

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

A. 510(k) Number:

k171695

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Marijuana, Cocaine, and Methamphetamine

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

W.H.P.M., Inc

F. Proprietary and Established Names:

First Sign Multi-Drug Cup Test

First Sign Multi-Drug Dip Card Test

First Sign Drug of Abuse Cup Test Marijuana

First Sign Drug of Abuse Dip Card Test Marijuana

G. Regulatory Information:

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

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

First Sign Multi-Drug Cup Test:

First Sign Multi-Drug Cup Test is a qualitative lateral flow immunoassay intended for the detection of Amphetamine, Cocaine, and Methamphetamine in human urine at cut-off concentrations of 500 ng/mL, 150 ng/mL, and 500 ng/mL respectively.

The tests provide only preliminary test results. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. It should be used particularly when the preliminary result is positive.

For in vitro diagnostic use only. The tests are intended for over-the-counter use.

First Sign Multi-Drug Dip Card Test:

First Sign Multi-Drug Dip Card Test is a qualitative lateral flow immunoassay test intended for the detection of Amphetamine, Cocaine, and Methamphetamine in human urine at cut-off concentrations of 500 ng/mL, 150 ng/mL, and 500 ng/mL, respectively.

The tests provide only preliminary test results. A more specific alternative method must be used to obtain a confirmed analytical result.. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. It should be used particularly when the preliminary result is positive. For in vitro diagnostic use only.

For in vitro diagnostic use only. The tests are intended for over-the-counter use.

First Sign Drug of Abuse Cup Test Marijuana:

First Sign Drug of Abuse Cup Test Marijuana is a qualitative lateral flow immunoassay intended for the detection of Marijuana in human urine at cut-off concentration of 20 ng/mL.

The tests provide only preliminary test results. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be used when you get any drug of abuse test result.

For in vitro diagnostic use only. The test is intended for prescription use.

First Sign Drug of Abuse Dip Card Test Marijuana:

First Sign Drug of Abuse Dip Card Test Marijuana is a qualitative lateral flow immunoassay intended for the detection of Marijuana in human urine at cut-off concentration of 20 ng/mL.

The tests provide only preliminary test results. The tests provide only preliminary test results. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be used when you get any drug of abuse test result.

For in vitro diagnostic use only. The test is intended for prescription use.

3. Special conditions for use statement(s):

For over-the-counter use (Amphetamine, Cocaine, and Methamphetamine).

For prescription use only (Marijuana).

4. Special instrument requirements:

Not applicable; this is a visually read single use device.

I. **Device Description:**

First Sign Multi-Drug Cup Test, First Sign Multi-Drug Dip Card Test, First Sign Drug of Abuse Cup Test Marijuana, and First Sign Drug of Abuse Dip Card Marijuana are lateral flow, immunochromatographic assays. The First Sign Multi-Drug Cup Test and the First Sign Multi-Drug Dip Card Test are for the qualitative detection of Amphetamine, Cocaine, and Methamphetamine in human urine. First Sign Drug of Abuse Cup Test Marijuana, and First Sign Drug of Abuse Dip Card Marijuana are for the qualitative detection of Marijuana in human urine. The products are single-use in vitro diagnostic devices, which come in the formats of Dip Cards or Cups. Each test kit contains a Test Device (in one of the two formats), 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):

Advin Multi-Drug Screen Test

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

k122809

3. Comparison with predicate:

Similarities and differences:

Item	Candidate Device: First Sign Multi-Drug Cup Test First Sign Multi-Drug Dip Card Test (k171695)	Predicate Device: Advin Multi-Drug Screen Test (k122809)
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Analyte and Cut-Off Values	Amphetamine: 500 ng/ml Cocaine: 150 ng/ml Methamphetamine: 500 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 use.	For over-the-counter and prescription use
Configurations	Dip Card, Cup	Same

Similarities and differences:

Item	Candidate Device: First Sign Drug of Abuse Cup Test Marijuana First Sign Drug of Abuse Dip Card Test Marijuana (k171695)	Predicate Device: Advin Multi-Drug Screen Test (k122809)
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Analyte and Cut-Off Values	Marijuana: 20 ng/mL	Marijuana: 50 ng/mL
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 prescription use only.	For over-the-counter and prescription use
Configurations	Dip Card, Cup	Same

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

Not applicable.

L. Test Principle:

Each assay test is a lateral flow chromatographic immunoassay. During testing, a urine specimen migrates upward by capillary action. If target drugs are present in the urine below its cut-off concentration, it will not saturate the binding sites of its specific antibody (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 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.

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. The samples used in the precision studies were prepared by spiking drug into negative urine samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blind- labeled by the person who prepared the samples and who did not take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days for each format of the device in a randomized order by three operators. The results obtained are summarized in the following tables:

Amphetamine Dip Card Format:

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+	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+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Amphetamine Cup Format:

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+	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-

Marijuana Dip Card Format

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

Marijuana Cup Format

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

Cocaine Dip Card Format

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

Cocaine Cup Format

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+	3-/47+	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+	3-/47+	50+/0-	50+/0-	50+/0-	50+/0-

Methamphetamine Dip Card Format

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

Methamphetamine Cup Format

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+	2-/48+	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+	2-/48+	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. A transport simulation study was performed to test extreme shipping temperatures. The manufacturer claims that the devices are stable at 4 - 30°C (39-86°F) for 24 months based on accelerated stability studies. Real time stability studies are ongoing.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Cross-reactivity:

To test specificity, drug metabolites and other components that are likely to cross-react in urine samples were tested using three lots of each format of the device. The substances were added to drug-free urine and cross-reactivity was determined based on the lowest concentration that produced a positive result. There were no differences observed between the two formats.

Amphetamine	Result Positive/Negative at (ng/ml)	% Cross-Reactivity
D-Amphetamine (Cut-off = 500 ng/mL)	Positive at 500	100%
L-Amphetamine	Positive at 60000	0.8%
D, L-Amphetamine	Positive at 1000	50%
Methylenedioxymphetamine (MDA)	Positive at 600	83%
R(-)-Apomorphine	Positive at 13000	4%
β-Phenylethylamine	Positive at 600	6%
Tyramine	Positive at 5000	10%
Tryptamine	Positive at 10000	0.5%
Hydroxymphetamine	Positive at 600	83%

D-Pseudoephedrine	Negative at 10^5	<0.5%
D-Methamphetamine	Negative at $\geq 10^5$	<0.5%
L-Methamphetamine	Negative at $\geq 10^5$	<0.5%
(±)-Methamphetamine	Negative at $\geq 10^5$	<0.5%
Ephedrine	Negative at $\geq 10^5$	<0.5%
3,4-Metylenedioxymethamphetamine (MDMA)	Negative at $\geq 10^5$	<0.5%
Metylenedioxymethamphetamine (MDE)	Negative at $\geq 10^5$	<0.5%
Phentermine	Negative at $\geq 10^5$	<0.5%

Cocaine	Result Positive/Negative at (ng/ml)	% Cross- Reactivity
Benzoylcegonine (Cut-off = 150 ng/mL)	Positive at 150	100%
Cocaine HCL	Positive at 3000	5%
Norocaine	Negative at $\geq 10^5$	<0.5%
Cocaethylene	Negative at $\geq 10^5$	<0.5%
Ecgonine	Negative at $\geq 10^5$	<0.5%

Methamphetamine	Result Positive/Negative at (ng/ml)	% Cross- Reactivity
D-Amphetamine (Cut-off = 150 ng/mL)	Positive at 500	100%
(±)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at 20000	2.5%
(±)-Methamphetamine	Positive at 1000	50%
P-Hydroxymehtamphetamine	Positive at 16000	3%
(±)3,4-MDMA	Positive at 2000	25%
L-Methamphetamine	Positive at 5000	10%
Fenfluramine	Positive at 40000	1.3%
L-Amphetamine	Positive at 60000	0.8%
Trimethobenzamide	Negative at $\geq 10^5$	<0.5%
Chloroquine	Negative at $\geq 10^5$	<0.5%
Ephedrine	Negative at $\geq 10^5$	<0.5%
Procaine (Novocain)	Negative at $\geq 10^5$	<0.5%
Ranitidine (Zantac)	Negative at $\geq 10^5$	<0.5%
D-Amphetamine	Negative at $\geq 10^5$	<0.5%
Oxazepam	Negative at $\geq 10^5$	<0.5%
Morphine	Negative at $\geq 10^5$	<0.5%
(±)3,4-MDA	Negative at $\geq 10^5$	<0.5%

Marijuana	Result Positive/Negative at (ng/ml)	% Cross- Reactivity
11-Nor- Δ^9 - Tetrahydrocannabinol-9-COOH (Cut-off = 20 ng/mL)	Positive at 20	100%
11-Hydroxy- Δ^9 - Tetrahydrocannabinol-9-COOH	Positive at 8000	0.25%
Δ^8 - Tetrahydrocannabinol	Positive at 5000	0.4%
Δ^9 - Tetrahydrocannabinol	Positive at 3000	0.7%
11-Nor- Δ^9 - Tetrahydrocannabinol-9-COOH	Positive at 30	67%
11-Nor- Δ^9 -THC-carboxy glucuronide	Positive at 5000	0.4%
Cannabinol	Negative at $\geq 10^5$	<0.5%
Cannabidiol	Negative at $\geq 10^5$	<0.5%

Interference:

Potential interfering substances found in human urine of physiological or pathological conditions were added 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 lots of each device. The compounds in the following table were tested at a concentration of 100 µg/mL, and did not show positive or negative interference. There were no differences observed for different device formats.

Acetaminophen (4-Acetamidophenol)	Erythromycin	Oxazepam
Acetophenetidin	β -Estradiol	Oxalic acid
N-Acetylprocainamide	Fenoprofen	Oxolinic acid
Acetylsalicylic acid	Furosemide	Oxymetazoline
Aminopyrine	Gentisic acid	Papaverine
Amoxicillin	Hydralazine	Penicillin-G
Ampicillin	Hydrochlorothiazide	Pentobarbital
Aspartame	Hydrocodone	Perphenazine
Ascorbic Acid	Hydrocortisone	Phenelzine
Apomorphine	O-Hydroxyhippuric acid	Phencyclidine
Atropine	3-Hydroxytyramine	Prednisone
Benzilic acid	Ibuprofen	Procaine
Benzoic acid	D,L-Isoproterenol	DL-Propranolol
Bilirubin	Isoxsuprine	D-Propocyphe
Cannabidiol	Ketamine	D-Pseudoephedrine
Chloralhydrate	Ketoprofen	Quinine
Chloramphenicol	Labetalol	Ranitidine
Chlorothiazide	Loperamide	Salicylic acid
Chlorpromazine	Meprobamate	Secobarital
Chloroquine	Maprotiline	Serotonin (5-

		Hydroxytyramine)
Cholesterol	Meperidine	Sulfamethazine
Clonidine	Methadone	Sulindac
Codeine	Methoxyphenamine	Tetrahydrocortisone 3-(β -D glucuronide)
Cortisone	Morpine-3- β -d- glucuronide	Tetrahydrozoline
(-) Cotinine	Nalidixic acid	Thiamine
Creatinine	Naloxone	Thioridazine
Deoxycorticosterone	Naltrexone	Triamterene
Dextromethorphan	Naproxen	DL-Tyrosine
Diclofenac	Niacinamide	Trifluoperazine
Diffunisal	Nifedipine	Trimethoprim
Digoxin	Norethindrone	D L-Tryptophan
Diphenhydramine	Norocodeine	Uric acid
Ecgonine methyl ester	Noscapine	Verapamil
EMDP	D,L-Octopamine	Zomepirac
Hemoglobin (1 mg/dL)	Albumin (1 mg/dL)	

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 in increments of 1 pH unit 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, results were all positive for samples at 25% above cut-off and all negative for samples at 25% below cut-off.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cut-off concentration appears in the precision/reproducibility section above (M.1.a.).

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were performed in-house with three laboratory assistants for each device format. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Amphetamine Dip Card Format

Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant Results of Amphetamine Dip Card Format

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer A	94912062	496	Positive
Viewer C	94911565	474	Positive
Viewer A	94912145	546	Negative
Viewer B	94912089	528	Negative
Viewer C	94912145	546	Negative

Amphetamine Cup Format

Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer B	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	1	14	26
	Negative	10	10	19	0	0

Discordant Results of Amphetamine Cup Format

Viewer	Sample Number	GC/MS Result	Cup Viewer Results
Viewer B	94911565	474	Positive
Viewer C	94912058	481	Positive
Viewer A	94912089	528	Negative
Viewer B	94912145	546	Negative

Cocaine Dip Card Format

Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant Results for Cocaine Dip Card Format

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer C	94911516	149	Positive
Viewer A	94912178	151	Negative
Viewer B	94911045	168	Negative
Viewer C	94911339	160	Negative

Cocaine Cup Format

Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	14	26
	Negative	10	10	19	0	0
Viewer B	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer	Positive	0	0	0	13	26

Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut- off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
C	Negative	10	10	20	1	0

Discordant Results Cocaine Cup Format

Viewer	Sample Number	GC/MS Result	Cup Viewer Results
Viewer A	94911516	149	Positive
Viewer B	94911033	139	Positive
Viewer B	94912178	151	Negative
Viewer C	94911339	160	Negative

Methamphetamine Dip Card Format

Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut- off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant Results for Methamphetamine Dip Card

Viewer	Sample Number	GC/MS Result	Dip Card Viewer Results
Viewer A	94911195	495	Positive
Viewer B	94912082	448	Positive
Viewer A	94912048	514	Negative
Viewer B	94912073	533	Negative
Viewer C	94912048	514	Negative

Methamphetamine Cup Format

Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut- off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	10	10	20	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant Results for Methamphetamine Cup

Viewer	Sample Number	GC/MS Result	Cup Viewer Results
Viewer A	94912072	445	Positive
Viewer C	94912082	448	Positive
Viewer A	94912073	533	Negative
Viewer B	94912073	533	Negative
Viewer C	94912048	514	Negative

Marijuana Dip Card Format

Dip Card		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut- off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	20	1	0

Discordant results Marijuana Dip Card

Viewer	Sample Number	GC/MS Result	Cup Viewer Results
Viewer A	94912036	18	Positive
Viewer B	94911685	17.8	Positive
Viewer A	94911819	22.6	Negative
Viewer B	94912007	21.3	Negative
Viewer C	94911788	22	Negative

Marijuana Cup Format

Cup		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut- off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer B	Positive	0	0	1	13	26
	Negative	10	10	19	1	0
Viewer C	Positive	0	0	1	13	26
	Negative	10	10	19	1	0

Discordant results Marijuana Cup

Viewer	Sample Number	GC/MS Result	Cup Viewer Results
Viewer A	94911691	19.7	Positive
Viewer B	94911686	17	Positive
Viewer C	94911685	17.8	Positive
Viewer A	94911788	22	Negative
Viewer C	94911819	22.6	Negative

b. Matrix comparison:

Not applicable. These devices are for use with urine samples only.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

A lay user study was performed at three intended user sites with 320 lay persons using the First Sign Multi-Drug Cup Test and the First Sign Multit-Drug Dip Card Test. The lay users had diverse educational and professional backgrounds and ranged in age from 21 to > 50 years. Urine samples were prepared at the following concentrations; +/-100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug-free pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and was blind labeled. Each participant was

provided with the package insert, one blind labeled sample and one device. The results are summarized below:

Comparison between GC/MS and Lay Person Results for Amphetamine Dip Card:

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	130	0	20
-50% Cut-off	20	245	0	20
-25% Cut-off	20	374	1	19
+25% Cut-off	20	649	20	0
+50% Cut-off	20	768	20	0
+75% Cut-off	20	857	20	0
+100% Cut-off	20	1019	20	0

Comparison between GC/MS and Lay Person Results for Cocaine Dip Card

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	37	0	20
-50% Cut-off	20	73	0	20
-25% Cut-off	20	109	0	20
+25% Cut-off	20	178	18	2
+50% Cut-off	20	223	20	0
+75% Cut-off	20	258	20	0
+100% Cut-off	20	301	20	0

Comparison between GC/MS and Lay Person Results for Methamphetamine Dip Card:

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	129	0	20
-50% Cut-off	20	259	0	20
-25% Cut-off	20	393	1	19
+25% Cut-off	20	669	20	0
+50% Cut-off	20	730	20	0
+75% Cut-off	20	930	20	0
+100% Cut-off	20	1028	20	0

Comparison between GC/MS and Lay Person Results for Amphetamine Cup:

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	130	0	20
-50% Cut-off	20	245	0	20
-25% Cut-off	20	374	0	20
+25% Cut-off	20	649	19	1
+50% Cut-off	20	768	20	0
+75% Cut-off	20	857	20	0
+100% Cut-off	20	1019	20	0

Comparison between GC/MS and Lay Person Results for Cocaine Cup

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	37	0	20
-50% Cut-off	20	73	0	20
-25% Cut-off	20	109	1	19
+25% Cut-off	20	178	20	0
+50% Cut-off	20	223	20	0
+75% Cut-off	20	258	20	0
+100% Cu-toff	20	301	20	0

Comparison between GC/MS and Lay Person Results for Methamphetamine Cup:

% of Cut-off	Number of samples	Drug Concentration by GC/MS (ng/mL)	Lay person Results	
			No. of Positive	No. of Negative
-100% Cut-off	20	0	0	20
-75% Cut-off	20	129	0	20
-50% Cut-off	20	259	0	20
-25% Cut-off	20	393	1	19
+25% Cut-off	20	669	20	0
+50% Cut-off	20	730	20	0
+75% Cut-off	20	930	20	0
+100% Cut-off	20	1028	20	0

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed.

A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading grade level of 7.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

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