

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

A. 510(k) Number:

k122419

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine (d-amphetamine), Barbiturates (secobarbital), Benzodiazepines (oxazepam), Cocaine (benzoylecgonine), Methamphetamine (d-methamphetamine), Methylenedioxymethamphetamine (MDMA), Methadone (methadone), Opiate 2000 (morphine), Morphine 300 (morphine), Oxycodone (oxycodone), Phencyclidine (phencyclidine), and Cannabinoids (THC) (delta-9-THC-COOH) and Tricyclic Antidepressants (nortriptyline).

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

UCP Biosciences, Inc

F. Proprietary and Established Names

UCP Home Drug Screening Test Cups

G. Regulatory Information:

Product	Classification	Regulation Section	Panel
DKZ	Class II	21 CFR 862.3100 Amphetamine test system	91 (Toxicology)
DIS	Class II	21 CFR 862.3150 Barbiturate test system	91 (Toxicology)
JXM	Class II	21 CFR 862.3170 Benzodiazepine test system	91 (Toxicology)

DIO	Class II	21 CFR 862.3250 Cocaine and cocaine metabolite test system	91 (Toxicology)
DJC	Class II	21 CFR 862.3610 Methamphetamine test system	91 (Toxicology)
DJR	Class II	21 CFR 862.3620 Methadone test system	91 (Toxicology)
DJG	Class II	21 CFR 862.3650 Opiate test system.	91 (Toxicology)
LCM		Unclassified, Enzyme immunoassay, phencyclidine	91 (Toxicology)
LDJ	Class II	21 CFR 862.3870 Cannabinoid test system	91 (Toxicology)
LFG	Class II	21 CFR 862.3910 Tricyclic antidepressant drugs test system	91 (Toxicology)

H. Intended Use:

1. Intended Use(s):

See indications for use below.

2. Indication(s) for use:

The UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection the following drugs and their metabolites in human urine:

<u>Test</u>	<u>Calibrator</u>	<u>Cut-off</u>
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Cocaine	Benzoyllecgonine	300 ng/mL
Marijuana	Delta-9-THC-COOH	50 ng/mL
Methadone	Methadone	300 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
MDMA	MDMA	500 ng/mL
Morphine	Morphine	300 ng/mL
Opiates 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for over-the-counter (OTC) users as the first step in a two step process to provide consumers, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing – the second step in the process, along with the materials for shipping the urine specimen to the laboratory, is provided. The test is also intended for health care professional users.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Oxycodone, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Oxycodone, Tricyclic Antidepressant in urine. The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring drug levels.

3. Special conditions for use statement(s):

For over-the-counter use and prescription use by health care professional users

4. Special instrument requirements:

Not applicable, as the device is a visually-read single use device.

I. Device Description:

The UCP Home Drug Screening Test Cups is capable of measuring 12 drugs listed in the intended use at a time. The UCP Home Drug Screening Test Cups can contain up to five strips that are capable of measuring up to three drugs per strip. The test includes user instructions, collection cups, transportation bag with absorbent pad, mailing box and identification labels with personal identification number to be used when sending positive urine specimens to the laboratory for confirmation.

J. Substantial Equivalence Information:

1. Predicate device names(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	Candidate Device	Predicate (k091588)
Intended Use	Same	Qualitative determination of drugs in human urine
Methodology	Same	Lateral flow immunochromatographic
Type of assay	Same	Qualitative
Matrix	Same	Urine
Cutoff	Same	Amphetamine: 1000 ng/mL
	Same	Barbiturates: 300 ng/mL
	Same	Benzodiazepines: 300 ng/mL
	Same	Cocaine: 300 ng/mL
	Same	Cannabinoids (THC): 50 ng/mL
	Same	Methadone: 300 ng/mL
	Same	Methamphetamine: 1000 ng/mL
	Same	MDMA: 500 ng/mL
	Same	Morphine: 300 ng/mL
	Same	Opiate: 2000 ng/mL
	Same	Oxycodone: 100 ng/mL
	Same	Phencyclidine: 25 ng/mL
Same	Tricyclic Antidepressants: 1000	
Intended user	Same	Over-the-counter (OTC) users and Professional users
Endpoint	Same	Colored lines
Differences		
Item	Candidate Device	Predicate
Drug(s) per strip	Up to three drugs per strip	One drug per strip

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

None were referenced.

L. Test Principle:

The UCP Home™ Drug Screening Cups 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 antibody 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. 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. Each strip in the device contains a procedural control that appears in the control line region 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 drug-free urine spiked to the following concentrations: negative (0%), 50% below the cutoff, 25% below the cutoff, 25% above the cutoff, 50% above the cutoff for each analyte and each device. Sample concentrations were confirmed by GC/MS. The samples were aliquots, coded, randomized and blinded. Each specimen, at each concentration analyte, was tested by total sixty (60) test devices from three different lots by three operators within 10 to 20 non-consecutive days. The results are displayed in the tables below:

Amphetamine

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%

Lot 3	+25%	20	0/20	100%
	+50%	20	0/20	100%

Barbiturates:

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	2/18	90%
	+50%	20	0/20	100%

Benzodiazepines

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	19/1	95%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Cocaine

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	2/18	90%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%

Marijuana (THC)

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%

Methadone

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%

Lot 2	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Methamphetamine

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	2/18	90%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

MDMA

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Morphine

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	2/18	90%
	+50%	20	0/20	100%
	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%

Lot 2	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%

Opiates 2000

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	18/2	90%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	19/1	95%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Oxycodone

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100
	-50%	20	20/0	100
	-25%	20	20/0	100
	+25	20	0/20	100
	+50	20	0/20	100
Lot 2	Negative	20	20/0	100
	-50%	20	20/0	100
	-25%	20	19/1	95
	+25	20	0/20	100
	+50	20	0/20	100
Lot 3	Negative	20	20/0	100
	-50%	20	20/0	100
	-25%	20	20/0	100
	+25	20	0/20	100
	+50	20	0/20	100

Phencyclidine

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	18/2	90%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%

	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	19/1	95%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

Tricyclic Antidepressants

	Concentration of sample (ng/mL)	Number of determinations	Results #Neg/#Pos	Precision (%)
Lot 1	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	1/19	95%
	+50%	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50%	20	20/0	100%
	-25%	20	20/0	100%
	+25%	20	0/20	100%
	+50%	20	0/20	100%

b. Linearity/assay reportable range:

Not applicable, the devices are intended for qualitative use.

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

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. For professional users, the sponsor states in the labeling when external QC materials should be tested.

Stability

Accelerated and real time stability studies have been conducted. Stability protocols and acceptance criteria were reviewed and found acceptable. The information supports that UCP Home Drug Screening Test Cups unopened stability is 18 months. Real time stability testing is ongoing.

d. Detection limit:

Analytical performance of the device around the cutoff is described in Section f. (Assay cut- off) below.

e. Analytical specificity:

Cross-reactivity was established by spiking similarly structured compounds into drug free urine at various concentrations. These solutions were tested using 3 lots of the UCP Home Drug Screening Test Cups. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds is presented below. This information is also provided in the labeling of the device.

Amphetamine:

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
D-Amphetamine	1000	100%
D,L-Amphetamine	2500	40%
L-Amphetamine	50000	2%
D-Methamphetamine	>100000	<1%
L-Methamphetamine	>100000	<1%
(±)3,4- Methylenedioxyamphetamine (MDA)	2000	50%
Ephedrine	>100000	<1%
3,4-Methylenedioxythylamphetamine (MDEA)	>100000	<1%

Methamphetamine

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
(±) Methamphetamine	2,000	50%
(+) Methamphetamine	1000	100%
(±) 3,4-Methylenedioxymethamphetamine (MDMA)	2,000	50%
Ranidine (Zantac)	> 100,000	<1%
3,4-Methylenedioxyamphetamine (MDA)	>100,000	<1%
D-Amphetamine	>100,000	<1%
L-Amphetamine	>100,000	<1%
Ephedrine	>100,000	<1%

Barbiturates

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Secobarbital	300	100%
Phenobarbital	2500	12%
Butalbital	500	60%
Pentobarbital	1500	20%
Amobarbital	2500	12%
Cyclopentobarbital	500	60%
Butethal	800	37.5%
Barbital	300	100%
Butabarbital	1500	20%

Benzodiazepines

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Oxazepam	300	100%
Alprazolam	200	150%
α -Hydroxyalprazolam	1000	30%
Bromazepam	250	120%
Chlordiazepoxide	2500	12%
Clobazam	100	300%
Clonazepam	850	35.3%
Clorazepate	250	120%
Delorazepam	1600	18.8%
Diazepam	200	150%
Estazolam	200	150%
Flunitrazepam	300	100%
Lorazepam	1000	30%
Midazolam	1500	20%
Nitrazepam	100	300%
Nordiazepam	400	75%
Temazepam	150	200%
Triazolam	500	60%

Cocaine

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Cocaine	>100000	<1%
Benzoyllecgonine	300	100%
Ecgonine HCl	35000	0.86%

Marijuana

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
11-nor- Δ^8 -THC-9-COOH	50	100%
11-nor- Δ^9 -THC-9-COOH	50	100%
Δ^8 -Tetrahydrocannabinol	8000	0.6%
Δ^9 -Tetrahydrocannabinol	10000	0.5%
Cannabinol	10000	0.5%
Cannabidiol	100000	<1%

Methadone

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Methadone	300	100%
(\pm)2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%

MDMA

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
D-Amphetamine	>100000	<1%
L-Methamphetamine	100000	<1%
3,4-Methylenedioxyethylamphetamine (MDEA)	200	250%
3,4-Methylenedioxyamphetamine (MDA)	2000	25%

Morphine

Compounds	Response equivalent to cutoff	% Cross-
Morphine	300	100%
Codeine	300	100%
Heroin	300	100%
Hydrocodone	2000	15%
Hydromorphone	3500	8.6%
Morphine 3- β -D-glucuronide	300	100%
6-Monoacetylmorphine	600	50%
Normorphine	100000	<1%
Oxycodone	10000	3%
Oxymorphone	50000	<1%
Thebaine	7000	4.3%

Opiates 2000

Compounds	Response equivalent to cutoff (ng/mL)	% Cross- reactivity
Morphine	2000	100%
Codeine	2000	100%
Heroin	2000	100%
Hydrocodone	10000	20%
Hydromorphone	7000	28.6%
Morphine 3- β -D-glucuronide	2000	100%
6-Monoacetylmorphine	5000	40%
Normorphine	100000	2%
Oxycodone	20000	10%
Oxymorphone	100000	2%
Thebaine	70000	2.9%

Oxycodone

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Oxycodone	100	100%
Morphine	50000	<1%
Codeine	25000	<1%
Morphine 3-β-D-glucuronide	50000	<1%
Hydrocodone	1600	6.25%
Hydromorphone	15000	0.7%
Normorphone	100000	<1%
Oxymorphone	1500	6.7%

Phencyclidine

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	<1%

Tricyclic Antidepressants

Compounds	Response equivalent to cutoff (ng/mL)	% Cross-reactivity
Notriptiline	1000	100%
Trimipramine	4500	22%
Amitriptyline	1000	100%
Promazine	3000	33.33%
Desipramine	1000	100%
Imipramine	1000	100%
Clomipramine	7500	13.33%
Doxepin	3000	33.33%
Maprotiline	50000	2%

Structurally un-related and interference:

The following unrelated compounds were found not to cross-react with UCP Home Drug Screening Test Cups when tested spiked (100 mg/mL) into drug free urine or urine spiked with each drug at $\pm 50\%$, $\pm 25\%$ of the cut-off values:

Acetaminophen, Acetylsalicylic Acid, Amikacin, Ampicillin, Arterenal, Aspirin, Atropine, Benzoic Acid, Oxalic Acid, Caffeine, Methanol, Ethanol, Lidocaine, Thioridazine, Trifluoperazine, Penicillin-G, Phenylpropanalamine, Ranitidine, Salicylic Acid, Albumin, Bilirubin, Creatinine, Hemoglobin, Glucose, Vitamin C (L-Ascorbic Acid), and Uric Acid

Evaluation of Specific Gravity and pH on the test results:

To evaluate the effect of pH value on the test results, negative urine samples were adjusted to pH levels 4.5, 5.0, 6.0, 7.0, 8.0, and 9.0. The samples were then spiked with each drug at $\pm 50\%$, $\pm 25\%$ of the cut-off values. Testing was performed on 3 lots of UCP Home Drug Screening Test Cups.

To evaluate the effect of specific gravity, the urine samples having specific gravities of 1.005, 1.01, 1.02, 1.025, and 1.030, 1.032, and 1.035 were spiked with each drug at $\pm 50\%$, $\pm 25\%$ of the cut-off values. Testing was performed on 3 lots of UCP Home Drug Screening Test Cups.

The testing results demonstrate that varying pHs and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Cutoff studies were performed by validating the test performance around the claimed cutoff concentration of each test. The targeted drugs were spiked into human urine known to be drug-free in each test to the following concentrations: 0, $\pm 50\%$ of the cutoff, $\pm 25\%$ of the cutoff.

The concentrations of each drug were confirmed by GC/MS. To determine the analytical sensitivity, 20 replicates at each concentration of each drug were run by 3 operators with total 60 replicates from three lots. The results were summarized below:

Amphetamine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Barbiturates Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	18/2	90%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	1/19	95%

	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Benzodiazepine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Cocaine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Marijuana Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Methadone Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Methamphetamine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	1/19	95%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

MDMA Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Morphine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Opiates 2000 Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Oxycodone Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Phencyclidine Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	2/18	90%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

Tricyclic Antidepressants Cutoff Study:

	Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos	Positive (%)
Lot 1	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 2	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	20/0	100%
	Cutoff	20	3/17	85%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%
Lot 3	Negative	20	20/0	100%
	-50% Cutoff	20	20/0	100%
	-25% Cutoff	20	19/1	95%
	Cutoff	20	1/19	95%
	+25% Cutoff	20	0/20	100%
	+50% Cutoff	20	0/20	100%

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison for UCP Home Drug Screening Test Cups was performed in-house with total 120 (60 negative and 60 positive) unaltered clinical samples by three operators, two operators have relevant experience, one operator has no experience other than reading the instructions for use. The samples were blinded and device results were compared to GC/MS results. The results are presented in the table below:

Amphetamine:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 2	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 3	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Combined results from three operators	Positive results	0	0	10	48	98.3%
	Negative results	48	12	2	0	
Accuracy Rate		100%	100%	83.3%	100%	

Barbiturates:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 2	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	1	12	48	99.2%
	Negative results	48	11	0	0	
Accuracy Rate		100%	91.7%	100%	100%	

Benzodiazepines:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	3	16	95%
	Negative results	16	3	1	0	
Operator 2	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 3	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Combined results from three operators	Positive results	0	2	11	48	97.5%
	Negative results	48	10	1	0	
Accuracy Rate		100%	83.3%	91.7%	100%	

Cocaine:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 2	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	0	12	48	100%
	Negative results	48	12	0	0	
Accuracy Rate		100%	100%	100%	100%	

Methodone:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 2	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	1	12	48	99.2%
	Negative results	48	11	0	0	
Accuracy Rate		100%	91.7	100%	100%	

MDMA:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 2	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	1	11	48	98.3%
	Negative results	48	11	1	0	
Accuracy Rate		100%	91.7%	91.7%	100%	

Methamphetamine:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 2	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	0	11	48	99.2%
	Negative results	48	12	1	0	
Accuracy Rate		100%	100%	91.7%	100%	

Morphine:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 2	Positive results	0	0	3	16	100%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	1	12	48	99.2%
	Negative results	48	11	0	0	
Accuracy Rate		100%	91.7%	100%	100%	

Opiates 2000:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 2	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	2	12	48	98.3%
	Negative results	48	10	0	0	
Accuracy Rate		100%	83.3%	100%	100%	

Marijuana (THC):

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 2	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Combined results from three operators	Positive results	0	1	10	48	97.5%
	Negative results	48	11	2	0	
Accuracy Rate		100%	91.7%	83.3%	100%	

Phencyclidine:

		Negative Urine	Near Cutoff Negative by GC/MS (Between - 50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 2	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	0	11	48	99.2%
	Negative results	48	12	1	0	
Accuracy Rate		100%	100%	91.7%	100%	

Oxycodone:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Operator 2	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Operator 3	Positive results	0	0	4	16	100%
	Negative results	16	4	0	0	
Combined results from three operators	Positive results	0	1	12	48	99.2%
	Negative results	48	11	0	0	
Accuracy Rate		100%	91.7%	100%	100%	

Tricyclic Antidepressant:

		Negative Urine	Near Cutoff Negative by GC/MS (Between -50% and the cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	Total accuracy rate
Operator 1	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 2	Positive results	0	0	3	16	97.5%
	Negative results	16	4	1	0	
Operator 3	Positive results	0	1	4	16	97.5%
	Negative results	16	3	0	0	
Combined results from three operators	Positive results	0	1	10	48	97.5%
	Negative results	48	11	2	0	
Accuracy Rate		100%	91.7%	83.3%	100%	

Discordant table in the method comparison study using unaltered clinical samples:

Sample Numbers	Drug Test	Cutoff value (ng/mL)	Result (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)	
				Drug /Metabolite	GC/MS value (ng/ml)
AMP-61	Amphetamine	1000	Negative	D-Amphetamine	1215
AMP-69	Amphetamine	1000	Negative	D-Amphetamine	1215
BAR-55	Barbiturates	300	Positive	Secobarbital	285
BZO-51	Benzodiazepines	300	Positive	Oxazepam	289
BZO-58	Benzodiazepines	300	Positive	Oxazepam	289
BZO-66	Benzodiazepines	300	Negative	Diazepam	209
MTD-50	Methadone	300	Positive	Methadone	230
MDMA-52	MDMA	500	Positive	MDMA	480
MDMA-63	MDMA	500	Negative	MDMA	525
MET-62	Methamphetamine	1000	Negative	D-Methamphetamine	1195
MOP-51	Morphine	300	Positive	Morphine	285
OPI-53	Opiates 2000	2000	Positive	Codeine	1952
OPI-55	Opiates 2000	2000	Positive	Morphine	1852
THC-52	THC	50	Positive	Delta-9-THC-COOH	45
THC-62	THC	50	Negative	Delta-9-THC-COOH	55
THC-66	THC	50	Negative	Delta-9-THC-COOH	55
PCP-63	Phencyclidine	25	Negative	Phencyclidine	26
OXY-56	Oxycodone	100	Positive	Oxycodone	87
TCA-54	Tricyclic Antidepressant	1000	Positive	Nortriptyline	836
TCA-64	Tricyclic Antidepressant	1000	Negative	Amitriptyline	1215
TCA-70	Tricyclic Antidepressant	1000	Negative	Amitriptyline	1215

b. Lay user study:

A lay user study was conducted in three locations with 115 lay persons. Fifty-eight females and fifty-seven males from ages of 18 to 77 years of age, with a range of educational backgrounds participated in the study. None of the participants had experience with a point of care drug testing product.

Quality control samples for test cups were prepared to contain a strong negative (0 % of the cutoff), a very weak negative (-50% of cutoff), a weak negative (-25% of cutoff), a weak positive (+25% of cutoff), a strong positive (+50% of cutoff) and a very strong positive (+300% of the cutoff) of each drug. Pure drug or metabolite was spiked into drug free human urine. All specimens (except TCA samples) were verified by GC/MS. TCA samples were verified by HPLC. There were 456 observations. The results are summarized below:

Drug	Results	Drug Concentration					
		Negative	-50%	-25%	+25%	+50%	+300%
AMP	Positive	0	0	2	16	18	17
	Negative	140	17	16	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%
BAR	Positive	0	0	3	15	18	17
	Negative	140	17	15	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%
BZO	Positive	0	0	2	14	18	17
	Negative	140	17	16	4	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	77.8%	100%	100%
COC	Positive	0	0	4	15	18	17
	Negative	140	17	14	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	77.8%	83.3%	100%	100%
MTD	Positive	0	0	1	16	18	17
	Negative	140	17	17	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	94.4%	88.9%	100%	100%
MET	Positive	0	0	2	16	18	17
	Negative	140	17	16	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%

MDMA	Positive	0	0	3	15	18	17
	Negative	140	17	15	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%
MOP	Positive	0	0	2	15	18	17
	Negative	140	17	16	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%
OXY	Positive	0	0	2	15	18	17
	Negative	140	17	16	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%
OPI	Positive	0	0	2	16	18	17
	Negative	140	17	16	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%
PCP	Positive	0	0	3	15	18	17
	Negative	140	17	15	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%
TCA	Positive	0	0	2	15	18	17
	Negative	140	17	16	3	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%
THC	Positive	0	0	2	17	18	17
	Negative	140	17	16	1	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	88.9%	94.4%	100%	100%

Discordant table in the lay user study:

No	Drug Test	Cutoff value (ng/mL)	Result (POS/NEG)	Drug/Metabolite GC/MS value	
				Drug or Metabolite	GC/MS value (ng/ml)
1.	Amphetamine	1000	Positive	D-Amphetamine	750
2.	Amphetamine	1000	Positive	D-Amphetamine	750
3.	Amphetamine	1000	Negative	D-Amphetamine	1250
4.	Amphetamine	1000	Negative	D-Amphetamine	1250
5.	Barbiturates	300	Positive	Secobarbital	225
6.	Barbiturates	300	Positive	Secobarbital	225
7.	Barbiturates	300	Positive	Cyclopentobarbital	375
8.	Barbiturates	300	Negative	Secobarbital	375
9.	Barbiturates	300	Negative	Secobarbital	375
10.	Barbiturates	300	Negative	Cyclopentobarbital	625
11.	Benzodiazepines	300	Positive	Oxazepam	225
12.	Benzodiazepines	300	Positive	Estazolam	150
13.	Benzodiazepines	300	Negative	Oxazepam	375
14.	Benzodiazepines	300	Negative	Oxazepam	375
15.	Benzodiazepines	300	Negative	Oxazepam	375
16.	Benzodiazepines	300	Negative	Estazolam	250
17.	Cocaine	300	Positive	Benzoyllecgonine	225
18.	Cocaine	300	Positive	Benzoyllecgonine	225
19.	Cocaine	300	Positive	Benzoyllecgonine	225
20.	Cocaine	300	Positive	Benzoyllecgonine	225
21.	Cocaine	300	Negative	Benzoyllecgonine	375
22.	Cocaine	300	Negative	Benzoyllecgonine	375
23.	Cocaine	300	Negative	Benzoyllecgonine	375
24.	Methadone	300	Positive	Methadone	225
25.	Methadone	300	Negative	Methadone	375
26.	Methadone	300	Negative	Methadone	375
27.	Methamphetamine	1000	Positive	D- Methamphetamine	750
28.	Methamphetamine	1000	Positive	D- Methamphetamine	750
29.	Methamphetamine	1000	Negative	D- Methamphetamine	1250

30.	Methamphetamine	1000	Negative	D- Methamphetamine	1250
31.	MDMA	500	Positive	MDMA	375
32.	MDMA	500	Positive	MDMA	375
33.	MDMA	500	Positive	MDMA	375
34.	MDMA	500	Negative	MDMA	625
35.	MDMA	500	Negative	MDMA	625
36.	MDMA	500	Negative	MDMA	625
37.	Morphine	300	Positive	Morphine	225
38.	Morphine	300	Positive	Morphine	225
39.	Morphine	300	Negative	Morphine	375
40.	Morphine	300	Negative	Morphine	375
41.	Morphine	300	Negative	Codeine	375
42.	Oxycodone	100	Positive	Oxycodone	75
43.	Oxycodone	100	Positive	Oxycodone	75
44.	Oxycodone	100	Negative	Oxycodone	125
45.	Oxycodone	100	Negative	Oxycodone	125
46.	Oxycodone	100	Negative	Oxycodone	125
47.	Opiates 2000	2000	Positive	Morphine	1500
48.	Opiates 2000	2000	Positive	Codeine	1500
49.	Opiates 2000	2000	Negative	Morphine	2500
50.	Opiates 2000	2000	Negative	Morphine	2500
51.	Phencyclidine	25	Positive	Phencyclidine	18.75
52.	Phencyclidine	25	Positive	Phencyclidine	18.75
53.	Phencyclidine	25	Positive	Phencyclidine	18.75
54.	Phencyclidine	25	Negative	Phencyclidine	31.25
55.	Phencyclidine	25	Negative	Phencyclidine	31.25
56.	Phencyclidine	25	Negative	Phencyclidine	31.25
57.	Tricyclic Antidepressant	1000	Positive	Nortriptyline	750
58.	Tricyclic Antidepressant	1000	Positive	Imipramine	750
59.	Tricyclic Antidepressant	1000	Negative	Nortriptyline	1250
60.	Tricyclic Antidepressant	1000	Negative	Nortriptyline	1250

61.	Tricyclic Antidepressant	1000	Negative	Desipramine	1250
62.	THC	50	Positive	Delta-9-THC-COOH	37.5
63.	THC	50	Positive	Delta-9-THC-COOH	37.5
64.	THC	50	Negative	Delta-9-THC-COOH	62.5

A Flesh-Kincaid reading analysis was performed on package inserts and the score revealed a reading grade level of 7.

Each participant was given a pre and post-study questionnaire. The pre-study questionnaire collected personal information about each participant. The post-study questionnaire was used to determine if the lay users understood the test instruction and the meaning of the results. Consumers were asked questions about the test, control line, prescription drug and food interference and confirmation of results. The results from the post-questionnaire were acceptable as nearly all of the participants answered the questions correctly (99.1%).

b. Matrix comparison:

Not applicable. The assay is intended for urine samples.

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.