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

A. 510(k) Number:
k132812

B. Purpose for Submission:
New Device

C. Measurand:
Amphetamine (d-amphetamine), Barbiturates (secobarbital), Benzodiazepines (oxazepam), Buprenorphine (buprenorphine), Cocaine (benzoylecgonine), Methamphetamine (d-methamphetamine), Methylenedioxymethamphetamine (MDMA), Methadone (methadone), Opiate 2000 (morphine), Morphine 300 (morphine), Oxycodone (oxycodone), Phencyclidine (phencyclidine), Propoxyphene (propoxyphene), 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 Multi-Drug Test Key Cups

G. Regulatory Information:

Product	Classificatio	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)
JXN	Class II	21 CFR 862.3700 Propoxyphene 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	Class II	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 Multi-Drug Test Key Cups are rapid tests for preliminary detection of the following drugs in human urine:

Test	Calibrated to	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 ng/mL
Cocaine	Benzoylecgonine	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
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The test configuration comes with a 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 in a urine sample. The second step is to send preliminary positive samples for confirmation testing by GCMS. The test is not intended to distinguish between prescription use or abuse of the following drugs: Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants.

There are no uniformly recognized cutoff concentration levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressant in urine.

Clinical considerations and professional judgment should be applied to any drug of abuse test results, particularly when preliminary positive results are indicated.

3. Special conditions for use statement(s):

The OTC test can contain various combinations of drugs including either the morphine 300 cutoff or the opiates 2000 cutoff.

4. Special instrument requirements:

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

I. Device Description:

The UCP Multi-Drug Test Key Cups are capable of measuring the 14 drugs listed in the intended use at one time. The UCP Multi-Drug Test Key Cups can measure up to three drugs per strip. The test is activated by a key. 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 preliminary positive urine specimens to the laboratory for confirmation.

J. Substantial Equivalence Information:

1. Predicate device names(s)

UCP Home Drug Screening Test Cups

2. Predicate K number(s):

k130463

3. Comparison with predicate:

Similarities		
Item	**Candidate Device**	**Predicate (k130463)**
Intended Use	Same	Qualitative and preliminary detection 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	Buprenorphine: 10 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	Propoxyphene: 300 ng/mL
	Same	Tricyclic Antidepressants: 1000 ng/mL
Endpoint	Same	Colored lines

Differences		
Item	**Candidate**	**Predicate**
Sample Application	Key-activated	Direct

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

None referenced.

L. Test Principle:

The UCP Multi-Drug Test Key Cups employ lateral flow immunochromatographic technology based on the principle of competitive binding. If the sample does not contain the drugs (or if they are present in concentrations below the cutoff level) binding sites of antibody coated particles in the device will not be saturated. The antibody-coated particles will then be captured by immobilized colloidal gold-labeled 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 is composed of nitrocellulose and contains the test line with mouse monoclonal antibodies specific to each drug. The test strips also contain a procedural control line region containing a goat polyclonal antibody against gold-protein conjugate to indicate 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, and 50% above the cutoff for each analyte. Sample concentrations were confirmed by GC/MS. The samples were aliquoted, coded, randomized and masked. Each specimen, at each concentration analyte, was tested on a total of 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. Also see section 2.b., below, for additional results obtained by the intended user that include results for high positive and low negative concentrations.

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

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

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	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	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

Buprenorphine

	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	1/19	95
	+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
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

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
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

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

Propoxyphene

	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 device is intended for qualitative use.

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

External control standards are not supplied with this device. For prescription use, the sponsor provides instruction for testing QC materials.

Stability:
The sponsor's stability protocols and acceptance criteria were reviewed and found acceptable. The information supports that UCP Multi-Drug Test Key Cups unopened stability is 18 months. Real time stability testing is ongoing. (Instructions note that opened tests should be used immediately.)

d. Detection limit:

Analytical performance of the device around the cutoff is described in Section a. (Precision/Reproducibility) above.

e. Analytical specificity:

Cross-reactivity was evaluated by spiking similarly structured compounds into drug free urine. These solutions were tested using 3 lots of the UCP Home Drug Screening Test Cups. Results are expressed as a minimum concentration of 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.

Amphetamine

Compounds	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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-Methylenedioxeythylamphetamine (MDEA)	>100000	<1%

Methamphetamine

Compounds	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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%

Buprenorphine

Compounds	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)**	**% Cross-reactivity**
Buprenorphine	10	100
Norbuprenorphine	15	66.67
Buprenorphine-3-D-glucuronide	12.5	80
Norbuprenorphine-3-D-glucuronide	175	5.71
Morphine-3-D-glucuronide	100000	<1%
Morphine	>100000	<1%
Oxymorphone	>100000	<1%
Hydromorphone	>100000	<1%

Cocaine

Compounds	**Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)**	**% Cross-reactivity**
Cocaine	>100000	<1%
Benzoylecgonine	300	100%
Ecgonine HCI	35000	0.86%

Marijuana

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)	% Cross-reactivity
Methadone	300	100%
(±)2-Ethy1-1,5-dimethy1-3,3-diphenylpyrrolinium	50000	0.6%
Doxylamine	50000	0.6%

MDMA

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)	% Cross-reactivity
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%
Normorphone	100000	<1%
Oxycodone	10000	3%
Oxymorphone	50000	<1%
Thebaine	7000	4.3%

Opiates 2000

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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%
Normorphone	100000	2%
Oxycodone	20000	10%

Oxymorphone	100000	2%
Thebaine	70000	2.9%

Oxycodone

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)	% Cross-reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	15000	<1%

Propoxyphene

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (ng/mL)	% Cross-reactivity
Propoxyphene	300	100
Norpropoxyphene	600	50
Methadone	100000	<1

2-ethyl-1,5-dimethyl-3,3-diphenylpyrroline (EDDP)	100000	<1

Tricyclic Antidepressants

Compounds	Concentration that yields response approximately equivalent to that of target drug at the cutoff concentration (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%

Interference testing for structurally unrelated compounds:

The following structurally unrelated compounds were found not to interfere with UCP Home Drug Screening Test Cups when tested spiked (100 mg/mL) into drug free urine or urine spiked with each drug at ±50%, ± 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, Creatine, Hemoglobin, Glucose, Vitamin C (L-Ascorbic Acid), 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 ±50%, ± 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 ±50%, ± 25% of the cut-off values. Testing was performed on 3 lots of UCP Home

Drug Screening Test Cups. The testing results demonstrated that the varying pH and specific gravities listed above do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Analytical performance of the device around the cutoff is described in Section a. (Precision/Reproducibility) above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison for UCP Home Drug Screening Test Cups was performed with total 80 (40 negative and 40 positive) unaltered clinical samples by three operators. The samples were masked and device results were compared to GC/MS results. For classes of drugs (e.g. barbiturates, benzodiazepines, tricyclic antidepressants) testing included a minimum of 3 drugs for each class. The results are presented in the table below:

		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 Agreement with GCMS
Amphetamine	Positive Results	0	0	3	36	98.8%
	Negative Results	36	4	1	0	
Barbiturates	Positive Results	0	1	8	32	98.8%
	Negative Results	32	7	0	0	
Benzodiazepines	Positive Results	0	1	7	32	97.5%
	Negative Results	32	7	1	0	
Buprenorphine	Positive Results	0	1	4	36	98.8%
	Negative Results	36	3	0	0	
Cocaine	Positive Results	0	0	8	32	100%
	Negative Results	29	11	0	0	

Methadone	Positive Results	0	1	4	36	98.8%
	Negative Results	36	3	0	0	
MDMA	Positive Results	0	1	3	36	97.5%
	Negative Results	36	3	1	0	
Methamphetamine	Positive Results	0	0	5	34	98.8%
	Negative Results	34	6	1	0	
Morphine	Positive Results	0	1	4	36	98.8%
	Negative Results	36	3	0	0	
Opiates 2000	Positive Results	0	2	8	32	97.5%
	Negative Results	33	5	0	0	
Marijuana	Positive Results	0	1	3	36	97.5%
	Negative Results	36	3	1	0	
PCP	Positive Results	0	0	3	36	98.8%
	Negative Results	36	4	1	0	
Oxycodone	Positive Results	0	0	4	36	100%
	Negative Results	36	4	0	0	
Propoxyphene	Positive Results	0	1	11	29	98.8%
	Negative Results	28	11	0	0	
TCA	Positive Results	0	1	5	34	97.5%
	Negative Results	35	4	1	0	

Summary of discordant results shown in the table above:

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-42	Amphetamine	1000	Negative	D-Amphetamine	1215
BAR-39	Barbiturates	300	Positive	Secobarbital	285
BZO-34	Benzodiazepines	300	Positive	Oxazepam	289
BZO-45	Benzodiazepines	300	Negative	Diazepam	209
BUP-40	Buprenorphine	10	Positive	Buprenorphine	9
MTD-38	Methadone	300	Positive	Methadone	230
MDMA-40	MDMA	500	Positive	MDMA	480
MDMA-43	MDMA	500	Negative	MDMA	525
MET-42	Methamphetamine	1000	Negative	D-Methamphetamine	1195
MOP-39	Morphine	300	Positive	Morphine	285
OPI-38	Opiates 2000	2000	Positive	Codeine	1952
OPI-39	Opiates 2000	2000	Positive	Morphine	1852
THC-40	THC	50	Positive	Delta-9-THC-COOH	45
THC-42	THC	50	Negative	Delta-9-THC-COOH	55
PCP-43	Phencyclidine	25	Negative	Phencyclidine	26
PPX-38	Propxyphene	300	Positive	Propoxyphene	275
TCA-40	Tricyclic Antidepressant	1000	Positive	Nortriptyline	836
TCA-43	Tricyclic Antidepressant	1000	Negative	Amitriptyline	1215

b. <u>Lay user study</u>:

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 drug testing product.

Quality control samples for test cups were prepared to contain the following

levels: cutoff concentration; -50% below the cutoff; -25% below the cutoff;, +25% above the cutoff;, +50% above the cutoff and +300% above the cutoff for each drug. The drugs used for spiking included D-Amphetamine for amphetamine, secobarbital and cyclopentobarbital for barbiturates, oxazepam and estazolam for benzodiazepines, buprenorphine for buprenorphine, benzylecgonine for cocaine, methadone for methadone, D-methamphetamine for methamphetamine, MDMA for MDMA, morphine for morphine, morphine, heroin and codeine for opiates 2000, oxycodone for oxycodone, Delta-9-THC-COOH for marijuana, PCP for PCP, propoxyphene for propoxyphene, and nortriptyline and amitriptyline for tricyclic antidepressants. All samples (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	16	18	17
	Negative	140	17	15	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%
BZO	Positive	0	0	3	16	18	17
	Negative	140	17	15	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%
BUP	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%
COC	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%
MTD	Positive	0	0	3	16	18	17
	Negative	140	17	15	2	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%
MET	Positive	0	0	1	17	18	17
	Negative	140	17	17	1	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%
MDMA	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%
MOP	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%
OXY	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%
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	1	17	18	17
	Negative	140	17	17	1	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	94.4%	94.4%	100%	100%
PPX	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%

TCA	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%
THC	Positive	0	0	3	17	18	17
	Negative	140	17	15	1	0	0
	Total	140	17	18	18	18	17
	Agreement with GC/MS	100%	100%	83.3%	94.4%	100%	100%

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.