

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

A. 510(k) Number:

k050540

B. Purpose for Submission:

Clearance of new device.

C. Measurand:

Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Methamphetamine (methamphetamine), Methamphetamine (MDMA), Methadone, Opiates (300 and 2000), Oxycodone, and Phencyclidine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

UCP Biosciences, Inc.

F. Proprietary and Established Names:

UCP Rapid™ Drug Screening Test Strips
UCP Rapid™ Drug Screening Test Devices

G. Regulatory Information:

1. Regulation section:

862.3100, Amphetamine Test System
862.3150, Barbiturate Test System
862.3170, Benzodiazepine Test System
862.3870, Cannabinoids Test System
862.3250, Cocaine and Cocaine Metabolite Test System
862.3620, Methadone Test System
862.3610, Metamphetamine Test System (includes MDMA)
862.3650, Opiates and Test System (includes Oxycodone)
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

All Class II

3. Product code:

DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM, respectively

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

see indications below.

2. Indication(s) for use:

The UCP Rapid™ Drug Screening Tests are rapid, qualitative, competitive binding immunoassays for the detection of Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Methamphetamine (methamphetamine), Methamphetamine (MDMA), Methadone, Opiates, Oxycodone, and Phencyclidine and their metabolites in human urine at the following cutoff concentrations:

Amphetamine (d-Amphetamine)	1000 ng/mL
Barbiturate (Secobarbital)	300 ng/mL
Benzodiazepine (Oxazepam)	300 ng/mL
Cannabinoid (11-nor- Δ^9 -THC-9 COOH)	50 ng/mL
Cocaine (Benzoylecgonine)	300 ng/mL
Methamphetamine (d-Methamphetamine)	1000 ng/mL
MDMA (d,l-MDMA)	500 ng/mL
Methadone (Methadone)	300 ng/mL
Opiates 300 (Morphine)	300 ng/mL
Opiates 2000 (Morphine)	2000 ng/mL
Oxycodone (Oxycodone)	100 ng/mL
Phencyclidine (Phencyclidine)	25 ng/mL

The test provides only preliminary test results, 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 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 Professional and In Vitro Diagnostics use only.

4. Special instrument requirements:

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

I. Device Description:

The UCP Rapid™ Drug Screening Test Strip and Device is a competitive binding immunoassay used for the qualitative determination of drug and drug metabolite. The devices contain membrane strips 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 Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Opiates, Oxycodone, THC and Phencyclidine. Both devices are single-use and visually read. One is a dipstick device and the other is a cassette device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

- ACON AMP One Step Amphetamine Test Strip and Test Device
- ACON mAMP One Step Methamphetamine Test Strip and Test Device
- ACON BAR One Step Barbiturates Test Strip and Test Device
- ACON BZO One Step Benzodiazepine Test Strip and Test Device
- ACON COC One Step Cocaine Test Strip and Test Device
- ACON OPI One Step Opiates Test Strip and Test Device
- ACON MOP One Step Opiates Test Strip and Test Device
- ACON MDMA One Step Ecstasy Test Strip and Test Device
- ACON MTD One Step Methadone Test Strip and Test Device
- ACON OXY One Step Oxycodone Test Strip and Test Device
- ACON PCP One Step Phencyclidine Test Strip and Test Device
- ACON THC One Step Marijuana Test Strip and Test Device

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

k011672, k011673, k012824, k012300, k010841, k011353, k013380, k022589, k012595, k033047, k011730 and k003557 respectively.

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Qualitative determination of drugs in human urine.	Qualitative determination of drugs in human urine.
Matrix	Human Urine	Human Urine
Test Principle	Immunochromatographic, lateral flow	Immunochromatographic, lateral flow
Cutoff Concentrations	same	same

Differences are the manufacturers and reagent formulations.

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

Department of Health and Human Service, Mandatory Guidelines for Federal Workplace Drug Testing Program, Fed Register. 53(69): 11970-11979, 1988.
Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA) research Monograph 73, 1986.

L. Test Principle:

The UCP Rapid™ Drug Screening Tests 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 sufficient amount of

sample is applied to the sample pad of the test device, the sample migrates through the test device by capillary action. If the drug or drug metabolite concentration in the sample is below the cutoff level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line (in the test region) of the nitrocellulose membrane to form a red line, a negative result. If the concentration of drug in the sample is at a cutoff level or higher, it will bind with antibodies conjugates with colloidal gold particles so that no line will develop in the test region, a positive result. The colloidal gold antibody conjugate should bind to the C line (control region) and form a purple-colored band regardless of the presence of drug or drug metabolite in the urine specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision/Reproducibility studies were performed using commercially available drug standards in which the drug concentrations were confirmed by GC/MS. The standard was diluted in normal, drug-free human urine to give drug concentrations at the following levels: 0, 50% below cutoff, 25% below cut-off, cutoff, 25% above cut-off and 50% above cut-off. A total of 60 determinations were made at each concentration for each analyte. Testing was performed four times per day for five days by three operators (two are trained laboratory workers and one is a professional with limited laboratory experience) using one lot of testing devices in the sponsor’s facility. All samples tested at 0, -50% yielded negative results and all samples +50% yielded positive results. Within lot Precision Study data for -25%, cutoff and + 25% is summarized below:

25% Below Cutoff

	AMP	BAR	BZD	COC	MET	MDMA	MTD	OPI 300	OPI 2000	OXY	PCP	THC
Total # determinations	60	60	60	60	60	60	60	60	60	60	60	60
Concentration (ng/mL)	750	225	225	225	750	375	225	225	1500	75	18.75	37.5
#NEG/#POS	50/10	51/9	60/0	55/5	57/3	59/1	55/5	56/4	60/0	50/10	60/0	60/0
Precision	83%	85%	100%	92%	95%	98%	92%	93%	100%	83%	100%	100%

Cutoff

	AMP	BAR	BZD	COC	MET	MDMA	MTD	OPI 300	OPI 2000	OXY	PCP	THC
Total # determinations	60	60	60	60	60	60	60	60	60	60	60	60
Concentration (ng/mL)	1000	300	300	300	1000	500	300	300	2000	100	25	50
#NEG/#POS	3/57	2/58	4/56	0/60	2/58	4/56	4/56	3/57	4/56	0/60	3/57	2/58
Precision	95%	97%	93%	100%	97%	93%	93%	95%	93%	100%	95%	97%

25% Above Cutoff

	AMP	BAR	BZD	COC	MET	MDMA	MTD	OPI 300	OPI 2000	OXY	PCP	THC
Total # determinations	60	60	60	60	60	60	60	60	60	60	60	60
Concentration (ng/mL)	1250	375	375	375	1250	625	375	375	2500	125	31.25	62.5
#NEG/#POS	0/60	0/60	0/60	0/60	0/60	0/60	0/60	0/60	0/60	0/60	0/60	0/60
Precision	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Inter Lot Reproducibility:

To test inter lot reproducibility, normal human urine known to be drug-free was spiked with commercially available drug standard to the following levels: 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. Testing was performed using three different lot numbers, 20 samples of each lot were run at each of the concentrations for each drug over 30 days. All samples tested at 0, -50% yielded negative results and all samples +50% yielded positive results. Inter lot Precision Study data from -25%, cutoff and +25% is summarized below:

25% Below	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	20	20	20	18/2	17/3	18/2	90%	85%	90%	88%
BAR	20	20	20	17/3	18/2	17/3	85%	90%	85%	86.7%
BZD	20	20	20	16/4	17/3	18/2	80%	85%	90%	85%
COC	20	20	20	18/2	17/2	18/2	90%	85%	90%	88.3%
MET	20	20	20	18/2	17/3	16/4	90%	85%	80%	85%
MDMA	20	20	20	16/4	18/2	16/4	80%	90%	80%	83.3%
OPI 300	20	20	20	17/3	18/2	17/3	85%	90%	85%	86.7%
MTD	20	20	20	17/3	16/4	18/2	85%	80%	90%	85%
OPI 2000	20	20	20	17/3	16/4	18/2	85%	80%	90%	85%
OXY	20	20	20	18/2	18/2	17/3	90%	90%	85%	88.3%
PCP	20	20	20	18/2	16/2	18/2	90%	80%	90%	86.7%
THC	20	20	20	16/4	17/3	18/2	80%	85%	90%	85%

Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
BAR	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
BZD	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
COC	20	20	20	1/19	20/0	20/0	95%	100%	100%	98.3%
MET	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
MDMA	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OPI 300	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
MTD	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OPI 2000	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OXY	20	20	20	1/19	20/0	20/0	95%	100%	100%	98.3%
PCP	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
THC	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%

25% Above	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
BAR	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
BZD	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
COC	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
MET	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
MDMA	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OPI 300	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
MTD	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OPI 2000	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
OXY	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
PCP	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%
THC	20	20	20	20/0	20/0	20/0	100%	100%	100%	100%

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

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 that the correct technique has been used. Users are informed not to interpret the test if no red line appears in the control zone.

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. User should follow local, state and federal guidelines for testing QC material.

Stability:

Real time stabilities studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:
When stored at 2 – 30 °C product is good until expiration date which is 18 months.

d. Detection limit:

Sensitivity of UCP Rapid™ Drug Tests was characterized by validating the test performance around the claimed cutoff concentration of the test. The following targeted drugs were spiked into human urine known to be drug-free:

Test Name	Targeted Drug
Amphetamine (AMP)	d-Amphetamine
Barbiturates (BAR)	Secobarbital
Benzodiazepine (BZD)	Oxazepam
Cocaine (COC)	Benzoyllecgonine
Marijuana (THC)	11-nor- Δ^9 COOH
Methadone (MTD)	Methadone
Methamphetamine (MET)	d-Methamphetamine
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine
Opiates 300 (OPI300)	Morphine
Opiates 2000 (OPI2000)	Morphine
Oxycodone (OXY)	Oxycodone
Phencyclidine (PCP)	Phencyclidine

The cutoff of each drug test was determined by the lowest concentration of drug which produces at least 50% positive results in total numbers of determinations. 20 replicates were run at each drug concentration from 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. The results are summarized below:

Analyte	Drug-free Urine	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff
Amphetamine	100%	100%	10%	85%	100%	100%
Barbiturates	100%	100%	15%	95%	100%	100%
Benzodiazepine	100%	100%	100%	60%	90%	100%
Cocaine	100%	100%	15%	95%	100%	100%
Methamphetamine	100%	100%	10%	100%	100%	100%
MDMA	100%	100%	100%	55%	80%	100%
Opiates 300	100%	100%	15%	95%	100%	100%

Analyte	Drug-free Urine	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff
Opiates 2000	100%	100%	15%	100%	100%	100%
Methadone	100%	100%	100%	70%	95%	100%
Oxycodone	100%	100%	25%	100%	100%	100%
Phencyclidine	100%	100%	10%	95%	100%	100%
Cannabinoid	100%	100%	10%	90%	100%	100%

The data presented in this section is consistent with the results from the precision study. Based on the above data, sensitivity of the assay for the 12 analytes is as follows:

Amphetamine (AMP) 1000ng/mL	Methamphetamine (MDMA) 500ng/mL
Barbiturate (BAR) 300ng/mL	Methamphetamine (MET) 1000ng/mL
Benzodiazepine (BZD) 300ng/mL	Opiates (OPI 300) 300ng/mL
Cannabinoid (THC) 50ng/mL	Opiates (OPI 2000) 2000ng/mL
Cocaine (COC) 300ng/mL	Oxycodone (OXY) 100ng/mL
Methadone (MTD) 300ng/MI	Phencyclidine (PCP) 25ng/mL

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine/a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the tables below:

Amphetamine	
Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	1000
d,l-amphetamine	2500
l-amphetamine	50,000
(+)methamphetamine	>100,000
3,4-Methylenedioxyethylamphetamine(MDMA)	>100,000
Pseudoephedrine	200,000
3,4-Methylenedioxyamphetamine (MDA)	2,000
(±) Phenylpropanolamine (PPA)	75,000
Ephedrine	350,000

Methamphetamine and MDMA

Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	>100,000 for both
l-amphetamine	>100,000 and n/a
(+/-)methamphetamine	2,000 and >100,000
(+)methamphetamine	1,000 and >100,000
3,4-Methylenedioxyethylamphetamine(MDEA)	35,000 and 300
3,4-Methylenedioxymethamphetamine (MDMA)	2,000 and 500
3,4-Methylenedioxyamphetamine (MDA)	>100,000 and 50,000
(+) Phenylpropanolamine (PPA)	75,000 and not reported
Ephedrine	50,000 and not reported

Opiates 300 and 2000

Drug compound	Response equivalent to cutoff in ng/mL
6-monoacetylmorphine	600 and 5000
Codeine	300 and 2,000
Normorphone	100,000 for both
Hydrocodone	75,000 for both
Hydromorphone	3,500 and 7,000
Oxycodone	10,000 and 20,000
Morphine	300 and 2,000
Morphine-3- β -glucuronide	300 and 2,000
Oxymorphone	50,000 and 100,000
Thebaine	7,000 and 70,000

Cocaine

Compound	Response equivalent to cutoff in ng/mL
Benzoylcegonine	300
Ecgonine HCl	35,000
Cocaine	>100,000

Cannabinoids (THC)

Compound	Response equivalent to cutoff in ng/mL
Cannabinol	10,000
11-Nor- Δ^8 -Tetrahydrocannabinol carboxylic acid	50
11-Nor- Δ^9 -Tetrahydrocannabinol carboxylic acid	50
Δ^8 -Tetrahydrocannabinol	8,000
Δ^9 -Tetrahydrocannabinol	10,000
Cannabidiol	100,000

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
4-hydroxyphencyclidine	15,000
Phencyclidine	25

Barbiturates

Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Alphenal	400
Phenobarbital	300
Butalbital	500
Pentobarbital	600
Amobarbital	600
Aprobarbital	300
Barbital	300
Butabarbital	300
Butethal	200
Cyclopentobarbital	600

Benzodiazepines

Compound	Response equivalent to cutoff in ng/mL
Alprazolam	1000
Chlordiazepoxide	800
Diazepam	300
Oxazepam	300
Clonazepam	2500
Flunitrazepam	750
Nitrazepam	400
Bromazepam	25,000
Clobazam	400
Estazolam	500
Flurazepam	1000
Lorazepam	3000
Lormetazepam	10,000
Medazepam	50,000
Nordiazepam	800
Prazepam	5000
Temazepam	200

Methadone

Compound	Response equivalent to cutoff in ng/mL
Methadone	300
Doxylamine	50,000
(±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium	50,000

Oxycodone

Compound	Response equivalent to cutoff in ng/mL
Oxycodone	100
Morphine	50,000
Codeine	25,000
Morphine 3-β-D glucuronide	50,000
Hydromorphone	15,000
Normorphine	100,000
Oxymorphone	1500

The following list of substances showed no interference at a concentration of 100 ug/mL in either drug-free or drug positive urines:

Common Substances:	
Acetaminophen	Aspirin
Acetylsalicylic Acid	Atropine
Amikacin	Benzoic Acid
Amitriptyline	Oxalic Acid
Ampicillin	Caffeine
Arterenol	Methanol
Ethanol	Penicillin-G
Lidocaine	Phenylpropanalamine
Thioridazine	Ranitidine
Trifluoperazine	Salicylic Acid
Biological Materials:	
Albumin	Vitamin (L-Ascorbic Acid)
Bilirubin	Uric Acid
Creatine	Urine pH (4.5-9.0)
Hemoglobin	Urine Specific Gravity (1.002-1.035g/mL)
Glucose	

f. *Assay cut-off:*

The identified cutoff concentrations for amphetamine, cocaine, methamphetamine (MDMA), opiates 2000, Phencyclidine and THC are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). Analytical performance of the device around the cutoff is described in Section 1.M.d above. The test will yield a positive result when a given drug exceeds this concentration in the urine sample.

2. Comparison studies:

a. *Method comparison with predicate device:*

128 unaltered clinical urine samples per drug type were evaluated. Specimens obtained from reference laboratories were tested using the predicate device and the Gas Chromatography/Mass Spectrometry (GC/MS). For each drug test, approximately 10% of samples had drug concentration between 50% below the cutoff and the cutoff concentration, another 10% of samples had drug concentrations between the cutoff and 50% above the cutoff concentration. The study was performed at the sponsor's facility by one member of the sponsor's staff.

Comparison of UCP Rapid™ Drug Screening Test to the Predicate

		Predicate							
		AMP		BAR		BZO		COC	
		pos	neg	pos	neg	pos	neg	pos	neg
UCP Rapid™ Drug Screening Test	Positive	64	0	63	1	62	2	64	0
	Negative	1	63	1	63	2	62	0	64
%Agreement among Positive		100%		98%		97%		100%	
% Agreement among Negative			98%		98%		97%		100%

		Predicate							
		THC		MDMA		OPI 300		OPI 2000	
		pos	neg	pos	neg	pos	neg	pos	neg
UCP Rapid™ Drug Screening Test	Positive	64	0	62	2	64	0	64	0
	Negative	1	63	2	62	0	64	0	64
%Agreement among Positive		100%		97%		100%		100%	
% Agreement among Negative			98%		97%		100%		100%

		Predicate							
		MET		PCP		OXY		METHADONE	
		pos	neg	pos	neg	pos	neg	pos	neg
UCP Rapid™ Drug Screening Test	Positive	64	0	64	0	63	1	63	1
	Negative	1	63	1	63	1	63	02	62
%Agreement among Positive		100%		100%		98%		98%	
% Agreement among Negative			98%		98%		98%		97%

Candidate Device Results vs. stratified GC/MS Values

	Candidate Device Results	Negative by the predicate device or less than half the cutoff concentration by GC/MS analysis	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)	% Agreement (among positives and negatives)
AMP	Positive	0	0	11	52	100%
	Negative	52	12	1	0	98%
BAR	Positive	0	1	11	52	98%
	Negative	52	11	1	0	98%
BZD	Positive	0	2	10	52	97%
	Negative	52	10	2	0	97%
COC	Positive	0	0	12	52	100%
	Negative	52	12	0	0	100%
MET	Positive	0	0	11	52	100%
	Negative	52	12	1	0	98%
MDMA	Positive	0	2	10	52	97%
	Negative	52	10	2	0	97%
MTD	Positive	0	1	10	52	98%
	Negative	52	11	2	0	97%
OPI 300	Positive	0	0	12	52	100%
	Negative	52	12	0	0	100%
OPI 2000	Positive	0	0	12	52	100%
	Negative	52	12	0	0	100%
OXY	Positive	0	1	11	52	98%
	Negative	52	11	1	0	98%
PCP	Positive	0	0	11	52	100%
	Negative	52	12	1	0	98%
THC	Positive	0	0	11	52	100%
	Negative	52	12	1	0	98%

Comparison testing was performed between the test strip device and the cassette device. Normal human urine known to be drug-free was spiked with commercially available drug standard to the following levels: 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. Testing was performed using the same lot number, 20 samples were run at each of the concentrations for each drug. For each drug at each drug concentration the results were identical.

b. Matrix comparison:

Not applicable. This device is only for use with urine samples.

3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - b. *Clinical specificity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - 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.