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

A. 510(k) Number:

k091588

B. Purpose for Submission:

This submission is for the addition of an over-the-counter (OTC) claim for already cleared prescription devices: k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, morphine, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclics antidepressants) were both cleared for a strip/ cassette methodology. k072062 supported the cup format for the same device.

C. Measurand:

Amphetamine (d-amphetamine), Barbiturates (secobarbital), Benzodiazepines (oxazepam), Cocaine (benzoylecgonine), Methamphetamine (d-methamphetamine), Methylenedioxymethamphetamine (MDMA), Methadone (methadone), Opiates 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 tests for drugs in urine.

E. Applicant:

UCP Biosciences Inc.

F. Proprietary and Established Names:

UCP Home™ Drug Screening Test Cards

UCP Home™ Drug Screening Test Cup

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
DKZ	II	21 CFR 862.3100 Amphetamine test system	91 (Tox)
DIS	II	21 CFR 862.3150 Barbiturate test system	91 (Tox)
JXM	II	21 CFR 862.3170 Benzodiazepine test system	91 (Tox)
DIO	II	21 CFR 862.3250 Cocaine and cocaine metabolite test system	91 (Tox)
DJC	II	21 CFR 862.3610 Methamphetamine test system	91 (Tox)
DMB	II	21 CFR 862.3620 Methadone test system	91 (Tox)
DJG	II	21 CFR 862.3650 Opiate test system.	91 (Tox)
LCM	II	Unclassified, Enzyme immunoassay, phencyclidine	91 (Tox)
LDJ	II	21 CFR 862.3870 Cannabinoid test system	91 (Tox)
LFG	II	21 CFR 862.3910 Tricyclic antidepressant drugs test system	91 (Tox)

H. Intended Use:

1. Intended use(s):

   See indications for use statement below.

2. Indication(s) for use:
   The UCP Home Drug Screening Tests are rapid, qualitative, competitive binding immunoassays for the detection the following drugs and their metabolites in human urine:

Test	Calibrator	Cut-off
Amphetamine	D-Amphetamine	1000 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 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
Opiate 2000	Morphine	2000 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL

The tests contain two formats: 1) Test Card; 2) Test Cup. 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, including but not limited to concerned parents, 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 health care professional users

4. Special instrument requirements:

   None

I. Device Description:

The UCP Home Drug Screening Test Card is capable of measuring 10 of the 13 drugs listed in the intended use at a time. The test cards contain up 10 strips (each strip can hold one drug), five strips on one side of the card and 5 strips on the back side of the card. The UCP Home Drug Screening Test Cup can contain up to five strips that are capable of measuring one drug per strip. Both formats include 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 name(s):

   UCP Rapid Drug Screening Tests

   UCP Multiple Drug Screen Test Cups

2. Predicate K number(s):

   k050540

   k072062

3. Comparison with predicate:

   This device is the exact same device as the predicate device. This device has the same drugs, cutoffs and same matrix.

   This device differs from the predicate in that it is intended to be used over-the-counter and prescription use whereas the predicates are for prescription use only.

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

None referenced.

L. Test Principle:

The UCP Home™ Drug Screening Tests and 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:

   This submission is for an OTC claim. Performance characteristics for each of the drugs are found in the following 510(k) numbers: k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclics

antidepressants).

b. Linearity/assay reportable range:

See k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclics antidepressants).

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

This device has internal process controls. 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. The sponsor informs the user not to interpret the test if a colored line failed to appear in the control region. External controls are not supplied with this device.

The sponsor conducted an incremental time study to support the devices claimed read time of 5 to 10 minutes. Concentrations of amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone and tricyclics antidepressants were prepared at +/-50% and +/-25% of the cutoffs. Twenty determinations were read at each cutoff concentration at 5, 7 and 10 minute intervals. The results supported the sponsors read time of 5 to 10 minutes for the test card and cup.

d. Detection limit:

See k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclic antidepressants).

e. Analytical specificity:

See k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclics antidepressants).

f. Assay cut-off:

See k050540 (amphetamine, cocaine, methamphetamine, MDMA, opiates, phencyclidine, THC, benzodiazepine, methadone, barbiturates oxycodone) and k061457 (tricyclics antidepressants).

2. Comparison studies:

a. Method comparison with predicate device:

Test Cards:

The sponsor conducted a lay user study for test cards with 115 lay persons in three locations: Texas, Pennsylvania and California. Fifty-eight females and fifty-seven males from ages of 18 to 75 years of age participated in the study. Fifty-eight participants had a high school education or less, fifty-seven participants had completed college courses. None of the participants had experience with a point of care drug testing product.

Test Cups:

The sponsor conducted a lay user study for test cups with 110 lay persons in three locations: Texas, Pennsylvania and California. Fifty-five females and fifty-five males from ages of 18 to 75 years of age participated in the study. Fifty-five participants had a high school education or less, fifty seven participants had completed college courses. None of the participants had experience with a point of care drug testing product.

Quality control samples for test cards and cups were prepared to contain a strong negative (0 % of the cutoff), a very weak negative (50% of cutoff), a weak negative (75% of cutoff), a weak positive (125% of cutoff), a strong positive (150% of cutoff) and a very strong positive (300% of the cutoff) of each drug. The quality control specimens were prepared at concentrations shown below. 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. In the drug test card study, 4 users tested three samples, 10 users tested five samples, 96 users tested four samples and 5 users tested one two samples. There were 456 total observations. In the drug test cup study, 3 users tested six samples, 96 users tested four samples, 9 users tested five samples, 1 user tested two samples and 1 user tested seven samples. There were 456 observations.

UCP Home Drug Screening Test Card

Drug	Cutoff (ng/mL)	**Card** Results	Drug Concentrations						
			Negative	50% of C/O	75% of C/O	125% of C/O	150% of C/O	300% of C/O	Total % correct
AMP	1000	Positive	0	0	1	17	18	17	
		Negative	140	17	17	1	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	94.4	94.4	100	100	99.1
BAR	300	Positive	0	0	3	16	18	17	
		Negative	140	17	15	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.3	88.9	100	100	97.8

BENZO	300	Positive	0	0	0	14	18	17	
		Negative	140	18	18	4	0	0	
		Total	140	18	18	18	18	17	
		% Agreement	100	100	100	77.8	100	100	98.2
COC	300	Positive	0	0	2	15	18	17	
		Negative	140	17	16	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	83.3	100	100	97.8
Methadone	300	Positive	0	0	1	17	18	17	
		Negative	140	17	17	1	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	94.7	94.4	100	100	99.1
Methamp	1000	Positive	0	0	2	16	18	17	
		Negative	140	17	16	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	88.9	100	100	98.2
MDMA	500	Positive	0	0	3	14	18	17	
		Negative	140	17	15	4	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.3	77.8	100	100	96.9
Morphine	300	Positive	0	0	3	15	18	17	
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.3	83.3	100	100	97.4
Oxycod.	100	Positive	0	0	2	14	18	17	
		Negative	140	17	16	4	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	77.8	100	100	97.4
Opiates (Morphine)	2000	Positive	0	0	3	15	19	18	
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	19	18	
		% Agreement	100	100	83.3	83.3	100	100	97.4
PCP	25	Positive	0	0	1	16	18	17	
		Negative	140	17	17	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	94.4	88.9	100	100	98.7
TCA	1000	Positive	0	0	2	16	18	17	
		Negative	140	17	16	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	88.9	100	100	98.2
THC	50	Positive	0	0	2	16	19	18	
		Negative	140	17	16	2	0	0	
		Total	140	17	18	18	19	18	
		% Agreement	100	100	88.9	88.9	100	100	98.2

UCP Home Drug Screening Test Cups

Drug	Cutoff (ng/mL)	**Cup** Results	Drug Concentrations						
			Negative	50% of C/O	75% of C/O	125% of C/O	150% of C/O	300% of C/O	Total % correct
AMP	1000	Positive	0	0	3	16	18	17	
		Negative	140	17	15	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.3	88.9	100	100	97.8
BAR	300	Positive	0	0	4	15	18	17	
		Negative	140	17	14	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	77.8	83.3	100	100	96.9
BENZO	300	Positive	0	0	1	14	18	17	
		Negative	140	17	17	4	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	94.4	77.8	100	100	97.8
COC	300	Positive	0	0	2	15	18	17	
		Negative	140	17	16	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	83.3	100	100	97.8
Methadone	300	Positive	0	0	2	16	18	17	
		Negative	140	17	16	2	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	88.9	100	100	98.2
Methamp	1000	Positive	0	0	2	15	18	17	
		Negative	140	17	16	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.8	83.3	100	100	97.8
MDMA	500	Positive	0	0	3	15	18	17	
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.2	83.3	100	100	97.4
Morphine	300	Positive	0	0	3	15	18	17	
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.2	83.3	100	100	97.4
Oxycod.	100	Positive	0	0	2	15	18	17	
		Negative	140	17	16	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	88.9	83.3	100	100	97.8
Opiates	2000	Positive	0	0	3	15	19	18	

(Morphine)									
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	19	18	
		% Agreement	100	100	83.3	83.3	100	100	97.4
PCP	25	Positive	0	0	3	15	18	17	
		Negative	140	17	15	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	84.2	83.3	100	100	97.4
TCA	1000	Positive	0	0	4	15	18	17	
		Negative	140	17	14	3	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	77.8	83.3	100	100	96.9
THC	50	Positive	0	0	3	14	18	17	
		Negative	140	17	15	4	0	0	
		Total	140	17	18	18	18	17	
		% Agreement	100	100	83.3	77.8	100	100	96.9

A Flesh-Kincaid reading analysis was performed on both package inserts (cards and cups) 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 were of the post-questionnaire were acceptable as 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.