

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

A. 510(k) Number:

k152908

B. Purpose for Submission:

Addition of EDDP to a previously cleared device

C. Measurand:

Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine (MDMA), Morphine, Opiates 2000, Phencyclidine, Propoxyphene, and Tricyclic antidepressants.

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

UCP Biosciences, Inc.

F. Proprietary and Established Names:

UCP Compact Drug Test Cards

UCP Compact Drug Test Cups

G. Regulatory Information:

Product Code	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)
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	21 CFR 862.3100 Enzyme immunoassay, phencyclidine	91 (Toxicology)

Product Code	Classification	Regulation Section	Panel
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:

UCP Compact™ Drug Tests Cards and UCP Compact™ Drug Tests Cups are rapid, qualitative, competitive binding immunoassays for qualitatively the detection of the following drugs and their metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Marijuana	Delta-9-THC-COOH	50 ng/mL
Cocaine	Benzoyllecgonine	300 ng/mL
Amphetamine	D-Amphetamine	1000 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
Opiates	Morphine	2000 ng/mL
Morphine	Morphine	300 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	300 ng/mL
Buprenorphine	Buprenorphine	10 ng/mL
Methadone	Methadone	300 ng/mL
EDDP	EDDP	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
MDMA	MDMA	500 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL
Tricyclic Antidepressants	Nortriptyline	1000 ng/mL

The tests are intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide the consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory test in the second step of the two-step process, is provided in the package labeling.

The test configuration comes with single drug screening test or any combinations of multiple drug screening tests. 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 multidrug of abuse urine test device shows the drug was or was not present at the cutoff level. The tests provide only preliminary test results, which must 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 result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.

3. Special conditions for use statement(s):

For Over-The-Counter (OTC) use.
For In Vitro Diagnostics only.

4. Special instrument requirements:

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

I. Device Description:

UCP Compact Drug Tests are competitive binding, lateral flow immunochromatographic assays for qualitatively the detection of Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, EDDP (Methadone metabolite), Marijuana, Methamphetamine, MDMA, Methadone, Opiates, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants and their metabolites at the cut-off levels as indicated. The tests are available in card and cup formats and performed without the use of a separate instrument.

J. Substantial Equivalence Information:

1. Predicate device name(s):

UCP Compact™ Drug Test Cards/UCP Compact™ Drug Test Cups
Advin Multi-Drug Screen Test Dip Card and Advin Multi-Drug Test Cup

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

k122809
k131811

3. Comparison with predicate:

Similarities		
Item	Device	Predicate (k122809 and k131811)
Intended Use	Same	Intended for qualitative detection of drugs of abuse and their metabolites
Test Principle	Same	Lateral flow immunochromatographic technology based on the principle of competitive binding
Type of Assay	Same	Qualitative
Matrix	Same	Urine
Cut-offs	Same	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	Buprenorphine: 10 ng/mL
Same	Propoxyphene: 300 ng/mL	
Same	EDDP: 300 ng/mL	
Intended User	Same	Over-the-counter (OTC) users and professional users
Test Format	Same	Test card and test cup
Storage	Same	2 – 30 °C
Endpoint	Same	Colored Lines
Read Time	Same	5 minutes

Differences		
Item	Device	Predicate (k131811)
Total Number of Tests	Contains 16 drug tests including an EDDP test	Contains 15 drug tests

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

Not applicable.

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:

Precision/ Reproducibility performance for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, Morphine, Phencyclidine, Barbiturates, Buprenorphine, Benzodiazepines, Methadone, Oxycodone, MDMA, Propoxyphene, Tricyclic Antidepressants drug tests in UCP Compact Drug Tests was established in the following 510(k) submissions: k061457, k091588, K091612, k110515, k122419, k123863, k130463, k131811, and k132812.

Precision/Reproducibility studies for the EDDP drug test were conducted by analyzing five different concentrations of EDDP in urine specimens: negative, 50% below the cutoff, 25% below the cutoff, cutoff, 25% above the cutoff, 50% above the cutoff, 75% above the cutoff and 100% above the cutoff. Each urine specimen, with each concentration of EDDP was prepared by spiking different concentrations of EDDP into drug-free normal human urine specimens (negative human urine), the final concentration of EDDP in urine specimens was confirmed by gas chromatography mass spectrometry (GC/MS). Each sample was tested four times daily for 20 non-consecutive days by one operator at each concentration. A total of 60 determinations tested by three operators were made at each concentration. The data are summarized below:

Summary of Precision /Reproducibility Study

EDDP Compact Drug Test Card:

Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos
0	60	60/0
-50% cutoff	60	60/0
-25% cutoff	60	56/4
+25% cutoff	60	2/58
+50% cutoff	60	0/60
+75% cutoff	60	0/60
+100% cutoff	60	0/60

EDDP Compact Drug Test Cup:

Concentration (ng/mL)	Total numbers of Determinations	Results #Neg/#Pos
0	60	60/0
-50% cutoff	60	60/0
-25% cutoff	60	58/2
+25% cutoff	60	3/57
+50% cutoff	60	0/60
+75% cutoff	60	0/60
+100% cutoff	60	0/60

b. Linearity/assay reportable range:

Not applicable. These devices are for qualitative use only.

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

Procedural controls are included in the test strip and device. A red colored line appearing in the control zone is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with these tests; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow local, state, and federal guidelines to run the external controls.

Stability:

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

d. Detection limit:

See Precision/Reproducibility section in M.1.a above.

e. Analytical specificity:

Analytical specificity and cross-reactivity for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, Morphine, Phencyclidine, Barbiturates, Buprenorphine, Benzodiazepines, Methadone, Oxycodone, MDMA, Propoxyphene, and Tricyclic Antidepressants was established in the following 510(k) submissions: k061457, k091588, K091612, k110515, k122419, k123863, k130463, k131811, k132812.

Analytical specificity and cross-reactivity for the EDDP drug test was established by spiking various concentrations of similarly structured drug compounds into drug-free urine (negative control). By analyzing results of various concentration of each compound with the EDDP test, the concentration of the compound that produced a response approximately equivalent to the cutoff concentration of the assay was determined. Results of those studies appear in the table(s) below:

EDDP

Compound	Concentration at which the response was equivalent to the cutoff of 300 ng/mL	Cross-Reactivity
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300 ng/mL	100%
Methadone	>100,000 ng/mL	<1%
Doxylamine	>100,000 ng/mL	<1%

Interferences for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, Morphine, Phencyclidine, Barbiturates, Buprenorphine, Benzodiazepines, Methadone, Oxycodone, MDMA, Propoxyphene, and Tricyclic Antidepressants drug tests in UCP Compact Drug Tests were established in the following 510(k) submissions: k061457, k091588, K091612, k110515, k122419, k123863, k130463, k131811, and k132812. The following list of substances showed no interference at a concentration of 100 µg/mL 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, L-Ascorbic Acid, and Uric Acid when tested with the EDDP test.

Samples above and below the analyte cutoff were adjusted to obtain specific gravities of 1.002, 1.005, 1.01, 1.02, 1.025, 1.03, and 1.035. The cup and card formats with all drug test strips, and the EDDP single panel cup and card formats were tested at each specific gravity; the cup and the test card formats were tested separately.

The pH of samples above and below the analyte cutoff were adjusted to pH 4.5, 5, 6, 7, 8, 9, and pH 10. The cup and card formats with all drug test strips, and the EDDP single panel cup and card formats were tested at each pH; the cup and the test card formats were tested separately.

The results demonstrated that pH and specific gravity do not affect the results from the device.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison performance for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, Morphine, Phencyclidine, Barbiturates, Buprenorphine, Benzodiazepines, Methadone, Oxycodone, MDMA, Propoxyphene, and Tricyclic Antidepressants drug tests in UCP Compact Drug Tests was established in the following 510(k) submissions: k061457, k091588, K091612, k110515, k122419, k123863, k130463, k131811, k132812.

The method comparison study for the EDDP test was conducted using 80 clinical urine samples. The clinical urine samples were obtained from reference laboratories, where all clinical urine specimens were tested by (GC/MS). Each sample was tested with both the cup and card formats of the device.

UCP Compact EDDP Cup format vs. GC/MS at cutoff 300 ng/mL

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	1*	8	32
Negative	32	7	0	0

*EDDP concentration was 289 ng/ml for the discordant result.

% Agreement among positive is 100%.

% Agreement among negative is 98%.

UCP Compact EDDP Card format vs. GC/MS at cutoff 300 ng/mL

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	1*	8	32
Negative	32	7	0	0

*EDDP concentration was 289 ng/ml for the discordant result.

% Agreement among positive is 100%.

% Agreement among negative is 98%.

b. *Matrix comparison:*

Not applicable. The assay is intended for 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):

A consumer study was conducted of the UCP Compact Drug Test Cards among 115 lay persons in the three geographic regions. Fifty seven females and fifty eight males from ages ranged from 18 and 77 years participated the studies. Fifty seven participants had high school education or less, fifty eight participants had finished college courses. None of the participants had experience using drug testing products before. The urine samples were prepared at the following concentrations: 0% of cutoff, 50% of cutoff, 75% of cutoff, 125% of cutoff, 150% of cutoff and 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 with the exception of TCA which was confirmed by HPLC. Each participant was asked to read the test instruction before performing the test, and then ran the test independently without additional help. The test results by the lay users are summarized as below:

Amphetamines

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	15	18	17	97.4%
Negative	140	17	15	3	0	0	
% Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%	

Barbiturates

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	17	16	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

Benzodiazepine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	16	18	17	98.7%
Negative	140	17	17	2	0	0	
% Agreement with GC/MS	100%	100%	94.4%	88.9%	100%	100%	

Buprenorphine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	17	18	17	98.2%
Negative	140	17	15	1	0	0	
% Agreement with GC/MS	100%	100%	83.3%	94.4%	100%	100%	

Cocaine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

EDDP

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	18	18	17	98.7%
Negative	140	17	15	0	0	0	
% Agreement with GC/MS	100%	100%	83.3%	100%	100%	100%	

Methadone

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	16	18	17	98.2%
Negative	140	17	16	2	0	0	
% Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%	

Methamphetamine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	15	18	17	97.4%
Negative	140	17	15	3	0	0	
% Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%	

MDMA

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	16	18	17	98.2%
Negative	140	17	16	2	0	0	
% Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%	

Morphine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	15	18	17	98.2%
Negative	140	17	17	3	0	0	
% Agreement with GC/MS	100%	100%	94.4%	83.3%	100%	100%	

Oxycodone

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

Opiates

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	15	18	17	97.4%
Negative	140	17	15	3	0	0	
% Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%	

Phencyclidine

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	16	18	17	98.2%
Negative	140	17	16	2	0	0	
% Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%	

Propoxyphene

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	16	18	17	98.7%
Negative	140	17	17	2	0	0	
% Agreement with GC/MS	100%	100%	94.4%	88.9%	100%	100%	

Tricyclic Antidepressants

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

THC

Drug Test Card Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	0	15	18	17	98.7%
Negative	140	17	18	3	0	0	
% Agreement with GC/MS	100%	100%	100%	88.3%	100%	100%	

In a different study for the additional format, the sponsor performed a consumer study of UCP Compact Drug Test Cup with 115 lay persons in the three geographic regions. Fifty seven females and fifty eight from ages ranged from 18 and 77 years participated the studies. Fifty seven participants had 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 at the following concentrations: 0% of cutoff, 50% of cutoff, 75% of cutoff, 125% of cutoff, 150% of cutoff and 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 with the exception of TCA which was confirmed by HPLC. Each participant was asked to read the test instruction before performing the test, and then ran the test independently without additional help. The test results by the lay users are summarized below:

Amphetamines

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	13	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

Barbiturates

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	16	18	17	97.8%
Negative	140	17	15	2	0	0	
% Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%	

Benzodiazepine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	15	18	17	98.2%
Negative	140	17	17	3	0	0	
% Agreement with GC/MS	100%	100%	94.4%	83.3%	100%	100%	

Buprenorphine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	17	17	16	98.7%
Negative	140	17	16	1	0	0	
% Agreement with GC/MS	100%	100%	88.9%	94.4%	100%	100%	

Cocaine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	17	18	17	98.2%
Negative	140	17	15	1	0	0	
% Agreement with GC/MS	100%	100%	83.3%	94.4%	100%	100%	

EDDP

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	18	18	17	98.7%
Negative	140	17	15	0	0	0	
% Agreement with GC/MS	100%	100%	83.3%	100%	100%	100%	

Methadone

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	16	18	17	98.2%
Negative	140	17	16	2	0	0	
% Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%	

Methamphetamine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

MDMA

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	16	18	17	98.7%
Negative	140	17	17	2	0	0	
% Agreement with GC/MS	100%	100%	94.4%	88.9%	100%	100%	

Morphine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	15	18	17	97.4%
Negative	140	17	15	3	0	0	
% Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%	

Oxycodone

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

Opiates

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	13	18	17	97.4%
Negative	140	17	15	5	0	0	
% Agreement with GC/MS	100%	100%	83.3%	83.3%	100%	100%	

Phencyclidine

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	16	18	17	98.2%
Negative	140	17	16	2	0	0	
% Agreement with GC/MS	100%	100%	88.9%	88.9%	100%	100%	

Propoxyphene

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	1	16	18	17	98.7%
Negative	140	17	17	2	0	0	
% Agreement with GC/MS	100%	100%	94.4%	88.9%	100%	100%	

Tricyclic Antidepressants

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	2	15	18	17	97.8%
Negative	140	17	16	3	0	0	
% Agreement with GC/MS	100%	100%	88.9%	83.3%	100%	100%	

THC

Drug Test Cup Results by Lay User	GC/MS Test Results						Total % Agreement with GC/MS
	<50% of cutoff	50% of Cutoff	75% of Cutoff	125% of Cutoff	150% of Cutoff	300% of Cutoff	
Positive	0	0	3	16	18	17	97.8%
Negative	140	17	15	2	0	0	
% Agreement with GC/MS	100%	100%	83.3%	88.9%	100%	100%	

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.