

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

A. 510(k) Number:

k061457

B. Purpose for Submission:

New Device

C. Measurand:

Tricyclic antidepressants in urine.
Propoxyphene in urine.

D. Type of Test:

Qualitative

E. Applicant:

UCP Biosciences Inc.

F. Proprietary and Established Names:

UCP Rapid™ Drug Screening Tricyclic Antidepressants Test
UCP Rapid™ Drug Screening Propoxyphene Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LFG	II	21 CFR 862.3910	91 (Tox)
JXN	II	21 CFR 862.3700	91 (Tox)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The UCP Rapid™ Drug Screening Tricyclic Antidepressant Test and UCP

Rapid™ Drug Screening Propoxyphene Test are rapid, qualitative, competitive binding immunoassays for the detection of Tricyclic Antidepressants, Propoxyphene and their metabolites in human urine at the following cutoff levels:

<u>Test</u>	<u>Calibrator</u>	<u>Cut-off</u>
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL

The tests provide only preliminary data, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). The test configuration comes with either single drug test or in combination with multiple other drug tests. 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 prescription use only.

4. Special instrument requirements:

Not applicable (N/A)

I. Device Description:

The UCP™ Drug Screening Tricyclic Antidepressants and Propoxyphene test are both lateral flow chromatographic immunoassays that contain two test formats, a dipstick test strip and a cassette test card format. The dipstick test strip format is initiated by dipping the test strip into urine. The cassette test device uses the same principle however urine is added to a sample well of a cassette.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON TCA One Step Tricyclic Antidepressant Test Strip and Device

Instant-View Propoxyphene Urine Test and Cassette.

2. Predicate 510(k) number(s):

k021526 and k022915, respectively.

3. Comparison with predicate:

The device is similar to the predicates in that they measure the same analyte in the same matrix, have the same intended use, utilize the same test methodology and cutoff concentrations. There were no differences noted.

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

None Referenced

L. Test Principle:

The UCP Rapid Drug Screening Tricyclic Antidepressants and Propoxyphene Test Devices and Strips are one-step lateral flow immunoassays containing 1) a purple-colored conjugate pad with colloidal gold conjugated with anti-drug antibodies, 2) a nitrocellulose membrane with a test line (T line coated with the drug antigen) and a control line (C line coated with goat anti-mouse IgG antibodies). The test is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. The test devices are cassettes that allow for urine to be added and the urine migrates through the test device by capillary action. The test strips are dipped into urine specimens and the urine migrates through the test strip by capillary action.

If the drug or drug metabolite concentration in the specimen is below the cutoff level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is at a cutoff level or higher, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will develop in the test region, which indicates a positive result. The colloidal gold-antibody conjugate should bind to the C line and form a purple-colored and regardless of the presence of drug or drug metabolite in the urine specimen as long as a sufficient sample volume has been applied.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision was assessed for both TCA and Propoxyphene by conducting a within lot and a lot-to-lot precision study. The lot-to-lot precision study used drug free human urine spiked with commercially available drug standards that produced concentrations of -50% cutoff, -25% cutoff, the cutoff, +25% cutoff and +50% cutoff. The samples were tested with 3 lots of each assay device by three operators over a period of 10 days (N=60). Two operators are trained laboratory workers and one is professional with limited laboratory background. The results are presented in the charts below.

Tricyclic Antidepressants Inter Lot Reproducibility

Concentration (ng/mL)	N	Lot #1		Lot #2		Lot #3	
		Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision
0	60	20/0	100%	20/0	100%	20/0	100%
500	60	20/0	100%	20/0	100%	20/0	100%
750	60	18/2	90%	17/3	85%	18/2	90%
1000	60	1/19	95%	1/19	95%	0/20	100%
1250	60	0/20	100%	0/20	100%	0/20	100%
1500	60	0/20	100%	0/20	100%	0/20	100%

Propoxyphene Inter Lot Reproducibility

Concentration (ng/mL)	N	Lot #1		Lot #2		Lot #3	
		Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision
0	60	20/0	100%	20/0	100%	20/0	100%
150	60	20/0	100%	20/0	100%	20/0	100%
225	60	18/2	90%	19/1	95%	17/3	85%
300	60	1/19	95%	0/20	95%	0/20	100%
375	60	0/20	100%	0/20	100%	0/20	100%
450	60	0/20	100%	0/20	100%	0/20	100%

A within lot precision study was conducted for both drugs with drug free human urine spiked with commercially available drug standards that produced concentrations of -50% cutoff, -25% cutoff, the cutoff, +25% cutoff and +50% cutoff. Each specimen, at each concentration analyte, was tested four times daily for five consecutive days by the same three operators (same lot) at the sponsor's facility. The results are listed in the charts below.

Tricyclic Antidepressants within lot precision:

Concentration (ng/mL)	N	Results #Neg/#Pos	Precision (%)
0	60	60/0	100%
500	60	60/0	100%
750	60	50/10	83%
1000	60	3/57	95%
1250	60	0/60	100%
1500	60	0/60	100%

Propoxyphene within precision study:

Concentration (ng/mL)	N	Results #Neg/#Pos	Precision (%)
0	60	60/0	100%
150	60	60/0	100%
225	60	55/5	92%
300	60	1/59	98%
375	60	0/60	100%
450	60	0/60	100%

In order to show that both formats of the device (strips and cassette) are equivalent in readability, and additional bridging study was conducted. Normal drug free urine was spiked with commercially available drug standard to the same levels indicated in the charts above. Twenty UCP test strips and 20 UCP cassette devices from the same lots were tested and summarized in the charts below.

Tricyclic Antidepressants Test Bridging Study

Concentration (ng/mL)	N	UCP Rapid TCA Strip		UCP Rapid TCA Cassette	
		Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision
0	40	20/0	100%	20/0	100%
500	40	20/0	100%	20/0	100%
750	40	18/2	90%	18/2	90%
1000	40	0/20	100%	0/20	100%
1250	40	0/20	100%	0/20	100%
1500	40	0/20	100%	0/20	100%

Propoxyphene Test Bridging Study

Concentration (ng/mL)	N	UCP Rapid PPX Strip		UCP Rapid PPX Cassette	
		Results # Neg/ Pos	Precision	Results # Neg/ Pos	Precision
0	60	20/0	100%	20/0	100%
150	60	20/0	100%	20/0	100%
225	60	17/3	85%	17/3	85%
300	60	0/20	100%	0/20	95%
375	60	0/20	100%	0/20	100%
450	60	0/20	100%	0/20	100%

The results of the three precision studies show that there is no significant lot-to-lot or within lot variability. The bridging study also shows that the two formats (strip and cassette) are equivalent.

b. *Linearity/assay reportable range:*

Not applicable (N/A). This assay is intended for qualitative use.

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

This device has internal process controls. A colored line appearing in the control region confirms that sufficient sample volume has been used. Users are informed not to interpret the test if a colored line failed to appear in the control region.

External controls are not supplied with this device.

d. *Detection limit:*

Sensitivity of the UCP Rapid Drug Screening Tests was characterized by validating the test performance around the claimed cutoff concentrations. The results support the sponsors chosen cutoffs of 1000 ng/mL for TCA and 300 for propoxyphene. See the Precision section above for additional information regarding test performance around the cutoff.

e. *Analytical specificity:*

Cross-reactivity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine/a negative control. The sponsored determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay (1000 ng/mL for TCA and 300 for propoxyphene). The cross-reactivity results are listed in the table below.

Tricyclic Antidepressants

Compound	Response Equivalent to cutoff in ng/mL
Nortriptyline	1,000
Trimipramine	4,500
Amitriptyline	1,000
Promazine	2,000
Desipramine	1,000
Imipramine	1,000
Clomipramine	18,000
Doxepine	1,000
Maprotiline	2,000

Propoxyphene

Compound	Response equivalent to cutoff in ng/mL
Propoxyphene	300
Norpropoxyphene	600
Methadone	100,000
2-ethyl,5-dimethyl-3,3-diphenylpropylamine (EDDP)	100,000

The sponsor tested many common substances and biological materials for interference with the UCP Rapid Drug Screening Tests at a concentration of 100 mg/mL in drug-free and drug positive urines. The sponsor states that they was no cross-reactivity detected. The compounds are listed in the package insert.

The sponsor evaluated urine pH for test interference in negative urine specimens and in specimens with concentrations of 50% above the cutoff. The specimens were adjusted to pH ranges from 4.5 to 9. The testing results were summarized in the tables below. The results showed that there was no interference from urine pH ranging from 4.5 to 9 with either the TCA or the PPX test.

Negative Urine

pH range	TCA	PPX
pH 4.5	-	-
pH 5	-	-
pH 6	-	-
pH 7	-	-
pH 8	-	-
pH 9	-	-

50% above the cutoff Urine

(TCA positive urine: Nortriptyline at 1500 ng/mL)

(PPX positive urine: Propoxyphene at 450 ng/mL)

pH range	TCA	PPX
pH 4.5	+	+
pH 5	+	+
pH 6	+	+
pH 7	+	+
pH 8	+	+
pH 9	+	+

The sponsor evaluated specific gravity interference by adding distilled water

and sodium chloride to negative urine specimens and to specimens that were 50% above the cutoff. The specific gravity values ranged from 1.002 to 1.035. The control used was an unaltered urine sample. The results are listed in the table below and showed that urine specific gravity does not interfere with the TCA and propoxyphene tests.

Negative Urine

Specific Gravity	TCA	PPX
1.01 (control)	-	-
1.002	-	-
1.02	-	-
1.035	-	-

150% cutoff urine sample

Specific Gravity	TCA	PPX
1.01 (control)	+	+
1.002	+	+
1.02	+	+
1.035	+	+

f. Assay cut-off:

The identified cutoff concentrations of the assays are commonly found in industry. There are no recommended cutoffs for these assays by the Substance Abuse and Mental Health Services Administration (SAMHSA). TCA has a cutoff of 1000 ng/mL and propoxyphene has a cutoff of 300 ng/mL.

2. Comparison studies:

a. Method comparison with predicate device:

The UCP Rapid Drug Screening TCA and PPX Tests were compared to the predicate devices and reference methods. The TCA test was compared to HPLC and the PPX was compared to the GC/MS reference method. One hundred and forty (140) clinical urine samples containing drug free urine (52), nortriptyline (48), amitriptyline (16), imipramine (10), desipramine (10) and Nortriptyline/Amitriptyline combined (4) were tested by the predicate devices and on the reference methods at the sponsor's facility. Thirteen percent of the clinical urine samples contained drug concentrations between 50% below the cutoff and the cutoff for each drug tested. Another thirteen percent of the clinical urine samples contained drug concentrations between the cutoff and 50% above the cutoff for each drug tested.

Tricyclic Antidepressant Comparison Study:
Candidate Device Results vs. Predicate Device Results

	Positive by Predicate Device	Negative by Predicate Device
Positive by Candidate Device	68	2
Negative by Candidate Device	5	65

% Agreement among positive is 97%

% Agreement among negative is 93%

Candidate Device Results vs. HPLC at cutoff 1000 ng/mL values

Candidate Device Results	Less than half the cutoff concentration	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	17 *	52
Negative	52	18 **	1 *	0

GC/MS values are used to categorize the samples in this table.

% Agreement among positive is 100%

% Agreement among negative is 98.6%

* 12 samples contained nortriptyline above 1000 ng/mL and below 1500 ng/mL, 6 samples contained amitriptyline, desipramine, or imipramine at concentrations equivalent to >1000 ng/mL nortriptyline and < 1500 ng/mL nortriptyline.

** 12 samples contained nortriptyline below 1000 ng/mL and above 500 ng/mL, 6 samples contained amitriptyline, desipramine, or imipramine at concentrations equivalent to <1000 ng/ml nortriptyline and >500 ng/mL nortriptyline.

UCP Rapid Drug Screening PPX Test Vs Predicate Device Results

	Positive by Predicate Device	Negative by Predicate Device
Positive by UCP Device	63	1
Negative by UCP Device	1	63

* Percent agreement among positive is 98%

*Percent agreement among negative is 98%

UCP Rapid Drug Screening PPX Test vs. GC/MS at cutoff 300 ng/mL value

UCP Device Results	Less than half the cutoff conc.	Between 50% below the cutoff and the cutoff conc.	Between the cutoff and 50% above the cutoff con.	More than 50% above the cutoff conc.
Positive	0	1	11	52
Negative	52	11	1	0

* Percent agreement among positive is 98%

*Percent agreement among negative is 98%

b. Matrix comparison:

Not applicable. This assay is intended for only one sample matrix.

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.