For Prescription Use Only including point-of-care

For *in vitro* diagnostic use only.

OralTox® Oral Fluid Drug Test Package Insert

Catalogue No.: See Box Label

INTENDED USE

The OralTox® Oral Fluid Drug Test is a competitive binding, lateral flow immunochromatographic assay for the qualitative and simultaneous detection of Amphetamine, Cocaine, Marijuana (THC), Methamphetamine, Opiates, Phencyclidine, Oxycodone and Methadone 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)	Benzoylecgonine	20
Marijuana (THC)	Delta-9-Tetrahydrocannabinol	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	d-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
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. It is not intended to detect intermittent dosing of Oxycodone. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

SUMMARY

The OralTox Oral Fluid Drug test is a rapid immunoassay based on the principle of competitive inhibition binding. Therefore, drugs that may be present in the oral fluid specimen compete against their respective drug conjugate for binding sites on their specific antibody.
During testing a portion of oral fluid specimen migrates upward through a membrane strip by capillary action. Based on the presence or absence of a drug, if present, in the oral fluid specimen below its cutoff concentration will not saturate the binding sites of its specific antibody. The antibody will then react with the drug protein conjugate and a visible colored line will show up in the test region of the specific drug strip the presence of drug above the cutoff concentration in the oral fluid specimen will saturate all the binding sites of the antibody, Therefore, the colored line will not form in the test line region. A drug positive oral fluid specimen will not generate a colored line in the specific test line region of the strip because of the drug competition, while a drug negative oral fluid specimen will generate a line in the test line region due to the absence of drug competition. For a procedural control, a pink colored line will always appear at the control line region, indicating that the proper volume of specimen was added and that membrane wicking occurred.
A presumptive positive test result does not always mean that a person took illegal drugs and a negative test does not always mean that a person did not take illegal drugs; there are several factors that influence the reliability of the test results. There is a possibility that other substances and/or factors may interfere with the test and cause incorrect test results.

MATERIALS

Materials Provided

- OralTox Oral Fluid Drug Test
- Oral Fluid collection swab
- Package Insert

Materials Not Provided

* Positive and Negative Oral Fluid controls
Timer

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use the device after the expiration date printed on the pouch. Do not use the test if the foil pouch is damaged.
- OralTox should remain in the sealed pouch until ready for use.
- Do not reuse tests.

STORAGE AND STABILITY

- OralTox should be stored at 2-30°C (36-86°F) in the original sealed pouch.
- DO NOT FREEZE.
- The product is stable when stored at room temperature (39°F-86°F) until the date printed on the pouch.
- The pouch containing the test device should be sealed until ready for use.
- Always allow the test device to warm up to room temperature before conducting any testing.

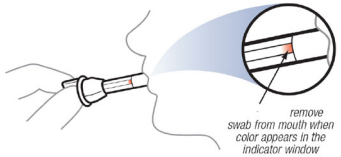
SPECIMEN COLLECTION

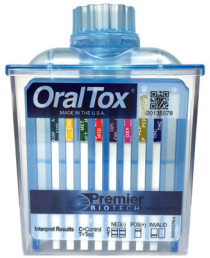
- OralTox oral fluid drug test is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.

PROCEDURE

Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.

- Bring tests, and/or controls to room temperature (15-30°C) before use.
- The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this assay.
- Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) and then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab**. Important**: Do not bite, suck, or chew on the sponge [6]. If after 7 minutes the saturation indicator has not turned color discard the device and repeat the test.
- Remove collection swab from mouth and insert it sponge first into the screening device, screw until the locking flange locks in place.
- Set device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Results for any single analyte can be read as negative as soon as two lines appear on the analyte strip. Read presumptive positive results at 10 minutes. **NOTE:** Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed of or sent to laboratory for confirmation (on presumptive positive result).



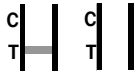


Read Test Results:

INTERPRETATION OF RESULTS

PRESUMPTIVE POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T). A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).
Negative results can be read as soon as test and control line appear on any strip (often within 2 minutes). A negative result indicates that the drug concentration is below the detectable level.



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact Premier Biotech customer service. 888 686 9909

UNDERSTANDING THE TEST RESULTS

1. A presumptive positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others.

2. IMPORTANT: The result you obtained is called presumptive for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Please refer to the Confirmation Testing section of this labeling[7].

3. What Is A False Positive Test?

   The definition of a false positive test would be an instance where the OralTox Oral Fluid Drug Test is positive even though target drugs are not in the sample. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may also cause a false positive test result with this product.

4. What Is A False Negative Test?

   The definition of a false negative test is that the initial target drugs are present but is not detected by OralTox Oral Fluid Drug Test.

LIMITATIONS

- The OralTox Oral Fluid Drug Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Liquid chromatography/mass spectrometry/mass spectrometry (LC-MS/MS) is the preferred confirmatory method.
- There is a possibility that other substances and/or factors not listed below may interfere with the test and cause incorrect results (e.g., technical or procedural errors). Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.
- This test has been developed for testing human oral fluid only. Do NOT use this device to test any other fluids.
- A positive result does not indicate level of intoxication, administration route or concentration in oral fluid. A positive result might be obtained from certain foods or food supplements.
- A negative result may not necessarily indicate drug-free oral fluid. Negative results can be obtained when drug is present but below the Cutoff level of the test.
- The test does not distinguish between drugs of abuse and certain medications.
- The ability to detect intermittent Oxycodone dosing has not been demonstrated.
- The Anticipated window of detection of Oxycodone in oral fluid at 20 ng/mL is:

OXY Formulation and Dose	Minimum Detection Time Following First Dose (hr)	Maximum Detection Time Following Last Dose (hr)
Abuse-deterrent, single oral dose	0.25	12 to 28[1]

[1] Cone, EJ, et al. Prescription Opioids. III. Disposition of Oxycodone in Oral Fluid and Blood Following Controlled Single-Dose Administration. Journal of Analytical Toxicology. 2015; 39: 192-202.

QUALITY CONTROL

- OralTox provides a built-in control band for each test strip to indicate that the test has performed correctly. The control band should always appear regardless of the presence of drugs it confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.
- Control materials are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance. Quality control testing should be performed with each new lot, each new shipment and every thirty days to check storage. Positive and Negative Salivabuse™ Oral Fluid Control are available from Biochemical Diagnostics (800) 223-4835 and are recommended to be used.
- Positive or Negative Salivabuse Oral Fluid Control (1.0mL) may be directly pipetted into the cup for control testing. Only one sample, a control or a patient sample can be tested each time.
- Follow local, state and federal laws and regulations.

CONFIRMATION TESTING

- The presumptive positive sample should be mailed to the laboratory the same day by standard overnight shipping.
- Confirmation of results requires specialized equipment that not all laboratories process, including a centrifuge and specialized extraction device. Without this specialized equipment laboratories may not be able to obtain enough sample volume to confirm all tests. Please contact Premier Biotech for more information
- Contact Premier Biotech customer service at 888-686-9909 for details.

MORE INFORMATION AND RESOURCES

You can contact your health care provider, or any of the following organizations listed below for additional information and/or counseling regarding substance abuse prevention and treatment:

- American Council for Drug Education (ACDE)
  1-800-DRUGHELP / www.ade.org
- Center for Substance Abuse Treatment (CSAT)
  1-877-SAMHSA-7 / www.samhsa.gov

- The National Council on Alcoholism and Drug Dependence (NCADD) 1-800-NCA-CALL / www.ncadd.org
- Pride Youth Program Formerly Parent's Resource Institute for Drug Education, Inc. (PRIDE) 1-800-668-9277 www.prideyouthprogram.org
- The Treatment Center 1-877-409-9043 / www.thetreatmentcenter.org/

PERFORMANCE CHARACTERISTICS

A. Accuracy

Accuracy of OralTox Oral Fluid Drug Test was established by analyzing 842 clinical oral fluid specimens in parallel with LC-MS/MS. The sensitivity of the OralTox Oral Fluid Drug Test was determined by tested LC-MS/MS confirmed drug concentration at negative, <-50% cutoff, -50% cutoff- cutoff, cutoff-+50% cutoff, and >+50% cutoff. The results are summarized below:

AMP

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	229	0	229	100
Less than Half the Cutoff	92	0	92	100
Near Cutoff Negative	64	2	62	97
Near Cutoff Positive	38	36	2	95
High Positive	54	54	0	100

COC

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	390	0	390	100
Less than Half the Cutoff	21	0	21	100
Near Cutoff Negative	19	1	18	95
Near Cutoff Positive	15	14	1	93
High Positive	77	77	0	100

MTD

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	277	0	277	100
Less than Half the Cutoff	13	0	13	100
Near Cutoff Negative	20	4	16	80
Near Cutoff Positive	15	13	2	87
High Positive	173	173	0	173

MET

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	324	0	324	100
Less than Half the Cutoff	48	0	48	100
Near Cutoff Negative	16	2	14	88
Near Cutoff Positive	15	14	1	93
High Positive	118	118	0	100

OPI

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	323	0	323	100
Less than Half the Cutoff	50	0	50	100
Near Cutoff Negative	16	2	14	88
Near Cutoff Positive	19	18	1	95
High Positive	114	114	0	100

OXY

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	152	0	152	100
Less than Half the Cutoff	47	0	47	100
Near Cutoff Negative	32	5	27	84.4
Near Cutoff Positive	29	25	4	86.2
High Positive	174	174	0	100

PCP

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	407	0	407	100
Less than Half the Cutoff	22	0	22	100
Near Cutoff Negative	8	2	6	75
Near Cutoff Positive	6	6	0	100
High Positive	36	36	0	100

THC

% of Cutoff	Number of samples	Operator results		The percentage of correct results (%)
		No. of Positive	No. of Negative	
Drug-Free	359	0	359	100
Less than Half the Cutoff	26	0	26	100
Near Cutoff Negative	8	0	8	100
Near Cutoff Positive	12	9	3	75
High Positive	52	52	0	100

B. Specificity and Cross-Reactivity

The following table lists compounds that are positively detected in OralTox Oral Fluid Drug Test.

Drug	Concentration(ng/mL)	% Cross-Reactivity
D - Amphetamine	50	100%
1-Amphetamine	4000	1.25%
d/l- Amphetamine	50	100%
Methoxyamphetamine	200	25%
Methylenedioxyamphetamine (MDA)	250	20%
Benzodioxolylbutanamine (BDB)	10000	0.5
3-Hydroxy Tyramine	5000	1%
d,l-Phenylpropanolamine	1000	5%
d,l-p-Chloramphetamine	300	17%
Phenethylamine	300	17%
Phentermine	>10000	<0.5%
Methylenedioxyethylamphetamine	>10000	<0.5%
Methylenedioxymethamphetamine	>10000	<0.5%
d-Methamphetamine	>10000	<0.5%
l-Methamphetamine	>10000	<0.5%
Hydroxyamphetamine	>10000	<0.5%
Dimethylamylamine (DMAA)	>10000	<0.5%
Methylbenzodioxolylbutanamine	>10000	<0.5%
para-Methoxymethamphetamine	>10000	<0.5%
Phendimetrazine	>10000	<0.5%
Phenmetrazine	>10000	<0.5%
Ephedrine (d-, or l-, or d-l form)	>100000	<0.05%
Diphenhydramine	>100000	<0.05%
d-Pseudoephedrine	>100000	<0.05%
Fenfluramine	>100000	<0.05%
Isoxsuprine	>100000	<0.05%
l-Pseudoephedrine	>100000	<0.05%
Mephentermine	>100000	<0.05%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Cocaine	**20**	
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%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Methadone	30	100%
Alpha-Methadol	125	24%
Doxylamine	12500	0.24%
2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrrolidine (EDDP)	10000	0.3%
Phencyclidine	12500	0.24%
2-Ethyl-5-methyl-3,3-diphenylpyrroline (EMDP)	100000	0.03%
LAAM	10000	0.3%

Drug	Concentration(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	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%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Morphine	40	100%
Acetylmorphine	100	40%
Codeine	50	80%
Ethylmorphine	100	40%
Heroin (diacetylmorphine)	1250	40%
Dihydrocodeine	50	80%
Hydromorphone	250	16%
Thebaine	>20000	<0.2%
Norcodeine	15000	0.3%
Morphine-6- β-d-glucuronide	100	40%
Oxycodone	25000	0.2%
Oxymorphone	25000	0.2%
Nalorphine	25000	0.2%
Hydrocodone	100	40%
6-monoacetylmorphine (6-AM)	100	40%
Morphine 3- β-d-glucuronide	100	40%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Oxycodone	20	100%
Hydrocodone	1000	2%
Hydromorphone	6250	0.3%
Naloxone	6250	0.3%
Oxymorphone	1000	2%
Dihydrocodeine	Negative at 10000	<0.2%
Buprenorphine	Negative at 10000	<0.2%
6-monoacetylmorphine (6-AM)	Negative at 10000	<0.2%
Codeine	Negative at 10000	<0.2%
Heroin (diacetylmorphine)	Negative at 10000	<0.2%
Morphine	Negative at 10000	<0.2%
Morphine -3-β-d-glucuronide	Negative at 10000	<0.2%
Ethylmorphine	Negative at 10000	<0.2%

Drug	Concentration(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	15	67%
4-hydroxyphencyclidine	10	100%
EDDP	Negative at 10000	<0.1%
Ketamine	Negative at 10000	<0.1%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Prazepam	Negative at 10000	<0.1%
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%

Drug	Concentration(ng/mL)	% Cross-Reactivity
Delta-9-Tetrahydrocannabinol	40	100%
11-nor-Δ^9-THC-9-COOH	12	333%
Δ^8-Tetrahydrocannabinol	75	53%
11-hydroxy-Δ^9-THC	300	13%
Cannabinol	2000	2%
Cannabidiol (CBD)	10,000	0.4%
11-Nor-Δ^9-THC-carboxy-glucuronide	75	53%
(-)-11-nor-9-carboxy-Δ^9-THC	50	80%
11-nor-Δ^8-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 Carboxylic Acid	20	200%
Δ^9-THC Carboxylic Acid	12	333%

C. Precision-Reproducibility-Cutoff

This study is performed 2 runs/day for each of the three lots and lasts 10 days at three intended user sites. The results are given below:

Amphetamine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
12.5	60	60	0	60	0	60	0
25	60	60	0	60	0	60	0
37.5	60	55	5	54	6	56	4
50	60	7	53	9	51	11	49
62.5	60	5	55	5	55	6	54
75	60	0	60	0	60	0	60
87.5	60	0	60	0	60	0	60
100	60	0	60	0	60	0	60

Cocaine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
5	60	60	0	60	0	60	0
10	60	60	0	60	0	60	0
15	60	56	4	55	5	54	6
20	60	8	52	10	50	12	48
25	60	6	54	6	54	4	56
30	60	0	60	0	60	0	60
35	60	0	60	0	60	0	60
40	60	0	60	0	60	0	60

Methadone concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
7.5	60	60	0	60	0	60	0
15	60	60	0	60	0	60	0
22.5	60	54	6	55	5	55	5
30	60	11	49	12	48	10	50
37.5	60	5	55	4	56	5	55
45	60	0	60	0	60	0	60
52.5	60	0	60	0	60	0	60
60	60	0	60	0	60	0	60

Methamphetamine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
12.5	60	60	0	60	0	60	0
25	60	60	0	60	0	60	0
37.5	60	54	6	55	5	55	5
50	60	10	50	11	49	12	48
62.5	60	5	55	4	56	4	56
75	60	0	60	0	60	0	60
87.5	60	0	60	0	60	0	60
100	60	0	60	0	60	0	60

Morphine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
10	60	60	0	60	0	60	0
20	60	60	0	60	0	60	0
30	60	55	5	55	5	54	6
40	60	12	48	12	48	10	50
50	60	3	57	5	55	4	56
60	60	0	60	0	60	0	60
70	60	0	60	0	60	0	60
80	60	0	60	0	60	0	60

Oxycodone concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
5	60	60	0	60	0	60	0
10	60	60	0	60	0	60	0
15	60	55	5	54	6	56	4
20	60	10	50	11	49	11	49
25	60	5	55	4	56	3	57
30	60	0	60	0	60	0	60
35	60	0	60	0	60	0	60
40	60	0	60	0	60	0	60

Phencyclidine concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
2.5	60	60	0	60	0	60	0
5	60	60	0	60	0	60	0
7.5	60	54	6	54	6	55	5
10	60	12	48	11	49	12	48
12.5	60	4	56	5	55	4	56
15	60	0	60	0	60	0	60
17.5	60	0	60	0	60	0	60
20	60	0	60	0	60	0	60

Cannabinoids concentration (ng/mL)	N	Lot1		Lot2		Lot3	
		-	+	-	+	-	+
0	60	60	0	60	0	60	0
10	60	60	0	60	0	60	0
20	60	60	0	60	0	60	0
30	60	54	6	54	6	55	5
40	60	10	50	10	50	11	49
50	60	5	55	4	56	5	55
60	60	0	60	0	60	0	60
70	60	0	60	0	60	0	60
80	60	0	60	0	60	0	60

The following Cutoff values for the device are verified.

Calibrator	**Cutoff (ng/mL)**
d-Amphetamine	50
Cocaine	20
Methadone	30
d-Methamphetamine	50
Morphine	40
Oxycodone	20
Phencyclidine	10
Delta-9 -Tetrahydrocannabinol	40

D. Effect of Oral Fluid pH

The pH of an aliquot of negative oral fluid is adjusted in the range of 4.00 to 9.00 in 1 pH unit increments and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked, pH-adjusted oral fluid was tested with the OralTox Saliva Drug Test. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

E. Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free oral fluid or drug-positive oral fluids. The following compounds show no cross-reactivity when tested with the OralTox Oral Fluid Drug Test at a concentration of 10 µg/mL.

Acetaminophen	Digoxin	Omeprazole
Acetylcodeine	diltiazem HCl	Papaverine
Allobarbital	Diphenhydramine HCl	Pentazocine
Alprazolam	DL-Propranolol	Phenytoin
Amobarbital	Estradiol	Pioglitazone HCl
Apomorphine	Estrone	Prednisolone
Atenolol	Fluconazole	Prednisone
Atropine	Furosemide	Procainamide HCl
Baclofen	Hexobarbital	Promethazine
Benzocaine	Hydrochlorothiazide	Quinine HCl
Butabarbital	Ibuprofen	R,R(-)-Pseudoephedrine
Caffeine	Imipramine	Salicylic Acid
Carbamazepine	Lamotrigine	Sertraline HCL
Chlordiazepoxide	Levetiracetam	Simvastin
Chlorpromazine	Lidocaine	Theophylline
Cimetidine	Lormetazepam	Thiamine
Citalopram HBr	L-Thyroxine	Topiramate
Clobazam	Metformin HCl	Valproic Acid
Clomipramine	Methylphenidate HCl	Verapamil
Clonazepam	Metoprolol	Zonisamide
Clonidine	Metronidazole	
Clopidogrel bisulfate	Montelukast sodium salt	
Cortisol	Naltrexone	
Cotinine	Naproxen	
d,l-Salbutamol	Nicotinamide	
Deoxycorticosterone	Nicotine	
Dextromethorphan	Noscapine	

LITERATURE REFERENCES

1. Moolchan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addicion Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.
2. Jenkins, A.J., Oyler, J.M. and Cone, E.J. Comparison of Heroin and Cocaine Concentrations in Saliva with Concentrations in Blood and Plasma. J. Anal. Toxicology. 19: 359-374 (1995).
3. Kidwell, D.A., Holland, J.C., Athanaselis, S. Testing for Drugs of Abuse in Saliva and Sweat. J. Chrom. B. 713: 111-135 (1998).
4. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 10th edition. Biomedical Publications, 2014.
5. Hawks RL, Chiang CN, eds. Oral Fluid Testing for Drugs of Abuse. Rockville: Department of Health and Human Services, National Institute of Drug Abuse; 1986.
6. Substance Abuse and Mental Health Services Administration. Mandatory Guidelines for Federal Workplace Drug Testing Programs. 53 Federal Register;1988
7. McBay AJ. Drug-analysis technology—pitfalls and problems of drug testing. Clin Chem. 1987 Oct; 33 (11 Suppl):33B-40B.
8. Cone, EJ, et al. Prescription Opioids. III. Disposition of Oxycodone in Oral Fluid and Blood Following Controlled Single-Dose Administration. Journal of Analytical Toxicology. 2015; 39: 192-202.

GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer	②	Do not reuse

Manufactured by:
Premier Biotech Inc.
723 Kasota Avenue SE, Minneapolis MN 55414
www.premierbiotech.com