



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K232228

B Applicant

Shanghai Accurature Diagnostics Co., Ltd.

C Proprietary and Established Names

Multi-drug Urine Test Cup, Multi-drug Urine Test Dip Card, Accurature Multi-drug Urine Test Cup, Accurature Multi-drug Urine Test Dip Card

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
LCM	Unclassified		
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
LAF	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology

DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
JXN	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Cocaine, Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Marijuana

C Type of Test:

Qualitative lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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

Drug	Abbreviation	Cutoff
Amphetamine	AMP	1000 ng/mL
Secobarbital	BAR	300 ng/mL
Buprenorphine	BUP	10 ng/mL
Oxazepam	BZO	300 ng/mL
Cocaine	COC	300 ng/mL

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

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

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

For prescription use only.

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

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

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

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific

alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For over-the-counter use.

C Special Conditions for Use Statement(s):

Rx and OTC

D Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A Device Description:

Multi-drug Urine Test Cup, Multi-drug Urine Test Dip Card, Accurature Multi-drug Urine Test Cup, and Accurature Multi-drug Urine Test Dip Card are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Marijuana, Cocaine, Methamphetamine, Morphine, Oxazepam, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine and Methadone in human urine samples. The products are single-use in vitro diagnostic devices. The candidate device will be sold in two formats: Multi-drug Urine Test Dip Card and Multi-drug Urine Test Cup.

B Principle of Operation:

The Multi-drug Urine Test Cup, Multi-drug Urine Test Dip Card, Accurature Multi-drug Urine Test Cup, and Accurature Multi-drug Urine Test Dip Card are immunoassays based on the competitive binding principle. Drugs that may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody. During testing, a urine specimen migrates upward by capillary action. If present in the urine specimen below its cutoff concentration, a drug will not saturate the binding sites of its specific antibody coated on the particles. The antibody-coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cutoff concentration because it will saturate all the binding sites of the antibody coated on the particles. A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

V Substantial Equivalence Information:

A Predicate Device Name(s):

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

B Predicate 510(k) Number(s):

K153050

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K232228</u>	<u>K153050</u>
Device Trade Name	Multi-drug Urine Test Cup, Multi-drug Urine Test Dip Card, Accurature Multi-drug Urine Test Cup, Accurature Multi-drug Urine Test Dip Card	Rapid Single/Multi-drug test Cup; Rapid Single/Multi-drug test Dipcard
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of Drug-of-abuse in human urine.	Same
Specimen	Human urine	Same
Methodology	Competitive binding, Lateral flow Immuno-chromatographic assay based on the principle of antigen antibody immunochemistry	Same
Cutoff	Amphetamine (AMP): 1000 ng/ml Barbiturates (BAR): 300 ng/mL Buprenorphine (BUP): 10 ng/ml Benzodiazepines (BZO): 300 ng/mL Cocaine (COC): 300 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Methamphetamine (MET): 1000 ng/ml Morphine (MOR): 300 ng/mL Methadone (MTD): 300 ng/ml Oxycodone (OXY): 100 ng/ml Phencyclidine (PCP): 25 ng/ml	Same

	Marijuana (THC): 50 ng/ml	
General Device Characteristic Differences		
Cutoff	Amphetamine (AMP): 1000 ng/ml Barbiturates (BAR): 300 ng/mL Buprenorphine (BUP): 10 ng/ml Benzodiazepines (BZO): 300 ng/mL Cocaine (COC): 300 ng/ml Methylenedioxymethamphetamine (MDMA): 500 ng/ml Methamphetamine (MET): 1000 ng/ml Morphine (MOR): 300 ng/mL Methadone (MTD): 300 ng/ml Oxycodone (OXY): 100 ng/ml Phencyclidine (PCP): 25 ng/ml Marijuana (THC): 50 ng/ml	The number of drugs detected are different

VI Standards/Guidance Documents Referenced:

None

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were carried out at three Point-of-Care sites for samples with concentrations of -100% cutoff, - 75% cutoff, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff , +75% cutoff and +100% cutoff. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were

tested in a blinded fashion. For each concentration, tests were performed in three runs per day for 10 days per device using 3 reagent lots by 6 operators. The results obtained are summarized in the following tables:

Test Cup:

Drug Test	% of cutoff	Number of Determinations per lot	Results					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
AMP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	8	82	9	81
	cutoff	90	73	17	72	18	73	17
	+25%cutoff	90	82	8	81	9	80	10
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BAR	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	10	80	8	82	9	81
	cutoff	90	72	18	73	17	73	17
	+25%cutoff	90	83	7	82	8	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BUP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	8	82	8	82
	cutoff	90	73	17	74	16	74	16
	+25%cutoff	90	83	7	82	8	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BZO	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	7	83	7	83	8	82
	cutoff	90	71	19	72	18	72	18
	+25%cutoff	90	80	10	81	9	81	9
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
COC	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90

	-25%cutoff	90	8	82	8	82	7	83
	cutoff	90	74	16	73	17	73	17
	+25%cutoff	90	82	8	81	9	81	9
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MDMA	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	10	80	10	80	9	81
	cutoff	90	70	20	72	18	71	19
	+25%cutoff	90	79	11	80	10	79	11
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MET	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	8	82	8	82
	cutoff	90	72	18	73	17	73	17
	+25%cutoff	90	82	8	81	9	81	9
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MOP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	11	79	10	80	10	80
	cutoff	90	71	19	70	20	71	19
	+25%cutoff	90	82	8	83	7	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MTD	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	7	83	8	82	8	82
	cutoff	90	73	17	74	16	73	17
	+25%cutoff	90	81	9	81	9	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
OXY	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	10	80	9	81	9	81
	cutoff	90	71	19	72	18	72	18

	+25%cutoff	90	82	8	81	9	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
PCP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	10	80	9	81
	cutoff	90	72	18	71	19	71	19
	+25%cutoff	90	83	7	82	8	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
THC	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	7	83	6	84	8	82
	cutoff	90	74	16	75	15	74	16
	+25%cutoff	90	81	9	82	8	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0

Test Dip Card:

Drug Test	% of cutoff	Number of Determinations per lot	Results					
			Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
AMP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	11	79	9	81	11	79
	cutoff	90	70	20	72	18	71	19
	+25%cutoff	90	83	7	83	7	79	11
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BAR	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	11	79	12	78	7	83
	cutoff	90	76	14	78	12	75	15
	+25%cutoff	90	79	11	79	11	83	7
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BUP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90

	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	12	78	8	82	7	83
	cutoff	90	73	17	74	16	74	16
	+25%cutoff	90	80	10	83	7	78	12
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
BZO	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	11	79	8	82
	cutoff	90	72	18	77	13	74	16
	+25%cutoff	90	83	7	81	9	78	12
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
COC	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	12	78	8	82	7	83
	cutoff	90	71	19	71	19	72	18
	+25%cutoff	90	80	10	79	11	80	10
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MDMA	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	9	81	7	83
	cutoff	90	76	14	73	17	71	19
	+25%cutoff	90	82	8	80	10	80	10
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MET	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	11	79	10	80	12	78
	cutoff	90	70	20	75	15	76	14
	+25%cutoff	90	79	11	78	12	80	10
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MOP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	7	83	9	81	12	78

	cutoff	90	71	19	72	18	73	17
	+25%cutoff	90	80	10	81	9	82	8
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
MTD	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	9	81	12	78	10	80
	cutoff	90	76	14	70	20	76	14
	+25%cutoff	90	83	7	80	10	83	7
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
OXY	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	10	80	10	80	8	82
	cutoff	90	70	20	71	19	74	16
	+25%cutoff	90	79	11	82	8	79	11
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
PCP	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	12	78	12	78	9	81
	cutoff	90	77	13	73	17	71	19
	+25%cutoff	90	80	10	78	12	83	7
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0
THC	Negative	90	0	90	0	90	0	90
	-75%cutoff	90	0	90	0	90	0	90
	-50%cutoff	90	0	90	0	90	0	90
	-25%cutoff	90	12	78	7	83	8	82
	cutoff	90	74	16	78	12	73	17
	+25%cutoff	90	78	12	77	11	83	7
	+50%cutoff	90	90	0	90	0	90	0
	+75%cutoff	90	90	0	90	0	90	0
	+100%cutoff	90	90	0	90	0	90	0

2. Linearity:

N/A

3. Analytical Specificity/Interference:

Cross-Reactivity:

To test cross-reactivity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound is listed below. The highest concentration tested is shown if no cross reactivity was observed.

Test Cup:

AMP	Result Positive at (ng/ml)	%Cross-Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	20000	5%
DL - Amphetamine	1000	10%
Phentermine	1300	77%
Hydroxyamphetamine	700	143%
Methylenedioxyamphetamine (MDA)	1800	56%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
Ephedrine	>100000	<1%
Methylenedioxyethylamphetamine	>100000	<1%
3,4-methylenedioxymethamphetamine (MDMA)	>100000	<1%

BAR	Result Positive at (ng/ml)	%Cross-Reactivity
Secobarbital	300	100%
Amobarbital	300	100%
Alphenal	750	40%
Aprobarbital	300	100%
Butabarbital	2500	12%
Butethal	2500	12%
Butalbital	2500	12%
Cyclopentobarbital	600	50%
Pentobarbital	2500	12%
Phenobarbital	300	100%

BOP	Result Positive at (ng/ml)	%Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	25	40%
Morphine	>100000	Not detected

Oxymorphone	>100000	Not detected
Hydromorphone	>100000	Not detected

BZO	Result Positive at (ng/ml)	%Cross-Reactivity
Alprazolam	200	150%
Bromazepam	1,500	19%
Chlordiazepoxide HCL	1,500	19%
Clobazam	100	300%
Clonazepam	750	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,500	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
A-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,500	19%
RS-Lorazepam glucuronide	160	188%
Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
Temazepam	100	300%
Triazolam	2,500	12%

COC	Result Positive at (ng/ml)	%Cross-Reactivity
Benzoyllecgonine	300	100%
Cocaethylene	300	100%
Cocaine HCl	300	100%
Ecgonine HCl	35,000	1%

MDMA	Result Positive at (ng/ml)	%Cross-Reactivity
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
d-methamphetamine	3000	17%
d-amphetamine	>100000	Not detected

l-amphetamine	>100000	Not detected
l-methamphetamine	>100000	Not detected

MET	Result Positive at (ng/ml)	%Cross- Reactivity
D-Methamphetamine	1,000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000	5%
Procaine (Novocaine)	60,000	2%
Trimethobenzamide	20,000	5%
Methamphetamine	1000	100%
Ranitidine (Zantac)	50,000	2%
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	3000	33%
Chloroquine	50,000	2%
Ephedrine	100,000	1%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%

MOP	Result Positive at (ng/ml)	%Cross-Reactivity
Morphine	300	100%
O6-Acetylmorphine	500	60%
Codeine	300	100%
Ethyl Morphine	6500	5%
Heroin	600	50%
Hydromorphone	3120	10%
Hydrocodone	50000	0.60%
Levorphanol	1500	20%
Oxycodone	30000	1%
Procaine	15000	2%
Thebaine	6500	5%
morphine 3-β-D-glucuronide	300	100%

MTD	Result Positive at (ng/ml)	%Cross-Reactivity
Methadone	300	100%
Doxylamine	5,000	6%
EDDP	>100000	Not Detected
EMDP	>100000	Not Detected
LAAM HCl	>100000	Not Detected
Alpha Methadol	>100000	Not Detected

OXY	Result Positive at (ng/ml)	%Cross-Reactivity
Oxycodone	100	100%
Codeine	50,000	0.20%
Ethyl Morphine	75,000	0.10%
Thebaine	50,000	0.20%
Oxymorphone	750	13%
Dihydrocodeine	12500	0.80%
Hydromorphone	>100000	Not Detected
Hydrocodone	>100000	Not Detected
Morphine	>100000	Not Detected
Acetylmorphine	>100000	Not Detected
Buprenorphine	>100000	Not Detected
Ethylmorphine	>100000	Not Detected
Naloxone	50,000	0.2%
Naltrexone	50,000	0.2%

PCP	Result Positive at (ng/ml)	%Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	100	25%

THC	Result Positive at (ng/ml)	%Cross-Reactivity
11-nor- Δ^9 -THC-9-COOH	50	100%
Delta-9-Tetrahydrocannabinol	50,000	0.10%
11-nor-delta-9-THC-carboxyglucuronide	75	67%
(-)- 11-nor-9-carboxy-delta9-THC	75	67%
11-Nor- Δ^9 -Tetrahydrocannabinol	50	100%
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000	1%
11-Nor- Δ^8 -Tetrahydrocannabinol	50	100%
Δ^8 -THC-COOH	50,000	0.10%

Test Dip Card:

AMP	Result Positive at (ng/ml)	%Cross-Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	20000	5%
DL - Amphetamine	1000	10%
Phentermine	1300	77%
Hydroxyamphetamine	700	143%
Methylenedioxyamphetamine (MDA)	1800	56%

d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
Ephedrine	> 100000	<1%
Methylenedioxyethylamphetamine	> 100000	<1%
3,4-methylenedioxymethamphetamine (MDMA)	> 100000	<1%

BAR	Result Positive at (ng/ml)	%Cross-Reactivity
Secobarbital	300	100%
Amobarbital	300	100%
Alphenal	750	40%
Aprobarbital	300	100%
Butabarbital	2500	12%
Butethal	2500	12%
Butalbital	2500	12%
Cyclopentobarbital	600	50%
Pentobarbital	2500	12%

BOP	Result Positive at (ng/ml)	%Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	25	40%
Morphine	>100000	Not detected
Oxymorphone	>100000	Not detected
Hydromorphone	>100000	Not detected

BZO	Result Positive at (ng/ml)	%Cross-Reactivity
Alprazolam	200	150%
Bromazepam	1,500	19%
Chlordiazepoxide HCL	1,500	19%
Clobazam	100	300%
Clonazepam	750	38%
Clorazepate Dipotassium	200	150%
Delorazepam	1,500	19%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
A-Hydroxyalprazolam	1260	24%
(±) Lorazepam	1,500	19%
RS-Lorazepam glucuronide	160	188%

Midazolam	12,500	2%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Oxazepam	300	100%
Temazepam	100	300%
Triazolam	2,500	12%

COC	Result Positive at (ng/ml)	%Cross-Reactivity
Benzoyllecgonine	300	100%
Cocaethylene	300	100%
Cocaine HCl	300	100%

MDMA	Result Positive at (ng/ml)	%Cross-Reactivity
D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000	17%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
d-methamphetamine	3000	17%
d-amphetamine	>100000	Not detected
l-amphetamine	>100000	Not detected
l-methamphetamine	>100000	Not detected

MET	Result Positive at (ng/ml)	%Cross-Reactivity
D-Methamphetamine	1,000	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000	5%
Procaine (Novocaine)	60,000	2%
Trimethobenzamide	20,000	5%
Methamphetamine	1000	100%
Ranitidine (Zantac)	50,000	2%
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	3000	33%
Chloroquine	50,000	2%
Ephedrine	100,000	1%
Fenfluramine	50,000	2%

p-Hydroxymethamphetamine	10,000	10%
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MOP	Result Positive at (ng/ml)	%Cross-Reactivity
Morphine	300	100%
O6-Acetylmorphine	500	60%
Codeine	300	100%
Ethyl Morphine	6500	5%
Heroin	600	50%
Hydromorphone	3120	10%
Hydrocodone	50000	0.60%
Levorphanol	1500	20%
Oxycodone	30000	1%
Procaine	15000	2%
Thebaine	6500	5%

MTD	Result Positive at (ng/ml)	%Cross-Reactivity
Methadone	300	100%
Doxylamine	5,000	6%
EDDP	>100000	Not Detected
EMDP	>100000	Not Detected
LAAM HCl	>100000	Not Detected
Alpha Methadol	>100000	Not Detected

OXY	Result Positive at (ng/ml)	%Cross-Reactivity
Oxycodone	100	100%
Codeine	50,000	0.20%
Ethyl Morphine	75,000	0.10%
Thebaine	50,000	0.20%
Oxymorphone	750	13%
Dihydrocodeine	12500	0.80%
Hydromorphone	>100000	Not Detected
Hydrocodone	>100000	Not Detected
Morphine	>100000	Not Detected
Acetylmorphine	>100000	Not Detected
Buprenorphine	>100000	Not Detected
Ethylmorphine	>100000	Not Detected

PCP	Result Positive at (ng/ml)	%Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	100	25%

THC	Result Positive at (ng/ml)	%Cross-Reactivity
11-nor- Δ^9 -THC-9-COOH	50	100%
Delta-9-Tetrahydrocannabinol	50,000	0.10%
11-nor-delta-9-THC-carboxyglucuronide	75	67%
(-)- 11-nor-9-carboxy-delta9-THC	75	67%
11-Nor- Δ^9 -Tetrahydrocannabinol	50	100%
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000	1%
11-Nor- Δ^8 -Tetrahydrocannabinol	50	100%
Δ^8 -THC-COOH	50,000	0.10%

Interfering substances:

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and urine samples with concentrations of the target drugs at 25% below and 25% above Cutoff levels. These urine samples were tested using three lots of each device. The compounds were tested at 100 $\mu\text{g/mL}$ (unless otherwise noted in the table). No interference was observed for any of the compounds tested, and the list of compounds is provided in the following table.

Acetaminophen	O-Hydroxyhippuric Acid	Labetalol	D-Norpropoxyphene
Acyclovir	Olanzapine	Liverite	Domperidone
Afrin	Omeprazole	Loperamide	Doxylamine
Aminophylline	Oxalic Acid	Loratadine	Epinephrine Hydrochloride
Aminopyrine	Oxolinic Acid	Naproxen	Erythromycin
Benzilic Acid	Oxymetazoline	Mifepristone	Esomeprazole Magnesium
Benzoic Acid	Ondansetran	Mirtazapine	Furosemide
Bilirubin	Paliperidone	Montelukast Sodium	Gabapentin
Bupropion	Pantoprazole	Phenelzine	Gentisic Acid
Captopril	Papaverine	Pioglitazone Hydrochloride	3-Hydroxy- tyramine
Ciprofloxacin Hydrochloride	Paroxetine Hydrochloride	Piracetam	Isosorbide Dinitrate
Citalopram	Penfluridol	Pravastatin Sodium	Isoxsuprine
Clarithromycin	Penicillin V Potassium	Prednisone	Lamotrigine
Deoxy-corticosterone	Penicillin-G	Propylthiouracil	Levofloxacin Hydrochloride
Dextromethorphan	Acetophenetidin	Promethazine	Levonorgestrel
Diclofenac	Amiodarone Hydrochloride	Quetiapine Fumarate	Levothyroxine Sodium
Diflunisal	Albumin	Quinine	Minocycline

D-Pseudo- ephedrine	Amoxicillin	Ranitidine	Nalidixic Acid
Duloxetine	Ampicillin	Rifampicin	Niacinamide
Dicyclomine	Atropine	Risperidone	Nifedipine
β-Estradiol	Carbamazepine	Salicylic Acid	Nikethamide
Ethanol	Cefradine	Serotonin	Sulfamethazine
Fenofibrate	Cephalexin	Sertraline Hydrochloride	Sulindac
Fenoprofen	Chloral Hydrate	Sildenafil Citrate	Tetrahydrocortisone 3-acetate
Glibenclamide	Clonidine	Simvastatin	Tetrahydrocortisone 3-(β-D-glucuronide)
Gliclazide	Clopidogrel Hydrogen Sulphate	Sodium Valproate	Tetrahydrozoline
Glipizide	Clozapine	Spironolactone	Tetracycline
Ibuprofen	D,L-Tyrosine	Acetylsalicylic Acid	Thiamine
Ketoconazole	Digoxin	Apomorphine	Thioridazine
Ketoprofen	Diphenhydramine	Amlodipine Mesylate	Topiramate
Lidocaine Hydrochloride	Dirithromycin	Aripiprazole	Tramadol Hydrochloride
Lisinopril	Ecgonine Methyl Ester	Aspartame	Trazodone Hydrochloride
Lithium Carbonate	Effexor	Atomoxetine	Triamterene
Metoprolol Tartrate	Enalapril Maleate	Atorvastatin Calcium	Trifluoperazine
Magnesium	Fentanyl Citrate	Chloramphenicol	Trimethoprim
Meperidine	Fluoxetine Hydrochloride	Chlorothiazide	Uric Acid
Meprobamate	Fluvoxamine	Chloroquine	Valproate
Mosapride Citrate	Glucose	Cholesterol	Verapamil
Maprotiline	Haloperidol	(-) Cotinine	Vitamin B2
Nimodipine	Hemoglobin	chlorpheniramine	Vitamin C
Norethindrone	Ketamine	D,L-Octopamine	
N-Acetylprocainamide	Kratom powder	D,L-Propranolol	

Effect of Urinary Specific Gravity and pH:

To investigate the effect of urine specific gravity and urine pH, urine samples, with specific gravity ranging from 1.000 to 1.035 or urine samples with pH ranging from 4 to 9 were spiked with the target drugs to concentrations at 50% below and 50% above Cutoff levels. These samples were tested using three lots of each device. Results were all positive for samples at +50% Cutoff and all negative for samples at -50% Cutoff.

4. Assay Reportable Range:

Not Applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The device is traceable to commercially available reference materials.

6. Detection Limit:

Not applicable.

7. Assay Cut-Off:

Refer to Section VII.A.1

B Comparison Studies:

1. Method Comparison with Predicate Device:

Method comparison:

Method comparison studies were performed by three operators. Eighty (80) unaltered clinical samples were run for each target drug. The samples were tested in a blinded fashion and compared to LC/MS results. The results are presented in the tables below:

Amphetamine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Secobarbital Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Buprenorphine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Oxazepam Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Cocaine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Methylenedioxy-methamphetamine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	20	10	2	0

Methamphetamine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	20	10	2	0

Morphine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	20	10	2	0

Methadone Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Oxycodone Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Phencyclidine Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	20	10	2	0

Marijuana Cup:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Amphetamine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Secobarbital Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Buprenorphine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Oxazepam Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Cocaine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Methylenedioxy-methamphetamine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff

Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Methamphetamine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Morphine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Methadone Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	18	20
	Negative	10	20	10	2	0

Oxycodone Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of	Between cutoff and	>50% above cutoff
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				cutoff and cutoff	50% above cutoff	
Viewer A	Positive	0	0	0	18	20
	Negative	10	20	10	2	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	19	20
	Negative	10	20	10	1	0

Phencyclidine Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer B	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

Marijuana Dip Card:

Test Cup		Drug-free	<50% below cutoff	Between 50% of cutoff and cutoff	Between cutoff and 50% above cutoff	>50% above cutoff
Viewer A	Positive	0	0	0	19	20
	Negative	10	20	10	1	0
Viewer B	Positive	0	0	0	20	20
	Negative	10	20	10	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	20	10	0	0

2. Lay user study

A lay user study was performed using the Multi-Drug Test Cup/Dip Card at three intended use sites with 603 lay persons. The lay users had diverse ages and educational and professional backgrounds. Urine samples were prepared at multiple concentrations (Negative (-100%), +/- 75%, +/-50%, +/-25% of the cutoff) by spiking drugs into drug free pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and tested in a blinded fashion.

Test Cup:

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
AMP	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	19	1	95
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	20	0	100
BAR	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	20	0	100
BUP	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
BZO	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	19	1	95
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	20	0	100
COC	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100

MDMA	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
MET	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
MOP	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
MTD	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	19	1	95
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
OXY	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
PCP	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100
	+75% Cutoff	20	0	20	100
THC	-100% Cutoff	20	0	20	100
	-75% Cutoff	20	0	20	100
	-50% Cutoff	161	0	161	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	42	42	0	100

	+75% Cutoff	20	0	20	100
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Test Dip Card:

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
AMP	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
BAR	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
BUP	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	19	1	95
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
BZO	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
COC	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100

MDMA	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
MET	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
MOP	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
MTD	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
OXY	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
PCP	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100
	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100
	-100% Cutoff	20	0	20	100
	-75% Cutoff	19	0	19	100
	-50% Cutoff	160	0	160	100
	-25% Cutoff	20	0	20	100

THC	+25% Cutoff	20	20	0	100
	+50% Cutoff	41	41	0	100
	+75% Cutoff	20	20	0	100

3. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling support the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.