



February 2, 2018

Premier Biotech Inc  
% Lisa Pritchard  
Regulatory, Quality & Compliance Consultant  
DuVal & Associates  
1820 Medical Arts Building, 825 Nicollet Mall  
Minneapolis, MN, 55402

Re: k171403

Trade/Device Name: OralTox Oral Fluid Drug Test  
Regulation Number: 21 CFR 862.3610  
Regulation Name: Methamphetamine test system  
Regulatory Class: Class II  
Product Code: DJC, DIO, DJG, LCM, LDJ, DKZ  
Dated: January 4, 2018  
Received: January 5, 2018

Dear Lisa Pritchard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR

Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Courtney H. Lias -S**

Courtney H. Lias, Ph.D.  
Director  
Division of Chemistry and Toxicology Devices  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
k171403

Device Name  
OralTox Oral Fluid Drug Test

### Indications for Use (Describe)

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 and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoylcegonine	20
Marijuana (THC)	Delta-9 Tetrahydrocannabinol	40
Methamphetamine (MET)	d-Methamphetamine	40
Opiates (OPI)	Morphine	40
Phencyclidine (PCP)	Phencyclidine	10

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, Mass Spectrometry (LC/MS/MS) 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) SUMMARY

1. Date: February 1, 2018
2. Submitter: Premier Biotech Inc  
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4. Device Name: OralTox Oral fluid Drug Test

Classification:

Product Code	CFR #	Panel
DJC	21 CFR, 862.3610 Methamphetamine Test System	Toxicology
DIO	21 CFR, 862.3250 Cocaine Test System	Toxicology
DJG	21 CFR, 862.3650 Opiate Test System	Toxicology
DKZ	21 CFR, 862.3100 Amphetamine Test System	Toxicology
LCM	Enzyme Immunoassay Phencyclidine Test System	Toxicology
LDJ	21 CFR, 862.3870 Cannabinoids Test System	Toxicology

5. Predicate Devices: K103227

The Oratect Oral Fluid Drug Screen Device

6. Intended 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 and their metabolites:

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Cocaine (COC)	Benzoyllecgonine	20
Marijuana (THC)	Delta-9 -Tetrahydrocannabinol	40
Methamphetamine (MET)	d-Methamphetamine	40
Opiates (OPI)	Morphine	40
Phencyclidine (PCP)	Phencyclidine	10

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, Mass Spectrometry (LC/MS/MS) 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.

7. Device Description

The OralTox Oral fluid Drug Test is immunochromatographic assay that uses a lateral flow system for the qualitative detection of Amphetamine, Cocaine, Cannabinoids, Methamphetamine, Opiates and Phencyclidine (target analytes) in human oral fluid. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

8. Substantial Equivalence Information

A summary comparison of features of the OralTox Oral fluid Drug Test and the predicate devices is provided in following tables.

**Table 1: Features Comparison of OralTox Oral fluid Drug Test and the Predicate Devices**

Item	Device	Predicate - K103227
<b>Indication(s) for Use</b>	For the qualitative determination of drugs of abuse in human oral fluid.	Same
<b>Calibrators</b>	D-Amphetamine Cocaine Delta-9-Tetrahydrocannabinol D-Methamphetamine Morphine Phencyclidine	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
<b>Type of Test</b>	Qualitative	Same
<b>Specimen Type</b>	Human Oral fluid	Same
<b>Cut-Off Values</b>	AMP 50 ng/mL COC 20 ng/mL THC 40 ng/mL MET 50 ng/mL MOP 40 ng/ML PCP 10 ng/mL	Same

<b>Intended Use</b>	For prescription uses.	Same
<b>Configurations</b>	Cups	Testing Pad

## 9. Test Principle

The OralTox Salvia Drug Test is rapid test for the qualitative detection of Amphetamine, Cocaine, Cannabinoids, Methamphetamine, Morphine and Phencyclidine in oral fluid samples. The tests are lateral flow chromatographic immunoassays. During testing, an oral fluid specimen migrates upward 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.

## 10. Performance Characteristics

### 1. Analytical Performance

#### a. Precision-Reproducibility-Cut-Off

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. 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 following are summaries.

#### Amphetamine

Result / drug	-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

Result / drug	-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

Result / drug	-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

drug \ Result	-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

drug \ Result	-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

drug \ Result	-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 following cut-off values for the candidate devices have been verified.

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

#### b. Linearity

Not applicable.

#### c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C.

#### d. Interference

Potential interfering substances were added to drug-free oral fluid and target drugs oral fluid with concentrations at 50% below and 50% above Cut-Off levels. These oral fluid samples were tested using three batches of the OralTox device. Compounds that showed no interference for all the six drugs at a concentration of 10µg/mL are summarized in the following table.

Acetaminophen	Digoxin	Nicotinamide
Acetylcodeine	Dihydrocodeine	Nicotine
Allobarbital	diltiazem HCl	Noscapine
Alprazolam	Diphenhydramine HCl	Omeprazole
Amobarbitol	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	

Food items such as methanol cough drops, cough syrup, cola, mouthwash, coffee, tea, milk, sugar, chewing gum, alcohol, baking soda, salt, cranberry juice, orange juice, food coloring (red, blue, green), toothpaste, tomatoes and MSG were added in either drug-free oral fluid or oral fluid containing the target drug with concentrations of 50% below and 50% above cutoff levels to a concentration of 5%. None of the substances showed interference.

Hemoglobin showed no interference at 100 µg/mL.

Cigarette smoking showed no interference.

#### e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in oral fluid samples were tested using three batches of the OralTox device. The following are summaries.

<b>d-Methamphetamine (Cut-off=50 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
D - Methamphetamine	50	100%
L - Methamphetamine	5000	1%
Methoxymethamphetamine	50	100%
Ephedrine	250	20%
Phenylephrine	1250	4%
Procaine	2500	2%
Methylephedrine	500	10%
Methylenedioxyethylamphetamine	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%

<b>Cocaine (Cut-off=20 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross- Reactivity</b>
Cocaine	20	100%
Benzoylcegonine	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%

<b>Morphine (Cut-off=40 ng/mL)</b>	<b>Result Positive at(ng/ml)</b>	<b>% Cross- Reactivity</b>
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- $\beta$ -glucuronide	100	40%
Oxycodone	25000	0.2%
Oxymorphone	25000	0.2%
Nalorphine	25000	0.2%
Hydrocodone	100	40%
6-Monoacetylmorphine	100	40%
Morphine 3- $\beta$ -glucuronide	100	40%

<b>d-Amphetamine (Cut-off=50 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross-Reactivity</b>
D - Amphetamine	50	100%
l-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 (MDMA)	Negative at 10000	<0.5%
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%
Methylbenzodioxylbutanamine	Negative at 10000	<0.5%
para-Methoxymethamphetamine	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 100000	<0.05%
diphenhydramine	Negative at 100000	<0.05%
d-Pseudoephedrine	Negative at 100000	<0.05%
Fenfluramine	Negative at 100000	<0.05%
Isoxsuprine	Negative at 100000	<0.05%
l-Pseudoephedrine	Negative at 100000	<0.05%
Mephentermine	Negative at 100000	<0.05%

<b>PCP (Cut-off=10 ng/mL)</b>	<b>Result Positive at (ng/mL)</b>	<b>% Cross- Reactivity</b>
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%

<b>Delta-9-Tetrahydrocannabinol (Cut-off=40 ng/mL)</b>	<b>Result Positive at(ng/ml)</b>	<b>% Cross-Reactivity</b>
Delta-9-Tetrahydrocannabinol	40	100%
11-nor- $\Delta$ 9-THC-9 COOH	12	333%
$\Delta$ 8-Tetrahydrocannabinol	75	53%
11-hydroxy- $\Delta$ 9-THC	300	13%
Cannabinol	2000	2%
Cannabidiol	10,000	0.4%
11-Nor- $\Delta$ 9-THC-carboxy- glucuronide	75	53%
(-)-11-nor-9-carboxy- $\Delta$ 9-THC	50	80%
11-nor- $\Delta$ 8-THC-9-COOH	20	200%
8-beta-11-dihydroxy- $\Delta$ 9-THC	300	13%
8-beta-hydroxy- $\Delta$ 9-THC	200	20%
Exo-THC	75	53%
1-11-Nor- $\Delta$ 9-THC-9- Carboxylic Acyl-Glucuronide	15	267%
$\Delta$ 8-THC	82.5	49%
$\Delta$ 8-THC Carboxylic Acid	20	200%
$\Delta$ 9-THC Carboxylic Acid	12	333%

f. 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.

g. Drug Recovery Study

Negative oral fluid samples in glass bottles were spiked with the drug to concentrations of -50% and +50% of the cutoff. The samples were transferred to OralTox devices and store at room temperature, at -20°C and at 40°C. Over 90% recoveries were observed for all drugs in the OralTox devices. Oral fluid samples can be stored in the device at -20°C for at least 3 months. Oral fluid samples can be shipped overnight in the device for LC-MS confirmation.

2. Comparison Studies

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**

<b>Concentration Range (by LC-MS/MS)</b>	<b>Number of samples</b>	<b>Test Results</b>		<b>The percentage of correct results (%)</b>
		<b>No. of Positive</b>	<b>No. of Negative</b>	
<b>Drug-Free</b>	324	0	324	100

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

**Discordant Results of Methamphetamine**

Sites	Sample Number	LC/MS Result	Test Results
Site B	45770	49.4	Positive
Site A	80256	48.9	Positive
Site B	22566	55.0	Negative

**Cocaine**

Concentration Range (by LC-MS/MS)	Number of samples	Test results		The percentage of correct results (%)
		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	19	1	18	95
Near Cutoff Positive	15	14	1	93
High Positive	77	77	0	100

**Discordant Results of Cocaine**

Sites	Sample Number	LC/MS Result	Test Results
Site B	99877	17.0	Positive
Site B	91597	22.7	Negative

**Morphine**

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		The percentage of correct results (%)
		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	16	2	14	88
Near Cutoff Positive	19	18	1	95

<b>High Positive</b>	114	114	0	100
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#### Discordant Results of Morphine

Sites	Sample Number	LC/MS Result	Test Results
Site B	67267	35.4	Positive
Site B	28314	37.1	Positive
Site B	75525	42.4	Negative

#### Amphetamine

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		The percentage of correct results (%)
		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	61	2	59	97
Near Cutoff Positive	39	36	3	92
High Positive	54	54	0	100

#### Discordant Results of Amphetamine

Sites	Sample Number	LC/MS Result	Test Results
Site B	78904	48.3	Positive
Site B	72977	49.6	Positive
Site A	45520	53.2	Negative
Site B	65667	52.1	Negative
Site C	76422	53.5	Negative

#### Phencyclidine

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

#### Discordant Results of Phencyclidine

Sites	Sample Number	LC/MS Result	Test Results
Site B	25874	9.75	Positive
Site B	23049	9.89	Positive

#### Cannabinoids

Concentration Range (by LC-MS/MS)	Number of samples	Test Results		The percentage of correct results (%)
		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	7	0	7	100
Near Cutoff Positive	9	6	3	67
High Positive	54	54	0	100

#### Discordant Results of Cannabinoids

Sites	Sample Number	LC/MS Result	Test Results
Site A	25484	45.6	Negative
Site A	28940	41.2	Negative
Site D	28976	48.0	Negative

### 3. Clinical Studies

Not applicable.

### 11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, interference, specificity, and method comparison studies of the devices, it's concluded that the OralTox Oral fluid Drug Test is substantially equivalent to the predicate.