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

A. 510(k) Number:

k063545

B. Purpose for Submission:

This submission is for the addition of oxycodone (with 100 and 300 ng/mL cutoffs) and to change the cutoffs for amphetamine, methamphetamine and cocaine in the previously cleared devices. In addition, the multi-analyte drug of abuse cup/cassette will be marketed as over-the-counter (OTC) and for prescription use. Oxycodone, Buprenorphine, and Norbuprenorphine will not be OTC but will remain for prescription use only.

C. Measurand:

Oxycodone, amphetamine, methamphetamine, cocaine, barbiturates, benzodiazepines, morphine, methadone, phencyclidine, tricyclic antidepressants, THC, and methylenedioxymethamphetamine (MDMA).

D. Type of Test:

Qualitative Lateral Flow Immunoassay

E. Applicant:

Alfa Scientific Designs, Inc.

F. Proprietary and Established Names:

Instant-View Amphetamine (300) Urine Test	Instant-Verdict Amphetamine (300) Urine Test	Amphetamine (300) Urine Test
Instant-View Cocaine (150) Urine Test	Instant-Verdict Cocaine (150) Urine Test	Cocaine (150) Urine Test
Instant-View Methamphetamine (300) Urine Test	Instant-Verdict Methamphetamine (300) Urine Test	Methamphetamine (300) Urine Test
Instant-View Oxycodone (100) Urine Test	Instant-Verdict Oxycodone (100) Urine Test	Oxycodone (100) Urine Test
Instant-View Oxycodone (300) Urine Test	Instant-Verdict Oxycodone (300) Urine Test	Oxycodone (300) Urine Test
Instant-View Multi-Drug of Abuse Urine Test	Instant-Verdict Multi-Drug of Abuse Urine Test	Multi-Drug of Abuse Urine Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	II	862.3650, Enzyme Immunoassay, Opiates	91 (Tox)
DKZ	II	862.3100, Enzyme Immunoassay, Amphetamine	91 (Tox)
DIO	II	862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites	91 (Tox)
DJC	II	862.3610, Thin Layer Chromatography, Methamphetamine	91 (Tox)
DIS	II	862.3120, Enzyme immunoassay, Barbiturate	91 (Tox)
NFV (JXM)	II	862.3170, Test, Benzodiazepine, over the counter	91 (Tox)
NCI (DJG)	II	862.3640, Test, Morphine, over the counter	91 (Tox)
DJR	II	862.3620, Enzyme Immunoassay, Methadone	91 (Tox)
LCM	Unclassified, 510(k) required	862.3100, Enzyme immunoassay, phencyclidine	91 (Tox)
LFG	II	862.3910, Thin layer chromatography, tricyclic antidepressant drugs	91 (Tox)
LDJ	II	862.3870, Enzyme Immunoassay, Cannabinoids	91 (Tox)

H. Intended Use:

1. Intended use(s):

   See indications for use section below.

2. Indication(s) for use:

   The Oxycodone (300) test is a qualitative immunoassay for the rapid detection of oxycodone from human urine specimens. The calibrator for the drug is oxycodone at a cutoff concentration of 300 ng/ml. It is for health care professional use only.

   This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas

Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The Oxycodone (100) test is a qualitative immunoassay for the rapid detection of oxycodone from human urine specimens. The calibrator for the drug is oxycodone at the cutoff concentration of 100 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The Methamphetamine (300) test is a qualitative immunoassay for the rapid detection of methamphetamine from human urine specimens. The calibrator for the drug is methamphetamine at the cutoff concentration of 300 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The Cocaine (150) test device is a rapid qualitative immunoassay for the rapid detection of cocaine from human urine specimens. The calibrator for the drug is benzoylecgonine at cutoff concentration of 150 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The Amphetamine (300) test is a qualitative immunoassay for the rapid detection of amphetamine from human urine specimens. The calibrator for the drug is amphetamine at cutoff concentration of 300 ng/ml. It is for health care professional use only.

This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

The multi-drug of abuse device is a rapid qualitative immunoassay for screening potential abuse of one or more drugs listed below. The device detects any combination of the drugs or drug metabolites at or above the specified cut-off levels. It is for health care professional use.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
AMP300	Amphetamine	300 ng/ml
BAR	Barbiturates	200 ng/ml
BUP	Buprenorphine/Norbuprenorphine	10 ng/ml
BZD	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
COC150	Cocaine	150 ng/ml
MET	Methamphetamine	1000 ng/ml
MET500	Methamphetamine	500 ng/ml
MET300	Methamphetamine	300 ng/ml
MOR	Morphine	2000 ng/ml
MOR500	Morphine	500 ng/ml
MTD	Methadone	300 ng/ml
OXY100	Oxycodone	100 ng/ml
OXY300	Oxycodone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Tricyclics	1000 ng/ml
THC	Marijuana	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High

Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

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The multi-drug of abuse device is a rapid qualitative immunoassay for screening potential abuse of one or more drugs listed below. The device detects any combination of the drugs or drug metabolites at or above the specified cut-off levels.

Abbreviation	Test	Cutoff
AMP	Amphetamine	1000 ng/ml
BAR	Barbiturates	200 ng/ml
BZD	Benzodiazepine	300 ng/ml
COC	Cocaine	300 ng/ml
MET	Methamphetamine	1000 ng/ml
MOR	Morphine	2000 ng/ml
MTD	Methadone	300 ng/ml
PCP	Phencyclidine	25 ng/ml
TCA	Tricyclics	1000 ng/ml
THC	Marijuana	50 ng/ml
XTC	MDMA or Ecstasy	500 ng/ml

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level. This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

3. <u>Special conditions for use statement(s):</u>
   This test provides only a preliminary result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography / Mass Spectrometry (GC/MS) or High Performance Liquid Chromatography (HPLC) is the preferred confirmatory method. Clinical

consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.
For prescription use.

For the over the counter (OTC) multi-drug of abuse test, (in addition to the statement above) the sponsor has added the following statement:

This test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers, including but not limited to concerned parents, with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

The BAR, BZD, TCA test will yield preliminary positive results when BAR, BZD, and TCA is ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturate, benzodiazepine, tricyclic antidepressant in urine. The multi-drug of abuse urine test device shows the drug was or was not present at the cutoff level.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Instant-View Methamphetamine, Amphetamine, Cocaine and Oxycodone cassette kits and test strips are individually prepackaged in sets of 25 and 50 respectively. The Instant-View Multi-Drug of Abuse Urine Test has a cup and a dip card format and is available in two configurations.

The first configuration contains 12 drugs and is intended for over-the-counter use (OTC): AMP, BAR, BZD, COC, MET, MOR, MTD, PCP, PPX, TCA, THC and XTC.

The second configuration contains 14 drugs AMP, BAR, BUP/NBUP, BZD, COC, MET, MOR, MTD, OXY, PCP, PPX, TCA, THC and XTC and is intended for professional use only.

J. Substantial Equivalence Information:

1) Predicate Device Name	2) Predicate 510(k) number	Analytes included
Instant-View Multi-Drug of	k022564	AMP, BAR, BZD, COC,

Abuse Test		MET, MOR, MTD, PCP, THC
Instant -View Amphetamine Urine Test	k994395	AMP
Instant -View Cocaine Urine Test	k994403	COC
Instant -View Methamphetamine Urine Test	k003845	MET
Instant -View Propoxyphene Urine Test	k022915	PPX
Instant -View TCA Urine Test	k022693	TCA
Instant -View MDMA Screen Urine Test	k022501	XTC
Instant -View BUP/NBUP Screen Urine Test	k060527	BUP/NBUP
Oxycodone	k033047	OXY

3. Comparison with predicate:

The device is similar or the same as the previously cleared predicate(s) in the following ways: test principles, indication for use, used in a professional and point-of-care setting, read time and sample matrix. The candidate device and the predicates are both visually-read single use devices.

The differences are the addition of oxycodone and changes to the cutoffs for AMP, MET and COC are the cutoffs. The amphetamine cutoff has been lowered from 1000 ng/ml to 300, cocaine was lowered from 300 ng/ml to 150 ng/ml, and methamphetamine has been lowered from 500 to 300 ng/ml.

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

None referenced.

L. Test Principle:

The device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The goat-anti-rabbit IgG antibody-coated particles will then be captured by immobilized drug-specific conjugate. If the level of drug in the urine specimen is below the cutoff concentration, the T line appears as a visible burgundy line. If the level of drug in the urine specimen is above the cutoff, no T line develops. The control line (C line) serves as an internal quality control of certain testing steps. It should always appear as a burgundy-colored band regardless of the presence of the

drug if enough sample volume has been added to the test and if sample has correctly migrated up the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

Analytical performance data (summarized in section M.1) is for the new test strips only: amphetamine (300 ng/mL), cocaine (150 ng/mL), methamphetamine (300 ng/mL), and oxycodone (100 and 300 ng/mL). Clinical performance to support OTC use of a subset of analytes is presented in Section M.2 below.

a. Precision/Reproducibility:

Precision was assessed by conducting with-in day, between day and between lot precision studies on three lots with six devices on four samples for three days. The four samples were 0, 75%, 125% and 300 or 333% of the chosen cutoff for each drug.

Cutoffs	Conc. for Amphetamine (ng/ml)	Conc. For Cocaine (ng/ml)	Conc. For Methamphetamine (ng/ml)	Conc. For Oxycodone (ng/ml)	Conc. For Oxycodone (ng/ml)
0%	0	0	0	0	0
75%	225	112.5	225	75	225
125%	375	187.5	375	125	375
300 or 333%	1000	450	1000	300	1000

The sponsor conducted these precision studies for both formats (dip strip and the cassette). The results of the three precision studies were the same for all of the drugs. No significant lot-to-lot or within lot variability among any of the devices was detected and the results are shown in the chart below.

Controls			Negative	75% Cutoff	125% Cutoff	300 or 333% Cutoff	Agreement		
							Within Days	Between Days	Between Lots
Expect Results			**6-**	**6-**	**6+**	**6+**			
Dip Strip	Lot I	Day 1	6-	6-	6+	6+	100%	100%	100%
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		
	Lot II	Day 1	6-	6-	6+	6+	100%	100%	
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		
	Lot III	Day 1	6-	6-	6+	6+	100%	100%	
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		
Cassette	Lot I	Day 1	6-	6-	6+	6+	100%	100%	100%
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		
	Lot II	Day 1	6-	6-	6+	6+	100%	100%	
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		
	Lot III	Day 1	6-	6-	6+	6+	100%	100%	
		Day 2	6-	6-	6+	6+	100%		
		Day 3	6-	6-	6+	6+	100%		

To demonstrate performance of the new test strips in a professional setting, 2 physician offices and one reference laboratory participated in a study that was conducted on both formats by a lab technician, medical assistant, and a physician. Six spiked samples (n=80), equivalent to 0, 50%, 75%, 125%, 150% and 300 or 333% of the cutoff, were prepared from a specimen and confirmed by GC/MS. The values and results are shown in the following charts below.

Cutoffs	Conc. for Amphetamine (ng/ml) (c/o 300)	Conc. For Cocaine (ng/ml) (c/o 150)	Conc. For Methamph. (ng/ml) (c/o 300)	Conc. For Oxycodone (ng/ml) (c/o 100)	Conc. For Oxycodone (ng/ml) (c/o 300)	N
Negative	0	0	0	0	0	10
50%	150	75	150	50	150	15
75%	225	112.5	225	75	225	15
125%	375	187.5	375	125	375	15
150%	450	225	450	150	450	15
300/ 333 %	1000	450	1000	300	1000	10

		Site 1	Site 2	Site 3
Amphetamine				
Agreement	Within Site	96.3%	96.3%	100%
	Between Site	97.5%		
Cocaine				
Agreement	Within Site	97.5%	97.5%	98.8%
	Between Site	97.9%		
Methamphetamine				
Agreement	Within Site	96.3%	96.3%	98.8%
	Between Site	97.1%		
Oxycodone (100 ng/ml)				
Agreement	Within Site	96.3%	96.3%	97.5%
	Between Site	96.7%		
Oxycodone (300 ng/ml)				
Agreement	Within Site	97.5%	97.5%	97.5%
	Between Site	97.5%		

The sponsor conducted a bridging study along with their cutoff study for each drug to show that the two formats (dip strip and cassette) are equivalent. The results demonstrated equivalency of the two formats. See cutoff section below for a summary of the data.

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

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

This device has internal process controls. A colored line appearing in the control region confirms that sufficient sample volume has been applied and that the sample has migrated correctly on the test strip. Users are informed not to interpret the test if a colored line failed to appear in the control region. External controls are not supplied with this device.

The sponsor conducted an accelerated degradation study to assess the shelf life of the tests. The sponsor has a real-time shelf-life study ongoing.

d. *Detection limit:*

A cutoff study (summarized below) was conducted at six different concentrations of each new test strip and format. Each concentration was confirmed with GC/MS.

Amphetamine

Cassette Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	150 (50%cutoff)	15-	15-	100%
	225 (75%cutoff)	15-	15-	100%
	375 (125%cutoff)	15+	12+, 3-	80%
	450 (150%cutoff)	15-	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	43-, 37+	96.3%

Dip Strip Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	150 (50%cutoff)	15-	15-	100%
	225 (75%cutoff)	15-	15-	100%
	375 (125%cutoff)	15+	12+, 3-	80%
	450 (150%cutoff)	15-	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	43-, 37+	96.3%

Cocaine

Cassette Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	75 (50%cutoff)	15-	15-	100%
	112.5 (75%cutoff)	15-	14-, 1+	93.3%
	187.5 (125%cutoff)	15+	14+, 1-	93.3%
	225 (150%cutoff)	15+	15+	100%
	450 (300% cutoff)	10+	10+	100%
Total		40-, 40+	41-, 40+	97.5%

Dip Strip Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	75 (50% cutoff)	15-	15-	100%
	112.5 (75% cutoff)	15-	14-, 1+	93.3%
	187.5 (125% cutoff)	15+	14+, 1-	93.3%
	225 (150% cutoff)	15+	15+	100%
	450 (300% cutoff)	10+	10+	100%
Total		40-, 40+	41-, 40+	97.5%

Methamphetamine

Cassette Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	150 (50% cutoff)	15-	15-	1005
	225 (75% cutoff)	15-	15-	100%
	375 (125% cutoff)	15+	13+, 2-	86.7%
	450 (150% cutoff)	15+	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	42-, 38+	97.5%

Dip Strip Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	150 (50% cutoff)	15-	15-	1005
	225 (75% cutoff)	15-	15-	100%
	375 (125% cutoff)	15+	13+, 2-	86.7%
	450 (150% cutoff)	15+	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	42-, 38+	97.5%

Oxycodone (100 ng/ml)

Cassette Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	50 (50% cutoff)	15-	15-	100%
	75 (75% cutoff)	15-	14-, 1+	93.3%
	125 (125% cutoff)	15+	13+, 2-	86.7%
	150 (150% cutoff)	15+	15+	100%
	300 (300% cutoff)	10+	10+	100%
Total		40-, 40+	41-, 39+	96.3%

Dip Strip Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10-	10-	100%
	50 (50% cutoff)	15-	15-	100%
	75 (75% cutoff)	15-	14-, 1+	93.3%
	125 (125% cutoff)	15+	13+, 2-	86.7%
	150 (150% cutoff)	15+	15+	100%
	300 (300% cutoff)	10+	10+	100%
Total		40-, 40+	41-, 39+	96.3%

Oxycodone (300 ng/ml)

Cassette Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10 -	10 -	100%
	150 (50% cutoff)	15-	15-	100%
	225 (75% cutoff)	15-	14-, 1+	93.3%
	375 (125% cutoff)	15+	14+, 1-	93.3%
	450 (150% cutoff)	15+	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	40-, 40+	97.5%

Dip Strip Test		Expected Result	Test Result	Agreement
Controls (ng/ml)	0 (negative)	10 -	10 -	100%
	150 (50% cutoff)	15-	15-	100%
	225 (75% cutoff)	15-	14-, 1+	93.3%
	375 (125% cutoff)	15+	14+, 1-	93.3%
	450 (150% cutoff)	15+	15+	100%
	1000 (333% cutoff)	10+	10+	100%
Total		40-, 40+	40-, 40+	97.5%

The results support the sponsor's chosen cutoffs of 300 ng/mL for Amphetamine and methamphetamine, 150 ng/ml for cocaine and 100 and 300 ng/mL for oxycodone.

e. Analytical specificity:

Cross-reactivity for the new test strips was evaluated by spiking various concentrations of similarly structured drug compounds into a drug-free urine negative control. When a positive result was obtained, the sample was diluted to half of the concentration and tested again. The sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentrations of the assays. The cross-reactivity testing results are listed below.

Amphetamine

Chemical compounds	**Concentration (ng/ml)**
d-amphetamine	300
l-amphetamine	20,000
d,l-amphetamine	300
3,4-methylenedioxyamphetamine	20,000

Cocaine

Chemical compounds	**Concentration (ng/ml)**
Cocaine HCl	150
Benzoylecgonine	150
Isoxsuprine	1500

Methamphetamine

Chemical compounds	**Concentration (ng/ml)**
d-methamphetamine	300
l-methamphetamine	25,000
d-amphetamine	50,000
l-amphetamine	10,000
3,4-methylenedioxyamphetamine	50,000

Oxycodone- (for both cutoffs of 100 and 300 ng/ml)

Chemical compounds	**Concentration (ng/ml)**
Oxycodone	100 and 300
Morphine	20,000
Hydrocodone	100,000
Ethyl morphine	100,000

The sponsor tested many common substances and biological materials (113) for cross-reactivity with the drug of abuse tests at a concentration of 100 µg/mL in drug-free and drug positive urines. The sponsor states that there were no deviations from the expected results. The compounds tested are listed in the table below.

Chemical compounds (100μg/ml)		
Acetaminophen	Acetylsalicyclic acid	Aminopyrine
N-Acetylprocainamide	Ampicillin	Acetophenetidin
Amoxicillin	Apomorphine	Atropine
L-Ascorbic acid	Aspartame	Benzlilic acid
Benzoic acid	Benzphetamine	Bilirubin
D/L-Brompheniramine	Caffeine	Cannabidol
Chloralhydrate	Chloramphenicol	Chlorothiazide
D/L-Chloropheniramine	Chlorpromazine	Chloroquine
Cholesterol	Chlonidine	Cortisone
L-Cotinine	Creatinine	Deoxycorticosterone
Dextromethorphan	Diclofenac	Diflunisal
Digoxin	Diphenhydramine	Ecgonine methyl ester
L-ψ–Ephedrine	β–Estradiol	Estrone-3-sulfate
Ethyl-p-aminobenzoate	L(-)-Epinephrine	Erythromycin
Fenoprofen	Furosemide	Gentisic acid
Hemoglobin	Hydralazine	Hydrochlorothiazide
Hydrocortisone	O-Hdorxyhippuric acid	p-Hydroxyamphetamine
p-Hydroxytyramine	Ibuprofen	Iproniazid
D/L-Isoproterenol	Isoxsuprine	Ketamine
Ketoprofen	Labetalol	Loperamide
Meperidine	Meprobamate	Methoxyphenamine
Methylphenidate	Naloxone	Nalidixic acid
Naproxen	Naltrexone	Nifedipine
Niacinamide	Norethindrone	D-Norpropoxyphene
Noscapine	D/L-Octopamine	Oxalic acid
Oxolinic acid	Oxymetazoline	Papaverine
Pencillin-G	Pentazocine hydrochloride	Perphenazine
Phenelzine	Trans-2-phenylcyclo-propylamine hydrochloride	
L-Phenylpropanolamine	β-Phenylethylamine	Phenylpropanolamine
Prednisone	D/L-Pseudoephedrine	D-Propoxyphene
D-Pseudoephedrine	Quinacrine	Quinine
Quindine	Ranitidine	Salicylic acid
Serotonin	Sulfamethazine	Sulindac
Tetrahydrocortisone 3 (β-D-glucuronide)		Terahydrozoline
Thiamine	Thioridazine	D/L-Tyrosine
Tolbutamine	Triamterene	Trifluoperazine
Trimethoprim	Tryptamine	D/L-Tryptophan
Tyramine	Uric acid	Verapamil
Zomepirac		

The sponsor evaluated urine pH for test interference in seven pooled negative urine specimens. The specimens were adjusted to pH ranging from 3 to 9 and

divided into two groups with concentrations of 50% below and above the cutoff. The testing results are summarized in the table below and the results were the same for all the drugs. The results showed that there was no interference from urine pH ranging from 3 to 9 and that the device formats (dip strip and cassettes) gave the same result. Both cassette and dip-strip format were tested in duplicate.

ID	PH Value	Cassette Test		Dip-strip Test	
		50% CUTOFF	**150% CUTOFF**	**50% CUTOFF**	**150% CUTOFF**
1	3.0	-	+	-	+
2	4.0	-	+	-	+
3	5.0	-	+	-	+
4	6.0	-	+	-	+
5	7.0	-	+	-	+
6	8.0	-	+	-	+
7	9.0	-	+	-	+

The sponsor evaluated specific gravity for test interference in seven pooled negative urine specimens. The specimens were adjusted to specific gravities ranging from 1.002 to 1.035 and divided into two groups with concentrations of 50% below and above the cutoff. The testing results are summarized in the table below and the results were the same for all the drugs. The results showed that there was no interference from specific gravity ranging from 1.002 to 1.035 and that the device formats (dip strip and cassettes) gave the same result. Both cassette and dip-strip format were tested in duplicate.

ID	SG Value	Cassette Test		Dip-Strip Test	
		50% Cutoff	**150% Cutoff**	**50% Cutoff**	**150% Cutoff**
1	1.002	-	+	-	+
2	1.005	-	+	-	+
3	1.011	-	+	-	+
4	1.016	-	+	-	+
5	1.020	-	+	-	+
6	1.021	-	+	-	+
7	1.023	-	+	-	+
8	1.027	-	+	-	+
9	1.033	-	+	-	+
10	1.035	-	+	-	+

The sponsor conducted a sample volume test for the both the cassette and the dip-strip test formats. The study showed that 3 to 5 drops of specimen are required for the cassette test and that the dip-strip devices should be dipped for at least 10

seconds to allow for proper absorption. The sponsor has recommended 4 drops in the package insert.

The sponsor also conducted a reading time test and the study revealed that both devices can obtain results from 4 to 7 minutes after adding the specimen. The sponsor has recommended reading the test after 4 minutes and before 7 minutes.

f. Assay cut-off:

Characterization of how the devices perform analytically around the claimed cutoff concentrations appears in the precision above.

2. Comparison studies:

a. Method comparison with predicate device:

The Instant-View Methamphetamine, Amphetamine, Cocaine and Oxycodone cassette kits and test strips were compared to the GC/MS reference method. Amphetamine (n=98), cocaine (n=108), methamphetamine (n=127) and oxycodone 100 and 300 ng/ml (n=84 and 115 respectively for each level) were obtained from a clinical urine sample provider. The results of the method comparison are shown in the tables below.

Amphetamine

Cassette Test		**Proposed Device**		**Total**	**Agreement**
		Positive	**Negative**		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~150)	0	4	4	100%
	50%-75% (150~225)	0	10	10	100%
	75%-Cutoff (225~300)	1	9	10	90%
	Cutoff-125%(300-375)	11	2	12	83.6%
	125-150% (375~450)	8	0	8	100
	Positive (>450)	23	0	20	100%
Total		43	55	98	96.9

Dip-Strip Test		**Proposed Device**		**Total**	**Agreement**
		Positive	**Negative**		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~150)	0	4	4	100%
	50%-75% (150~225)	0	10	10	100%
	75%-Cutoff (225~300)	1	9	10	90%
	Cutoff-125%(300-375)	11	2	12	83.6%
	125%-150% (375~450)	8	0	8	100
	Positive (>450)	23	0	20	100%
Total		43	55	98	96.9%

Cocaine

Cassette Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~75)	0	6	6	100%
	50%-75% (75-112.5)	0	8	8	100%
	75%-Cutoff (112.5-150)	1	11	12	91.7
	Cutoff-125%(150-187.5)	9	2	11	81.8%
	125-150% (187.5-225)	12	0	12	100
	Positive (>225)	29	0	29	100%
Total		51	57	108	97.2%

Dip-Strip Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~75)	0	6	6	100%
	50%-75% (75-112.5)	0	8	8	100%
	75%-Cutoff (112.5-150)	1	11	12	91.7
	Cutoff-125%(150-187.5)	9	2	11	81.8%
	125-150% (187.5-225)	12	0	12	100
	Positive (>225)	29	0	29	100%
Total		51	57	108	97.2%

Methamphetamine

Cassette Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~150)	0	3	3	100%
	50%-75% (150~225)	0	10	20	100%
	75%-Cutoff (225~300)	2	11	13	84.6
	Cutoff-125%(300-375)	12	3	15	80
	125%-150% (375~450)	13	0	13	100%
	Positive (>450)	40	0	40	100%
Total		67	60	127	96.4%

Dip-Strip Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	30	30	100%
	<50% (0~150)	0	3	3	100%
	50%-75% (150~225)	0	10	20	100%
	75%-Cutoff (225~300)	2	11	13	84.6%
	Cutoff-125%(300-375)	12	3	15	80%
	125%-150% (375~450)	13	0	13	100%
	Positive (>450)	40	0	40	100%
Total		67	60	127	100

Oxycodone (100 ng/ml)

Cassette Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	28	28	100%
	<75% (0~75)	0	6	6	100%
	75%~Cutoff (75~100)	1	8	9	88.9%
	Cutoff~125% (100~125)	8	1	9	88.9%
	Positive (>125)	32	0	32	100%
Total		41	43	84	97.6%

Dip-Strip Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	28	28	100%
	<75% (0~225)	0	6	6	100%
	75%~Cutoff (225~300)	1	8	9	88.9%
	Cutoff~125% (300~375)	8	1	9	88.9%
	Positive (>375)	32	0	32	100%
Total		41	43	84	97.6%

Oxycodone (300 ng/ml)

Cassette Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	28	28	100%
	<50% (0~150)	0	21	21	100%
	50%-75% (150~225)	1	9	10	90%
	75%-Cutoff (225~300)	0	10	10	100%
	Cutoff-125%(300-375)	9	1	10	90%
	125%-150% (375~450)	10	0	10	100%
	Positive (>450)	26	0	26	100%
Total		46	69	115	98.3%

Dip-Strip Test		Proposed Device		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	28	28	100%
	<50% (0~150)	0	21	21	100%
	50%-75% (150~225)	1	9	10	90%
	75%-Cutoff (225~300)	0	10	10	100%
	Cutoff-125%(300-375)	9	1	10	90%
	125%-150% (375~450)	10	0	10	100%
	Positive (>450)	26	0	26	100%
Total		46	69	115	98.3%

The sponsor also conducted lay user studies at five separate sites for the OTC

version of the multi-drug urine cup and cassette formats. The panel format was evaluated in two separate studies at five sites (123 cassette participants and 63 cup participants) lay-users between the ages of 10 to 80 with varying education levels and a trained professional were used. All participants had proper informed consent.

25	50%											150%
26	75%											125%
27	50%	300%	50%	300%	50%	300%	300%	50%	300%	50%	300%	50%
28	300%	50%	300%	50%	300%	50%	50%	300%	50%	300%	50%	300%

Study 1- Twenty-eight urine samples were prepared by spiking drug-free pooled urine with the drugs to specific concentrations. The concentrations of all the drugs were confirmed by GC/MS except for TCA, which was confirmed by HPLC. Each sample was divided into nine containers and blind-labeled (n=252). The samples were further split into two, one for the panel test and the other for the cup. Twenty-one lay-users at three sites were given a set of four samples (n=252) from 84 GC/MS confirmed blind-labeled samples, four complete devices (with all 12 test strips) and one package insert. The lay users tested 4 samples (panel or cup) and read all 48 results. The

Study 1	Drug Concentrations											
	AMP	BAR	BZD	COC	MET	MOR	MTD	PCP	PPX	TCA	THC	XTC
1	50%	150%	50%	150%	50%	150%	150%	50%	150%	50%	150%	50%
2	150%	50%	150%	50%	150%	50%	50%	150%	50%	150%	50%	150%
3	150%	50%										
4	125%	75%										
5		150%	50%									
6		125%	75%									
7			150%	50%								
8			125%	75%								
9				150%	50%							
10				125%	75%							
11					150%	50%						
12					125%	75%						
13						150%	50%					
14						125%	75%					
15							150%	50%				
16							125%	75%				
17								150%	50%			
18								125%	75%			
19									150%	50%		
20									125%	75%		
21										150%	50%	
22										125%	75%	
23											150%	50%
24											125%	75%

trained professional performed all 84 tests (both panel and cup). The subjects were asked to read the package insert and perform the test. The concentrations tested are shown in the table below.

Study 2- Eleven urine samples were prepared by spiking drug-free pooled urine specimens with the drugs to specific concentrations. The concentrations of all the drugs were confirmed by GC/MS except for TCA, which was confirmed by HPLC. Each sample was divided into sixty containers and blind-labeled (n=660). Twenty lay users at three sites were given two sets (panel A and panel B) of blind-labeled samples, devices and a package insert. Panel A is comprised of AMP100, BAR, BZD300, COC300, MET1000, MOR2000, AMP300, MET300, MOR3200, MTD, PCP and THC. Panel B is comprised of AMP500, BZD200, COC150, MET500, OXY100, BUP, KET, OXY300, PPX, TCA and XTC. Panel A samples included samples 1 to 6 and panel B samples include samples 7 to 11. The lay users tested all 11 samples and read 127 results (12 x 6=72 for panel A and 11 x 5=55 for panel B). The concentrations and panels tested are shown in the table below.

ID	Drug Concentration (ng/ml)														
	AMP	BAR	BUP	BZD	COC	KET	MET	MOR	MTD	OXY	PCP	PPX	TCA	THC	XTC
1		300			450			450			37.5				
2	150	800		150	1000		150	1000	150		100			25	
3	1500			450			450		450					75	
4	3000	100		1000	150		1500	150	1000		12.5			150	
5	450						3000	6000							
6								3000							
7					225	1500				450			1500		
8	250		5	100	450	3000	250			1000		150	3000		250
9	750		15	300			750					450			750
10	1500		30	800	75	500	1500			50		1000	500		1500
11										150					

The combined panel results from study one and two (123 lay users) and the cup results are shown below.

Panel results:

		Agreement	100%	99%	100%	100%
XTC	500	Positive	0	0	86	69
		Negative	300	96	1	0
		Total	300	96	87	69
		Agreement	100%	100%	99%	100%
AMP	1000	Positive	0	4	85	68
		Negative	360	92	2	1
		Total	360	96	87	69
		Agreement	100%	96%	98%	99%
BAR	200	Positive	0	1	86	69
		Negative	360	95	1	0
		Total	360	96	87	69
		Agreement	100%	99%	99%	100%
BZD	300	Positive	0	1	85	69
		Negative	360	95	2	0
		Total	360	96	87	69
		Agreement	100%	99%	98%	100%
COC	300	Positive	0	0	85	69
		Negative	360	96	2	0
		Total	360	96	87	69
		Agreement	100%	100%	98%	100%
MET	1000	Positive	0	2	85	69
		Negative	360	94	2	0
		Total	360	96	87	69
		Agreement	100%	98%	98%	100%
MOR	2000	Positive	2	2	85	69
		Negative	358	94	2	0
		Total	360	96	87	69
		Agreement	99%	98%	98%	100%
MTD	300	Positive	0	1	83	68
		Negative	360	95	4	1
		Total	360	96	87	69
		Agreement	100%	99%	95%	99%
PCP	25	Positive	0	0	87	69
		Negative	360	96	0	0
		Total	360	96	87	69
		Agreement	100%	100%	100%	100%
THC	50	Positive	0	2	85	69
		Negative	360	94	2	0
		Total	360	96	87	69
		Agreement	100%	98%	98%	100%
TCA	1000	Positive	0	1	87	69
		Negative	300	95	0	0
		Total	300	96	87	69

Drug	Cutoff (ng/ml)	Results	Drug Concentration			
			Negative	50%-Cutoff	Cutoff-150%	300%Cutoff

Cup results:

Drug	Cutoff (ng/ml)	Results	Drug Concentration			
			Negative	50% ~ Cutoff	Cutoff ~ 150%	300% Cutoff
AMP	1000	Positive	0	1	25	9
		Negative	180	35	2	0
		Total	180	36	27	9
		Agreement	100%	97.2%	92.6%	100.0%
BAR	200	Positive	0	0	26	9
		Negative	180	36	1	0
		Total	180	36	27	9
		Agreement	100%	100.0%	96.3%	100.0%
BZD	300	Positive	0	1	25	9
		Negative	180	35	2	0
		Total	180	36	27	9
		Agreement	100%	97.2%	92.6%	100.0%
COC	300	Positive	0	0	25	9
		Negative	180	36	2	0
		Total	180	36	27	9
		Agreement	100%	100%	92.6%	100.0%
MET	1000	Positive	0	1	27	9
		Negative	180	35	0	0
		Total	180	36	27	9
		Agreement	100%	97.2%	100.0%	100.0%
MOR	2000	Positive	0	2	26	9
		Negative	180	34	1	0
		Total	180	36	27	9
		Agreement	100%	94%	96%	100.0%
MTD	300	Positive	0	0	26	9
		Negative	180	36	1	0
		Total	180	36	27	9
		Agreement	100%	100%	96%	100.0%
PCP	25	Positive	0	0	27	9
		Negative	180	36	0	0
		Total	180	36	27	9
		Agreement	100%	100%	100%	100.0%
THC	50	Positive	0	1	27	9
		Negative	180	35	0	0
		Total	180	36	27	9
		Agreement	100%	97%	100%	100.0%
TCA	1000	Positive	0	0	26	9
		Negative	180	36	1	0
		Total	180	36	27	9
		Agreement	100%	100%	96%	100.0%
XTC	500	Positive	0	0	27	9
		Negative	180	36	0	0
		Total	180	36	27	9
		Agreement	100%	100%	100%	100.0%

The sponsor conducted an analysis of their package inserts and have stated that their package insert has received a 7th grade Flesh-Kincaid reading score and a Flesch Reading Ease score of 63.

The sponsor conducted a questionnaire for users to evaluate the cup and cassette format of the multi-drug device. The results are shown in the tables below.

Cassette Format	Very Easy to Understand	Easy to Understand	Understandable w/ some Difficulty	Difficult to Understand	Impossible to Understand	Total
Explanation of intended use of the test.	76 (61.8%)	45 (36.6%)	1 (0.8%)	1 (0.8%)	0	123
Directions to do the test	71 (57.7%)	51 (41.5%)	1 (0.8%)	0	0	123
Performing the test	87 (70.7%)	34 (27.6%)	2 (1.6%)	0	0	123
Direction to interpret the result	78 (63.4%)	44 (35.8%)	1 (0.8%)	0	0	123
Actual interpretation of the test result	67 (54.5%)	47 (38.2%)	9 (7.3%)	0	0	123

Urine Cup Format	Very Easy to Understand	Easy to Understand	Understandable w/ some Difficulty	Difficult to Understand	Impossible to Understand	Total
Explanation of intended use of the test.	28 (44.4%)	34 (54.0%)	1 (1.6%)	0	0	63
Directions to do the test	32 (50.8%)	30 (47.6%)	1 (1.6%)	0	0	63
Performing the test	31 (49.2%)	29 (46.0%)	2 (3.2%)	1 (1.6%)	0	63
Direction to interpret the result	30 (47.6%)	32 (50.8%)	1 (1.6%)	0	0	63
Actual interpretation of the test result	36 (57.1%)	25 (39.7%)	2 (3.2%)	0	0	63

b. Matrix comparison:

Not applicable. The assay is intended for urine samples..

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):

Not applicable

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 determination.