510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K210327

B Applicant

W.H.P.M., Inc.

C Proprietary and Established Names

First Sign Multi-Drug Test Dip Card
First Sign Multi-Drug Test Cup
First Sign Multi-Drug Screen Test Dip Card
First Sign Multi-Drug Screen Test Cup

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QBF	Class II	21 CFR 862.3700 - Propoxyphene Test System	TX - Clinical Toxicology
NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
NFY	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
NFT	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
NFW	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
NFV	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
PTG	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
LCM	Unclassified		

Product Code(s)	Classification	Regulation Section	Panel
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
QAW	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

Modification of previously cleared devices (k142353, k150162, k151441, k152551, k160793, and k171695) to add propoxyphene device (300 ng/mL cutoff)

B Measurand:

Propoxyphene

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

First Sign Multi-Drug Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL

Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug 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, Oxazepam, Butalbital, Nortriptyline, 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.

For in vitro diagnostic use only.

First Sign Multi-Drug Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Test Cup can consist of any combination of the above listed drug analytes. The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, 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.

For in vitro diagnostic use only.

First Sign Multi-Drug Screen Test Dip Card is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen 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, Oxazepam, Butalbital, Nortriptyline, 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.

For in vitro diagnostic use only. It is for prescription use.

First Sign Multi-Drug Screen Test Cup is competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine,

Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine (AMP)	1000ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Butalbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300ng/mL or 150 ng/mL
2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine (EDDT)	300 ng/mL
Methamphetamine (MET)	1000ng/mL or 500 ng/mL
Methylenedioxy-methamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000ng/mL or 300 ng/mL
Methadone (MDT)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

Configuration of the First Sign Multi-Drug Screen Test Cup can consist of any combination of the above listed drug analytes.

The test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Butalbital, Nortriptyline, 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.

For in vitro diagnostic use only. It is for prescription use.

C Special Conditions for Use Statement(s):
Rx and OTC

D Special Instrument Requirements:

None.

IV Device/System Characteristics:

A Device Description:

The FIRST SIGN Multi-Drug Test Dip Card, FIRST SIGN Multi-Drug Test Cup, FIRST SIGN Multi-Drug Screen Test Dip Card, FIRST SIGN Multi-Drug Screen Test Cup are immunochromatograph assays for the qualitative desction of Amphetamine, Buprenorphine, Butalbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine,

Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine,
Propoxyphene, Nortriptyline and Marijuana in human urine. Each assay uses a monoclonal antibodydye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

B Principle of Operation:

The First Sign Multi-Drug Test Dip Card, First Sign Multi-Drug Test Cup, First Sign Multi-Drug Screen Test Dip Card, and First Sign Multi-Drug Screen Test Cup are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Butalbital, Methadone, Buprenorphine, Phencyclidine, Methylenedioxymethamphetamine, Tricyclic Antidepressants, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine 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.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Wondfo T-Cup Multi-Drug Urine Test Cup

B Predicate 510(k) Number(s):
k182701

C Comparison with Predicate(s):

Device & Predicate Device(s):	K210327	K182701
Device Trade Name	First Sign Multi-Drug Test Dip Card First Sign Multi-Drug Test Cup First Sign Multi-Drug Screen Test Dip Card First Sign Multi-Drug Screen Test Cup	Wondfo T-Cup Multi-Drug Urine Test Cup
General Device Characteristic Similarities		
Indications For Use	For the qualitative detection of drugs of abuse in urine	Same
Assay Principle	Competitive binding, lateral flow	Same

Device & Predicate Device(s):	K210327	K182701
	immunochromatographic assay	
Matrix	Urine	Same
Test drug cutoffs (ng/mL)	Amphetamine (AMP): 1000 or 500 Oxazepam (BZO): 300 Cocaine (COC): 300 or 150 11-Nor-△9-Tetrahydrocannabinol-9-COOH (THC): 50 Methamphetamine (MET): 1000 or 500 Morphine (OPI 2000/MOP 300): 2000 or 300 Oxycodone (OXY): 100 Butalbital (BAR): 300 Methadone (MTD): 300 Buprenorphine (BUP): 10 D,L-Methylenedioxymethamphetamine (MDMA): 500 Phencyclidine (PCP): 25 Nortriptyline (TCA): 1000 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 Propoxyphene (PPX): 300	Same
General Device Characteristic Differences		
Intended Use	Prescription and over-the-counter	Over-the-counter

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Precision studies were carried out for samples with concentrations of ±100%, ±75%, ±50%, ±25% from the cutoff and at the 300 ng/mL cutoff for Propoxyphene (PPX). Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking target drug in drug-free urine samples. Each drug concentration was confirmed by LC/MS or GC/MS. For each concentration, tests were performed two runs per day for 25

days using three lots of test cups. The results for Propoxyphene are summarized in the following tables. The precision data for AMP1000, COC300 and THC were reported in k142353. Results for BUP, BAR and MOP 300 were reported in k152551. The data for BZO, MET1000 and MOP 2000 were reported in k150162. The data for MTD, PCP and OXY were reported in k151441. The data for EDDP, MDMA and TCA were reported in k160793. The data for AMP 500, COC150 and MET 500 were reported in k171695.

Propoxyphene dip card:

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+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	4-/46+	50+/0-	50+/0-	50+/0-	50+/0-

Propoxyphene cup:

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+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	2-/48+	50+/0-	50+/0-	50+/0-	50+/0-

2. Linearity:

Not applicable, these devices are intended for qualitative use only.

3. Analytical Specificity/Interference:

Interference Studies:
Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above propoxyphene cut-off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100 µg/mL are summarized in the following tables. There were no differences observed between the Dip Card and the Cup formats. The interferences data for AMP1000, COC300 and THC were reported in k142353. Results for BUP, BAR and MOP 300 were reported in k152551. The data for BZO, MET1000 and MOP 2000 were reported in k150162. The data for MTD, PCP and OXY were reported in k151441. The data for EDDP, MDMA and TCA were reported in k160793. The data for AMP 500, COC150 and MET 500 were reported in k171695.

The following compounds did not cause any positive or negative interference with the propoxyphene assay.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Ethanol	Oxolinic acid
N-Acetylprocainamide	Erythromycin	Oxymetazoline

Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-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	(±)-Octopamine	

Cross-Reactivity Studies:
Cross-reactivity studies were performed to determine drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for propoxyphene. The cross-reactivity data for AMP1000, COC300 and THC were reported in k142353. The data for BUP, BAR and MOP 300 were reported in k152551. The data for BZO, MET1000 and MOP 2000 were reported in k150162. The data for MTD, PCP and OXY were reported in k151441. The data for EDDP, MDMA and TCA were reported in k160793. The data for AMP 500, COC150 and MET 500 were reported in k171695.

Propoxyphene (Cut off = 300 ng/mL)	**Result Positive (ng/ml)**	**% Cross-Reactivity**
d-Propoxyphene	300	100%
Norpropoxyphene	1500	20%

Effect of Urine Specific Gravity and Urine pH:
To investigate the effect of 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 propoxyphene cut-off levels. These samples were tested using three lots of each device. Results 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 First Sign Multi-Drug Test Dip Card and First Sign Multi-Drug Test Cup.

4. Assay Reportable Range:

   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   A shelf-life stability of 24 months from the date of manufacture is claimed.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   See section VII.A.1.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   A method comparison study for the for the First Sign Multi-Drug Test Dip Card and the First Sign Multi-Drug Test Cup were performed in-house by three laboratory personnel for each candidate device. The operators tested 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The propoxyphene results are presented in the tables below. The accuracy data for AMP1000, COC300 and THC were reported in k142353. The data for BUP, BAR and MOP 300 were reported in k152551. The data for BZO, MET1000 and MOP 2000 were reported in k150162. The data for MTD, PCP and OXY were reported in k151441. The data for EDDP, MDMA and TCA were reported in k160793. The data for AMP 500, COC150 and MET 500 were reported in k171695.

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	19	20
	Negative	10	15	14	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	0	20	20
	Negative	10	15	15	1	0

Discordant Results for Propoxyphene Dip Card:

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer A	20200406-030	268.2	Positive
Viewer B	20200408-001	277.6	Positive
Viewer A	20200407-003	332.0	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	0	19	20
	Negative	10	15	15	1	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	15	14	0	0

Discordant Results for Propoxyphene Cup:

Viewer	Sample Number	LC/MS Result	Dip Card Viewer Results
Viewer B	20200408-032	292.8	Positive
Viewer C	20200408-032	292.8	Positive
Viewer A	20200406-010	327.4	Negative

Lay user study:
A lay user study was conducted at three intended user sites by 280 lay users for each device format. The lay users had diverse educational and professional backgrounds and 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, 1 blind labeled sample and a device. Each device was tested. Typical results are summarized in the below tables.

First Sign Multi-Drug Test Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150):

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
AMP 500	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
BAR 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
BZO 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	100%	100%	100%
BUP 10	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
COC 150	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
EDDP 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MDMA 500	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MET 500	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
MOP 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MTD 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
OXY 100	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	100%	100%	100%
PCP 25	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
PPX 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
TCA 1000	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
THC 50	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%

First Sign Multi-Drug Test Configuration 2 (including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300):

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
AMP 500	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
BAR 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
BZO 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	100%	100%	100%
BUP 10	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
COC 150	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
EDDP 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MDMA 500	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MET 500	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
MOP 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
MTD 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
OXY 100	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20

Assay	Results	Concentration						
		-100% Cut off	-75% Cut off	-50% Cut off	-25% Cut off	+25% Cut off	+25% Cut off	+25% Cut off
	% Correct Results	100%	100%	100%	100%	100%	100%	100%
PCP 25	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
PPX 300	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	100%	95%	100%	100%
TCA 1000	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%
THC 50	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	% Correct Results	100%	100%	100%	95%	100%	100%	100%

2. Matrix Comparison:

Not applicable. The assays are only intended for use with urine samples.

C Clinical Studies:

Not applicable.

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

Not applicable.

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

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