

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

A. 510(k) Number:

k142800

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Methamphetamine, Cocaine, Morphine, Cannabinoid, Barbiturates, Benzodiazepines, Methadone, Methylenedioxymethamphetamine, Oxycodone, Phencyclidine

D. Type of Test:

Qualitative lateral flow immunochromatographic assay

E. Applicant:

Co-Innovation Biotech Co., Ltd.

F. Proprietary and Established Names:

Rapid Single/Multi-drug Test Cup

Rapid Single/Multi-drug Test Dipcard

G. Regulatory Information:

<u>Product Code</u>	<u>Classification</u>	<u>Regulatory Section</u>	<u>Panel</u>
DKZ	Class II	862.3100 Amphetamine test system	Toxicology (91)
DJC	Class II	862.3610 Methamphetamine test system	Toxicology (91)
DIO	Class II	21 CFR 862.3250 Cocaine test system	Toxicology (91)
DNK	Class II	21 CFR 862.3640 Morphine test system	Toxicology (91)
LDJ	Class II	21 CFR 3870 Cannabinoid test	Toxicology (91)

		system	
DIS	Class II	21 CFR 862.3150 Barbiturate test system	Toxicology (91)
JXM	Class II	21 CFR 862.3170 Benzodiazepine test system	Toxicology (91)
DJR	Class II	21 CFR 862.3620 Methadone test system	Toxicology (91)
DJG	Class II	21 CFR 862.3650 Opiate test system	Toxicology (91)
LCM	Unclassified	Enzyme immunoassay, Phencyclidine test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) 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	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.

3. Special conditions for use statement(s):

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

4. Special instrument requirements:

No applicable; these are visually read single use devices.

5. **Device Description:**

The 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 can be performed without the use of an instrument. The devices are available in one of two formats: 1) Test Cup and 2) Test Dipcard. The test configurations consist of single drug screening tests or any combinations of multiple drug screening tests.

J. Substantial Equivalence Information:

1. Predicate device name(s):

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

2. Predicate 510(k) number(s):

k122809

3. Comparison with predicate:

Similarities		
Item	Candidate: Rapid Single/Multi-drug Test Cup and Dipcard k142165	Predicate: Advin Multi-Drug Screen Test Dip Card, Cup and Cassette k122089
Indication for use	Qualitative detection of drugs-of-abuse in urine	Same
Intended Users	OTC and Prescription Use	Same

Similarities		
Item	Candidate: Rapid Single/Multi-drug Test Cup and Dipcard k142165	Predicate: Advin Multi-Drug Screen Test Dip Card, Cup and Cassette k122089
Specimen	Urine	Same
Read time	5 minutes	Same
Results	Qualitative	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same

Differences		
Item	Rapid Single/Multi-drug Test Cup and Dipcard k142165	Advin Multi-Drug Screen Test Dip Card, Cup and Cassette k122089
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: 1000 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
Configurations	Dipcard and Cup	Cassette, Dipcard and Cup

K. Standard/Guidance Document Referenced (if applicable):

None were referenced.

L. Test Principle:

The Rapid Single/Multi-drug test Cup and the Rapid Single/Multi-drug test Dipcard employ lateral flow immunochromatographic technology based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of monoclonal antibody (mouse) coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region indicating a negative result. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody, indicating a preliminary positive result. Each

device contains a procedural control that appears in the control line region regardless of the presence of drug, indicating that the sample has migrated properly on the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

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. Results from these studies are presented in the following tables:

Precision data of Rapid Single-drug Amphetamine (AMP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	8	52	6	54	10	50
1000ng/mL	Cutoff	60	36	24	34	26	36	24
1250ng/mL	+25%	60	50	10	52	8	54	6
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Amphetamine (AMP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	6	54	8	52	8	52
1000ng/mL	Cutoff	60	34	26	36	24	32	28

1250ng/mL	+25%	60	52	8	52	8	54	6
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Amphetamine (AMP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	10	50	8	52	6	54
1000ng/mL	Cutoff	60	36	24	32	28	34	26
1250ng/mL	+25%	60	56	4	54	6	54	6
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Amphetamine (AMP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	6	54	6	54	8	52
1000ng/mL	Cutoff	60	34	26	38	22	36	24
1250ng/mL	+25%	60	54	6	58	2	56	4
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Cocaine (COC) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	8	52
300ng/mL	Cutoff	60	34	26	36	24	34	26
375ng/mL	+25%	60	54	6	56	4	56	4

450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Cocaine (COC) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	8	52	6	54	4	56
300ng/mL	Cutoff	60	36	24	34	26	38	22
375ng/mL	+25%	60	56	4	54	6	52	8
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Cocaine (COC) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	8	52	6	54	4	56
300ng/mL	Cutoff	60	34	26	36	24	32	28
375ng/mL	+25%	60	56	4	54	6	52	8
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Cocaine (COC) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	6	54
300ng/mL	Cutoff	60	34	26	36	24	34	26
375ng/mL	+25%	60	54	6	56	4	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0

600ng/mL	+100%	60	60	0	60	0	60	0
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Precision data of Rapid Single-drug Metamphetamine (MET) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	4	56	4	56	6	54
1000ng/mL	Cutoff	60	36	24	34	26	34	26
1250ng/mL	+25%	60	56	4	56	4	54	6
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Metamphetamine (MET) test (Cup)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	4	56	8	52	6	54
1000ng/mL	Cutoff	60	34	26	36	24	38	22
1250ng/mL	+25%	60	54	6	56	4	58	2
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Metamphetamine (MET) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	6	54	8	52	4	56
1000ng/mL	Cutoff	60	38	22	36	24	36	24
1250ng/mL	+25%	60	54	6	56	4	56	4
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Metamphetamine (MET) test (Cup)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
250ng/mL	-75%	60	0	60	0	60	0	60
500ng/mL	-50%	60	0	60	0	60	0	60
750ng/mL	-25%	60	4	56	6	54	6	54
1000ng/mL	Cutoff	60	34	26	38	22	36	24
1250ng/mL	+25%	60	56	4	58	2	58	2
1500ng/mL	+50%	60	60	0	60	0	60	0
1750ng/mL	+75%	60	60	0	60	0	60	0
2000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Morphine (MOP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
500ng/mL	-75%	60	0	60	0	60	0	60
1000ng/mL	-50%	60	0	60	0	60	0	60
1500ng/mL	-25%	60	10	50	8	52	6	54
2000ng/mL	Cutoff	60	44	16	42	18	40	20
2500ng/mL	+25%	60	56	4	54	6	54	6
3000ng/mL	+50%	60	60	0	60	0	60	0
3500ng/mL	+75%	60	60	0	60	0	60	0
4000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Morphine (MOP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
500ng/mL	-75%	60	0	60	0	60	0	60
1000ng/mL	-50%	60	0	60	0	60	0	60
1500ng/mL	-25%	60	8	52	10	50	8	52
2000ng/mL	Cutoff	60	42	18	44	16	44	16
2500ng/mL	+25%	60	54	6	56	4	56	4
3000ng/mL	+50%	60	60	0	60	0	60	0
3500ng/mL	+75%	60	60	0	60	0	60	0
4000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Morphine (MOP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
500ng/mL	-75%	60	0	60	0	60	0	60
1000ng/mL	-50%	60	0	60	0	60	0	60
1500ng/mL	-25%	60	8	52	10	50	8	52
2000ng/mL	Cutoff	60	42	18	40	20	44	16
2500ng/mL	+25%	60	54	6	56	4	56	4
3000ng/mL	+50%	60	60	0	60	0	60	0
3500ng/mL	+75%	60	60	0	60	0	60	0
4000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Morphine (MOP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
500ng/mL	-75%	60	0	60	0	60	0	60
1000ng/mL	-50%	60	0	60	0	60	0	60
1500ng/mL	-25%	60	6	54	8	52	10	50
2000ng/mL	Cutoff	60	40	20	44	16	42	18
2500ng/mL	+25%	60	56	4	54	6	54	6
3000ng/mL	+50%	60	60	0	60	0	60	0
3500ng/mL	+75%	60	60	0	60	0	60	0
4000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Marijuana (THC) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
12.5ng/mL	-75%	60	0	60	0	60	0	60
25ng/mL	-50%	60	0	60	0	60	0	60
37.5ng/mL	-25%	60	6	54	4	56	8	52
50ng/mL	Cutoff	60	34	26	38	22	36	24
62.5ng/mL	+25%	60	50	10	52	8	54	6
75ng/mL	+50%	60	60	0	60	0	60	0
87.5ng/mL	+75%	60	60	0	60	0	60	0
100ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Marijuana (THC) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
12.5ng/mL	-75%	60	0	60	0	60	0	60
25ng/mL	-50%	60	0	60	0	60	0	60
37.5ng/mL	-25%	60	8	52	6	54	6	54
50ng/mL	Cutoff	60	36	24	38	22	36	24
62.5ng/mL	+25%	60	52	8	56	4	54	6
75ng/mL	+50%	60	60	0	60	0	60	0
87.5ng/mL	+75%	60	60	0	60	0	60	0
100ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Marijuana (THC) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
12.5ng/mL	-75%	60	0	60	0	60	0	60
25ng/mL	-50%	60	0	60	0	60	0	60
37.5ng/mL	-25%	60	8	52	4	56	6	54
50ng/mL	Cutoff	60	36	24	34	26	38	22
62.5ng/mL	+25%	60	50	10	52	8	54	6
75ng/mL	+50%	60	60	0	60	0	60	0
87.5ng/mL	+75%	60	60	0	60	0	60	0
100ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Marijuana (THC) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
12.5ng/mL	-75%	60	0	60	0	60	0	60
25ng/mL	-50%	60	0	60	0	60	0	60
37.5ng/mL	-25%	60	6	54	8	52	4	56
50ng/mL	Cutoff	60	38	22	36	24	36	24
62.5ng/mL	+25%	60	52	8	56	4	54	6
75ng/mL	+50%	60	60	0	60	0	60	0
87.5ng/mL	+75%	60	60	0	60	0	60	0
100ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Barbiturates (BAR) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	4	56
300ng/mL	Cutoff	60	38	22	36	24	34	26
375ng/mL	+25%	60	56	4	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Barbiturates (BAR) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	4	56	6	54	4	56
300ng/mL	Cutoff	60	38	22	38	22	36	24
375ng/mL	+25%	60	54	6	56	4	58	2
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Barbiturates (BAR) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	4	56	6	54	8	52
300ng/mL	Cutoff	60	36	24	34	26	38	22
375ng/mL	+25%	60	56	4	54	6	54	6
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Barbiturates (BAR) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	2	58	4	56
300ng/mL	Cutoff	60	38	22	36	24	34	26
375ng/mL	+25%	60	58	2	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Benzodiazepines (BZO) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	8	52	6	54	4	56
300ng/mL	Cutoff	60	36	24	38	22	36	24
375ng/mL	+25%	60	54	6	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Benzodiazepines (BZO) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	6	54
300ng/mL	Cutoff	60	38	22	36	24	34	26
375ng/mL	+25%	60	56	4	54	6	52	8
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Benzodiazepines (BZO) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	6	54
300ng/mL	Cutoff	60	38	22	34	26	36	24
375ng/mL	+25%	60	56	4	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Benzodiazepines (BZO) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	8	52	4	56	6	54
300ng/mL	Cutoff	60	36	24	36	24	38	22
375ng/mL	+25%	60	52	8	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Methylenediozymethamphetamine (MDMA) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
125ng/mL	-75%	60	0	60	0	60	0	60
250ng/mL	-50%	60	0	60	0	60	0	60
375ng/mL	-25%	60	6	54	8	52	10	50
500ng/mL	Cutoff	60	34	26	36	24	32	28
625ng/mL	+25%	60	54	6	56	4	52	8
750ng/mL	+50%	60	60	0	60	0	60	0
875ng/mL	+75%	60	60	0	60	0	60	0
1000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Methylenediozymethamphetamine (MDMA) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
125ng/mL	-75%	60	0	60	0	60	0	60
250ng/mL	-50%	60	0	60	0	60	0	60
375ng/mL	-25%	60	8	52	6	54	6	54
500ng/mL	Cutoff	60	36	24	34	26	36	24
625ng/mL	+25%	60	52	8	54	6	56	4
750ng/mL	+50%	60	60	0	60	0	60	0
875ng/mL	+75%	60	60	0	60	0	60	0
1000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Methylenediozymethamphetamine (MDMA) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
125ng/mL	-75%	60	0	60	0	60	0	60
250ng/mL	-50%	60	0	60	0	60	0	60
375ng/mL	-25%	60	10	50	6	54	8	52
500ng/mL	Cutoff	60	36	24	34	26	34	26
625ng/mL	+25%	60	52	8	56	4	54	6
750ng/mL	+50%	60	60	0	60	0	60	0
875ng/mL	+75%	60	60	0	60	0	60	0
1000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Methylenediozymethamphetamine (MDMA) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
125ng/mL	-75%	60	0	60	0	60	0	60
250ng/mL	-50%	60	0	60	0	60	0	60
375ng/mL	-25%	60	8	52	10	50	6	54
500ng/mL	Cutoff	60	32	28	34	26	36	24
625ng/mL	+25%	60	56	4	54	6	52	8
750ng/mL	+50%	60	60	0	60	0	60	0
875ng/mL	+75%	60	60	0	60	0	60	0
1000ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Methadone (MTD) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	4	56	2	58	6	54
300ng/mL	Cutoff	60	32	28	36	24	34	26
375ng/mL	+25%	60	56	4	54	6	58	2
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Methadone (MTD) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	4	56
300ng/mL	Cutoff	60	34	26	38	22	36	24
375ng/mL	+25%	60	54	6	58	2	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Methadone (MTD) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	6	54	4	56	2	58
300ng/mL	Cutoff	60	36	24	34	26	36	24
375ng/mL	+25%	60	56	4	58	2	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Methadone (MTD) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
75ng/mL	-75%	60	0	60	0	60	0	60
150ng/mL	-50%	60	0	60	0	60	0	60
225ng/mL	-25%	60	2	58	4	56	4	56
300ng/mL	Cutoff	60	38	22	34	26	36	24
375ng/mL	+25%	60	58	2	54	6	56	4
450ng/mL	+50%	60	60	0	60	0	60	0
525ng/mL	+75%	60	60	0	60	0	60	0
600ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Oxycodone (OXY) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
25ng/mL	-75%	60	0	60	0	60	0	60
50ng/mL	-50%	60	0	60	0	60	0	60
75ng/mL	-25%	60	2	58	6	54	4	56
100ng/mL	Cutoff	60	34	26	36	24	34	26
125ng/mL	+25%	60	54	6	56	4	58	2
150ng/mL	+50%	60	60	0	60	0	60	0
175ng/mL	+75%	60	60	0	60	0	60	0
200ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Oxycodone (OXY) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
25ng/mL	-75%	60	0	60	0	60	0	60
50ng/mL	-50%	60	0	60	0	60	0	60
75ng/mL	-25%	60	6	54	4	56	8	52
100ng/mL	Cutoff	60	36	24	38	22	34	26
125ng/mL	+25%	60	56	4	56	4	58	2
150ng/mL	+50%	60	60	0	60	0	60	0
175ng/mL	+75%	60	60	0	60	0	60	0
200ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Oxycodone (OXY) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
25ng/mL	-75%	60	0	60	0	60	0	60
50ng/mL	-50%	60	0	60	0	60	0	60
75ng/mL	-25%	60	8	52	4	56	6	54
100ng/mL	Cutoff	60	38	22	36	24	34	26
125ng/mL	+25%	60	56	4	58	2	54	6
150ng/mL	+50%	60	60	0	60	0	60	0
175ng/mL	+75%	60	60	0	60	0	60	0
200ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Oxycodone (OXY) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
25ng/mL	-75%	60	0	60	0	60	0	60
50ng/mL	-50%	60	0	60	0	60	0	60
75ng/mL	-25%	60	6	54	8	52	4	56
100ng/mL	Cutoff	60	34	26	36	24	38	22
125ng/mL	+25%	60	54	6	58	2	56	4
150ng/mL	+50%	60	60	0	60	0	60	0
175ng/mL	+75%	60	60	0	60	0	60	0
200ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Phencyclidine (PCP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
6.3ng/mL	-75%	60	0	60	0	60	0	60
12.5ng/mL	-50%	60	0	60	0	60	0	60
18.8ng/mL	-25%	60	6	54	6	54	4	56
25ng/mL	Cutoff	60	38	22	36	24	38	22
31.3ng/mL	+25%	60	56	4	56	4	58	2
37.5ng/mL	+50%	60	60	0	60	0	60	0
43.8ng/mL	+75%	60	60	0	60	0	60	0
50ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Single-drug Phencyclidine (PCP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
6.3ng/mL	-75%	60	0	60	0	60	0	60
12.5ng/mL	-50%	60	0	60	0	60	0	60
18.8ng/mL	-25%	60	4	56	4	56	6	54
25ng/mL	Cutoff	60	36	24	38	22	34	26
31.3ng/mL	+25%	60	54	6	56	4	56	4
37.5ng/mL	+50%	60	60	0	60	0	60	0
43.8ng/mL	+75%	60	60	0	60	0	60	0
50ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Phencyclidine (PCP) test (Dipcard)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Dipcard Lot 1		Test Dipcard Lot 2		Test Dipcard Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
6.3ng/mL	-75%	60	0	60	0	60	0	60
12.5ng/mL	-50%	60	0	60	0	60	0	60
18.8ng/mL	-25%	60	2	58	4	56	6	54
25ng/mL	Cutoff	60	36	24	38	22	34	26
31.3ng/mL	+25%	60	58	2	56	4	54	6
37.5ng/mL	+50%	60	60	0	60	0	60	0
43.8ng/mL	+75%	60	60	0	60	0	60	0
50ng/mL	+100%	60	60	0	60	0	60	0

Precision data of Rapid Multi-drug Phencyclidine (PCP) test (CUP)

Approximate Concentration of sample	% of cutoff	Number of determinations	Test Cup Lot 1		Test Cup Lot 2		Test Cup Lot 3	
			Pos	Neg	Pos	Neg	Pos	Neg
0ng/mL	Negative	60	0	60	0	60	0	60
6.3ng/mL	-75%	60	0	60	0	60	0	60
12.5ng/mL	-50%	60	0	60	0	60	0	60
18.8ng/mL	-25%	60	4	56	4	56	6	54
25ng/mL	Cutoff	60	38	22	36	24	34	26
31.3ng/mL	+25%	60	56	4	54	6	52	8
37.5ng/mL	+50%	60	60	0	60	0	60	0
43.8ng/mL	+75%	60	60	0	60	0	60	0
50ng/mL	+100%	60	60	0	60	0	60	0

b. *Linearity/assay reportable range:*

Not Applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

External controls are not supplied with this device. The labeling provides information on where external controls can be obtained.

Stability:

Accelerated and real time studies have been conducted for The Rapid Single/Multi-drug Test Cup and the Rapid Single/Multi-drug Test Dipcard devices. Protocols and acceptance criteria were reviewed and found to be acceptable. The information supports the following expiration date for the unopened (shelf-life) stability: 24 months under 4 to 30° C for both the Test Cup and Dipcard formats.

d. *Detection limit:*

Not applicable. These are qualitative devices.

e. *Analytical specificity:*

I. Cross Reactivity

Cross reactivity with structurally similar compounds was tested for each device. Each compound was spiked into drug-free urine. If any positive result was observed, the compounds were further diluted with known drug-free urine. The lowest concentration that produced a positive result was identified as the cross-reactive concentration and the percent (%) cross-reactivity was determined. The study results for both formats (dipcard and cup) were the same and are reported below:

Cross reactivity test data for Rapid Single/Multi-drug test for Amphetamine (AMP)

Compound	Concentration (ng/mL)	% Cross-Reactivity
d-Amphetamine	1000	100%
l-Amphetamine	50000	2%
d,l-Amphetamine	2500	40%
3,4-methylenedioxyamphetamine (MDA)	2000	50%
The compounds (d-methamphetamine, l-methamphetamine, 3,4-methylenedioxymethamphetamine (MDMA), methylenedioxyethylamphetamine (MDEA) showed no cross-reactivity in the assay at concentration of 100µg/mL.		

Cross reactivity test data for Rapid Single/Multi-drug test for Cocaine (COC)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Benzoyllecgonine	300	100%
Cocaine	800	37.5%
Cocaethylene	12500	2.4%
Ecgonine HCl	35000	0.9%

Cross reactivity test data for Rapid Single/Multi-drug test for Metamphetamine (MET)

Compound	Concentration (ng/mL)	% Cross-Reactivity
d-methamphetamine	1000	100%
l-methamphetamine	8000	12.5%
p-hydroxymethamphetamine	30000	3.3%
3,4-methylenedioxyamphet (MDMA)	2000	50%
3,4-Methylenedioxyethylamphet (MDEA)	50000	2%

The compounds (d-amphetamine, l-amphetamine, 3,4-methylenedioxyamphetamine (MDA)) showed no cross-reactivity in the assay at concentration of 100µg/mL.

Cross reactivity test data for Rapid Single/Multi-drug test for Morphine (MOP)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Morphine	2000	100%
Codeine	2000	100%
Hydrocodone	15000	13.3%
Hydromorphone	10000	20%
6-Monoacetylmorphine (6-MAN)	5000	40%
Morphine 3-β-D-glucuronide	2000	100%
Oxycodone	>100000	2%
Hydromorphone	10000	20%

Cross reactivity test data for Rapid Single/Multi-drug test for Marijuana (THC)

Compound	Concentration (ng/mL)	% Cross-Reactivity
11-nor-Δ ⁹ -THC-9-COOH	50	100%
11-nor-Δ ⁸ -THC-9-COOH	50	100%
Δ ⁹ -THC	15000	0.3%
Δ ⁸ -THC	10000	0.5%

Cannabinol	20000	0.3%
The compound Cannabidiol showed now cross reactivity in the assay at a concentration of 100µg/mL.		

Cross reactivity test data for Rapid Single/Multi-drug test for Barbiturate (BAR)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Secobarbital	300	100%
Amobarbital	500	60%
Alphenol	150	200%
Aprobarbital	200	150%
Butobarbital	75	400%
Butalbital	1500	20%
Butethal	100	300%
Cyclopentobarbital	600	50%
Pentobarbital	700	42.9%
Phenobarbital	300	100%

Cross reactivity test data for Rapid Single/Multi-drug test for Benzodiazepines (BZO)

Compound	Concentration (ng/mL)	% Cross-Reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α-Hydroxyalprazolam	1100	27.3%
Bromazepam	1000	30%
Chlordiazepoxide	2000	15%
Clobazam	100	300%
Clonazepam	800	37.5%
Clorazepate	200	150%
Delorazepam	1600	18.8%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	1000	30%
Flunitrazepam	350	85.7%
Lorazepam	1200	25%
Midazolam	2500	12%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	120	250%
Triazolam	1000	30%

Cross reactivity test data for Rapid Single/Multi-drug test for Methylenedioxymetamphetamine (MDMA) test

Compound	Concentration (ng/mL)	% Cross-Reactivity
(±) 3,4-Methylenedioxymetamphetamine (MDMA)	500	100%
3,4-methylenedioxyamphetamine (MDA)	2200	22.7%
3,4-methylenedioxyethylamphetamine (MDEA)	240	208.3%
d-methamphetamine (MAMP)	100000	0.3%
The compounds d-amphetamine, l-amphetamine and l-methamphetamine showed no cross reactivity in the assay at a concentration of 100µg/mL.		

Cross reactivity test data for Rapid Single/Multi-drug test for Methadone (MTD) test

Compound	Concentration (ng/mL)	% Cross-Reactivity
Methadone	300	100%
(±)2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%

Cross reactivity test data for Rapid Single/Multi-drug test for Oxycodone (OXY) test

Compound	Concentration (ng/mL)	% Cross-Reactivity
Oxycodone	100	100%
Naloxone	50000	0.2%
Naltrexone	50000	0.2%
Morphine 3-β-D-glucuronide	50000	0.2%
Hydrocodone	3000	3.3%
Hydromorphone	75000	0.1%
Oxymorphone	1000	10%

Cross reactivity test data for Rapid Single/Multi-drug test for Phencyclidine (PCP) test

Compound	Concentration (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	0.2%

II. Exogenous Interference:

Interference from structurally similar and dissimilar compounds was evaluated by spiking them at a concentration of 100 µg/mL into urine containing drug concentrations at ±50% of the cutoff. The concentrations of the target drugs were confirmed with GC/MS. Each sample was tested in 3 replicates using each device format (dipcard and cup). The compounds listed in this table were found not to interfere with test results at a test concentration of 100 µg/mL.

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

Dextromethorphan	Nadolol	Tolbutamide
Diclofenac	Nalidixic acid	Trifluoperazine
Diflunisal	Naproxen	Tryptamine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nicotine	Verapamil
Ephedrine	Nifedipine	Zomepirac

III. Effect of urinary pH: The pH of an aliquot of negative a urine pool adjusted to a pH range of 3 to 9 in 1 pH unit increments was spiked with $\pm 50\%$ cutoffs and each device format (dipcard and cup) was evaluated. All concentrations were confirmed by GC/MS. No interference was observed from pH for the target drugs.

IV. Effect of urinary specific gravity: Each device format (dipcard and cup) was evaluated for interference from specific gravity. Drug free urine was adjusted to $\pm 50\%$ cutoffs and concentrations confirmed by GC/MS. The specific gravity studies were conducted on specific gravity ranges from 1.002 to 1.040 and no interference was observed from specific gravity for the target drugs.

f. Assay cut-off:

The test cut-off was evaluated in the precision studies. See precision studies above in section 1.M.1.a.

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor conducted method comparison studies using unaltered clinical specimens compared to GC/MS. Each sample was divided into 2 sets, one for cup format testing and one for dipcard format testing. All aliquots were blindly labeled by a nonparticipant and samples were randomized prior to testing. The study was conducted by 4 nurses at two POC sites. The single and multi-drug dipcard tests were tested at one site and the single and multi-drug cup tests were tested at the second site. Different nurses evaluated each test. For each drug analyte, a total of 80 specimens were tested for each of the single drug and multi-drug dipcard and the single drug and multi-drug cup tests. Results were the same for single and multi-drug test cups and also the same for single and multi-drug test dipcards. The results are presented below:

Rapid Single/Multi drug Test Cup		GC/MS					Total
		Negative (drug free)	Negative (< -50% cut off)	Near cutoff negative (-50% cutoff to cutoff)	Near cutoff positive (cutoff to +50% cutoff)	Positive (> +50% cutoff)	
AMP	+	0	0	0	6	34	80
	-	33	2	5	0	0	
COC	+	0	0	0	6	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80
	-	30	3	6	0	0	
MOP	+	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	

Rapid Single/Multi drug Test Dipcard		GC/MS					Total
		Negative (drug free)	Negative (< -50% cut off)	Near cutoff negative (-50% cutoff to cutoff)	Near cutoff positive (cutoff to +50% cutoff)	Positive (> +50% cutoff)	
AMP	+	0	0	0	6	34	80
	-	33	2	5	0	0	
COC	+	0	0	0	6	35	80
	-	33	1	6	0	0	
MET	+	0	0	1	5	35	80

	-	30	3	6	0	0	
MOP	+	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

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

b. Matrix comparison:

No applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable.

b. *Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

Home Use Consumer Study:

Groups of three hundred and sixty (360) lay users were used to test both the single drug and multi-drug test devices. Different groups tested the Dipcard format and Cup 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 user study 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. Each lay user was provided the package insert in English to perform the test, 1 blind labeled sample and a device. Results of the study are presented below:

Home Use Consumer studies data of Rapid Single-drug Test (AMP)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
500	-50%	60	0	60	100	0	60	100
750	-25%	60	8	52	87	7	53	88
1250	+25%	60	51	9	85	50	10	83
1500	+50%	60	60	0	100	60	0	100
2000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (AMP)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
500	-50%	60	0	60	100	0	60	100
750	-25%	60	6	54	90	9	51	85
1250	+25%	60	53	7	88	54	6	90
1500	+50%	60	60	0	100	60	0	100
2000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (COC)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	5	55	92	6	54	90
375	+25%	60	54	6	90	56	4	93
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (COC)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	4	56	93	6	54	90
375	+25%	60	53	7	88	56	4	93
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (MET)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
500	-50%	60	0	60	100	0	60	100
750	-25%	60	6	54	90	4	56	93
1250	+25%	60	53	7	88	55	5	92
1500	+50%	60	60	0	100	60	0	100
2000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (MET)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
500	-50%	60	0	60	100	0	60	100
750	-25%	60	5	55	92	4	56	93
1250	+25%	60	54	6	90	58	2	97
1500	+50%	60	60	0	100	60	0	100
2000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (MOP2000)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
1000	-50%	60	0	60	100	0	60	100

1500	-25%	60	9	51	85	8	52	87
2500	+25%	60	56	4	93	58	2	97
3000	+50%	60	60	0	100	60	0	100
4000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (MOP2000)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
1000	-50%	60	0	60	100	0	60	100
1500	-25%	60	7	53	88	6	54	90
2500	+25%	60	57	3	95	55	5	92
3000	+50%	60	60	0	100	60	0	100
4000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (THC)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
25	-50%	60	0	60	100	0	60	100
37.5	-25%	60	7	53	88	6	54	90
62.5	+25%	60	50	10	83	52	8	87
75	+50%	60	60	0	100	60	0	100
100	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (THC)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
25	-50%	60	0	60	100	0	60	100
37.5	-25%	60	8	52	87	4	56	93
62.5	+25%	60	53	7	88	54	6	90
75	+50%	60	60	0	100	60	0	100
100	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (BAR)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	5	55	92	6	54	90
375	+25%	60	54	6	90	56	4	93
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (BAR)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	4	56	93	5	55	92
375	+25%	60	57	3	95	54	6	90
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (BZO)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	7	53	88	8	52	87
375	+25%	60	56	4	93	55	5	92
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (BZO)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	6	54	90	5	55	92
375	+25%	60	54	6	90	56	4	93
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (MDMA)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
250	-50%	60	0	60	100	0	60	100
375	-25%	60	6	54	90	5	55	92
625	+25%	60	53	7	88	56	4	93
750	+50%	60	60	0	100	60	0	100
1000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (MDMA)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
250	-50%	60	0	60	100	0	60	100

375	-25%	60	4	56	93	6	54	90
625	+25%	60	55	5	92	54	6	90
750	+50%	60	60	0	100	60	0	100
1000	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (MTD)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	4	56	93	6	54	90
375	+25%	60	54	6	90	57	3	95
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (MTD)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
150	-50%	60	0	60	100	0	60	100
225	-25%	60	3	57	95	5	55	92
375	+25%	60	56	4	93	54	6	90
450	+50%	60	60	0	100	60	0	100
600	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (OXY)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
50	-50%	60	0	60	100	0	60	100
75	-25%	60	4	56	93	5	55	92
125	+25%	60	57	3	95	56	4	93
150	+50%	60	60	0	100	60	0	100
200	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (OXY)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
50	-50%	60	0	60	100	0	60	100
75	-25%	60	6	54	90	4	56	93
125	+25%	60	55	5	92	56	4	93
150	+50%	60	60	0	100	60	0	100
200	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Single-drug Test (PCP)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
12.5	-50%	60	0	60	100	0	60	100
18.8	-25%	60	3	57	95	4	56	93
31.3	+25%	60	54	6	90	56	4	93
37.5	+50%	60	60	0	100	60	0	100
50	+100%	60	60	0	100	60	0	100

Home Use Consumer studies data of Rapid Multi-drug Test (PCP)

Conc (ng/mL)	% of cutoff	N	Dipcard		Agreement (%)	Cup		Agreement (%)
			Positive	Negative		Positive	Negative	
0	Neg	60	0	60	100	0	60	100
12.5	-50%	60	0	60	100	0	60	100
18.8	-25%	60	6	54	90	5	55	92
31.3	+25%	60	57	3	95	54	6	90
37.5	+50%	60	60	0	100	60	0	100
50	+100%	60	60	0	100	60	0	100

After testing, the participants were asked to fill out a questionnaire in English. The results showed that 100% of respondents stated the tests were easy to use and the instructions were clear. A SMOG readability assessment was performed on the Instructions Insert and resulted in a reading level of 6.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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