

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

A. 510(k) Number:

k131110

B. Purpose for Submission:

New devices

C. Measurand:

Amphetamine, Methamphetamine, Cocaine, Cannabinoid, Morphine

D. Type of Test:

Qualitative lateral flow chromatographic competitive binding immunoassay

E. Applicant:

Co-Innovation Biotech Co., Ltd.

F. Proprietary and Established Names:

One-Step Single/Multi-drug Test Cup

One-Step Single/Multi-drug Test Dipcard

G. Regulatory Information:

1. Regulation section:

Regulation	Name	Classification	Product Code	Panel
21 § 862.3100	Amphetamine test system	II	DKZ	Toxicology (91)
21 § 862.3610	Methamphetamine test system	II	DJC	Toxicology (91)
21 § 862.3640	Morphine test system	II	DKN	Toxicology (91)
21 § 862.3870	Cannabinoid test system	II	LDJ	Toxicology (91)
21 § 862.3250	Cocaine and cocaine metabolite test system	II	DIO	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

One Step Single/Multi-drug Test Cup and One Step 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 or above the following cut-off concentrations:

Test	Calibrator	Cut-off level
Marijuana (THC)	Delta-9-THC-COOH	50 ng/mL
Cocaine (COC)	Benzoylcegonine	300 ng/mL
Amphetamine (AMP)	D-Amphetamine	1000 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1000 ng/mL
Morphine 2000 (MOP)	Morphine	2000 ng/mL

The tests contain two formats: 1) Test Cup, 2) Test Dipcard. The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for in vitro diagnostics use. They are intended for prescription use.

These tests provide only a preliminary analytical test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the One Step Multi-drug Test Cup Insert or One Step Single/Multi-drug Test Dipcard Insert, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. 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):

These assays are intended for prescription use only.

4. Special instrument requirements:

Not applicable; these are visually read, single use devices.

I. Device Description:

The One Step Single/Multi-drug devices have 2 formats—a dipcard and a test cup.

The formats can accommodate a single drug test or a combination of the five drugs of abuse in k131110. The One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive binding, lateral flow immunochromatographic assays for the qualitative detection of Amphetamine, Cocaines, Marijuana, Methamphetamine, Morphine and their metabolites at specific cutoffs (see Indications for Use). The devices are individually packaged in pouches which are opened as needed by the user.

J. Substantial Equivalence Information:

1. Predicate device name(s):

UCP Home™ Drug Screening Test Cards

UCP Home™ Drug Screening Test Cup

2. Predicate K number(s):

k091588

3. Comparison with predicate:

Similarities		
Item	Device (k131110)	Predicate (k091588)
Indication for use	Qualitative detection of drugs-of-abuse in urine	Same
Specimen	Urine	Same
Cutoff	Cocaine: 300 ng/mL Methamphetamine: 1000 ng/mL Amphetamine: 1000 ng/mL Marijuana: 50 ng/mL	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
Configuration	Dipcard and Cup	Same

Differences		
Item	Device	Predicate
Intended Users	Prescription Use	Over the Counter

Differences		
Item	Device	Predicate
		(OTC) Use and Prescription Use
Storage	4 - 30 °C	2 - 30 °C
Morphine cutoff	2000 ng/mL	300 ng/mL

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

None listed.

L. Test Principle:

The One Step Single/Multi-drug Test Cup and One Step Single/Multi-drug Test Dipcard are competitive immunoassays that are used to screen for the presence of Amphetamine, Cocaine, Methamphetamine, Morphine and Marijuana in urine using monoclonal antibodies. It is a chromatographic absorbent device in which Amphetamine, Cocaine, Methamphetamine, Morphine and/or Marijuana competitively combine to a limited number of antibody-dye conjugate binding sites.

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action. The urine mixes with the antibody-dye conjugate, and flows across the pre-coated membrane, in which Amphetamine, Cocaine, Methamphetamine, Morphine and/or Marijuana antigen is coated respectively. When the drug levels are at or above the cutoffs, the drugs in the sample bind to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Regions (T) of the device. This prevents the development of a distinct colored band in the test region (T), indicating a positive result for each drug.

When the drug levels are zero or below the cutoffs, antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored band in the test region (T) which indicates a negative result. To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were performed at 3 hospitals, by two individuals per site. Samples were analyzed in 3 runs per day over 10 non-consecutive days using 3 lots each of Dipcard and Test Cup (N=60 per lot). Drug free urine samples were spiked for each assay at $\pm 75\%$ cutoff, $\pm 50\%$ cutoff, $\pm 25\%$

cutoff ,cutoff and high positive. All urine concentrations were confirmed by GC/MS. A negative sample was also included in each precision study. Results are summarized below for each lot and device.

Single test Dipcard:

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP (cutoff 1000 ng/mL)	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	50/10	52/8	48/12
	1000	60	26/34	28/32	28/32
	1250	60	12/48	6/54	10/50
	1500	60	4/56	4/56	6/54
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
COC (cutoff 300 ng/mL)	0	60	60/0	60/0	60/0
	75	60	60/0	60/0	60/0
	150	60	60/0	60/0	60/0
	225	60	56/4	58/2	54/6
	300	60	24/36	22/38	24/36
	375	60	6/54	4/56	8/52
	450	60	0/60	2/58	2/58
	525	60	0/60	0/60	0/60
	600	60	0/60	0/60	0/60
THC (cutoff 50 ng/mL)	0	60	60/0	60/0	60/0
	12.5	60	60/0	60/0	60/0
	25.0	60	60/0	60/0	60/0
	37.5	60	56/4	52/8	58/2
	50.0	60	24/36	22/38	26/34
	62.5	60	12/48	6/54	10/50
	75.0	60	2/58	0/60	2/58
	87.5	60	0/60	0/60	0/60
	100.0	60	0/60	0/60	0/60
MET (cutoff 1000 ng/mL)	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	58/2	54/6	58/2
	1000	60	28/32	26/34	24/36
	1250	60	6/54	8/52	6/54

	1500	60	0/60	4/56	2/58
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
MOP (cutoff 2000 ng/mL)	0	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	1000	60	60/0	56/4	60/0
	1500	60	52/8	50/10	56/4
	2000	60	20/40	16/44	16/44
	2500	60	4/56	2/58	8/52
	3000	60	0/60	0/60	0/60
	3500	60	0/60	0/60	0/60
	4000	60	0/60	0/60	0/60

Multi-drug Test Dipcard:

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	54/6	50/10	52/8
	1000	60	26/34	28/32	26/34
	1250	60	4/56	8/52	6/54
	1500	60	2/58	4/56	4/56
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
COC	0	60	60/0	60/0	60/0
	75	60	60/0	60/0	60/0
	150	60	60/0	60/0	60/0
	225	60	58/2	56/4	56/4
	300	60	22/38	24/36	24/36
	375	60	4/56	2/58	6/54
	450	60	0/60	2/58	2/58
	525	60	0/60	0/60	0/60
	600	60	0/60	0/60	0/60
THC	0	60	60/0	60/0	60/0
	12.5	60	60/0	60/0	60/0
	25.0	60	60/0	60/0	60/0
	37.5	60	52/8	54/6	54/6

	50.0	60	24/36	24/36	26/34
	62.5	60	10/50	6/54	8/52
	75.0	60	2/58	0/60	0/60
	87.5	60	0/60	0/60	0/60
	100.0	60	0/60	0/60	0/60
MET	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	56/4	58/2	56/4
	1000	60	24/36	22/38	26/34
	1250	60	4/56	2/58	4/56
	1500	60	2/58	0/60	2/58
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
MOP	0	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	1000	60	60/0	60/0	58/2
	1500	60	54/6	56/4	52/8
	2000	60	18/42	14/46	16/44
	2500	60	2/58	2/58	4/56
	3000	60	0/60	0/60	0/60
	3500	60	0/60	0/60	0/60
	4000	60	0/60	0/60	0/60

Single Test Cup

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	50/10	54/6	52/8
	1000	60	28/32	24/36	26/34
	1250	60	8/52	6/54	8/52
	1500	60	4/56	2/58	6/54
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
COC	0	60	60/0	60/0	60/0

	75	60	60/0	60/0	60/0
	150	60	60/0	60/0	60/0
	225	60	56/4	56/4	58/2
	300	60	22/38	24/36	24/36
	375	60	4/56	4/56	6/54
	450	60	0/60	0/60	2/58
	525	60	0/60	0/60	0/60
	600	60	0/60	0/60	0/60
THC	0	60	60/0	60/0	60/0
	12.5	60	60/0	60/0	60/0
	25.0	60	60/0	60/0	60/0
	37.5	60	54/6	58/2	56/4
	50.0	60	28/32	22/38	24/36
	62.5	60	10/50	6/54	10/50
	75.0	60	0/60	4/56	4/56
	87.5	60	0/60	0/60	0/60
	100.0	60	0/60	0/60	0/60
MET	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	56/4	56/4	58/2
	1000	60	24/36	26/34	22/38
	1250	60	6/54	10/50	8/52
	1500	60	0/60	2/58	0/60
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
MOP	0	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	1000	60	60/0	60/0	58/2
	1500	60	54/6	52/8	50/10
	2000	60	18/42	20/40	16/44
	2500	60	2/58	4/56	6/54
	3000	60	0/60	0/60	0/60
	3500	60	0/60	0/60	0/60
4000	60	0/60	0/60	0/60	

Multi-test Cup

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Result (Negative/Positive)		
			Lot 1	Lot 2	Lot 3
AMP	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	52/8	54/6	54/6
	1000	60	26/34	24/36	28/32
	1250	60	6/54	8/52	6/54
	1500	60	4/56	2/58	2/58
	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
COC	0	60	60/0	60/0	60/0
	75	60	60/0	60/0	60/0
	150	60	60/0	60/0	60/0
	225	60	56/4	54/6	58/2
	300	60	22/38	24/36	22/38
	375	60	6/54	8/52	4/56
	450	60	0/60	2/58	0/60
	525	60	0/60	0/60	0/60
	600	60	0/60	0/60	0/60
THC	0	60	60/0	60/0	60/0
	12.5	60	60/0	60/0	60/0
	25.0	60	60/0	60/0	60/0
	37.5	60	58/2	54/6	56/4
	50.0	60	22/38	28/32	26/34
	62.5	60	6/54	10/50	6/54
	75.0	60	0/60	4/56	2/58
	87.5	60	0/60	0/60	0/60
	100.0	60	0/60	0/60	0/60
MET	0	60	60/0	60/0	60/0
	250	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	750	60	54/6	56/4	54/6
	1000	60	26/34	24/36	24/36
	1250	60	8/52	6/54	6/54
	1500	60	2/58	0/60	0/60

	1750	60	0/60	0/60	0/60
	2000	60	0/60	0/60	0/60
MOP	0	60	60/0	60/0	60/0
	500	60	60/0	60/0	60/0
	1000	60	58/2	60/0	60/0
	1500	60	50/10	54/6	52/8
	2000	60	16/44	14/46	14/46
	2500	60	6/54	2/58	4/56
	3000	60	0/60	0/60	0/60
	3500	60	0/60	0/60	0/60
	4000	60	0/60	0/60	0/60

b. Linearity/assay reportable range:

Not applicable. The tests are for qualitative use.

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

Control Materials

External control materials are not supplied with this device; however, this device has internal process controls. A colored line appearing in the control region reflects that sufficient sample volume was applied and that adequate membrane wicking occurred. Users are informed that the test is invalid if a line fails to appear in the control region. The sponsor states in the labeling when external QC materials should be tested.

Accelerated and real time studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable for both devices. The manufacturer claims the following expiration date: closed pouch stability is for 2 years after manufacturing when stored at 4 -30° °C. Open pouch stability is 1.5 hours.

d. Detection limit:

Not applicable. The device is intended for qualitative use.

e. Analytical specificity:

Cross reactivity with structurally similar compounds was tested for each device. Each compound was spiked into drug-free urine to 100 mcg/mL. Each sample was tested in 5 replicates. If any positive result was observed, the compounds were further sequentially diluted to different concentrations and tested in quintuplicate to determine the lowest interference concentration that produces a positive result. 2 lots of dipcard and one lot of test cups were used for the study.

Results were:

Amphetamine

Compound	Quantity equivalent to cutoff (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 a concentration of 100mcg/mL.

Cocaine

Compound	Quantity equivalent to cutoff(ng/mL)	% Cross-Reactivity
Benzoylcegonine	300	100%
Cocaine	800	37.5%
Cocaethylene	12500	2.4%
Ecgonine HCl	35000	0.9%

Methamphetamine

Compound	Quantity equivalent to cutoff(ng/mL)	% Cross-Reactivity
d-Methamphetamine	1000	100%
l-Methamphetamine	8000	12.5%
p-hydroxymethamphetamine	30000	3.3%
3,4-methylenedioxy methamphetamine (MDMA)	2000	50%
3,4-Methylenedioxy ethylamphetamine (MDEA)	50000	2%

Morphine

Compound	Quantity equivalent to cutoff(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-b-D-glucuronide	2000	100%

The compounds oxycodone and oxymorphone showed no cross-reactivity in the assay at a concentration of 100 mcg/mL.

THC

Compound	Quantity equivalent to cutoff(ng/mL)	% Cross-Reactivity
11-nor- Δ 9-THC-9-COOH	10.5	100%
11-nor- Δ 8-THC-9-COOH	50	100%
Δ 9-THC	15000	0.3%
Δ 8-THC	10000	0.5%
Cannabidiol	20000	0.3%
Cannabinol	>100000	Not detected

Each device was evaluated for interference from pH. Drug-free urine was adjusted to \pm 50% cutoffs which were confirmed by GCMS or LCMS. 2 lots of dipcard, one lot of test cup tested were used for the study. pH was tested at 3, 4, 5, 6, 7, 8, 9. No interference was observed from pH for Amphetamine, Morphine, Methamphetamine, Cocaine or THC.

Each device was evaluated for interference from specific gravity. Drug-free urine was adjusted to \pm 50% cutoffs which were confirmed by GCMS or LCMS. 2 lots of dipcards, one lot of test cup tested were used for the study. SG was tested at 1.003, 1.010, 1.020, 1.030, 1.040 No interference was observed from specific gravity for Amphetamine, Morphine, Methamphetamine, Cocaine or THC.

Interference from structurally unrelated, or endogenous compounds was evaluated by spiking 100 mcg/mL into urine containing amphetamine, cocaine, methamphetamine, morphine, or THC at \pm 50% of cutoff, confirmed by GCMS or LCMS. Two lots of dipcards and one lot of test cups were used in the studies. The following compounds showed no interference in the presence of Amphetamine, Morphine, Methamphetamine, Cocaine or THC.

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	Hyrocortisone	Prednosolone
Caffeine	o-Hydroxyhippuric acid	Prednisone
Carbamazepine	p-Hydroxytyramine	d, l-Propranolol
Cephalexin	Ibuprofen	d, l-Pseudoephedrine
Chloralhydrate	Indomehtacin	Quinacrine
Chloramphenicol	Iproniazid	Quinine
Chlorthiazide	d, l-Isoproterenol	Quinidine
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	Thiamine
Deoxycorticosterone	Methoxyphenamine	Thioridazine
Dexamethasone	Methylphenidate	d, l-Thyroxine
Dextromethorphan	Nadolol	Tolbutamine
Diclofenac	Nalidixic acid	Tolbutamide
Diflunisal	Naproxin	Trifluoperaxine
Digoxin	Nicinamide	Tryptamine
Diphenhydramine	Nicotine	Uric acid
Ephedrine	Nifedipine	Verapamil
		Zomepirac

f. Assay cut-off:

The cut-off characterization study results can be found in the precision section of this summary.

2. Comparison studies:

a. Method comparison with predicate device:

For all tests formats the sponsor conducted studies on one lot of dipcards and test cups each of 2 hospital labs. One hospital used 1 lot of dipcards, the other lab used 1 lot of test cups. Testing was performed on both devices using

between 165-186 unaltered clinical samples. All samples were compared to GCMS. Sample identification was masked to the users.

Single Test Dipcards:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (greater than 50% above the cutoff)	Total
AMP	+	0	0	1	10	29	176
	-	117	7	11	1	0	
COC	+	0	0	1	9	31	186
	-	133	0	12	0	0	
THC	+	0	0	1	12	31	165
	-	107	4	9	1	0	
MET	+	0	0	1	17	44	165
	-	85	4	13	1	0	
MOP	+	0	0	2	19	57	165
	-	67	5	15	0	0	

Analysis of Discordant Results:

One Step Single drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff (ng/mL)	Test Result	Drug Concentration (ng/mL)	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylcegonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor- Δ^9 --THC-9-COOH
THC	50	Negative	59	11-nor- Δ^9 --THC-9-COOH

Single Test Cup:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff concentration	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (greater than 50% above the cutoff)	Total
AMP	+	0	0	1	10	29	176
	-	117	7	11	1	0	
COC	+	0	0	1	9	31	186
	-	133	0	12	0	0	
THC	+	0	0	1	12	31	165
	-	107	4	9	1	0	
MET	+	0	0	1	17	44	165
	-	85	4	13	1	0	
MOP	+	0	0	2	19	57	165
	-	67	5	15	0	0	

Analysis of Discordant Results:

One Step Single drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylcegonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor- Δ^9 --THC-9-COOH
THC	50	Negative	59	11-nor- Δ^9 --THC-9-COOH

80 clinical urine specimens for each drug were analyzed by GC/MS and by one lot of the corresponding One Step Multi-drug Test Dipcard and one lot of the One Step Multi-drug Test Cups.

Multi-test Dipcards:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	Total
AMP	+	0	0	1	10	29	80
	-	25	3	11	1	0	
COC	+	0	0	1	9	31	80
	-	27	0	12	0	0	
THC	+	0	0	1	12	27	80
	-	26	4	9	1	0	
MET	+	0	0	1	12	27	80
	-	24	2	13	1	0	
MOP	+	0	0	2	11	29	80
	-	21	2	15	0	0	

Analysis of Discordant Results:

One Step Multi-drug Test Dipcard			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentratio	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoylcegonine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor- Δ^9 --THC-9-
THC	50	Negative	59	11-nor- Δ^9 --THC-9-

Multi-drug Test Cups:

Drug Test	Co-Innovation Result	Drug free by GC/MS analysis	Less than half the cutoff	Near Cutoff Negative (Between 50% below the cutoff and the cutoff)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff)	High Positive (greater than 50% above the cutoff)	Total
AMP	+	0	0	1	10	29	80
	-	2	3	11	1	0	
COC	+	0	0	1	9	31	80
	-	2	0	12	0	0	
THC	+	0	0	1	12	27	80
	-	2	4	9	1	0	
MET	+	0	0	1	12	27	80
	-	2	2	13	1	0	
MOP	+	0	0	2	11	29	80
	-	2	2	15	0	0	

Analysis of Discordant Results:

One Step Multi-drug Test Cup			GC/MS Analysis	
Drug Test	Cutoff(ng/mL)	Test Result	Drug Concentration	Drug in Urine
AMP	1000	Positive	867	Amphetamine
AMP	1000	Negative	1175	Amphetamine
COC	300	Positive	172	Benzoyllecgonine
MET	1000	Positive	904	Methamphetamine
MET	1000	Negative	1248	Methamphetamine
MOP	2000	Positive	1608	Morphine
MOP	2000	Positive	1875	Morphine
THC	50	Positive	40	11-nor- Δ^9 --THC-9-COOH
THC	50	Negative	59	11-nor- Δ^9 --THC-9-COOH

b. Matrix comparison:

Not applicable. This test is for urine only.

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):

Not applicable.

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.