

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

A. 510(k) Number:

K153646

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine (AMP)

Cocaine (COC)

Marijuana (THC)

D. Type of Test:

Qualitative Assay

E. Applicant:

Safecare BioTech Co., Ltd.

F. Proprietary and Established Names:

SAFECARE Urine Test Amphetamine (Cassette, Cup, DipCard)

SAFECARE Urine Test Cocaine (Cassette, Cup, DipCard)

SAFECARE Urine Test Marijuana (Cassette, Cup, DipCard)

G. Regulatory Information:

Item	Product Code	Classification	Regulation Section	Panel
SAFECARE Urine Test Amphetamine Cassette	LAF – Amphetamine	Class II	862.3610	91-Toxicology
SAFECARE Urine Test Amphetamine Cup	LAF – Amphetamine	Class II	862.3610	91-Toxicology

Item	Product Code	Classification	Regulation Section	Panel
SAFECARE Urine Test Amphetamine Dip Card	LAF – Amphetamine	Class II	862.3610	91-Toxicology
SAFECARE Urine Test Cocaine Cassette	DIO – Cocaine	Class II	862.3250	91-Toxicology
SAFECARE Urine Test Cocaine Cup	DIO – Cocaine	Class II	862.3250	91-Toxicology
SAFECARE Urine Test Cocaine Dip Card	DIO – Cocaine	Class II	862.3250	91-Toxicology
SAFECARE Urine Test Marijuana Cassette	LDJ – Marijuana	Class II	862.3870	91-Toxicology
SAFECARE Urine Test Marijuana Cup	LDJ – Marijuana	Class II	862.3870	91-Toxicology
SAFECARE Urine Test Marijuana Dip Card	LDJ – Marijuana	Class II	862.3870	91-Toxicology

H. Intended Use:

1. Intended use(s):

See indications for Use below.

2. Indication(s) for use:

SAFECARE Urine Test Amphetamine Cassette is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is

positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine Cup is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Amphetamine DipCard is a rapid test for the qualitative detection of Amphetamine in human urine at a cutoff concentration of 1000 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cassette is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine Cup is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Cocaine DipCard is a rapid test for the qualitative detection of Benzoyllecgonine in human urine at a cutoff concentration of 300 ng/ml.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cassette is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana Cup is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

SAFECARE Urine Test Marijuana DipCard is a rapid test for the qualitative detection of Cannabinoids in human urine at a cutoff concentration of 50 ng/mL.

The tests provide only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter and for prescription use.

3. Special conditions for use statement(s):

For over-the-counter and prescription use

4. Special instrument requirements:

Not applicable. The devices are visually read and single-use.

I. Device Description:

These devices are immunochromatographic assays for Amphetamine, Cocaine and Marijuana Urine Tests use a lateral flow, one step system for the qualitative detection of d-Amphetamine, Benzoyllecgonine and 11-nor- Δ^9 -THC-9-COOH in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs, with gold chloride and fixed drug-protein conjugates, and anti-mouse IgG polyclonal antibody in membranes.

The assays in this submission include a cassette, dip card, and cup formats. Each assay and format is available separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):
First Check Multi Drug Cup 12
2. Predicate 510(k) number(s):
K052115
3. Comparison with predicate:

Similarities		
Item	Device	Predicate (K052115)
Intended Use	For the qualitative determination of AMP, COC, and THC in urine	The First Check® Multi Drug Cup 12 for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (MET), Ecstasy (MDMA), Opiates (OPI), Phencyclidine (PCP), Benzodiazepine (BZO), Barbiturates (BAR), Methadone (MTD), Tri-cyclic Antidepressants (TCA) and Oxycodone (OXY) is a screening test for the rapid detection of the twelve drugs listed above in human urine.
Calibrator Drug	D-amphetamine 11-nor- Δ^9 -THC-9 COOH Benzoyllecgonine	D-amphetamine D-Methamphetamine Morphine Phencyclidine Oxazepam Secobarbital

Similarities		
Item	Device	Predicate (K052115)
		(+/-) Methadone Nortriptyline Oxycodone (+/-)3,4-MDMA 11-nor- Δ^9 -THC-9 COOH Benzoylcegonine
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Specimen Type	Human Urine	Same
Cut-Off Values	300 ng/mL (COC) 1000 ng/mL (AMP) 50 ng/mL (THC)	Same
Intended Populations	For over-the-counter use	Same

Differences		
Item	Device	Predicate
Configurations	Cup, Dip Card, Cassette	Cup

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

None were referenced

L. Test Principle:

SAFECARE Urine Tests are tests for the qualitative detection of Benzoylcegonine, or D-amphetamine, or 11-nor- Δ^9 -THC-9 COOH in urine samples. Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine specimen below its cut-off concentration, it will not saturate the binding sites of its specific antibody (monoclonal mouse antibody) coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample if sufficient volume of sample was applied.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were carried out for samples with concentrations of -100% cut-off, -75% cut-off, -50% cut-off, -25% cut-off, at the cut-off, +25% cut-off, +50% cut-off, +75% cut-off and +100% cut-off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blinded labeled and randomized. For each concentration, tests were performed two runs per day for 25 days.

AMP Cassette

AMP	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48/2+	25-/25+	47+/3-	50+/0-	50+/0-	50+/0-

AMP Dip Card

AMP	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

AMP Cup

AMP	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-

COC Cassette

COC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	47-/3+	31-/29+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	28-/22+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	28-/22+	49+/1-	50+/0-	50+/0-	50+/0-

COC Dip Card

COC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

COC Cup

COC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	47+/3-	50+/0-	50+/0-	50+/0-

THC Cassette

THC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	47-/3+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	47+/3-	50+/0-	50+/0-	50+/0-

THC Dip Card

THC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	47+/3-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-

THC Cup

THC	-100% cut off	-75% cut off	-50% cut off	-25% Cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	47+/3-	50+/0-	50+/0-	50+/0-

b. Linearity/assay reportable range:

Not applicable, these devices are intended for qualitative use only.

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

Stability

Real-time and accelerated stability studies were conducted on three lots of each device. The protocols for the stability studies were reviewed and found to be acceptable. The results of these studies indicated that all devices were found to be stable at 4-30°C (39-86°F) for 24 months based on the accelerated stability study at 50°C and a shelf life study at 30°C. Control materials are not provided with the device. The labeling provides information on how to obtain control materials.

Transportation Study

A Transportation stability study was conducted on three lots of each device. The protocols for the transportation stability study were reviewed and found to be

acceptable. The results of these studies indicated that all devices were found to be stable during transport of the device in temperatures between -20 and 50°C.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Compounds sharing structural or conformational similarity with the analytes were tested for cross-reactivity with the candidate device. The structurally related compounds that exhibited cross-reactivity with the candidate device were titrated to determine the percent cross-reactivity. The concentration (ng/mL) of cross-reactant that gives a response equivalent to the cutoff, and the percent cross-reactivity are presented in the table below.

Amphetamine Cross Reactivity

Drugs	Concentration (ng/ml)	Reactivity
D - Amphetamine	1000	100%
L - Amphetamine	20000	5%
D,L - Amphetamine	3000	33%
Phentermine	30000	3%
Hydroxyamphetamine	8000	12.5%
Methylenedioxyamphetamine (MDA)	20000	5%
d-Methamphetamine	Negative at 100000	<1%
l-Methamphetamine	Negative at 100000	<1%
ephedrine	Negative at 100000	<1%
Methylenedioxyethylamphetamine (MDE)	Negative at 100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	<1%

Cocaine Cross Reactivity

Drugs	Concentration (ng/ml)	Reactivity
Benzoylcegonine	300	100%
Cocaine HCl	750	40%
Cocaethylene	12500	2.4%
Ecgonine	32000	0.9%

THC Cross Reactivity

Drugs	Concentration (ng/ml)	Reactivity
11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5000	1%
11-Nor- Δ^8 -Tetrahydrocannabinol-9-COOH	50	100%
Cannabinol	20000	0.3%
Δ^8 -Tetrahydrocannabinol	10000	0.5%
Δ^9 -Tetrahydrocannabinol	10000	0.5%
Cannabidiol	20000	0.3%
11-Nor- Δ^9 -THC-carboxy glucuronide	2500	2%
(-)-11-nor-9-carboxy- Δ^9 -THC	2500	2%

Interference Study

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs. These urine samples were tested using three batches of each device for all formats.

Compounds that showed no interference at a concentration of 100 μ g/mL for different formats (cassette, cup, dipcard) are listed below:

4-Acetamidophenol	Chloralhydrate	Hydralazine	Papaverine
Acetophenetidin	Chloramphenicol	Hydrochlorothiazide	Penicillin-G
N-Acetylprocainamide	Chlordiazepoxide	Hydrocodone	Pentazocaine
Acetylsalicylic acid	Chlorothiazide	Hydrocortisone	Pentobarbital
Aminopyrine	(\pm) Chlorpheniramine	O-Hydroxyhippuric acid	Perphenazine
Amitriptyline	Chlorpromazine	3-Hydroxytyramine	Phencyclidine
Amobarbital	Chlorquine	Ibuprofen	Phenelzine
Amoxicillin	Cholesterol	Imipramine	Phenobarbital
Ampicillin	Clomipramine	(-) Isoproterenol	Phetoin
Ascorbic acid	Clonidine	Isoxsuprine	L-Phenylephrine
Aspartame	Cocaine hydrochloride	Ketamine	Phenylpropanolamine
Atropine	Codeine	Ketoprofen	Prednisolone
Benzilic acid	Cortisone	Labetalol	Prednisone
Benzoic acid	(-) Cotinine	Levorphanol	Procaine

Benzoyllecgonine	Creatinine	Loperamide	Promazine
Bilirubin	Deoxycorticosterone	Maprotiline	Promethazine
Brompheniramine	Dextromethorphan	Meperidine	D,L-Propranolol
Caffeine	Diazepam	Meprobamate	D-Propoxyphene
Cannabidiol	Diclofenac	Methadone	Quinidine
Cannabinol	Diflunisal	Methylphenidate	Quinine
Trimethoprim	Digoxin	Morphine-3-Dglucuronide	Ranitidine
Trimipramine	Diphenhydramine	Nalidixic acid	Salicylic acid
Tryptamine	Doxylamine	Naloxone	Secobarbital
D, L-Tyrosine	Ecgonine hydrochloride	Naltrexone	Sulfamethazine
Uric acid	Ecgonine methylester	Naproxen	Sulindac
Verapamil	(1R,2S)-(-)-Ephedrine	Niacinamide	Temazepam
Zomepirac	L-Ephedrine	Nifedipine	Tetracycline
Gentisic acid	(-) Y Ephedrine	Norcodein	Tetrahydrocortisone
Hemoglobin	Erythromycin	Norethindrone	Tetrahydrozoline
Oxycodone	β -Estradiol	D-Norpropoxyphene	Δ^9 -THC-COOH
Oxymetazoline	Estrone-3-sulfate	Noscapine	Thebaine
Triamterene	Ethyl-p-aminobenzoate	D,L-Octopamine	Thiamine
Trifluoperazine	Fenfluramine	Oxalic acid	Thioridazine
	Fenopropfen	Oxazepam	D,L-Thyroxine
	Furosemide	Oxolinic acid	Tolbutamine

Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples with of 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above cut-off levels. These samples were tested using three batches of each device for all formats. Results were all positive for samples at and above +25% cut-off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different formats.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration is described in the precision section, M.1.a. above.

2. Comparison studies:

a. *Method comparison with predicate device:*

The method comparison studies for the SAVECARE Urine Test (Amphetamine, Cocaine and Marijuana) were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results.

Amphetamine Cassette

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	19	20
	Negative	10	10	19	1†	0
Operator B	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0
Operator C	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0

% agreement among positives is 96.7%

% agreement among negatives is 95.8%

* Samples contained AMP at 872, 903, and 920 ng/mL

† Samples contained AMP at 1025 and 1086 ng/mL

Cocaine Cassette

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0
Operator B	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0
Operator C	Positive	0	0	1*	18	20
	Negative	10	10	19	2†	0

% agreement among positives is 96.7%

% agreement among negatives is 95.8%

* Samples contained COC at 294 and 293 ng/mL

† Samples contained COC at 319 and 325 ng/mL

THC Cassette

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2*	18	20
	Negative	10	10	18	2*	0
Operator B	Positive	0	0	2*	18	20
	Negative	10	10	18	2*	0
Operator C	Positive	0	0	2*	17	20
	Negative	10	10	18	3*	0

% agreement among positives is 94.2%

% agreement among negatives is 95%

* Samples contained THC at 46, 47, and 48 ng/mL

† Samples contained THC at 52 and 54 ng/mL

Amphetamine Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0
Operator B	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0
Operator C	Positive	0	0	1*	19	20
	Negative	10	10	19	1†	0

% agreement among positives is 96.7%

% agreement among negatives is 95.8%

* Samples contained AMP at 872, 903, and 920 ng/mL

† Samples contained AMP at 1025, 1086, and 1129 ng/mL

Cocaine Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	18	20
	Negative	10	10	19	2†	0
Operator B	Positive	0	0	1*	18	20
	Negative	10	10	19	2†	0
Operator C	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0

% agreement among positives is 95.8%

% agreement among negatives is 96.7%

* Samples contained COC at 294 and 293 ng/mL

† Samples contained COC at 319, 325, and 330 ng/mL

THC Cup

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	3*	17	20
	Negative	10	10	17	3†	0
Operator B	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0
Operator C	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0

% agreement among positives is 94.2%

% agreement among negatives is 94.2%

* Samples contained THC at 44, 46, 47, and 48 ng/mL

† Samples contained THC at 52 and 54 ng/mL

Amphetamine Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	1*	19	20
	Negative	10	10	19	1†	0
Operator B	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0
Operator C	Positive	0	0	1*	18	20
	Negative	10	10	19	2†	0

% agreement among positives is 95.8%

% agreement among negatives is 96.7%

* Samples contained AMP at 903 and 920 ng/mL

† Samples contained AMP at 1025, 1086, and 1129 ng/mL

Cocaine Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0
Operator B	Positive	0	0	1*	18	20
	Negative	10	10	19	2†	0
Operator C	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0

% agreement among positives is 95.8%

% agreement among negatives is 95.8%

* Samples contained COC at 288, 294, and 293 ng/mL

† Samples contained COC at 319, 325, and 330 ng/mL

THC Dip Card

Test		Drug-free	Low Negative (<50% the cutoff conc)	Near Cutoff Negative (Between <50% below up to the cutoff conc)	Near Cutoff Positive (Between the cutoff and 50% above cutoff conc)	High Positive (>50% above the cutoff conc)
Operator A	Positive	0	0	2*	19	20
	Negative	10	10	18	1†	0
Operator B	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0
Operator C	Positive	0	0	2*	18	20
	Negative	10	10	18	2†	0

% agreement among positives is 95.8%

% agreement among negatives is 95%

* Samples contained THC at 45, 46, 47, and 48 ng/mL

† Samples contained THC at 52 and 54 ng/mL

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

Lay User Study

A lay user study was performed at three intended user sites with 420 lay persons testing the amphetamine devices, 420 lay persons testing the cocaine devices and 420 lay persons testing the marijuana devices. A total of 208 females and 212 males tested the amphetamine samples, 205 females and 215 males tested cocaine samples, and 212 females and 208 males tested the marijuana samples. They had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device.

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.5.

AMP Cup

% of Cutoff	Number of samples	d- Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	250	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	2	18	90
+25% Cutoff	20	1250	17	3	85
+50% Cutoff	20	1500	20	0	100
+75% Cutoff	20	1750	20	0	100

AMP Dip Card

% of Cutoff	Number of samples	d- Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	250	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	3	17	85
+25% Cutoff	20	1250	18	2	90
+50% Cutoff	20	1500	20	0	100
+75% Cutoff	20	1750	20	0	100

AMP Cassette

% of Cutoff	Number of samples	d- Amphetamine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	250	0	20	100
-50% Cutoff	20	500	0	20	100
-25% Cutoff	20	750	2	18	90
+25% Cutoff	20	1250	18	2	90
+50% Cutoff	20	1500	20	0	100
+75% Cutoff	20	1750	20	0	100

COC Cup

% of Cutoff	Number of samples	Benzoylcegonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	20	150	0	20	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	375	18	2	90
+50% Cutoff	20	450	20	0	100
+75% Cutoff	20	525	20	0	100

COC Dip Card

% of Cutoff	Number of samples	Benzoyllecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	20	150	0	20	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	375	17	3	85
+50% Cutoff	20	450	20	0	100
+75% Cutoff	20	525	20	0	100

COC Cassette

% of Cutoff	Number of samples	Benzoyllecgonine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75	0	20	100
-50% Cutoff	20	150	0	20	100
-25% Cutoff	20	225	3	17	85
+25% Cutoff	20	375	17	3	85
+50% Cutoff	20	450	20	0	100
+75% Cutoff	20	525	20	0	100

THC Cup

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.5	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37.5	2	18	90
+25% Cutoff	20	62.5	18	2	90
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

THC Dip Card

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.5	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37.5	3	17	85
+25% Cutoff	20	62.5	18	2	90
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

THC Cassette

% of Cutoff	Number of samples	11-nor-D9-THC-9-COOH Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	12.5	0	20	100
-50% Cutoff	20	25	0	20	100
-25% Cutoff	20	37.5	3	17	85
+25% Cutoff	20	62.5	17	3	85
+50% Cutoff	20	75	20	0	100
+75% Cutoff	20	87.5	20	0	100

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

N. Proposed Labeling:

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

O. Conclusion:

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