	-50% cutoff	60	0	60	100%
	18.8ng/ml	-25% cutoff	60	6	54	90%
	31.3ng/ml	+25% cutoff	60	57	3	95%
	37.5ng/ml	+50% cutoff	60	60	0	100%
	50ng/ml	+100% cutoff	60	60	0	100%

720 questionnaires were distributed and collected. Results from the questionnaires indicated that 100% of users felt the test is easy to use and the test instructions are easy to understand.

Evaluation of the readability of the labeling

The entire package insert readability was assessed. The numbers of polysyllabic words are 12 words. The numbers of total sentences are 156. According to Appendix B the SMOG Readability Formula of "Labeling of Home-Use In Vitro Testing Products: Approved Guideline: GP-14A5", the reading level belong to 6 degree.

9. Conclusion:

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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