

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

A. 510(k) Number:

k182654

B. Purpose for Submission:

Modification of a previously cleared device to add 6 new drug test strips.

C. Measurand:

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

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Hangzhou Safecare Biotech Co., Ltd

F. Proprietary and Established Names:

SAFECARE Multi-Drug Urine Test Dip Card; SAFECARE Multi-Drug Urine 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 § 862.3650, Morphine Test System	Toxicology (91)
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(s):

Refer to Indications for Use below.

2. Indication(s) for use:

SAFECARE Multi-Drug Urine Test Dip Card is competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxymethamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Oxycodone	100 ng/mL
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 SAFECARE Multi-Drug Urine Test Dip Card 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 in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. The tests are intended for over-the-counter use.

SAFECARE Multi-Drug Urine Test Cup is 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	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	2000 ng/mL
Oxycodone	100 ng/mL
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 SAFECARE Multi-Drug Urine Test Cup 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 in order to obtain

a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. The tests are intended for over-the-counter use.

3. Special conditions for use statement(s):

For over the counter use.

4. Special instrument requirements:

Not applicable. The devices are visually read and single-use.

I. Device Description:

The SAFECARE Multi-Drug Urine Test Dip Card and SAFECARE Multi-Drug Urine Test Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxy-methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene (target analytes) in human urine. The devices are single-use in vitro diagnostic devices. SAFECARE Multi-Drug Urine Test Dip Card comes in the dip card format, and SAFECARE Multi-Drug Urine Test Cup comes in the cup format. Each test kit contains a 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(s):

Chemtrue Multi-Panel Drug Screen Dip Card Tests

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

k142396

3. Comparison with predicate:

Similarities		
Item	Candidate Device	Predicate Device (k142396)
Intended Use	Same	For the qualitative determination of drugs of abuse in human urine.
Analytes and cutoffs	Same	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine (COC): 300 ng/ml 11-Nor- Δ 9-Tetrahydrocannabinol-9-COOH

Similarities		
Item	Candidate Device	Predicate Device (k142396)
		(THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (OPI): 2000ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Methylenedioxy-methamphetamine (MDMA): 500 ng/ml Oxycodone (OXY): 100 ng/ml Buprenorphine (BUP): 10 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.
Intended Users	Same	Over the counter

Differences		
Item	Candidate Device	Predicate Device (k142396)
Configurations	Dipcard and Cup	Dipcard, cup, and cassette

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

None referenced

L. Test Principle:

The SAFECARE Multi-Drug Urine Test Dip Card and SAFECARE Multi-Drug Urine Test Cup are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital, Methadone, Methylenedioxy-methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene in urine samples. The tests are lateral flow chromatographic immunoassays. 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 line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-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 that the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't 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 obtained are summarized in the following tables for Methylenedioxy-methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene. Please refer to k181968 for precision data for Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital and Methadone.

Methylenedioxy-methamphetamine – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	26-/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-

Methylenedioxy-methamphetamine – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	25-/25+	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-

Oxycodone – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Oxycodone – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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-/25+	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-

Buprenorphine – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Buprenorphine – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Phencyclidine – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	26-/24+	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-

Phencyclidine – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	26-/24+	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-

Nortriptyline – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Propoxyphene – Dip Card

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	26-/24+	24-/26+	50+/0-	50+/0-	50+/0-

Propoxyphene – Cup

Results Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100%
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+	25-/25+	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):*

Real-time and accelerated stability studies were conducted on three lots of each device. The protocols for the stability studies were reviewed and found to be acceptable.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Interferences

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and urine with concentrations at 25% below and 25% above the cutoff levels for each analyte. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100 µg/mL, for either the SAFECARE Multi-Drug Urine Test Dip Card or the SAFECARE Multi-Drug Urine Test Cup, are listed in the following tables.

Acetaminophen (4-Acetamidophenol)	Ecgonine methyl ester	D,L-Octopamine
Acetophenetidin	EMDP	Oxalic acid
N-Acetylprocainamide	Erythromycin	Oxolinic acid
Acetylsalicylic acid	β -Estradiol	Oxymetazoline
Albumin	Fenoprofen	Papaverine
Aminopyrine	Furosemide	Penicillin-G
Amoxicillin	Gentisic acid	Perphenazine
Ampicillin	Hemoglobin	Phenelzine
Apomorphine	Hydralazine	Prednisone
Ascorbic acid	Hydrochlorothiazide	DL-Propranolol
Aspartame	Hydrocortisone	D-Pseudoephedrine
Atropine	O-Hydroxyhippuric acid	Quinine
Benzilic acid	3-Hydroxytyramine	Ranitidine
Benzoic acid	Ibuprofen	Salicylic acid
Bilirubin	D,L-Isoproterenol	Serotonin (5-Hydroxytyramine)
Chloralhydrate	Isoxsuprine	Sulfamethazine
Chloramphenicol	Ketamine	Sulindac

Chlorothiazide	Ketoprofen	Tetrahydrocortisone, 3-acetate
Chlorpromazine	Labetalol	Tetrahydrocortisone 3-(β - Dglucuronide)
Cholesterol	Loperamide	Tetrahydrozoline
Clonidine	Maprotiline	Thiamine
Cortisone	Meperidine	Thioridazine
(-) Cotinine	Meprobamate	Triamterene
Creatinine	Methoxyphenamine	DL-Tyrosine
Deoxycorticosterone	Nalidixic acid	Trifluoperazine
Dextromethorphan	Naloxone	Trimethoprim
Diclofenac	Naltrexone	D L-Tryptophan
Diflunisal	Naproxen	Tyramine
Digoxin	Niacinamide	Uric acid
Diphenhydramine	Nifedipine	Verapamil
Disopyramide	Norethindrone	Zomepirac
EDDP	Noscapine	

Cross-reactivity

To evaluate cross-reactivity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were tested using three lots of each device. The lowest concentrations of tested compounds that caused a positive result for each compound are listed below for Methylenedioxy-methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene. Cross-reactivity data was reported in k181968 for Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Secobarbital and Methadone. There were no differences in cross-reactivity observed between the SAFECARE Multi-Drug Urine Test Dip Card or the SAFECARE Multi-Drug Urine Test Cup.

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
Methylenedioxy-methamphetamine	500	100%
3,4-Methylenedioxyamphetamine	5000	10%
3,4-Methylenedioxyethylamphetamine	300	166%
d-methamphetamine	>100000	<1%
d-amphetamine	>100000	<1%
l-amphetamine	>100000	<1%
l-methamphetamine	>100000	<1%

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
Oxycodone	100	100%
Oxymorphone	250	40%
Hydrocodone	3125	3.2 %
Dihydrocodeine	>100000	<0.1%
Codeine	>100000	<0.1%
Hydromorphone	>100000	<0.1%
Morphine	>100000	<0.1%
Buprenorphine	>100000	<0.1%
Ethylmorphine	>100000	<0.1%

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	10	100%
Norbuprenorphine	50	20%
Norbuprenorphine-3-D-Glucuronide	100	10%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Hydromorphone	>100000	<0.01%

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxyphencyclidine	75	33%

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
Nortriptyline	1000	100%
Amitriptyline	750	133.30%
Clomipramine	10000	10%
Desipramine	200	500%
Doxepin	1250	80%
Imipramine	625	160%
Maprotiline	2000	50%
Nordoxepin	1000	100%
Promazine	1500	66.70%
Promethazine	25000	4%
Trimipramine	3000	33.30%
Cyclobenzaprine Hydrochloride	5000	20%
Norclomipramine	3000	33.30%

Compound	Result Positive at (ng/ml)	% Cross-Reactivity
d-Propoxyphene	300	100%
D-Norpropoxyphene	330	91%

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity and urine samples with pH 4 to 9 were spiked with the target analytes at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results for the pH and specific gravity samples were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed between the SAFECARE Multi-Drug Urine Test Dip Card or the SAFECARE Multi-Drug Urine Test Cup.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies for the SAFECARE Multi-Drug Urine Test Dip Card and SAFECARE Multi-Drug Urine Test Cup were performed with three laboratory assistants performing the tests for each device format. The operators analyzed 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Methylenedioxy-methamphetamine, Oxycodone, Buprenorphine, Phencyclidine, Nortriptyline and Propoxyphene. Method comparison results were reported in k181968 for Amphetamine, Oxazepam, Cocaine, Marijuana,

Methamphetamine, Morphine, Secobarbital and Methadone.

Methylenedioxy-methamphetamine

Dip Card		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM1822	491	Positive
Viewer B	AM5121	497	Positive
Viewer C	AM1822	491	Positive
Viewer C	AM5121	497	Positive
Viewer A	AM2281	517	Negative
Viewer A	AM3339	509	Negative
Viewer B	AM2281	517	Negative
Viewer B	AM6217	525	Negative
Viewer C	AM6217	525	Negative
Viewer C	AM3339	509	Negative

Methylenedioxy-methamphetamine

Cup		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	20
	Negative	10	10	18	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	2	18	20
	Negative	10	10	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	AM5135	491	Positive
Viewer A	AM6745	497	Positive
Viewer B	AM5135	491	Positive
Viewer C	AM5135	491	Positive
Viewer C	AM6745	497	Positive
Viewer A	AM8048	517	Negative
Viewer A	AM4472	509	Negative
Viewer B	AM4472	509	Negative
Viewer B	AM4835	525	Negative
Viewer C	AM8048	517	Negative
Viewer C	AM4472	509	Negative

Oxycodone

Dip Card		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	17	20
	Negative	10	10	19	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM8592	95	Positive
Viewer B	AM3867	98	Positive
Viewer C	AM7495	92	Positive
Viewer A	AM1177	104	Negative
Viewer A	AM3128	107	Negative
Viewer B	AM9817	106	Negative
Viewer B	AM9785	109	Negative
Viewer C	AM0928	108	Negative
Viewer C	AM1177	104	Negative
Viewer C	AM3128	107	Negative

Oxycodone

Cup		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	10	10	19	2	0
Viewer B	Positive	0	0	1	17	20
	Negative	10	10	19	3	0
Viewer C	Positive	0	0	1	17	20
	Negative	10	10	19	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	AM0623	98	Positive
Viewer B	AM5357	95	Positive
Viewer C	AM0623	98	Positive
Viewer A	AM7016	105	Negative
Viewer A	AM3335	106	Negative
Viewer B	AM7525	104	Negative
Viewer B	AM0654	107	Negative
Viewer B	AM3335	106	Negative
Viewer C	AM7016	105	Negative
Viewer C	AM7525	104	Negative
Viewer C	AM3335	106	Negative

Buprenorphine

Dip Card		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	10	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM7493	9	Positive
Viewer B	AM1093	9	Positive
Viewer C	AM1093	9	Positive
Viewer A	AM6936	11	Negative
Viewer A	AM0902	11	Negative
Viewer B	AM6497	11	Negative
Viewer B	AM0902	11	Negative
Viewer C	AM6936	11	Negative

Buprenorphine

Cup		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM8338	9	Positive
Viewer B	AM4130	9	Positive
Viewer C	AM4130	9	Positive
Viewer A	AM3059	11	Negative
Viewer A	AM5605	11	Negative
Viewer B	AM5605	11	Negative
Viewer B	AM2763	11	Negative
Viewer C	AM3059	11	Negative
Viewer C	AM2763	11	Negative

Phencyclidine

Dip Card		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	10	10	19	1	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	19	20
	Negative	10	10	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM1553	23	Positive
Viewer B	AM1159	24	Positive
Viewer C	AM1159	24	Positive
Viewer A	AM2982	25.3	Negative
Viewer B	AM5901	26	Negative
Viewer B	AM2982	25.3	Negative
Viewer C	AM2982	25.3	Negative

Phencyclidine

Cup		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	10	10	19	2	0
Viewer B	Positive	0	0	1	19	20
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	AM7467	24	Positive
Viewer B	AM6637	23	Positive
Viewer C	AM7467	24	Positive
Viewer A	AM1449	26	Negative
Viewer A	AM8727	25.3	Negative
Viewer B	AM8727	25.3	Negative
Viewer C	AM1449	26	Negative
Viewer C	AM8727	25.3	Negative

Nortriptyline

Dip Card		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	AM9403	982	Positive
Viewer B	AM2316	998	Positive
Viewer C	AM9403	982	Positive
Viewer A	AM7812	1004	Negative
Viewer A	AM0170	1031	Negative
Viewer B	AM4373	1023	Negative
Viewer B	AM0170	1031	Negative
Viewer C	AM7812	1004	Negative
Viewer C	AM4373	1023	Negative

Nortriptyline

Cup		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	AM0528	998	Positive
Viewer B	AM0528	998	Positive
Viewer C	AM0528	998	Positive
Viewer A	AM6084	1004	Negative
Viewer A	AM6157	1031	Negative
Viewer B	AM6084	1004	Negative
Viewer B	AM9869	1023	Negative
Viewer C	AM9869	1023	Negative
Viewer C	AM6157	1031	Negative

Propoxyphene

Dip Card		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	10	10	19	2	0
Viewer B	Positive	0	0	1	18	20
	Negative	10	10	19	2	0
Viewer C	Positive	0	0	0	17	20
	Negative	10	10	20	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Dip Card Viewer
Viewer A	AM9748	294	Positive
Viewer B	AM8770	290	Positive
Viewer A	AM6660	315	Negative
Viewer A	AM8794	306	Negative
Viewer B	AM6660	315	Negative
Viewer B	AM2236	309	Negative
Viewer C	AM6660	315	Negative
Viewer C	AM8794	306	Negative
Viewer C	AM2236	309	Negative

Propoxyphene

Cup		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	10	10	19	2	0
Viewer B	Positive	0	0	1	17	20
	Negative	10	10	19	3	0
Viewer C	Positive	0	0	1	18	20
	Negative	10	10	19	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Cup Viewer Results
Viewer A	AM7095	290	Positive
Viewer B	AM1226	294	Positive
Viewer C	AM7095	290	Positive
Viewer A	AM9825	306	Negative
Viewer A	AM6247	309	Negative
Viewer B	AM8797	315	Negative
Viewer B	AM9825	306	Negative
Viewer B	AM6247	309	Negative
Viewer C	AM8797	315	Negative
Viewer C	AM6247	309	Negative

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):

Lay User Study

A lay user study was performed at three intended user sites with 300 lay persons for each device format. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to >50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine 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. Each device was tested. Results are shown below.

SAFECARE Multi-Drug Urine Test Cup

Amphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	248	0	20	100
-50% Cutoff	160	505	0	160	100
-25% Cutoff	20	754	2	18	90
+25% Cutoff	20	1259	18	2	90
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1759	20	0	100

Cocaine

% of Cutoff	Number of samples	Drug Concentration by LC/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	74	0	20	100
-50% Cutoff	160	152	0	160	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	373	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	522	20	0	100

Marijuana

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	160	100
-25% Cutoff	20	37	2	18	90
+25% Cutoff	20	62	19	1	95
+50% Cutoff	40	75	40	0	100
+75% Cutoff	20	87	20	0	100

Secobarbital

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	226	3	17	85
+25% Cutoff	20	372	19	1	95
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	529	20	0	100

Oxazepam

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	149	0	160	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	520	20	0	100

Methamphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	251	0	20	100
-50% Cutoff	160	502	0	160	100
-25% Cutoff	20	758	3	17	85
+25% Cutoff	20	1259	19	1	95
+50% Cutoff	40	1512	40	0	100
+75% Cutoff	20	1759	20	0	100

Methadone

% of Cutoff	Number of samples	Drug Concentration by LC/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	74	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	376	19	1	95
+50% Cutoff	40	447	40	0	100
+75% Cutoff	20	522	20	0	100

Morphine

% of Cutoff	Number of samples	Drug Concentration by LC/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	505	0	20	100
-50% Cutoff	160	1009	0	160	100
-25% Cutoff	20	1510	3	17	85
+25% Cutoff	20	2511	19	1	95
+50% Cutoff	40	3031	40	0	100
+75% Cutoff	20	3521	20	0	100

Methylenedioxy-methamphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	123	0	20	100
-50% Cutoff	160	248	0	160	100
-25% Cutoff	20	376	2	18	90
+25% Cutoff	20	622	17	3	85
+50% Cutoff	40	741	40	0	100
+75% Cutoff	20	871	20	0	100

Oxycodone

% of Cutoff	Number of samples	Drug Concentration by LC/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	25	0	20	100
-50% Cutoff	160	49	0	160	100
-25% Cutoff	20	75	1	19	95
+25% Cutoff	20	124	19	1	95
+50% Cutoff	40	149	40	0	100
+75% Cutoff	20	175	20	0	100

Buprenorphine

% of Cutoff	Number of samples	Drug Concentration by LC/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	3	0	20	100
-50% Cutoff	160	5	0	160	100
-25% Cutoff	20	8	2	18	90
+25% Cutoff	20	13	19	1	95
+50% Cutoff	40	15	40	0	100
+75% Cutoff	20	18	20	0	100

Phencyclidine

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	13	0	160	100
-25% Cutoff	20	19	2	18	90
+25% Cutoff	20	31	18	2	90
+50% Cutoff	40	38	40	0	100
+75% Cutoff	20	44	20	0	100

Nortriptyline

% of Cutoff	Number of samples	Drug Concentration by LC/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	252	0	20	100
-50% Cutoff	160	499	0	160	100
-25% Cutoff	20	759	2	18	90
+25% Cutoff	20	1258	19	1	95
+50% Cutoff	40	1503	40	0	100
+75% Cutoff	20	1751	20	0	100

Propoxyphene

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	149	0	160	100
-25% Cutoff	20	225	2	18	90
+25% Cutoff	20	374	19	1	95
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	523	20	0	100

SAFECARE Multi-Drug Urine Test Dip Card

Amphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	248	0	20	100
-50% Cutoff	160	505	0	160	100
-25% Cutoff	20	754	1	19	95
+25% Cutoff	20	1259	17	3	85
+50% Cutoff	40	1508	40	0	100
+75% Cutoff	20	1759	20	0	100

Cocaine

% of Cutoff	Number of samples	Drug Concentration by LC/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	74	0	20	100
-50% Cutoff	160	152	0	160	100
-25% Cutoff	20	224	2	18	90
+25% Cutoff	20	373	18	2	90
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	522	20	0	100

Marijuana

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	160	100
-25% Cutoff	20	37	2	18	90
+25% Cutoff	20	62	19	1	95
+50% Cutoff	40	75	40	0	100
+75% Cutoff	20	87	20	0	100

Secobarbital

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	372	18	2	90
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	529	20	0	100

Oxazepam

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	149	0	160	100
-25% Cutoff	20	224	3	17	85
+25% Cutoff	20	376	19	1	95
+50% Cutoff	40	454	40	0	100
+75% Cutoff	20	520	20	0	100

Methamphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	251	0	20	100
-50% Cutoff	160	502	0	160	100
-25% Cutoff	20	758	2	18	90
+25% Cutoff	20	1259	18	2	90
+50% Cutoff	40	1501	40	0	100
+75% Cutoff	20	1759	20	0	100

Methadone

% of Cutoff	Number of samples	Drug Concentration by LC/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	74	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	376	18	2	90
+50% Cutoff	40	447	40	0	100
+75% Cutoff	20	522	20	0	100

Morphine

% of Cutoff	Number of samples	Drug Concentration by LC/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	505	0	20	100
-50% Cutoff	160	1009	0	160	100
-25% Cutoff	20	1510	1	19	95
+25% Cutoff	20	2511	18	2	90
+50% Cutoff	40	3005	40	0	100
+75% Cutoff	20	3521	20	0	100

Methylenedioxy-methamphetamine

% of Cutoff	Number of samples	Drug Concentration by LC/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	123	0	20	100
-50% Cutoff	160	248	0	160	100
-25% Cutoff	20	376	2	18	90
+25% Cutoff	20	622	18	2	90
+50% Cutoff	40	741	40	0	100
+75% Cutoff	20	871	20	0	100

Oxycodone

% of Cutoff	Number of samples	Drug Concentration by LC/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	25	0	20	100
-50% Cutoff	160	49	0	160	100
-25% Cutoff	20	75	1	19	95
+25% Cutoff	20	124	18	2	90
+50% Cutoff	40	149	40	0	100
+75% Cutoff	20	175	20	0	100

Buprenorphine

% of Cutoff	Number of samples	Drug Concentration by LC/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	3	0	20	100
-50% Cutoff	160	5	0	160	100
-25% Cutoff	20	8	2	18	90
+25% Cutoff	20	13	19	1	95
+50% Cutoff	40	15	40	0	100
+75% Cutoff	20	18	20	0	100

Phencyclidine

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	13	0	160	100
-25% Cutoff	20	19	2	18	90
+25% Cutoff	20	31	19	1	95
+50% Cutoff	40	38	40	0	100
+75% Cutoff	20	44	20	0	100

Nortriptyline

% of Cutoff	Number of samples	Drug Concentration by LC/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	252	0	20	100
-50% Cutoff	160	499	0	160	100
-25% Cutoff	20	759	1	19	95
+25% Cutoff	20	1258	19	1	95
+50% Cutoff	40	1503	40	0	100
+75% Cutoff	20	1751	20	0	100

Propoxyphene

% of Cutoff	Number of samples	Drug Concentration by LC/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	0	20	100
-50% Cutoff	160	149	0	160	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	374	19	1	95
+50% Cutoff	40	448	40	0	100
+75% Cutoff	20	523	20	0	100

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

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

O. Conclusion:

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