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

A. 510(k) Number:

k171403

B. Purpose for Submission:

New device

C. Measurands:

Amphetamine, cocaine, Marijuana, methamphetamine, morphine, and phencyclidine

D. Type of Test:

Qualitative, lateral flow immunochromatographic

E. Applicant:

Premiere Biotech, Incorporated

F. Proprietary and Established Names:

OralTox Oral Fluid Drug Test

G. Regulatory Information:

Product Code	Classification	Relation Section	Panel
DKZ	Class II	21CFR 862.3100, Amphetamine Test System	Toxicology (91)
DIO	Class II	21 CFR 862.3250, Cocaine and metabolites Test System	Toxicology (91)
LDJ	Class II	21 CFR 862.3870, Cannabinoids Test System	Toxicology (91)
DJC	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
LCM	Class II	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology (91)
DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below

2. Indication(s) for use:

The OralTox Oral Fluid Drug Test is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana (THC), Methamphetamine, Opiates and Phencyclidine, in human oral fluid at the cutoff concentrations listed below:

Test	Calibrator	Cut-off level
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Cannabinoids (THC)	Delta-9 Tetrahydrocannabinol	40 ng/mL
Methamphetamine (MET)	d-Methamphetamine	50 ng/mL
Morphine (MOP)	Morphine	40 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Liquid Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

For in vitro diagnostic use only.

3. Special conditions for use statement(s):

For prescription point-of-care use.

4. Special instrument requirements:

Not applicable, as the device is a visually-read single use device.

Device Description:

The OralTox Oral Fluid Drug Test is an immunochromatographic assay that uses a lateral flow system for the qualitative detection of Amphetamine, cocaine, cannabinoids, methamphetamine, morphine, phencyclidine (target analytes) in human oral fluid. The device has a built-in sample collection tool, including collection swab and sponge, as well as a saturation indicator strip. The saturation indicator strip turns red when a volume of oral fluid has been collected that is adequate for both the OralTox test and for confirmation testing at a laboratory if the result is a presumptive positive.

OralTox Oral Fluid Drug Tests tests are the first step in a two-step process. The second step is to send the sample for confirmatory laboratory testing using a more specific method (e.g., LC-MS/MS) if preliminary positive results are obtained.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Oratect Oral Fluid Drug Screen Device

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

   k103227

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Same	Preliminary Drug screening test for the qualitative detection of drug analytes in oral fluid (human saliva) For *In Vitro* Diagnostic Use
Drug analytes detected	Same	D-Amphetamine Cocaine Delta-9-Tetrahydrocannabinol D-Methamphetamine Morphine Phencyclidine
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry
Type of Test	Same	Qualitative
Specimen Type	Same	Human Oral fluid
Cutoffs	Same	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL MOP 40 ng/ML PCP 10 ng/mL
Differences		
Item	Device	Predicate
Configuration	Cups	Testing Pads

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

None referenced

L. Test Principle:

The OralTox Oral Fluid Drug Test is an immunochromatographic assay that uses a lateral

flow system for the qualitative detection of Amphetamine, cocaine, Marijuana, methamphetamine, morphine, and phencyclidine (target analytes) in human oral fluid. The tests are lateral flow chromatographic immunoassays, consisting of one test strip per analyte. During testing, an oral fluid specimen migrates up the test strip by capillary action. If target drugs present in the oral fluid specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision-Reproducibility-Cut-Off studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative oral fluid samples. The sponsor has stated that each drug concentration was confirmed by LC-MS/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 10 days per device lot in a randomized order. The sponsor provided the following summaries.

Amphetamine

	-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	60-/0+	60-/0+	60-/0+	55-/5+	53+/7-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	54-/6+	51+/9-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	56-/4+	49+/11-	54+/6-	60+/0-	60+/0-	60+/0-

Cocaine

	-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	60-/0+	60-/0+	60-/0+	56-/4+	52+/8-	54+/6-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	55-/5+	50+/10-	54+/6-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	54-/6+	48+/12-	56+/4-	60+/0-	60+/0-	60+/0

Methamphetamine

	-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	60-/0+	60-/0+	60-/0+	54-/6+	50+/10-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	55-/5+	49+/11-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	55-/5+	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-

Morphine

	-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	60-/0+	60-/0+	60-/0+	55-/5+	48+/12-	57+/3-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	55-/5+	48+/12-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	54-/6+	50+/10-	56+/4-	60+/0-	60+/0-	60+/0-

Phencyclidine

	-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	60-/0+	60-/0+	60-/0+	54-/6+	48+/12-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	54-/6+	49+/11-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	55-/5+	48+/12	56+/4-	60+/0-	60+/0-	60+/0-

Cannabinoids

	-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	60-/0+	60-/0+	60-/0+	54-/6+	50+/10-	55+/5-	60+/0-	60+/0-	60+/0-
Lot 2	60-/0+	60-/0+	60-/0+	54-/6+	50+/10-	56+/4-	60+/0-	60+/0-	60+/0-
Lot 3	60-/0+	60-/0+	60-/0+	55-/5+	49+/11-	55+/5-	60+/0-	60+/0-	60+/0-

The device has been developed with the following cutoffs:

Calibrator	**Cut-off (ng/mL)**
d-Methamphetamine	50
Cocaine	20
Morphine	40
d-Amphetamine	50
Phencyclidine	10
Delta-9-Tetrahydrocannabinol	40

Sample Volume:

A sample volume study was conducted to confirm the reproducibility of adequate sample volume collection by the device. Operators collected samples at two sites from a total 136 subjects (including drug users) following the device's instructions for use. Operators swept the inside of volunteer's mouth (cheek, gums, and tongue), and then held the swab in the subject's mouth until the color indicator within the collection device indicated that collection was complete.

The sponsor reported that all subjects evaluated were able to provide sufficient sample (so that the collection device's color indicator showed adequate collection) within the recommended seven minute collection timeframe. Mean volume collected was 2.5 +/- 0.2 mL, and time required for collection was 3.7 +/-1.7 minutes. The maximum time required for collection was reported as seven minutes, and the minimum volume collected was 2.2 mL.

b. *Linearity/assay reportable range:*

Not applicable. These devices are intended for qualitative use only.

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

Accelerated stability studies have been conducted for the device. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that when stored un-opened at 4-30 º C, the device is stable for 24 months. Real time studies have been conducted and are ongoing.

Sample Recovery

Sample volume recovery**:**

A sample volume recovery study was conducted to confirm that adequate sample volume could be extracted from the device for confirmatory testing after collection and shipping. Operators collected samples at two sites from a total 194 subjects (including drug users) following the device's instructions for use. Devices containing oral fluid samples were then sent to the confirmation laboratory using overnight shipping. The sponsor reported that the confirmation lab was able to extract sufficient sample volume for the confirmation testing of all six analytes for all samples collected.

Analyte recovery:

To confirm that preliminary positive results can be adequately measured via confirmation testing after being subject to the temperature conditions required for shipping and storage, negative oral fluid samples in glass bottles were spiked with a single analyte/bottle to concentrations approximately -50% and +50% of the cutoff. Samples were spiked using known standards. Each drug concentration was confirmed by LC-MS/MS. The samples were transferred to OralTox devices using the collection sponges. For each of 3 storage conditions (-20°C, 20-25°C, and 40°C), 12 devices were used (4 devices from each of 3 lots). For each device, drug was measured by LC-MS/MS at time zero and the devices containing the specimens were stored under the specified condition. Drug in the devices stored at 20-25°C and 40°C was measured by LC-MS/MS at two (2) days, and drug in the devices stored at -20°C was measured by LC-MS/MS at 90 days.

The minimum and maximum recovery from 12 devices per lot per storage condition is shown below.

Room Temperature 20-25°C (two day storage)

	MET +50	MET -50	COC +50	COC -50	MOR +50	MOR -50	AMP +50	AMP -50	PCP +50	PCP - 50	THC +50	THC -50
Max	100.1	100.0	100.5	97.8	100.3	102.0	100.3	99.7	98.4	99.8	99.0	100
Min	94.4	89.8	96.6	92.5	93.6	96.4	95.6	93.2	92.8	94.9	94.3	93.3

40 °C (two day storage)

	MET +50	MET -50	COC +50	COC -50	MOR +50	MOR -50	AMP +50	AMP -50	PCP +50	PCP -50	THC +50	THC -50
Max	105.4	100.4	99.3	100.0	100.6	100.0	99.6	98.6	97.4	96.3	100.5	98.3
Min	87.2	92.1	95.0	92.1	95.8	90.3	90.3	92.5	89.9	87.6	91.4	91.6

-20 °C (90 day storage)

	MET +50	MET -50	COC +50	COC -50	MOR +50	MOR -50	AMP +50	AMP -50	PCP +50	PCP -50	THC +50	THC -50
Max	100.0	102.2	100.3	98.1	102.1	100	100.4	103.9	100.1	99.4	100	102.9
Min	94.5	89.1	95.4	92.1	91.8	91.1	93.5	87.4	90.0	88.0	92.2	93.1

Results indicate that samples may be stored at room temperature for up to two days, elevated temperature for up to do days (40 °C), and for up to 90 days at – 20 °C, prior to confirmatory testing.

Quality control: Control materials are not supplied with the devices; however, the labeling provides information on how to obtain quality control materials. The device also contains a color indicator which is connected to the collection swab and turns red once sufficient oral fluid has been collected from a subject.

d. Detection limit:

See Precision/Reproducibility section in M.1.a above.

e. Analytical specificity:

To test cross reactivity, drug metabolites and other components that may be present in oral fluid samples were tested using three lots of the OralTox device. The following is a summary of the cross-reactivity study.

d-Methamphetamine (Cutoff=50 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
D -Methamphetamine	50	100%
L -Methamphetamine	5000	1%
Methoxymethamphetamine	50	100%
Ephedrine	250	20%
Phenylephrine	1250	4%
Procaine	2500	2%
Methylephedrine	500	10%
Methylenedioxyethylamphetamine (MDEA)	500	10%
3,4-methylenedioxy-methamphetamine (MDMA)	100	50%
Amphetamine	100000	0.05%
L-Amphetamine	Negative at 10000	<0.5%
D- Amphetamine	100000	0.05%
3,4-methylenedioxyamphetamine	Negative at 50000	<0.1%

Cocaine (Cut-off=20ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Cocaine	20	100%
Benzoylecgonine	20	100%
Cocaethylene	25	80%
Procaine	20000	0.1%
Ecgonine	50000	0.04%
Ecgonine methyl ester	10000	0.2%
Norcocaine	Negative at 10000	<0.2%

Morphine (Cut-off=40 ng/mL)	**Result Positive at(ng/mL)**	**% Cross-Reactivity**
Morphine	40	100%
Acetylmorphine	100	40%
Codeine	50	80%
Ethylmorphine	100	40%
Heroin	1250	40%
Dihydrocodone	50	80%
Hydromorphone	250	16%
Thebaine	Negative at 20000	<0.2%
Norcodeine	15000	0.3%
Morphine 6-β-glucuronide	100	40%
Oxycodone	25000	0.2%
Oxymorphone	25000	0.2%
Nalorphine	25000	0.2%
Hydrocodone	100	40%
6-Monoacetylmorphine	100	40%
Morphine 3-β-glucuronide	100	40%

d-Amphetamine (Cut-off=50 ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
D -Amphetamine	50	100%
1-Amphetamine	4000	1.25%
D,L-Amphetamine	50	100%
Methoxyamphetamine	200	25%
D,L-Amphetamine	10,000	0.5%
Methylenedioxyamphetamine(MDA)	250	20%
Benzodioxolylbutanamine (BDB)	10000	0.5
3-Hydroxy Tyramine	5000	1%
d,l-p-Chloramphetamine	300	17%
Phenethylamine	300	17%
d,l-Phenylpropanolamine	Negative at 10000	<0.5%
Phentermine	Negative at 10000	<0.5%
Methylenedioxyethylamphetamine (MDEA)	Negative at 10000	<0.5%
Methylenedioxy-methamphetamine	Negative at 10000	<0.5%

(MDMA)		
d-Methamphetamine	Negative at 10000	<0.5%
l-Methamphetamine	Negative at 10000	<0.5%
Hydroxyamphetamine	Negative at 10000	<0.5%
Dimethylamylamine (DMAA)	Negative at 10000	<0.5%
Methylbenzodioxolylbutanamine (MBDB)	Negative at 10000	<0.5%
para-Methoxymethamphetamine (PMMA)	Negative at 10000	<0.5%
Phendimetrazine	Negative at 10000	<0.5%
Phenmetrazine	Negative at 10000	<0.5%
Ephedrine (d-, or l-, or d-l form)	Negative at 10000	<0.05%
diphenhydramine	Negative at 10000	<0.05%
d-Pseudoephedrine	Negative at 10000	<0.05%
Fenfluramine	Negative at 10000	<0.05%
Isoxsuprine	Negative at 10000	<0.05%
l-Pseudoephedrine	Negative at 10000	<0.05%
Mephentermine	Negative at 10000	<0.05%

PCP (Cutoff=10ng/mL)	**Result Positive at (ng/mL)**	**% Cross-Reactivity**
Phencyclidine	10	100%
Hydrocodone	2000	0.5%
Hydromorphone	2000	0.5%
Nalorphine	10,000	0.1%
Tenocyclidine (TCP)	2000	0.5%
1-(1-phenylcyclohexyl)morpholine(PCM)	15	67%
4-hydroxyphencyclidine	10	100%
EDDP	Negative at 10000	<0.1%
Ketamine	Negative at 10000	<0.1%
Prazepam	Negative at 10000	<0.1%
Amitriptyline	Negative at 100000	<0.01%
Amitriptyline	Negative at 100000	<0.01%
(+) Brompheniramine	Negative at 100000	<0.01%
(+) Chlorphenamine	Negative at 100000	<0.01%
desmethylvenlafaxine	Negative at 100000	<0.01%
Chlorpromazine	Negative at 100000	<0.01%
Clomipramine	Negative at 100000	<0.01%
Cyclizine	Negative at 100000	<0.01%
Cyclobenzaprine	Negative at 100000	<0.01%
Dexbrompheniramine	Negative at 100000	<0.01%
Dextromethorphan	Negative at 100000	<0.01%
Diphenhydramine	Negative at 100000	<0.01%
Doxepin	Negative at 100000	<0.01%
Doxylamine	Negative at 100000	<0.01%
Imipramine	Negative at 100000	<0.01%
Thioridazine	Negative at 100000	<0.01%

Venlafaxine	Negative at 100000	<0.01%

Delta-9-Tetrahydrocannabinol (Cut-off=40 ng/mL)	**Result Positive at(ng/mL)**	**% Cross-Reactivity**
Delta-9-Tetrahydrocannabinol	40	100%
11-nor-Δ9-THC-9 COOH	12	333%
Δ8-Tetrahydrocannabinol	75	53%
11-hydroxy-Δ9-THC	300	13%
Cannabinol	2000	2%
Cannabidol	10,000	0.4%
11-Nor-Δ9-THC-carboxy-glucuronide	75	53%
(-)-11-nor-9-carboxy-Δ9-THC	50	80%
11-nor-Δ8-THC-9-COOH	20	200%
8-beta-11-dihydroxy- Δ 9-THC	300	13%
8-beta-hydroxy- Δ 9-THC	200	20%
Exo-THC	75	53%
l-11-Nor- Δ 9-THC-9-Carboxylic Acyl-Glucuronide	15	267%
Δ 8-THC	82.5	49%
Δ 8-THC Carboxylic Acid	20	200%
Δ 9-THC Carboxylic Acid	12	333%

Exogenous Interference: Potential interference from structurally unrelated compounds were tested by spiking the potentially interfering compound at a concentration of 10 ug/mL into drug free oral fluid or fluid containing the target drug with concentrations of 50% below and 50% above cutoff level. The following compounds were found not to interfere with test results at a concentration of 10ug/mL for all samples tested.

Acetaminophen	Digoxin	Nicotinamide
Acetylcodeine	Dihydrocodeine	Nicotine
Allobarbital	diltiazem HCl	Noscapine
Alprazolam	Diphenhydramine HCl	Omeprazole
Amobarbital	DL-Propranolol	Papaverine
Apomorphine	Doxylamine	Pentazocine
Atenolol	Ecgonine methylester	Phentermine
Atropine	Estradiol	Phenylpropanolamine
Baclofen	Estrone	Phenytoin
Benzocaine	Fluconazole	Pioglitazone HCl
Butabarbital	Furosemide	Prednisolone
Caffeine	Hexobarbital	Prednisone
Cannabidiol	Hydrochlorothiazide	Procainamide HCl

Carbamazepine	Ibuprofen	Procaine HCL
Chlordiazepoxide	Imipramine	Promethazine
Chlorpromazine	Lamotrigine	Quinine HCl
Cimetidine	Levetiracetam	R,R(-)-Pseudoephedrine
Citalopram HBr	Lidocaine	Salicylic Acid
Clobazam	Lormetazepam	Sertraline HCL
Clomipramine	L-Thyroxine	Simvastin
Clonazepam	Metformin HCl	Theophylline
Clonidine	Methylphenidate HCl	Thiamine
Clopidogrel bisulfate	Metoprolol	Topiramate
Cortisol	Metronidazole	Valproic Acid
Cotinine	Montelukast sodium salt	Verapamil
d,l-Salbutamol	Naloxone	Zonisamide
Deoxycorticosterone	Naltrexone	
Dextromethorphan	Naproxen	

The following potential interference from substances commonly present in oral fluid were evaluated by spiking into drug free oral fluid or oral fluid containing the target drug with concentrations of 50% below and 50% above cutoff level to a concentration of 5%: alcohol, baking soda, chewing gum, coffee, cola, cough syrup, cranberry juice, food coloring (blue, green, and red), methanol cough drops, milk, mouthwash, MSG, orange juice, salt, sugar, tea, toothpaste, and tomatoes. None of these substances showed any interference with the detection of any analyte (MET, COC, MOP, AMP, PCP, THC) using the device.

Potential interference from cigarette smoking, was evaluated by asking a participant to smoke a cigarette, after 15 minutes and oral fluid sample was collected and spiked with each drug at concentrations of cutoff +/- 50%. No interference with the detection of any analyte (MET, COC, MOP, AMP, PCP, THC) using the device was observed.

Potential interference from Hemoglobin was evaluated by adding it to drug free oral fluid or oral fluid containing the target drug with concentrations of 50% above and 50% below cutoff level to a concentration of 100ug/mL. No interference with the detection of any analyte (MET, COC, MOP, AMP, PCP, THC) using the device was observed.

Effect of oral fluid pH: To investigate the effect of oral fluid pH, oral fluid samples with pH 4 to 9 were spiked with target drugs at 50% below and 50% above Cut-Off levels. These samples were tested using three lots of the device. Results were all positive for samples at and above +50% Cut-Off and all negative for samples at and below -50% Cut-Off.

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

f. Assay cut-off:

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

2. Comparison studies:

a. Method comparison:

Method comparison studies for the OralTox Oral fluid Drug Test were performed at three testing sites with three operators at each site. Operators tested a total of 852 samples and compared to LC-MS/MS results. The results are presented in the tables below:

Methamphetamine

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	324	0	324	100
Less than Half the Cutoff Concentration	50	0	50	100
Near Cutoff Negative (-50% to the cutoff concentration)	15	2	13	87
Near Cutoff Positive (cutoff to 50%)	16	15	1	94
High Positive (>50% cutoff)	116	116	0	100

Discordant Results (Methamphetamine)

LC-MS/MS Result	Device Results
49.4	Positive
48.9	Positive
55.0	Negative

Cocaine

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	390	0	390	100
Less than Half the Cutoff Concentration	21	0	21	100
Near Cutoff Negative (-50% to the cutoff concentration)	19	1	18	95
Near Cutoff Positive (cutoff to 50%)	15	14	1	93
High Positive (>50% cutoff)	77	77	0	100

Discordant Cocaine Results:

LC-MS/MS Result	Device Results
17.0	Positive
22.7	Negative

Morphine:

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	323	0	323	100
Less than Half the Cutoff Concentration	50	0	50	100
Near Cutoff Negative (-50% to the cutoff concentration)	16	2	14	88
Near Cutoff Positive (cutoff to 50%)	19	18	1	95
High Positive (>50% cutoff)	114	114	0	100

Discordant Results for Morphine:

LC-MS/MS Result	Device Results
35.4	Positive
37.1	Positive
42.4	Negative

Amphetamine:

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	229	0	229	100
Less than Half the Cutoff Concentration	92	0	92	100
Near Cutoff Negative (-50% to the cutoff concentration)	61	2	59	97
Near Cutoff Positive (cutoff to 50%)	39	36	3	92
High Positive (>50% cutoff)	54	54	0	100

Discordant Results of Amphetamine:

LC-MS/MS Result	Device Results
48.3	Positive
49.5	Positive
53.2	Negative
52.1	Negative
53.5	Negative

Phencyclidine

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	407	0	407	100
Less than Half the Cutoff Concentration	20	0	20	100
Near Cutoff Negative (-50% to the cutoff concentration)	8	2	6	75
Near Cutoff Positive (cutoff to 50%)	4	4	0	100
High Positive (>50% cutoff)	38	38	0	100

Discordant Results for Phencyclidine:

LC-MS/MS Result	Test Results
9.75	Positive
9.89	Positive

Marijuana (THC)

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		percentage correct (%)
		No. of Positive	No. of Negative	
Drug-Free	359	0	359	100
Less than Half the Cutoff Concentration	27	0	27	100
Near Cutoff Negative (-50% to the cutoff concentration)	7	0	7	100
Near Cutoff Positive (cutoff to 50%)	9	6	3	67
High Positive (>50% cutoff)	54	54	0	100

Discordant Results for Marijuana (THC):

LC-MS/MS Result	Test Results
45.6	Negative
41.2	Negative
48.0	Negative

b. Matrix comparison:

Not applicable. These devices are for use with oral fluid 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):

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 decision.