

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

A. 510(k) Number:

k073078

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, methamphetamine, 3,4-methylenediozymethamphetamine (MDMA), buprenorphine, benzodiazepines, barbiturates, oxycodone, methadone, phencyclidine, propoxyphene, opiates, cocaine, tricyclics antidepressants and THC.

D. Type of Test:

Qualitative Lateral Flow Immunoassay

E. Applicant:

American Bio Medica Corporation

F. Proprietary and Established Names:

Rapid Tox Cup

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LAG	II	862.3610 Methamphetamine test system	91 (Tox)
DJG	II	862.3650, Enzyme Immunoassay, Opiates	91 (Tox)
DIO	II	862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites	91 (Tox)
DKE	II	862.3870	91 (Tox)

Product Code	Classification	Regulation Section	Panel
		Cannabinoid test system	
LCM	Unclassified	862.3100 Enzyme immunoassay, Phencyclidine	91 (Tox)
DKZ	II	862.3100 Amphetamine test system	91 (Tox)
JXM	II	862.3170 Enzyme immunoassay, Barbiturate	91 (Tox)
DJR	II	862.3620 Methadone test system	91 (Tox)
LFI	II	862.3910 Tricyclic antidepressant drugs test system	91 (Tox)
JXN	II	862.3700 Propoxyphene test system	91 (Tox)

H. Intended Use:

1. Intended use(s):

See indications for use section below.

2. Indication(s) for use:

Rapid Tox Cup™ is a one-step, lateral flow immunoassay contained in a polypropylene cup for the simultaneous detection of abused drugs in urine. 'Rapid Tox Cup'- is intended for use in the qualitative detection of the following drugs of abuse in human urine at the following levels:

Amphetamine	1000 ng/mL
Amphetamine	500 ng/mL
Methamphetamine	1000 ng/mL
Methamphetamine	500 ng/mL
3,4-methylenedioxymethamphetamine (MDMA)	1000 ng/mL
3,4-methylenedioxymethamphetamine (MDMA)	500 ng/mL
Buprenorphine	12.5 ng/mL
Benzodiazepines (Oxazepam)	300 ng/mL
Barbiturates (Butabarbital)	300 ng/mL
Oxycodone	100 ng/mL
Methadone	300 ng/mL
Phencyclidine	25 ng/mL

Propoxyphene	300 ng/mL
Opiates	300 ng/mL
Opiates	2000 ng/mL
Cocaine (Benzoylecgonine)	300 ng/mL
Cocaine (Benzoylecgonine)	150 ng/mL
Tricyclic Antidepressants (Amitriptyline)	1000 ng/mL
THC/ Cannabinoids (11 nor Δ 9-THC-9-carboxylic acid)	50 ng/mL

‘Rapid Tox Cup’ is intended for professional use. It is not intended for over-the-counter sale to non-professionals. This assay is a simplified screening method that provides only a preliminary result for use in determining the need for additional or confirmatory testing, i.e. gas-chromatography/mass spectrometry (GC/MS).

The barbiturate BAR, benzodiazepine BZO and tricyclic antidepressant TCA will yield preliminary positive results when BAR, BZO, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, or tricyclic antidepressant in urine.

‘Rapid Tox Cup’ provides only a preliminary analytical result. A more specific alternate method must be used in order to obtain a more confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are used.

3. Special conditions for use statement(s):

The barbiturate BAR, benzodiazepine BZO and tricyclic antidepressant TCA will yield preliminary positive results when BAR, BZO, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, or tricyclic antidepressant in urine.

‘Rapid Tox Cup’ provides only a preliminary analytical result. A more specific alternate method must be used in order to obtain a more confirmed analytical result. GC/MS is the preferred confirmatory method. Clinical and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are used.

4. Special instrument requirements:

Not applicable

I. Device Description:

The Rapid Tox Cup kit contains directions for use/package insert, 25 individually

foil-pouched test devices. Each device consists of up to 8 multi drug strips that contain up to 5 drugs per strip. Strips are produced in many configurations The cups are preassembled and the drugs contained within are tamper proof and are not interchangeable.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Amedica Bio Medica Rapid Tec 4, Rapid Tec 5, and Rapid Tox

2. Predicate K number(s):

k041712, k023869 and k053359, respectively

3. Comparison with predicate:

Similarities			
	Rapid Tox Cup	Rapid Tox	Rapid Tec (4 and 5)
Device Test Strips	Identical Strips	Identical Strips	Identical Strips
Results Reading	Identical	Identical	Identical
Confirmation	Sample can be sent in the cup itself or in a separate container.	Sample sent out in separate container.	Sample sent out in separate container.
Quality Control	Control Line Observation for valid test	Control Line Observation for valid test	Control Line Observation for valid test
Storage	Identical	Identical	Identical
Shelf Life	2 years	2 years	2 years
Rapid Reader compatible	No	Yes	Yes
Calibration Required	No	No	No
Cross Reactivity	Over 500 drugs tested, same results	Over 500 drugs tested, same results	Over 500 drugs tested, same results
Drug ID being tested	Drug abbreviation adjacent to test line	Drug abbreviation adjacent to test line	Drug abbreviation adjacent to test line
Differences			
Device Housing	Cup Format	Cassette Format	Card Format
Sampling Method	Fill Cup	Dip or Pipette	Dip or Pipette
Time to Results	3-5 minutes	3-5 minutes	5-7 minutes
Drug Testing Quantity	Can test to 14 drugs	Can test up to 10 drugs	Can test up to 5 drugs
Rapid Reader	No	Yes	Yes

compatible			
Stability Test Result	8 hours	8 hours	1 hour
Minimum Sample Volume	5 mL	100 µl	100 µl

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

None referenced

L. Test Principle:

The immunoassays employed in each test strip of the ‘Rapid Tox Cup’ are based on the reaction between antigens and antibodies. Each assay consists of a membrane strip onto which up to five different drug conjugates have been immobilized. A colloidal gold-antibody complex consisting of up to five antibodies is dried at one end of the membrane. In the absence of any drug in the urine sample, the colloidal gold-multi-antibody complex moves with the urine sample by capillary action to contact the immobilized drug conjugate. Antibody-antigen reactions occur forming a visible line in all “test” areas. The formation of a visible line in the test areas occur when the test is negative for the adjacent labeled drug. When drug is present in the urine sample, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the limited antibody binding sites on the colloidal gold-labeled antibody complex, thus preventing attachment of the labeled antibody to the drug conjugate. An absence of a color line in any of the test areas is indicative of a positive result. A control line, comprised of a different antibody/antigen reaction, is present on the membrane strip. The control line is not influenced by the presence or absence of a drug in the urine, and therefore, should be present in all reactions. Negative urine will produce up to six colored lines, and a positive sample will produce a colored line in the control area and no colored line(s) in the test area corresponding to the individual analyte(s) that are present in the sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Reproducibility was evaluated using commercially available control materials. Each sample, at each concentrations of each drug, was tested 4 times a day, twice a day for 5 days. A total of 40 determinations, at each concentration, were made.

Amphetamine-500 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
250	40	40 negative
400	40	38 negative
500	40	40 positive
625	40	40 positive

Amphetamine- 1000 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
500	40	40 negative
850	40	39 negative
1000	40	40 positive
1250	40	40 positive

Barbiturates- 300 ng/mL of butalbital

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
150	40	40 negative
225	40	40 negative
300	40	40 positive
375	40	40 positive

Benzodiazepines- 300 ng/mL of oxazepam

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
150	40	40 negative
225	40	40 negative
300	40	40 positive
375	40	40 positive

Methamphetamine-500 ng/mL

Conc. (ng/ml)	Total Determinations	Results
No drug present	40	40 negative
250	40	40 negative
375	40	36 negative
500	40	40 positive
625	40	40 positive

Methamphetamine- 1000 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
500	40	40 negative
750	40	40 negative
1000	40	40 positive
1250	40	40 positive

Buprenorphine- 12.5 ng/mL

Concentration (ng/mL)	Total Number of Determinations	Result
No drug present	40	40 negative
3.2	40	40 negative
6.3	40	40 negative
9.4	40	40 negative
12.5	40	40 positive
15.6	40	40 positive

Cocaine- 150 ng/mL

Concentration (ng/mL)	Total Number of Determinations	Result
No drug present	40	40 negative
75	40	40 negative
120	40	38 negative
150	40	40 positive
187	40	40 positive

Cocaine- 300 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
150	40	40 negative
225	40	40 negative
300	40	40 positive
375	40	40 positive

THC- 50 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
25	40	40 negative
38	40	40 negative
50	40	40 positive
75	40	40 positive

Opiates-300 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
150	40	40 negative
225	40	39 negative
300	40	40 positive
375	40	40 positive

Opiates-2000 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
1000	40	40 negative
1500	40	40 negative
2000	40	40 positive
2500	40	40 positive

Oxycodone-100 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No Drug Present	40	40 negative
25	40	40 negative
50	40	40 negative
75	40	40 negative
100	40	40 positive
125	40	40 positive

Methadone- 300 ng/mL

Conc. (ng/mL)	#	Result
No drug present	40	40 negative
150	40	40 negative
225	40	40 negative
300	40	40 positive
375	40	40 positive

MDMA-500 ng/mL

Conc. (ng/mL)	Total Determinations	Results
No drug present	40	40 negative
250	40	40 negative
375	40	40 negative
500	40	40 positive
625	40	40 positive

MDMA- 1000 ng/mL

Conc. (ng/mL)	Total Determinations	Result
No drug present	40	40 negative
500	40	40 negative
750	40	40 negative
1000	40	40 positive
1250	40	40 positive

TCA- 1000 ng/mL of nortriptyline

Conc. (ng/mL)	Total Determinations	Result
No drug present	40	40 negative
500	40	40 negative
750	40	39 negative
1000	40	40 positive
1250	40	40 positive

Propoxyphene- 300 ng/mL

Conc. (ng/mL)	Total determinations	Result
No drug present	40	40 negative
150	40	40 negative
225	40	40 negative
300	40	40 positive
375	40	40 positive

PCP- 25 ng/mL

Conc. (ng/mL)	Total Determinations	Result
No drug present	40	40 negative
13	40	40 negative
19	40	39 negative
25	40	40 positive
38	40	40 positive

b. Linearity/assay reportable range:

Not applicable. The assay is 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 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:*

See cutoff section below.

e. *Analytical specificity:*

The Rapid Tox Cup was evaluated for interference. A high concentration stock solution of each analyte was serially diluted (1:1) until negative results were obtained. The lowest concentrations that gave positive results are listed as the cross-reacting concentration in the package insert.

Amphetamine-500 ng/mL

Compound	Conc. (ng/mL)
d-amphetamine	500
d,l-amphetamine	500
l-amphetamine	20,000
Phentermine (α,α -dimethiphenethylamine)	1250
(+/-)-Methyenedioxyamphetamine	750

Amphetamine -1000 ng/mL

Compound	Conc. (ng/mL)
d-amphetamine	1000
d,l-amphetamine	1000
l-amphetamine	20,000
Phentermine (α,α -dimethiphenethylamine)	1250
(+/-)-Methyenedioxyamphetamine	750

Barbiturates- 300 ng/mL

Compound	Conc. (ng/mL)
Allobarbital	300
Amobarbital	1000
Aprobarbitol	150
Barbital	1250
Butabarbital	750
Butalbital	300
Butehal	500
5,5 Diphenylhydantoin	2500
Pentobarbital	300
Secobarbital	150
Tabutal	75

Benzodiazepines- 300 ng/mL

Compound	Conc. (ng/mL)
Alph-hydroxyalprazolam	10,000
Alprazolam	75
Bromazepam	400
Chlordiazepoxide	150
Clobazam	100
Clonazepam	300
Clorazepate	100
Desalkylfurazepam	500
Desmethyldiazepam	100
N-desmethyflunitrazepam	50
Diazepam	100
Estazolam	100
Flunitrazepam	150
2-hydroxyethylflurazepam	5000
4-hydroxynordiazepam	4000
Lorazepam	2200
Lorazepam glucuronide	250
Lormetazepam	500
Nitrazepam	75
Nordiazepam	150
Oxazepam	300
Oxazepam glucuronide	250
Sulindac	7500
Temazepam	100
Temazepam Glucuronide	75
Triazolam	1500

Methamphetamine- 500 ng/mL

Compound	Conc. (ng/ml)
(+)- methamphetamine	500
(+/-)- methamphetamine	725
(+/-)-3,4-methylenedioxyamphetamine (MDMA)	725
(+/-)-methylene-n-ethylmethamphetamine (MDEA)	20,000
Procaine	60,000
Ranitidine	50,000
Trimethobezamide	20,000

Methamphetamine 1000 ng/mL

Compound	Conc. (ng/mL)
(+)- methamphetamine	500
(+/-)- methamphetamine	1000
(+/-)-3,4-methylenedioxyamphetamine (MDMA)	2500
(+/-)-methylene-n-ethylmethamphetamine (MDEA)	20,000
Procaine	60,000
Ranitidine	50,000
Trimethobezamide	20,000

Buprenorphine 12.5 ng/mL

Compound	Conc. (ng/mL)
Buprenorphine	12.5
Buprenorphine glucuronide	10
Codeine	10000
Hydrocodone	25000
Lysergic Acid Diethylamide (LSD)	50000
Metoclopramide	50000
Morphine	25000
Nalmefene	75000
Nalophine	100
Norbuprenorphine	10000
Norbuprenorphine glucuronide	10000

Cocaine- 150 ng/mL

Compound	Conc. (ng/mL)
Benzoyllecgonine	300
Cocaethylene	300
Cocaine	100
Metoclopramide	80,000
Procaine	75,000

Cocaine 300 ng/mL

Compound	Conc. (ng/mL)
Benzoyllecgonine	300

Cocaethylene	300
Cocaine	100
Metoclopramide	80,000
Procaine	75,000

THC 50 ng/mL

Compound	Conc. (ng/mL)
11-hydroxy-delta-9-THC	5000
11-nor-D8-carboxy-delta-9-THC	50
11-nor-D9-carboxy-delta-9-THC	50
11-nor-D9-tetrahydrocannabinol-9-carboxylic acid glucuronide	2500
Delta-8-tetrahydrocannabinol	20,000
Delta-9-tetrahydrocannabinol	20,000

Opiates- 300 ng/mL

Compound: Opiates 300	Conc. (ng/mL)
6-acetyl morphine	500
Codeine	100
Eserine	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2000
Hydrocodone	1250
Morphine	300
Morphine-3-Glucuronide	75
Nalorphine	500
Norcodeine	35,000
Oxycodone	75,000
Thebaine	13,000

Opiates- 2000 ng/mL

Compound: Opiates 2000	Conc. (ng/mL)
6-acetyl morphine	1000
Codeine	800
Ethylmorphine	400
Heroin	10,000
Hydromorphone	2000
Hydrocodone	5000
Morphine	1600
Morphine-3 Glucuronide	2000
Oxycodone	50,000
Thebaine	26,000

Oxycodone-100 ng/mL

Compound	Conc. (ng/mL)
6-Acetylcodeine	25,000
6-Acetylmorphine	75,000
Codeine	12,000
Dihydromorphone	3,125
Hydromorphone	2,500
Hydrocodone	625
Morphine	6250
Noroxycodone	50,000
Oxycodone	100
Oxymorphone	100
Thebaine	25,000

Methadone- 300 ng/mL

Compound	Conc. (ng/mL)
Benzotropine Methane Sulfonate	30,000
Diphenhydramine	50,000
Disopyramide	60,000
Isopropamide	500
Methadone	300
(-)-alpha-Methadol	300
(-)-alpha-Acetylmethadol (LAAM)	2,500
Procyclide	50,000
Suxibuzone	25,000

MDMA- 500 ng/mL

Compound	Conc. (ng/mL)
(+/-)-3,4-methylenedioxymethamphetamine MDMA	500
(+/-)-methamphetamine	500
(+)-methamphetamine	500
(+/-)-3,4-methylene-n-ethylmethamphetamine (MDEA)	20,000
Procaine	50,000
Ranitidine	40,000
Trimethobenzamide	20,000

MDMA 1000 ng/mL

Compound	Conc. (ng/mL)
(+)- methamphetamine	500
(+/-)- methamphetamine	1000
(+/-)-3,4-methylenedioxymethamphetamine (MDMA)	1000
(+/-)-methylene-n-ethylmethamphetamine (MDEA)	20,000
Procaine	60,000
Ranitidine	50,000
Trimethobezamide	20,000

TCA 1000 ng/mL

Compound	Conc. (ng/mL)
Amitriptyline	1000
Clomipramine	75000
Cyclobenzaprine	8000
Cyproheptadine	50,000
Desipramine	1000
Doxepin	5000
Imipramine	1000
Norclomipramine	2500
Nordoxepin	500
Nortriptyline	1000
Promazine	12,500
Protriptyline	2000
Trimipramine	3000

Propoxyphene/Norpropoxyphene- 300 ng/mL

Compound	Conc. (ng/mL)
Propoxyphene	300
Norpropoxyphene	300

Phencyclidine- 25 ng/mL

Compound	Conc. (ng/mL)
Phencyclidine	25
4-hydroxyphencyclidine	90
Phencyclidine Morpholine	625

f. Assay cut-off:

The Rapid Tox Cup is designed to detect the concentrations listed in the indications for use section H.2. Ten determinations were made at each concentration of each single analyte. Sensitivity was defined as the lowest concentration of drug that produced positive results in all 10 replicates.

Amphetamine- 500 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
250	10	0	10
400	10	1	9
500	10	10	0
625	10	10	0

Amphetamine-1000 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
500	10	0	10
850	10	1	9
1000	10	10	0
1250	10	10	0

Barbiturates- 300 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

Benzodiazepines- 300 ng/mL of oxazepam

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

Methamphetamine-500 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
250	10	0	10
375	10	0	10
500	10	10	0
625	10	10	0

Methamphetamine- 1000 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
500	10	0	10
750	10	0	10
1000	10	10	0
1250	10	10	0

Buprenorphine- 12.5 ng/mL of buprenorphine

Conc. ng/mL	#	# Positive	# Negative
No Drug	10	0	10
2.5	10	0	10
5.0	10	0	10
7.5	10	0	10
10.0	10	1	9
12.5	10	10	0
15.0	10	10	0

Cocaine-150 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
75	10	0	10
120	10	1	9
150	10	10	0
187	10	10	0

Cocaine- 300 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

THC- 50 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
25	10	0	10
38	10	0	10
50	10	10	0
75	10	10	0

Opiates- 300 ng/mL

Conc. Morphine (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

Opiates 2000 ng/mL

Conc. Morphine (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
1000	10	0	10
1500	10	0	10
2000	10	10	0
2500	10	10	0

Oxycodone 100 ng/mL

Drug Concentration (ng/mL)	#	#Positive	#Negative
No drug present	10	0	10
50	10	0	10
75	10	0	10
100	10	10	0
125	10	10	0

Methadone 300 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

MDMA- 500 ng/mL

Conc. (ng/mL)	#	#Positive	# Negative
No drug present	10	0	10
250	10	0	10
375	10	0	10
500	10	10	0
625	10	10	0

MDMA- 1000 ng/mL

Conc. (ng/mL)	#	#Positive	# Negative
No drug present	10	0	10
500	10	0	10
800	10	1	9
1000	10	10	0
1250	10	10	0

TCA- 1000 ng/mL of nortriptyline

Concentration (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
500	10	0	10
750	10	0	10
1000	10	10	0
1250	10	10	0

Propoxyphene 300 ng/mL

Conc. (ng/mL)	#	# Positive	# Negative
No drug present	10	0	10
150	10	0	10
225	10	0	10
300	10	10	0
375	10	10	0

PCP 25 ng/mL

Phencyclidine (ng/mL)	#	# Positive	# Negative
0	10	0	10
13	10	0	10
19	10	1	9
25	10	10	0
37	10	10	0

2. Comparison studies:

a. *Method comparison with predicate device:*

Clinical urine specimens were obtained from a reference laboratory and tested using the Rapid Tox Cup, Gas Chromatography Mass Spectrometry (GC/MS), HPLC for tricyclic antidepressant and LC/MS for buprenorphine. Butalbital, phenobarbital, and pentobarbital samples were evaluated for barbiturates. Alprazolam, oxazepam, lorazepam, nordiazepam, and temazepam samples were evaluated for benzodiazepines. Amitriptyline, nortriptyline, imipramine and desipramine samples were included in the tricyclic antidepressant analysis. Buprenorphine samples were tested via an enzymatic hydrolysis method, followed by centrifugation and direct analysis of the total buprenorphine concentration.

	Candidate Device Results	No drug present	Negative (by predicate device or less than 50% 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
Amp 500 ng/mL	Positive		0	4	24	16	100%
	Negative	50	15	24	0	0	91%
Amp 1000 ng/mL	Positive		0	7	21	19	100%
	Negative	50	13	21	0	0	83%
Bar 300 ng/mL	Positive		0	3	11	34	100%
	Negative	50	16	12	0	0	90%
Benzo 300 ng/mL	Positive		0	7	13	27	100%
	Negative	50	15	21	0	0	84%
Methamp 500 ng/mL	Positive		0	4	22	30	100%
	Negative	50	6	16	0	0	84%
Methamp 1000 ng/mL	Positive		0	8	14	26	100%
	Negative	50	10	26	0	0	82%
Bupren 12.5 ng/mL	Positive		0	6	11	30	100%
	Negative	50	13	20	0	0	85%
COC 150 ng/mL	Positive		0	7	11	33	100%
	Negative	50	17	15	0	0	82%
COC 300 ng/mL	Positive		0	4	15	30	100%
	Negative	50	15	17	0	0	89%
THC 50 ng/mL	Positive		0	4	17	27	100%
	Negative	50	15	17	0	0	89%
Opiate 300 ng/mL	Positive		0	1	10	50	100%
	Negative	50	11	8	0	0	95%
Opiate 2000 ng/mL	Positive		0	11	12	28	100%
	Negative	50	29	19	0	0	81%
Oxycodone 100 ng/mL	Positive		0	1	9	37	100%
	Negative	50	10	13	0	0	93%
Methadone 300 ng/mL	Positive		0	7	10	30	100%
	Negative	50	22	14	0	0	84%
MDMA 500 ng/mL	Positive		0	8	9	31	100%
	Negative	50	16	15	0	0	80%
MDMA 1000 ng/mL	Positive		0	9	8	33	100%
	Negative	50	6	29	0	0	80%
TCA 1000 ng/mL	Positive		0	5	15	25	100%
	Negative	50	15	17	0	0	86%
Propoxyphene 300 ng/mL	Positive		0	4	7	31	100%
	Negative	50	8	14	0	0	85%
PCP 25 ng/mL	Positive		0	4	7	31	100%
	Negative	50	8	14	0	0	85%

b. Matrix comparison:

Not applicable.

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.