

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

A. 510(k) Number:

k182530

B. Purpose for Submission

New device

C. Measurand

Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine. Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline, d-Propoxyphene.

D. Type of Test

Qualitative immunochromatographic assay

E. Applicant

Shenzhen Bioeasy Biotechnology Co., Ltd

F. Proprietary and Established Names

BIOEASY Multi-Drug Test Cup

G. Regulatory Information

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGI Morphine	II	21 CFR § 862.3640, Morphine Test System	Toxicology (91)

Product Code	Classification	Regulation Section	Panel
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methylenedioxy- methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910, Tricyclic Antidepressant Drugs Test System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700, Propoxyphene Test System	Toxicology (91)

H. Intended Use

1. Intended Use

See Indications for Use below.

2. Indications for Use

BIOEASY Multi-Drug Test Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug Identifier	Cut-off Level
Amphetamine	1000ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL

Drug Identifier	Cut-off Level
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/ml
Methadone	300 ng/ml
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the BIOEASY Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

I. Device Description:

The BIOEASY Multi-Drug Test Cup tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamines, Oxazepam, Cocaine, Marijuana, Methamphetamines, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline, and d-Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices. Each test kit contains a Test Device, a package insert, and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch.

J. Substantial Equivalence Information:

1. Predicate device name:

Rapid Single/Multi-drug Test Cup

2. Predicate 510(k) number

k153050

3. Comparison with predicate:

Similarities:

Item	Device	Predicate - k153050
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/ml Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Cup	Same

Differences:

Item	Device	Predicate - k153050
Number of drugs detected	14 drugs of abuse	16 drugs of abuse

K. Standard/Guidance Document Referenced (if applicable)

None identified.

L. Test Principle:

The BIOEASY Multi-Drug Test Cup is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test region. The colored line will not form in the test line region if the target drug level exceeds its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical Performance

a. Precision Reproducibility

Precision studies were conducted for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. The samples were prepared by spiking drug into negative urine samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days per device in a randomized order. The results are summarized in the following tables:

Amphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Secobarbital

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Buprenorphine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Methylenedioxy-methamphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Methamphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Methodone

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

Oxycodone

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Phencyclidine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Propoxyphene

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Marijuana

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+ 75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

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 stability study protocols and acceptance criteria were reviewed and found to be acceptable.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Cross-reactivity:

Analytical specificity studies were performed to determine whether drugs and drug metabolites within the same class of drugs or with similar molecular structures cross-react in the test systems. Reference standards for the various metabolites and compounds were prepared at 100 µg/mL in pooled negative human urine samples. Compounds that tested positive were serially diluted until a negative result was observed. Results shown are expressed as the minimum concentration producing a positive result in the indicated assay.

AMP(Amphetamine) (D – Amphetamine Cut-off=1000 ng/mL)	Result	%Cross- Reactivity
D - Amphetamine	Positive at 1000 ng/mL	100%
L - Amphetamine	Positive at 20000 ng/mL	5%

AMP(Amphetamine) (D – Amphetamine Cut-off=1000 ng/mL)	Result	%Cross- Reactivity
DL - Amphetamine	Positive at 3000 ng/mL	33%
Phentermine	Positive at 30000 ng/mL	3.3%
Hydroxyamphetamine	Positive at 8000 ng/mL	12.5%
Methylenedioxyamphetamine (MDA)	Positive at 20000 ng/mL	5%
d-Methamphetamine	Positive > 100000 ng/mL	<1%
l-Methamphetamine	Positive > 100000 ng/mL	<1%
Ephedrine	Positive > 100000 ng/mL	<1%
Methylenedioxyethylamphetamine (MDE)	Positive > 100000 ng/mL	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Positive > 100000 ng/mL	<1%

BAR(Barbital) (Secobarbital, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Secobarbital	Positive at 300 ng/mL	100%
Amobarbital	Positive at 1000 ng/mL	30%
Alphenal	Positive at 62.5 ng/mL	480%
Aprobarbital	Positive at 250 ng/mL	120%
Butobarbital	Positive at 100 ng/mL	300%
Butethal	Positive at 500 ng/mL	60%
Butalbital	Positive at 5000 ng/mL	6%
Cyclopentobarbital	Positive at 500 ng/mL	60%
Pentobarbital	Positive at 200 ng/mL	150%
Phenobarbital	Positive at 300 ng/mL	100%

BUP(Buprenorphine) (Buprenorphine, Cut-off=10 ng/mL)	Result	%Cross- Reactivity
Buprenorphine	Positive at 10 ng/mL	100%
Buprenorphine -3-D-Glucuronide	Positive at 10 ng/mL	100%
Norbuprenorphine	Positive at 50 ng/mL	20%
Norbuprenorphine-3-D-Glucuronide	Positive at 10 ng/mL	10%
Morphine	Positive > 100000 ng/mL	<0.01%
Oxymorphone	Positive > 100000 ng/mL	<0.01%
Hydromorphone	Positive > 100000 ng/mL	<0.01%

BZO(Benzodiazepines) (Oxazepam, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Oxazepam	Positive at 300 ng/mL	100%
Alprazolam	Positive at 150 ng/mL	200%
a-Hydroxyalprazolam	Positive at 1000 ng/mL	30%

BZO(Benzodiazepines) (Oxazepam, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Bromazepam	Positive at 1000 ng/mL	30%
Chlordiazepoxide	Positive at 63 ng/mL	476.2%
Clonazepam	Positive at 2500 ng/mL	12%
Clobazam	Positive at 75 ng/mL	400%
Clorazepate dipotassium	Positive at 100 ng/mL	300%
Desalkylflurazepam	Positive at 500 ng/mL	60%
Diazepam	Positive at 500 ng/mL	60%
Estazolam	Positive at 500 ng/mL	60%
Flunitrazepam	Positive > 50000 ng/mL	<0.6%
D,L-Lorazepam	Positive at 10000 ng/mL	3%
Midazolam	Positive at 10000 ng/mL	3%
Nitrazepam	Positive at 75 ng/mL	400%
Norclordiazepoxide	Positive at 62.5 ng/mL	480%
Nordiazepam	Positive at 125 ng/mL	240%
Temazepam	Positive at 75 ng/mL	400%
Triazolam	Positive at 1000 ng/mL	33%

COC(Cocaine) (Benzoylecgonine, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Benzoylecgonine	Positive at 300 ng/mL	100%
Cocaine HCl	Positive at 750 ng/mL	40%
Cocaethylene	Positive at 12500 ng/mL	2.4%
Ecgonine	Positive at 32000 ng/mL	0.9%
Norcocaine	Positive at 100000 ng/mL	0.3%

MDMA(Methylenedioxyamphetamine) (Methylenedioxyamphetamine, Cut-off=500 ng/mL)	Result	%Cross- Reactivity
Methylenedioxyamphetamine (MDMA)	Positive at 500 ng/mL	100%
3,4-Methylenedioxyamphetamine (MDA)	Positive at 5000 ng/mL	10%
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at 300 ng/mL	166.7%
d-methamphetamine	Positive > 50000 ng/mL	< 1%
d-amphetamine	Positive > 50000 ng/mL	< 1%
l-amphetamine	Positive > 50000 ng/mL	< 1%
l-methamphetamine	Positive > 50000 ng/mL	< 1%

MET(Methamphetamine) (D(+)-Methamphetamine, Cut-off=1000 ng/mL)	Result	%Cross- Reactivity
D(+)-Methamphetamine	Positive at 1000 ng/mL	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 10000 ng/mL	10%
D/L-Methamphetamine	Positive at 1000 ng/mL	100%
p-Hydroxymethamphetamine	Positive at 10000 ng/mL	10%
D-Amphetamine	Positive > 100000 ng/mL	< 1%
L-Amphetamine	Positive > 100000 ng/mL	< 1%
Chloroquine	Positive at 50000 ng/mL	2%
(+/-)-Ephedrine	Positive at 4000 ng/mL	25%
L-Methamphetamine	Positive at 10000 ng/mL	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	Positive > 100000 ng/mL	< 1%
β -Phenylethylamine	Positive at 7500 ng/mL	13.3%
Trimethobenzamide	Positive at 20000 ng/mL	5%
(+/-)3,4-methylenedioxymethamphetamine (MDMA)	Positive at 10000 ng/mL	10%

MOP(Morphine) (Morphine, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Morphine	Positive at 300 ng/mL	100%
Codeine	Positive at 300 ng/mL	100%
Ethylmorphine	Positive at 310 ng/mL	96.8%
Hydrocodone	Positive at 25000 ng/mL	1.2%
Hydromorphone	Positive at 10000 ng/mL	3%
Levorphanol	Positive > 100000 ng/mL	< 0.3%
6-Acetylmorphine	Positive at 250 ng/mL	120%
Morphine-3- β -D-glucuronide	Positive at 10000 ng/mL	3%
Normorphine	Positive at 100000 ng/mL	0.3%
Oxycodone	Positive > 10000 ng/mL	< 3%
Oxymorphone	Positive > 10000 ng/mL	< 3%
Procaine	Positive > 10000 ng/mL	3%
Thebaine	Positive > 10000 ng/mL	< 3%
Heroin	Positive at 500 ng/mL	60%

MTD(Methadone) (Methadone, Cut-off=300 ng/mL)	Result	%Cross- Reactivity
Methadone	Positive at 300 ng/mL	100%
Doxylamine	Positive at 5000 ng/mL	6%
LAAM	Positive at 10000 ng/mL	3%
Alpha Methadol	Positive at 2000 ng/mL	15%

MTD(Methadone) (Methadone, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
EDDP	Positive > 100000 ng/mL	<0.3%
EMDP	Positive > 100000 ng/mL	<0.3%

OXY(Oxycodone) (Oxycodone, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Oxycodone	Positive at 100 ng/mL	100%
Dihydrocodeine	Positive > 100000 ng/mL	<0.1%
Codeine	Positive > 100000 ng/mL	<0.1%
Hydromorphone	Positive > 100000 ng/mL	<0.1%
Morphine	Positive > 100000 ng/mL	<0.1%
Buprenorphine	Positive > 100000 ng/mL	<0.1%
Ethylmorphine	Positive > 100000 ng/mL	<0.1%
Oxymorphone	Positive at 250 ng/mL	40%
Hydrocodone	Positive at 3125 ng/mL	3.2%

PCP(Phencyclidine) (Phencyclidine, Cut-off=25 ng/mL)	Result	%Cross-Reactivity
Phencyclidine	Positive at 25 ng/mL	100%
4-Hydroxyphencyclidine	Positive at 75 ng/mL	33.3%

PPX(Propoxyphene) (d-Propoxyphene, Cut-off=300ng/mL)	Result	%Cross-Reactivity
d-Propoxyphene	Positive at 300 ng/mL	100%
D-Norpropoxyphene	Positive at 333 ng/mL	90.1%

TCA(Nortriptyline) (Nortriptyline, Cut-off=1000 ng/mL)	Result	%Cross-Reactivity
Nortriptyline	Positive at 1000 ng/mL	100%
Amitriptyline	Positive at 750 ng/mL	133.3%
Clomipramine	Positive at 10000 ng/mL	10%
Desipramine	Positive at 200 ng/mL	500%
Doxepin	Positive at 1250 ng/mL	80%
Imipramine	Positive at 625 ng/mL	160%
Maprotiline	Positive at 2000 ng/mL	50%
Nordoxepin	Positive at 1000 ng/mL	100%
Promazine	Positive at 1500 ng/mL	66.7%
Promethazine	Positive at 25000 ng/mL	4%
Trimipramine	Positive at 3000 ng/mL	33.3%
Cyclobenzaprine	Positive at 5000 ng/mL	20%

TCA(Nortriptyline) (Nortriptyline, Cut-off=1000 ng/mL)	Result	%Cross- Reactivity
Norclomipramine	Positive at 3000 ng/mL	33.3%

THC(Cannabinoids) (11-nor-Δ9-THC-9-COOH, Cut-off = 50 ng/mL)	Result	% Cross- Reactivity
11-nor- Δ 9-THC-9-COOH	Positive at 50 ng/mL	100%
11-Hydroxy- Δ 9-Tetrahydrocannabinol	Positive at 50 ng/mL	100%
11-Nor- Δ 8-Tetrahydrocannabinol-9-COOH	Positive at 50 ng/mL	100%
Cannabinol	Positive at 20000 ng/mL	0.25%
Δ 8-Tetrahydrocannabinol	Positive at 15000 ng/mL	0.33%
Δ 9-Tetrahydrocannabinol	Positive at 15000 ng/mL	0.33%
Cannabidiol	Positive > 100000 ng/mL	<0.05%
11-Nor- Δ 9-THC-carboxy glucuronide	Positive at 75 ng/mL	66.7%
(-)-11-nor-9-carboxy- Δ 9-THC	Positive at 50 ng/mL	100%
11-nor- Δ 9-THC-9-COOH	Positive at 50 ng/mL	100%
11-Hydroxy- Δ 9-Tetrahydrocannabinol	Positive at 50 ng/mL	100%
11-Nor- Δ 8-Tetrahydrocannabinol-9-COOH	Positive at 50 ng/mL	100%
Cannabinol	Positive at 20000 ng/mL	0.25%

Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added at a concentration of 100 μ g/mL (albumin was tested at 100 mg/dL) to drug-free urine and urine with target drug concentrations at 25% below and 25% above Cut-off levels. These urine samples were tested using three batches of each device. No interference was observed for any compounds tested, and the list of compounds tested is provided in the following table:

Acetaminophen	β -Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol	Oxymetazoline
Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin (100 mg/dL)	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(\pm)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid

Benzoic acid	Isoproterenol	Serotonin (5-Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β -Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline
Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine
Diflunisal	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(\pm)-Octopamine	

f. Effect of Urine Specific Gravity and Urine pH

To investigate potential interferences due to urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity, or urine samples with pH 4 to 9, were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. For all devices and all lots tested, results were all positive for samples at +25% Cut-Off and all negative for samples below 25% Cut-Off.

g. Assay Cut-off

See M.1.a., above.

2. Comparison Studies

Method comparison studies for the BOEASY Multi-Drug Test Cup tests were performed in-house with three laboratory assistants for each device. Operators ran 80(40 negative and 40 positive) unaltered clinical samples for each target drug. The samples were blind-labeled and compared to results obtained by LC/MS. The results are presented in the tables below:

Amphetamine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	19
	Negative	5	16	17	2	0
Viewer B	Positive	0	0	4	20	19
	Negative	5	16	15	1	0
Viewer C	Positive	0	0	3	19	19
	Negative	5	16	16	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	AMPC439	981	Positive
Viewer A	AMPC449	768	Positive
Viewer B	AMPC439	981	Positive
Viewer B	AMPC449	768	Positive
Viewer B	AMPC412	976	Positive
Viewer B	AMPC387	981	Positive
Viewer C	AMPC412	976	Positive
Viewer C	AMPC493	961	Positive
Viewer C	AMPC387	981	Positive
Viewer A	AMPC341	1010	Negative
Viewer A	AMPC482	1010	Negative
Viewer B	AMPC482	1010	Negative
Viewer C	AMPC341	1010	Negative
Viewer C	AMPC352	1120	Negative

Secobarbital

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	17	22
	Negative	6	15	17	1	0
Viewer B	Positive	0	0	2	16	22
	Negative	6	15	17	2	0
Viewer C	Positive	0	0	1	17	22
	Negative	6	15	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BARC477	291	Positive
Viewer A	BARC375	265	Positive
Viewer B	BARC477	291	Positive
Viewer B	BARC375	265	Positive
Viewer C	BARC364	269	Positive
Viewer A	BARC384	312	Negative
Viewer B	BARC384	312	Negative

Buprenorphine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	20	18
	Negative	5	18	16	2	0
Viewer B	Positive	0	0	0	20	18
	Negative	5	18	17	2	0
Viewer C	Positive	0	0	2	21	18
	Negative	5	18	15	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BUPC379	9.67	Positive
Viewer C	BUPC359	8.94	Positive
Viewer C	BUPC379	9.67	Positive
Viewer A	BUPC322	10.1	Negative
Viewer A	BUPC429	11.2	Negative
Viewer B	BUPC322	10.1	Negative
Viewer B	BUPC348	10.2	Negative
Viewer C	BUPC348	10.2	Negative

Oxazepam

		Negative	Low Negative by LC/MS (less than-50%)	Near Cutoff Negative by LC/MS (Between-50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and+50%)	High Positive by LC/MS (greater than+50%)
Viewer A	Positive	0	0	2	20	18
	Negative	5	15	18	2	0
Viewer B	Positive	0	0	1	21	18
	Negative	5	15	19	1	0
Viewer C	Positive	0	0	2	21	18
	Negative	5	15	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BZOC343	298	Positive
Viewer A	BZOC322	296	Positive
Viewer B	BZOC322	296	Positive
Viewer C	BZOC343	298	Positive
Viewer C	BZOC435	292	Positive
Viewer A	BZOC301	314	Negative
Viewer A	BZOC348	312	Negative

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer B	BZOC348	312	Negative
Viewer C	BZOC301	314	Negative

Cocaine

		Negative	Low Negative by LC/MS (less than-50%)	Near Cutoff Negative by LC/MS (Between-50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and+50%)	High Positive by LC/MS (greater than+50%)
Viewer A	Positive	0	0	2	21	19
	Negative	6	17	15	0	0
Viewer B	Positive	0	0	2	20	19
	Negative	6	17	15	1	0
Viewer C	Positive	0	0	1	20	19
	Negative	6	17	14	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	COCC368	298	Positive
Viewer A	COCC340	294	Positive
Viewer B	COCC368	298	Positive
Viewer B	COCC315	282	Positive
Viewer C	COCC340	294	Positive
Viewer B	COCC317	301	Negative
Viewer C	COCC317	301	Negative

Methylnedioxyamphetamine

		Negative	Low Negative by LC/MS (less than-50%)	Near Cutoff Negative by LC/MS (Between-50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and+50%)	High Positive by LC/MS (greater than+50%)
Viewer A	Positive	0	0	1	19	20
	Negative	5	16	18	1	0
Viewer B	Positive	0	0	2	19	20
	Negative	5	16	17	1	0
Viewer C	Positive	0	0	2	19	20
	Negative	5	16	17	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MDMAC310	490	Positive
Viewer B	MDMAC306	497.5	Positive
Viewer B	MDMAC365	484.5	Positive
Viewer C	MDMAC310	490	Positive
Viewer C	MDMAC306	497.5	Positive
Viewer A	MDMAC316	505	Negative
Viewer B	MDMAC316	505	Negative
Viewer C	MDMAC484	565	Negative

Methamphetamine

		Negative	Low Negative by LC/MS (less than-50%)	Near Cutoff Negative by LC/MS (Between-50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and+50%)	High Positive by LC/MS (greater than+50%)
Viewer A	Positive	0	0	2	20	18
	Negative	5	16	17	2	0
Viewer B	Positive	0	0	1	21	18
	Negative	5	16	18	1	0
Viewer C	Positive	0	0	1	21	18
	Negative	5	16	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	METC498	921	Positive
Viewer A	METC479	984	Positive
Viewer B	METC467	973	Positive
Viewer C	METC479	984	Positive
Viewer A	METC343	1020	Negative
Viewer A	METC473	1110	Negative
Viewer B	METC473	1110	Negative

Morphine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	18	21
	Negative	5	16	17	1	0
Viewer B	Positive	0	0	2	18	21
	Negative	5	16	17	1	0
Viewer C	Positive	0	0	2	17	21
	Negative	5	16	17	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MOPC355	287	Positive
Viewer A	MOPC429	298	Positive
Viewer B	MOPC408	286	Positive
Viewer B	MOPC429	298	Positive
Viewer C	MOPC408	286	Positive
Viewer C	MOPC433	276	Positive
Viewer A	MOPC393	301	Negative
Viewer B	MOPC416	339	Negative
Viewer C	MOPC416	339	Negative
Viewer C	MOPC393	301	Negative

Metadone

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	21	18
	Negative	5	15	18	1	0
Viewer B	Positive	0	0	2	20	18
	Negative	5	15	18	2	0
Viewer C	Positive	0	0	3	22	18
	Negative	5	15	17	0	0

Discordant results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MTDC314	289	Positive
Viewer A	MTDC389	299	Positive
Viewer B	MTDC314	289	Positive
Viewer B	MTDC408	290	Positive
Viewer C	MTDC389	299	Positive
Viewer C	MTDC373	279	Positive
Viewer C	MTDC408	290	Positive
Viewer A	MTDC447	309	Negative
Viewer B	MTDC447	309	Negative
Viewer B	MTDC427	336	Negative

Oxycodone

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	4	18	22
	Negative	6	15	15	0	0
Viewer B	Positive	0	0	3	18	22
	Negative	6	15	16	0	0
Viewer C	Positive	0	0	3	18	22
	Negative	6	15	16	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	OXYC467	97.5	Positive
Viewer A	OXYC369	94.6	Positive
Viewer A	OXYC334	98.4	Positive
Viewer A	OXYC470	95.1	Positive
Viewer B	OXYC467	97.5	Positive
Viewer B	OXYC310	96.1	Positive
Viewer B	OXYC470	95.1	Positive
Viewer C	OXYC310	96.1	Positive
Viewer C	OXYC369	94.6	Positive
Viewer C	OXYC334	98.4	Positive

Phencyclidine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	3	18	18	2	0
Viewer B	Positive	0	0	2	20	20
	Negative	3	18	17	0	0
Viewer C	Positive	0	0	2	19	20
	Negative	3	18	17	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	PCPC441	24.8	Positive
Viewer B	PCPC411	24.7	Positive
Viewer B	PCPC441	24.8	Positive
Viewer C	PCPC462	24.7	Positive
Viewer C	PCPC411	24.7	Positive
Viewer A	PCPC477	25.3	Negative
Viewer A	PCPC368	27.8	Negative
Viewer C	PCPC477	25.3	Negative

Propoxyphene

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	5	15	19	2	0
Viewer B	Positive	0	0	2	19	20
	Negative	5	15	18	1	0
Viewer C	Positive	0	0	1	19	20
	Negative	5	15	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	PPXC472	286	Positive
Viewer B	PPXC472	286	Positive
Viewer B	PPXC320	278	Positive
Viewer C	PPXC320	278	Positive
Viewer A	PPXC493	318	Negative
Viewer A	PPXC382	306	Negative
Viewer B	PPXC382	306	Negative
Viewer C	PPXC493	318	Negative

Nortriptyline

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	20	19
	Negative	5	15	18	1	0
Viewer B	Positive	0	0	2	18	19
	Negative	5	15	18	3	0
Viewer C	Positive	0	0	2	19	19
	Negative	5	15	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	TCAC319	979	Positive
Viewer A	TCAC470	944	Positive
Viewer B	TCAC319	979	Positive
Viewer B	TCAC346	958	Positive
Viewer C	TCAC346	958	Positive
Viewer C	TCAC470	944	Positive
Viewer A	TCAC479	1190	Negative
Viewer B	TCAC398	1050	Negative
Viewer B	TCAC331	1180	Negative
Viewer B	TCAC479	1190	Negative
Viewer C	TCAC398	1050	Negative
Viewer C	TCAC331	1180	Negative

Marijuana

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	18
	Negative	6	14	18	3	0
Viewer B	Positive	0	0	2	20	18
	Negative	6	14	18	2	0
Viewer C	Positive	0	0	2	19	18
	Negative	6	14	18	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	THCC402	46	Positive
Viewer A	THCC368	48.8	Positive
Viewer B	THCC363	46.95	Positive
Viewer B	THCC402	46	Positive
Viewer C	THCC363	46.95	Positive
Viewer C	THCC368	48.8	Positive
Viewer A	THCC478	55.5	Negative
Viewer A	THCC493	50.5	Negative
Viewer A	THCC496	57.5	Negative
Viewer B	THCC478	55.5	Negative
Viewer B	THCC318	56	Negative
Viewer C	THCC493	50.5	Negative
Viewer C	THCC318	56	Negative
Viewer C	THCC496	57.5	Negative

Lay user study

A lay user study was performed at three intended user sites with 300 lay persons. The lay users had diverse ages and educational and professional backgrounds. Urine samples were prepared at multiple concentrations (Negative, +/-75%, +/-50%, +/-25% of the cutoff) by spiking drugs into drug free pooled specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was

provided with the package insert, one blind labeled sample and a device, and no additional training. Summary results are shown below.

The results summary for AMP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS (ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	261	0	20	100
-50% Cutoff	160	507	0	160	100
-25% Cutoff	20	771	1	19	95
+25% Cutoff	20	1290	19	1	95
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1870	20	0	100

The results summary for BAR:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75.9	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	220	1	19	95
+25% Cutoff	20	360	19	1	95
+50% Cutoff	40	429	40	0	100
+75% Cutoff	20	501	20	0	100

The results summary for COC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	81.5	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	395	19	1	95

+50% Cutoff	40	455	40	0	100
+75% Cutoff	20	520	20	0	100

The results summary for BUP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	2.57	0	20	100
-50% Cutoff	160	5.14	0	160	100
-25% Cutoff	20	6.76	1	19	95
+25% Cutoff	20	12.8	19	1	95
+50% Cutoff	40	15.1	40	0	100
+75% Cutoff	20	17.2	20	0	100

The results summary for MET:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	268	0	20	100
-50% Cutoff	160	526	0	160	100
-25% Cutoff	20	769	1	19	95
+25% Cutoff	20	1270	19	1	95
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1780	20	0	100

The results summary for MTD:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76.8	0	20	100
-50% Cutoff	160	147	0	160	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	375	19	1	95
+50% Cutoff	40	441	40	0	100

+75% Cutoff	20	504	20	0	100
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The results summary for MOP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	79	0	20	100
-50% Cutoff	160	158	0	160	100
-25% Cutoff	20	246	1	19	95
+25% Cutoff	20	389	20	0	100
+50% Cutoff	40	469	40	0	100
+75% Cutoff	20	530	20	0	100

The results summary for OXY:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	24.5	0	20	100
-50% Cutoff	160	49.3	0	160	100
-25% Cutoff	20	71.1	1	19	95
+25% Cutoff	20	118	19	1	95
+50% Cutoff	40	147	40	0	100
+75% Cutoff	20	169	20	0	100

The results summary for PCP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	6.27	0	20	100
-50% Cutoff	160	12.5	0	160	100
-25% Cutoff	20	17.9	1	19	95
+25% Cutoff	20	30.8	19	1	95
+50% Cutoff	40	36.4	40	0	100
+75% Cutoff	20	42.8	20	0	100

The results summary for THC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	13	0	20	100
-50% Cutoff	160	25.3	0	160	100
-25% Cutoff	20	41	1	19	95
+25% Cutoff	20	65	19	1	95
+50% Cutoff	40	79	40	0	100
+75% Cutoff	20	93	20	0	100

The results summary for BZO:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	70.8	0	20	100
-50% Cutoff	160	148	0	160	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	390	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	504	20	0	100

The results summary for MDMA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	137	0	20	100
-50% Cutoff	160	250	0	160	100
-25% Cutoff	20	351	1	19	95
+25% Cutoff	20	600	19	1	95
+50% Cutoff	40	745	40	0	100
+75% Cutoff	20	925	20	0	100

The results summary for TCA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	273	0	20	100
-50% Cutoff	160	509	0	160	100
-25% Cutoff	20	809	1	19	95
+25% Cutoff	20	1190	18	2	90
+50% Cutoff	40	1510	40	0	100
+75% Cutoff	20	1680	20	0	100

The results summary for PPX:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay Person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	77.4	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	227	1	19	95
+25% Cutoff	20	351	19	1	95
+50% Cutoff	40	420	40	0	100
+75% Cutoff	20	492	20	0	100

Lay users also completed surveys on the ease of understanding the package insert instructions, and the results were found to be acceptable. A Flesch-Kincaid reading analysis was performed on the package insert and the scores revealed a reading grade level of 7.

3. Clinical Studies

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.