

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

A. 510(k) Number:

k130463

B. Purpose for Submission:

Addition of Buprenorphine and Propoxyphene to Existing Device

C. Measurand:

Cannabinoids (THC) (delta-9-THC-COOH), Cocaine (benzoylecgonine), Amphetamine (d-amphetamine), Methamphetamine (d-methamphetamine), Opiate 2000 (morphine), Morphine 300 (morphine), Phencyclidine (phencyclidine), Barbiturates (secobarbital), Benzodiazepines (oxazepam), Buprenorphine (buprenorphine), Methadone (methadone), Oxycodone (oxycodone), Methylenedioxymethamphetamine (MDMA), Propoxyphene (propoxyphene), 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 Cards

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)
JXN	Class II	21 CFR 862.3700 Propoxyphene 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, UCP Home Drug Screening Test Cups are rapid, qualitative, competitive binding immunoassays for the detection of 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
Buprenorphine	Buprenorphine	10 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

Propoxyphene	Propoxyphene	300 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 tests are 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 prescription use.

The tests will yield preliminary positive results when the prescription drugs Barbiturates, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, Tricyclic Antidepressants are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Barbiturate, Benzodiazepines, Buprenorphine, Oxycodone, Propoxyphene, 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

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 and the UCP Home Drug Screening Test Cards are capable of measuring 14 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 and in a dipcard format for the UCP Home Drug Screening Test Cards. These tests include user instructions, collection cups, Drug Screening Test Card (in a foil pouch), 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 (k130463)	Predicate (k091588)
Intended use	Intended for qualitative detection of drugs and their metabolites in human urine	Same
Test Principle	Lateral flow immunochromatographic technology based on the principle of competitive binding	Same
Type of assay	Qualitative	Same
Matrix	Urine	Same
Cutoff	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 ng/mL	Same
Intended user	Over-the-counter (OTC) users and Professional users	Same
Storage	2 to 30 °C	Same
Endpoint	Colored lines	Same
Read time	5 minutes	Same
Differences		
Item	Device (k130463)	Predicate (k091588)
Drugs	Contains additional OTC drugs buprenorphine and propoxyphene	Does not contain drugs buprenorphine and propoxyphene

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

None were referenced.

L. Test Principle:

The UCP Home™ Drug Screening Cups and The UCP Home™ Drug Screening Test Cards 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:

This submission is for the addition of buprenorphine and propoxyphene to a previously cleared device. Performance characteristics for each of the drugs are found in the

following 510(k) numbers: k091588 for all analytes except for buprenorphine and propoxyphene. Please see k091612 for buprenorphine and k061457 for propoxyphene.

b. Linearity/assay reportable range:

Not applicable. The tests are for qualitative use.

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

Control Materials

External control materials are not supplied with this device; however, this device has internal process controls. A colored line appearing in the control region reflects that sufficient sample volume was applied and that adequate membrane wicking occurred. Users are informed that the test is invalid if a line fails to appear in the control region. For prescription use, 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 and UCP Home Drug Screening Test Cards have unopened stabilities of 18 months.

Real time stability testing is ongoing.

d. Detection limit:

See k091588 for all analytes except for buprenorphine and propoxyphene. Please see k091612 for buprenorphine, and k061457 for propoxyphene.

e. Analytical specificity:

See k091588 for all analytes except for buprenorphine and propoxyphene. Please see k091612 for buprenorphine, and k061457 for propoxyphene.

f. Assay cut-off:

See k091588 for all analytes except for buprenorphine and propoxyphene. Please see k091612 for buprenorphine, and k061457 for propoxyphene.

2. Comparison studies:

a. Method comparison with predicate device:

See k091588 for all analytes except for buprenorphine and propoxyphene. Please see k091612 for buprenorphine, and k061457 for propoxyphene.

b. Lay user study:

1) The Consumer study in UCP Home Drug Screening Test Cards:

The study was conducted among 115 lay persons in the three geographic regions. Fifty seven females and fifty eight males from ages ranging from 18 and 77 years participated in the studies. Fifty seven participants had a high school education or less, fifty eight participants had finished college courses. None of the participants had experiences using drug testing products before. The urine samples were prepared to contain strong negative (0% of cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a very weak positive (125% of cutoff), a weak positive (150% of cutoff) and high positive (300% of Cutoff). The urine samples with various drug concentrations were prepared by spiking pure drugs or drug metabolites into drug free human urine, the final drug concentrations in each urine sample were confirmed by GC/MS except for TCA. TCA concentrations in the urine samples was confirmed by HPLC. Each participant was asked to read the test instruction before performing the test, and then run the test independently without additional help. The test results by the lay users are summarized as below:

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Amphetamines	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Barbiturates	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	17	0	17	100%
	+300%	16	0	16	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Benzodiazepines	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	1	17	94.4%
	+25%	18	4	14	77.8%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Buprenorphine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	1	17	94.4%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Cocaine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	2	16	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Methadone	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Methamphetamine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
MDMA	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	14	4	77.8%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Morphine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	17	1	94.4%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Oxycodone	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Opiates	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Phencyclidine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Propoxyphene	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	17	1	94.4%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Tricyclic Antidepressants	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Test Card		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
THC	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Amphetamine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Barbiturates	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	14	4	77.8%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Benzodiazepines	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	17	1	94.4%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Buprenorphine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	1	17	94.4%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Cocaine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	14	4	77.8%
	+25%	18	1	17	94.4%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Methadone	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Methamphetamine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
MDMA	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	17	1	94.4%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Morphine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Oxycodone	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Opiates	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Phencyclidine	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Propoxyphene	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	17	1	94.4%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
Tricyclic Antidepressants	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	16	2	88.9%
	+25%	18	3	15	83.3%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

Cup		Number of samples	OTC user		% Agreement with GC/MS
Drug	Concentration		Negative	Positive	
THC	Negative	140	140	0	100%
	-50%	17	17	0	100%
	-25%	18	15	3	83.3%
	+25%	18	2	16	88.9%
	+50%	18	0	18	100%
	+300%	17	0	17	100%

c. Matrix Comparison:

Not applicable. The assay is intended for urine samples.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

b. 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.