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

A. 510(k) Number:

k091612

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Buprenorphine, Cocaine and Methamphetamine

D. Type of Test:

Qualitatively, immunochromatographic assay

E. Applicant:

UPC BioSciences, Inc.

F. Proprietary and Established Names:

UCP Rapid™ Drug Screening BUP, AMP 300, mAMP 500 and Cocaine 150 Tests

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650, Opiate test system	91- Toxicology
DKZ	Class II	21 CFR 862.3100, Amphetamine test system	91- Toxicology
LAF	Class II	21 CFR 862.3610, Methamphetamine test system	91-Toxicology
DIO	Class II	21 CFR 862.3250, Cocaine and cocaine metabolite test system	91-Toxicology

H. Intended Use:

1. Intended use(s):

   See the Indications for Use below

2. Indication(s) for use:

   The UCP Drug Screening Buprenorphine, Amphetamine 300, Methaphetamine 500, Cocaine 150 Tests are rapid, qualitative, competitive binding immunoassays for the detection the following drug in human urine:

Test	Calibrator	Cut-off
Buprenorphine	Buprenorphine	10 ng/mL
Amphetamine	D-Amphetamine	300 ng/mL
Methamphetamine	D-Methamphetamine	500 ng/mL
Cocaine	Benzoylecgonine	150 ng/mL

   The tests contain three formats:1) Test Card/Strip, 2) Test Device, 3) Test Cup. The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. The test is intended for in vitro diagnostics use.

   This assay provides only preliminary results. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

3. Special conditions for use statement(s):

   The device is for in vitro diagnostic prescription use.

   This device is indicated for use in point-of-care settings.

   This assay provides only preliminary results. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or Liquid chromatography/mass spectrometry (LC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

4. Special instrument requirements:

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

I. Device Description:

The UCP Drug Screening Amphetamine, Buprenorphine, Cocaine and Methamphetamine are test strips contained within the following formats; dipstick (dip card), cassette (test device) and test cup. Each device can contain from 1 to 4 drug test strips. The strips contain a membrane coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against the drug being tested.

Controls are recommended but not provided

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON BUP One Step Buprenorphine Test Strip
ACON BUP One Step Buprenorphine Test Device

ACON AMP-300 One Step Amphetamine Test Strip
ACON AMP-300 One Step Amphetamine Test Device

ACON mAMP-500 One Step Methamphetamine Test Strip
ACON mAMP-500 One Step Methamphetamine Test Device

ACON COC-150 One Step Cocaine Test Strip
ACON COC-150 One Step Cocaine Test Device

2. Predicate K number(s):

K033299, k060466, k041822 and k032903 respectively

3. Comparison with predicate:

Item	Similarities/Differences Device	Predicate
Intended use	Is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drug(s) and/or drug metabolites in human urine.	Same
Sample matrix	Urine	Same
Analytes	Amphetamines, Burenorphine, Cocaine, Methamphetamine,	Same
Cutoffs	BUP 10, AMP 300, mAMP 500 and COC 150	Same

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

None were identified.

L. Test Principle:

UCP Drug Screening devices are a one-step lateral flow immunoassay containing a purple-colored conjugate pad with colloidal gold conjugate with anti-drug antibodies, a nitrocellulose membrane with a test line (T) and a control line (C). The T line is coated with the drug antigen and the C line is 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. When a sufficient amount of sample is applied the sample migrates through the test device by capillary action. If the concentration of drug is below the cutoff level, the anti-drug antibodies in the colloidal gold particles will bind to the drug antigens coated in the test zone producing a band which indicates a negative result. If the drug concentration is at the cutoff level or higher no band will form in the test zone indicating a preliminary positive. A band should form in the control region regardless of the presence of drug or drug metabolite in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility was evaluated by spiking drug free negative urine to the following concentrations (Negative, 50%, 75%, 125%, 150% and 200% of the cutoff) for each analyte. Testing was performed at three Point-of-Care sites three operators/site each testing one of three formats. Each sample, at each concentrations of each drug, was blind labeled and tested 1 to 2 times a day, for 10 non-consecutive days. A total of 30 determinations, at each concentration, were made. Results are presented in the tables below:

Amphetamine cutoff 300 ng/mL

Drug Concentration (ng/mL)	% of cutoff	Total number of Determinations	Dip Card results #Neg/#Pos	Cassette results #Neg/#Pos	Cup results #Neg/#Pos
0	Negative	30	30/0	30/0	30/0
150	50%	30	30/0	30/0	30/0
225	75%	30	20/10	19/11	18/12
375	125%	30	11/19	12/18	13/17
450	150%	30	0/30	0/30	0/30
600	200%	30	0/30	0/30	0/30

Methamphetamine cutoff 500 ng/mL

Drug Concentration (ng/mL)	% of cutoff	Total number of Determinations	Dip Card results #Neg/#Pos	Cassette results #Neg/#Pos	Cup results #Neg/#Pos
0	Negative	30	30/0	30/0	30/0
250	50%	30	30/0	30/0	30/0
375	75%	30	18/12	19/11	18/12
625	125%	30	11/19	13/17	11/19
750	150%	30	0/30	0/30	0/30
1000	200%	30	0/30	0/30	0/30

Cocaine cutoff 150 ng/mL

Drug Concentration (ng/mL)	% of cutoff	Total number of Determinations	Dip Card results #Neg/#Pos	Cassette results #Neg/#Pos	Cup results #Neg/#Pos
0	Negative	30	30/0	30/0	30/0
75	50%	30	30/0	30/0	30/0
112.5	75%	30	20/10	19/11	19/11
187.5	125%	30	9/21	12/18	12/18
225	150%	30	0/30	0/30	0/30
300	200%	30	0/30	0/30	0/30

Buprenorphine cutoff 10 ng/mL

Drug Concentration (ng/mL)	% of cutoff	Total number of Determinations	Dip Card results #Neg/#Pos	Cassette results #Neg/#Pos	Cup results #Neg/#Pos
0	Negative	30	30/0	30/0	30/0
5	50%	30	30/0	30/0	30/0
7.5	25%	30	20/10	19/11	18/12
12.5	125%	30	11/19	13/17	11/19
15	150%	30	0/30	0/30	0/30
20	200%	30	0/30	0/30	0/30

b. Linearity/assay reportable range:

Not applicable. This is a qualitative test.

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 applied and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if a line fails to appear in the control region. External controls are not supplied with this device.

d. Detection limit:

Analytical performance of the device around the cutoff is described in the precision section 1.a above.

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug free urine. The concentration of the drug that produced a response equivalent to the cutoff concentration of the assay was determined. Results are in the tables below:

Buprenorphine

Compound	Response equivalent to cutoff (ng/mL)
Buprenorphine	10 ng/mL
Norbuprenorphine	15 ng/mL
Buprenorphine-3-D-glucuronide	12.5 ng/mL
Norbuprenorphine-3-D-glucuronide	175 ng/mL
Morphine-3-D-glucuronide	100,000 ng/mL
Morphine	> 100,000 ng/mL
Oxymorphone	> 100,000 ng/mL
Hydromorphone	> 100,000 ng/mL

Amphetamine

Compound	Response equivalent to cutoff (ng/mL)
D-Amphetamine	300 ng/mL
D,L-amphetamine	850 ng/mL
L-Amphetamine	17,500 ng/mL
D-Methamphetamine	100,000 ng/mL
L-Methamphetamine	> 100,000 ng/mL
(±) 3,4-Methylethyenedioxyamphetamine (MDA)	650 ng/mL
Ephedrine	> 100,000 ng/mL
3,4-Methylenedioxyethyamphetamine (MDEA)	> 100,000 ng/mL

Methamphetamine

Compound	Response equivalent to cutoff (ng/mL)
(±) Methamphetamine	1,000 ng/mL
(+) Methamphetamine	500 ng/mL
(±) 3,4-Methylenedioxymethamphetamine (MDMA)	1,000 ng/mL
Ranidine (Zantac)	> 100,000 ng/mL
3,4-Methylenedioxyamphteamine (MDA)	> 100,000 ng/mL
D-Amphetamine	> 100,000 ng/mL
L-Amphetamine	> 100,000 ng/mL
Ephedrine	> 100,000 ng/mL

Cocaine

Compound	Response equivalent to cutoff (ng/mL)
Cocaine	> 100,000 ng/mL
Benzoylecogonine	150 ng/mL
Ecgonine HCL	17,000 ng/mL

Unrelated Compounds, Prescription and Over –the-Counter Medication

A 100 µg/mL of various common compounds were added to negative and positive urine samples and assayed. None of the common compounds listed affected the expected results.

Common Drugs	Ethanol	**Biological**
Acetaminophen	Lidocaine	Albumin
Acetylsalicylic Acid	Methanol	Bilirubin
Amikacin	Oxalic Acid	Creatine
Ampicillin	Penicillin-G	Glucose
Arterenal	Phenylpropanalamine	Hemoglobin
Asprin	Ranitidine	Vitamin (L-Ascorbic Acid)
Atropine	Salicyclic Acid	Uric Acid
Benzoic Acid	Thioridazine	Urine pH 4.5-9.0
Caffeine	Trifluoperazine	Urine Specific Gravity 1.002-1.035

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results.

pH and Specific Gravity

To test for possible positive and/or negative interference a negative urine sample and a positive, 50% above the cutoff for each drug urine sample were divided into six aliquots and adjusted to the following pH concentrations 4.5, 5.0, 6.0, 7.0, 8.0 and 9.0. No interference due to pH was observed.

To test for possible positive and/or negative interference from specific gravity, distilled water or sodium chloride was added to negative urine samples or 150% cutoff urine samples to obtain samples having specific gravity of 1.002, 1.020, 1.025, 1.030 and 1.035. No interference due to specific gravity was observed.

f. Assay cut-off:

BUP	10 ng/mL
AMP	300 ng/mL
mAMP	500 ng/mL
COC	150 ng/mL

Characterization of how the device performs around the claimed cutoff concentration appears in the precision section 1.a, above.

2. Comparison studies:

a. Method comparison with predicate device:

Performance was evaluated by 3 operators at one point-of-care site. Each operator tested 80 unaltered clinical samples for each drug on one of three formats. The samples were compared to the GC/MS or LC/MS/MS. The results are presented in the tables below:

Test Card

Durg ng/mL	Candidate Device Results	Less than half the cutoff concentration by GC/MS or LC/MS/MS	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)
BUP (10)	Positive	0	0	6	32
	Negative	32	8	2	0
AMP (300)	Positive	0	0	6	32
	Negative	32	8	2	0
mAMP (500)	Positive	0	1	8	32
	Negative	32	7	0	0
COC (150)	Positive	0	1	8	32
	Negative	32	7	0	0

Test Cassette

Durg ng/mL	Candidate Device Results	Less than half the cutoff concentration by GC/MS or LC/MS/MS	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)
BUP (10)	Positive	0	0	6	32
	Negative	32	8	2	0
AMP (300)	Positive	0	0	6	32
	Negative	32	8	2	0
mAMP (500)	Positive	0	1	8	32
	Negative	32	7	0	0
COC (150)	Positive	0	1	8	32
	Negative	32	7	0	0

Test Cup

Durg ng/mL	Candidate Device Results	Less than half the cutoff concentration by GC/MS or LC/MS/MS	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)
BUP (10)	Positive	0	0	7	32
	Negative	32	8	1	0
AMP (300)	Positive	0	0	6	32
	Negative	32	8	2	0
mAMP (500)	Positive	0	1	8	32
	Negative	32	7	0	0
COC (150)	Positive	0	1	8	32
	Negative	32	7	0	0

b. Matrix comparison:

Not applicable. The assay is intended for use with urine samples only

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.