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

A. 510(k) Number:

k170222

B. Purpose for Submission:

Modification to the test strip size of previously cleared Prescription-only device and addition of Over The Counter (OTC) claim.

C. Measurands:

Amphetamines, barbiturates, benzodiazepines, buprenorphine, cocaine, MDMA, methadone, methamphetamines, opiates, oxycodone, phencyclidine, THC/Cannabinoids, and tricyclic antidepressants.

D. Type of Test:

Qualitative lateral flow immunoassay

E. Applicant:

American Bio Medica Corporation, Inc.

F. Proprietary and Established Names:

Rapid TOX Cup II

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DKZ	Class II	21CFR 862.3100, Amphetamine Test System	Toxicology (91)
DIS	Class II	21 CFR 862.3150, Barbiturates Test System	Toxicology (91)
JXM	Class II	21 CFR 862.3170, Benzodiazepines Test System	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)

Product Code	Classification	Regulation Section	Panel
DIO	Class II	21 CFR 862.3250, Cocaine and metabolites Test System	Toxicology (91)
LAF	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
DJR	Class II	21 CFR 862.3620, Methadone Test System	Toxicology (91)
LCM	Unclassified, 510(k) required	Enzyme Immunoassay, Phencyclidine	Toxicology (91)
LDJ	Class II	21 CFR 862.3870 Cannabinoid test system	Toxicology (91)
LFG	Class II	21 CFR 862.3910, Tricyclic antidepressant drugs test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use.

2. Indication(s) for use:

The Rapid TOX Cup II is an in vitro diagnostic drugs of abuse testing device intended for use in the qualitative detection of the following drugs of abuse testing in a human urine specimen:

Analyte	Calibrator	Cutoff (ng/mL)
Amphetamine	D-amphetamine	1000
Amphetamine	D-amphetamine	500
Barbiturates (Butalbital)	Butalbital	300
Benzodiazepines (Oxazepam)	Oxazepam	300
Buprenorphine	Buprenorphine	12.5
Cocaine	Benzoylecgonine	300
Cocaine	Benzoylecgonine	150
MDMA	MDMA (Methylenedioxymethamphetamine)	500
Methadone	Methadone	300
Methamphetamine	D-methamphetamine	1000
Methamphetamine	D-methamphetamine	500
Opiates	Morphine	2000
Opiates	Morphine	300
Oxycodone	Oxycodone	100
Phencyclidine	Phencyclidine	25
Marijuana	11-nor-Δ9-THC-9- carboxylic-acid	50
Tricyclic Antidepressants	Nortriptyline	1000

The test is intended for over-the-counter use.

This assay may yield positive results when barbiturates, benzodiazepines, or tricyclic antidepressants are ingested at or above therapeutic doses. There are no uniformly recognized cutoff levels for barbiturates, benzodiazepines, or tricyclic antidepressants in urine. The assay is not intended to distinguish between prescription use or abuse of these drugs.

Rapid TOX Cup II 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):

   For over-the-counter, in vitro diagnostic use only.

4. Special instrument requirements:

   Not applicable, as the devices are visually-read single-use devices.

I. Device Description:

The devices consist of:

- A test cup (and lid) with 3 to 5 drug test strips with each strip testing for either 1 or 4 drugs simultaneously. Configuration 1 provides 5 test strips to test for a total of 14 drugs. Configuration 2 provides 3 test strips to test for a total of 12 drugs. The test cup and lid come in a sealed foil pouch.
- Package insert (instructions for use)
- Pre-addressed mailing box, plastic transport bag and identification label to send the sample for confirmation lab testing.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Rapid TOX Cup

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

   k073078

3. Comparison with predicate:

Similarities		
Item	Candidate Device: Rapid TOX Cup II	Predicate – k073078 Rapid TOX Cup
Specimen	Urine	Same
Test Format	Cup	Same
Intended Use	Qualitative detection of one or more drugs of abuse	Same
Methodology	Qualitative one-step lateral flow immunoassay	Same

Differences		
	Candidate Device: Rapid TOX Cup II	Predicate – k073078 Rapid TOX Cup
Use Setting	Over-the-counter use	For professional use only
Analytes	Amphetamine 1000 ng/mL	Amphetamine 1000 ng/mL

Differences		
	Candidate Device: Rapid TOX Cup II	Predicate – k073078 Rapid TOX Cup
	Amphetamine 500 ng/mL Methamphetamine 1000 ng/mL Methamphetamine 500 ng/mL 3,4-methylenedioxymethamphetamine (MDMA) 500 ng/mL Buprenorphine 12.5 ng/mL Benzodiazepines (Oxazepam) 300 ng/mL Barbiturates (Butalbital) 300 ng/mL Oxycodone 100 ng/mL Methadone 300 ng/mL Phencyclidine 25 ng/mL Opiates 300 ng/mL Opiates 2000 ng/mL Cocaine (Benzoylecgonine) 300 ng/mL Cocaine (Benzoylecgonine) 150 ng/mL Tricyclic Antidepressants (Nortriptyline) 1000 ng/mL THC/Cannabinoids (11 norΔ9-THC-9-carboxylic acid) 50 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 (Butalbital) 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 (Nortriptyline) 1000 ng/mL THC/Cannabinoids (11 norΔ9-THC-9-carboxylic acid) 50 ng/mL
Test Strip size	64 mm x 3.5 mm	84 mm x 5 mm
Jar and insert size	Insert is a smaller size to accommodate smaller test strips; Jar is same size (8oz) with a wider mouth to facilitate sample collection	Insert accommodates strip size Jar is 8oz.
Cup composition	Polyethylene	Polypropylene

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

None referenced.

L. Test Principle:

Each Rapid TOX Cup II test device contains test strips for several drugs of abuse. The test

strip consists of a membrane strip with an immobilized drug conjugate. A colloidal gold-labeled antibody complex is dried at one end of the membrane. The specifically labeled drug (drug conjugate) competes for antibody binding sites with drugs or metabolites that may be present in the urine specimen.

An internal quality control line, comprised of a different antibody/antigen reaction is contained in on each membrane strip. The control line is not influenced by the presence or absence of drug analytes in the urine specimen, and therefore, it should be visible in all samples tested.

In the absence of specified drug(s) in the urine specimen, the colloidal gold-labeled antibody complex moves with the urine by capillary action to contact the immobilized drug conjugate. An antibody-antigen reaction occurs forming a visible line in the "test" area. The formation of two (2) visible lines (control and test lines) occurs when the test is negative or below the cut-off for the drug.

When a drug analyte is present in the urine specimen, the drug or metabolite will compete with the immobilized drug conjugate in the test area for the antibody binding sites on the colloidal gold-labeled antibody complex. If a sufficient amount of drug analyte is present, it will fill all of the available binding sites, thus preventing attachment of the labeled antibody to the drug conjugate. The formation of a control line, and the absence of a test line is indicative of a preliminary positive result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

Each analyte for the precision study was tested at the following concentrations: Negative, and -75%, -50%, -25%, +25%, +50% and +75% of the specific cutoff for each drug assay. The panels were blinded and randomized prior to testing. Testing was performed using 3 lots of ABMC test strips and was performed once a day by 3 operators over 12 consecutive days, and the results of this testing are summarized as follows for each device.

Amphetamines 1000

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
250	-75%	36 neg / 0 pos
500	-50%	36 neg / 0 pos
750	-25%	33 neg / 3 pos
1250	+25%	0 neg / 36 pos
1500	+50%	0 neg / 36 pos
1750	+75%	0 neg / 36 pos

Methamphetamines 1000

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
250	-75%	36 neg / 0 pos
500	-50%	36 neg / 0 pos
750	-25%	31 neg / 5 pos
1250	+25%	0 neg / 36 pos
1500	+50%	0 neg / 36 pos
1750	+75%	0 neg / 36 pos

Amphetamines 500

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
125	-75%	36 neg / 0 pos
250	-50%	36 neg / 0 pos
375	-25%	27 neg / 9 pos
625	+25%	0 neg / 36 pos
750	+50%	0 neg / 36 pos
875	+75%	0 neg / 36 pos

Methamphetamines 500

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
125	-75%	36 neg / 0 pos
250	-50%	36 neg / 0 pos
375	-25%	31 neg / 5 pos
625	+25%	0 neg / 36 pos
750	+50%	0 neg / 36 pos
875	+75%	0 neg / 36 pos

MDMA 500

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
125	-75%	36 neg / 0 pos
250	-50%	36 neg / 0 pos
375	-25%	28 neg / 8 pos
625	+25%	0 neg / 36 pos
750	+50%	0 neg / 36 pos
875	+75%	0 neg / 36 pos

Cocaine 300

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
75	-75%	36 neg / 0 pos
150	-50%	36 neg / 0 pos
225	-25%	33 neg / 3 pos
375	+25%	0 neg / 36 pos
450	+50%	0 neg / 36 pos
525	+75%	0 neg / 36 pos

Cocaine 150

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
37.5	-75%	36 neg / 0 pos
75	-50%	36 neg / 0 pos
112.5	-25%	32 neg / 4 pos
187.5	+25%	0 neg / 36 pos
225	+50%	0 neg / 36 pos
262.5	+75%	0 neg / 36 pos

Opiates 2000

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
500	-75%	36 neg / 0 pos
1000	-50%	36 neg / 0 pos
1500	-25%	30 neg / 6 pos
2500	+25%	0 neg / 36 pos
3000	+50%	0 neg / 36 pos
3500	+75%	0 neg / 36 pos

Opiates 300

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
75	-75%	36 neg / 0 pos
150	-50%	36 neg / 0 pos
225	-25%	30 neg / 6 pos
375	+25%	0 neg / 36 pos
450	+50%	0 neg / 36 pos
525	+75%	0 neg / 36 pos

Benzodiazepines 300

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
75	-75%	36 neg / 0 pos
150	-50%	36 neg / 0 pos
225	-25%	30 neg / 6 pos
375	+25%	0 neg / 36 pos
450	+50%	0 neg / 36 pos
525	+75%	0 neg / 36 pos

Barbiturates 300

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
75	-75%	36 neg / 0 pos
150	-50%	36 neg / 0 pos
225	-25%	30 neg / 6 pos
375	+25%	0 neg / 36 pos
450	+50%	0 neg / 36 pos
525	+75%	0 neg / 36 pos

Methadone 300

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
75	-75%	36 neg / 0 pos
150	-50%	36 neg / 0 pos
225	-25%	34 neg / 2 pos
375	+25%	0 neg / 36 pos
450	+50%	0 neg / 36 pos
525	+75%	0 neg / 36 pos

PCP 25

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
6.25	-75%	36 neg / 0 pos
12.5	-50%	36 neg / 0 pos
18.75	-25%	33 neg / 3 pos
31.25	+25%	0 neg / 36 pos
37.5	+50%	0 neg / 36 pos
43.75	+75%	0 neg / 36 pos

THC 50

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
12.5	-75%	36 neg / 0 pos
25	-50%	36 neg / 0 pos
37.5	-25%	35 neg / 1 pos
62.5	+25%	0 neg / 36 pos
75	+50%	0 neg / 36 pos
87.5	+75%	0 neg / 36 pos

TCA 1000

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
250	-75%	36 neg / 0 pos
500	-50%	36 neg / 0 pos
750	-25%	30 neg / 6 pos
1250	+25%	0 neg / 36 pos
1500	+50%	0 neg / 36 pos
1750	+75%	0 neg / 36 pos

Buprenorphine 12.5

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
3.125	-75%	36 neg / 0 pos
6.25	-50%	36 neg / 0 pos
9.375	-25%	33 neg / 3 pos
15.625	+25%	0 neg / 36 pos
18.75	+50%	0 neg / 36 pos
21.875	+75%	0 neg / 36 pos

Oxycodone 100

Concentration (ng/mL)	% of cutoff	Results (Neg / Pos)
0	0	36 neg / 0 pos
25	-75%	36 neg / 0 pos
50	-50%	36 neg / 0 pos
75	-25%	35 neg / 1 pos
125	+25%	0 neg / 36 pos
150	+50%	0 neg / 36 pos
175	+75%	0 neg / 36 pos

b. *Linearity/assay reportable range:*

Not applicable. These devices are intended for qualitative use only.

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

The device has internal process controls. A control line appears in the control region confirming that sufficient sample volume has been applied to the test strip and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if the colored line does not appear in the control region. There are no external controls supplied with the device.

Device stability has been evaluated through accelerated and real-time studies. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable for two years (24 months) when stored at 2–30º C. Real-time studies are ongoing.

d. *Detection limit:*

See precision data in Section M1a above for assay performance around the claimed cutoff concentrations.

e. *Analytical specificity:*

The cross-reactivity of structurally similar compounds was evaluated in k073078.

Interferences. Potential interference of structurally dissimilar and endogenous compounds was evaluated in k073078. The following additional compounds were also tested for interference, where exogenous and endogenous compounds into samples at -50% and -50% of the cutoff. No positive or negative interference was observed from any of the following compounds when present at 100,000 ng/mL:

Acetaminophen	AcetylsalicylicAcid/ Aspirin	Albumin
Amikacin	Ampicillin	Arterenal
Atropine	Benzoic Acid	Bilirubin
Caffeine	Creatine	Ethanol
Glucose	Hemoglobin	Lidocaine
Methanol	Oxalic Acid	Penicillin-G
Phenylpropanalamine	Ranitidine	Salicylic Acid
Thioridazine	Trifluoperazine	Uric Acid
Vitamin C		

Specific gravity and pH

The effect of specific gravity for each analyte was evaluated by testing positive and negative samples at specific gravities ranging from 1.00 to 1.035. No interference was observed for all specific gravities tested.

The effect of pH for each analyte was evaluated by testing positive and negative samples over a range of pH levels. No interference was observed for all pH levels tested.

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:

The sponsor performed a method comparison study using unaltered clinical specimens and compared results from the Rapid TOX Cup II (RTC II) to a reference method. Results are summarized below:

AMP 500

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)
Positive	0	1*	6	50
Negative	38	4	0	0

*For the single false positive for Amphetamines, the concentration was determined by GC/MS to be 487 ng/mL.

AMP 1000

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)
Positive	0	0	6	43
Negative	45	9	0	0

BAR 300

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)
Positive	0	0	6	37
Negative	35	5	0	0

BZO 300

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)
Positive	0	0	6	37
Negative	54	8	0	0

BUP 12.5

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)
Positive	0	0	11	46
Negative	172	10	0	0

COC 150

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)
Positive	0	0	5	51
Negative	33	7	0	0

COC 300

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)
Positive	0	0	6	37
Negative	35	9	0	0

MDMA 500

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)
Positive	0	0	7	33
Negative	50	4	0	0

MTD 300

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)
Positive	0	0	8	41
Negative	31	10	0	0

METH 500

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)
Positive	0	0	5	42
Negative	41	4	0	0

METH 1000

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)
Positive	0	0	5	39
Negative	47	6	0	0

OPI 300

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)
Positive	0	0	6	56
Negative	152	5	0	0

OPI 2000

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)
Positive	0	0	6	40
Negative	164	5	0	0

OXY 100

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)
Positive	0	0	5	62
Negative	35	10	0	0

PCP 25

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)
Positive	0	1*	5	35
Negative	30	10	0	0

*For the single false positive for PCP, the concentration was determined by GC/MS to be 24.8 ng/mL

TCA 1000

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)
Positive	0	0	11	29
Negative	40	5	0	0

THC 50

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)
Positive	0	0	6	35
Negative	24	25	0	0

b. Matrix comparison:

Not applicable. These devices are 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):

A consumer study was performed for all analytes to evaluate the ability of untrained users to interpret the devices properly when given only the labeling (package insert) provided with the devices. A total of 430 demographically diverse untrained consumers at three sites took part in the study, with enrollment and testing over the course of five (5) days. Each day, individual participants tested two (2) contrived samples using one of two product configurations. On the last day, 20 participants only tested one (1) contrived sample.

Samples were created by spiking the analyte into drug-free urine pool. Each sample was aliquoted into an individual blind-labeled container. The concentrations analyzed for each analyte and cutoff were negative, 25%, 50%, 75%, 125%, 150%, and 175% of the cutoff, and were confirmed by a reference method. The results are summarized below:

AMP 500

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)
Positive	0	5	40	20
Negative	40	35	0	0

AMP 1000

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)
Positive	0	1	40	20
Negative	100	39	0	0

BAR 300

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)
Positive	0	3	40	20
Negative	100	37	0	0

BZO 300

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)
Positive	0	3	40	20
Negative	80	37	0	0

BUP 12.5

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)
Positive	0	2	40	20
Negative	160	38	0	0

COC 150

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)
Positive	0	2	40	20
Negative	40	38	0	0

COC 300

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)
Positive	0	1	40	20
Negative	60	39	0	0

MDMA 500

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)
Positive	0	4	40	20
Negative	40	36	0	0

MTD 300

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)
Positive	0	1	40	20
Negative	60	39	0	0

METH 500

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)
Positive	0	3	40	20
Negative	40	37	0	0

METH 1000

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)
Positive	0	2	40	20
Negative	80	38	0	0

OPI 300

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)
Positive	0	3	40	20
Negative	40	37	0	0

OPI 2000

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)
Positive	0	3	40	20
Negative	80	37	0	0

OXY 100

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)
Positive	0	1	40	20
Negative	100	39	0	0

PCP 25

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)
Positive	0	2	40	20
Negative	100	38	0	0

TCA 1000

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)
Positive	0	2	40	20
Negative	100	38	0	0

THC 50

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)
Positive	0	1	40	20
Negative	100	39	0	0

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.