For Forensic Use Only

OralTox™ Oral Fluid Drug Test Package Insert

Catalogue No.: See Box Label

INTENDED USE

OralTox™ Oral Fluid Drug Test is a competitive binding, lateral flow immunochromatographic assay for qualitative and simultaneous detection of drugs of abuse in human oral fluid specimens. The test system consists of one or more membrane strips mounted in a plastic cassette.

OralTox detects combinations of the following drugs at the cutoff concentrations listed below and their metabolites

Test	Calibrator	Cutoff (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Barbiturates (BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	10
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylecgonine	20
Cotinine (COT)	Cotinine	50
Fentanyl (FYL)	Fentanyl	10
K2/Spice (K2)	JWH-018/JWH-073	30
Ketamine (KET)	Ketamine	30
Marijuana (THC)	Delta-9 -Tetrahydrocannabinol	40
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	d-Methamphetamine	40
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Tramadol (TML)	Tramadol	30

The test provides only presumptive test results [1]. 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 presumptive result is positive [2].

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 binging sites on their specific antibody.
During testing a portion of the 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 a 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 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 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

- 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.
- Read the entire procedure carefully before testing

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 2-30°C (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 come to room temperature before conducting any testing

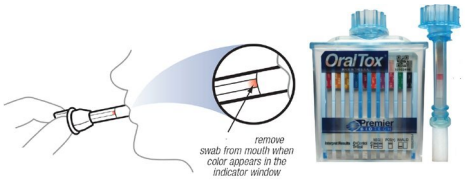
SPECIMEN COLLECTION

- 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].
- Remove collection swab from mouth and insert it sponge first into the screening device, screw until the locking flange locks in place. If after 7 minutes the saturation indicator has not turned color discard the device and repeat the test.
- Set device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Negative results can be read as soon as two lines appear on any test 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).



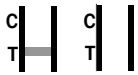
Other Drug Tests

INTERPRETATION OF RESULTS

- **Interpretation of DOA Results (See Previous Illustration)**

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

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.
3. The THC strip does not wick as quickly as the other strips. The THC strip is designed to wick slowly, which allows the sample and the antibody to incubate.

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 positive 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. If the sample is diluted, or the sample is contaminated this may cause a false negative result. Please refer to Specimen Collection to prevent diluted samples.

LIMITATIONS

1. OralTox should be only used for the qualitative detection of drugs of abuse in oral fluid.
2. This assay provides a presumptive analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result.. Clinical consideration and professional judgment should be applied to any test result, particularly when presumptive positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
5. A negative result does not at any time rule out the presence of drugs/metabolites in saliva, as they may be present below the minimum detection level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.

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.

CONFIRMATION TESTING

- The presumptive positive sample should be mailed to the laboratory the same days by standard overnight shipping.
- The confirmation laboratory will require a centrifuge and extraction device to remove the oral fluid sample from the device. Please contact Premier Biotech for more information
- Contact Premier Biotech customer service at 888-686-9909 for details.

PERFORMANCE CHARACTERISTICS

A Sensitivity
A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% Cutoff and ± 25% Cutoff and tested with OralTox Oral Fluid Drug Test. The results are summarized below.

Drug Conc. (Cutoff range)	n	AMP		BUP		BZO		COC		COT	
		-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0
-50% Cutoff	30	30	0	30	0	30	0	30	0	30	0
-25% Cutoff	30	30	0	28	2	30	0	29	1	30	0
Cutoff	30	12	18	11	19	14	16	12	18	11	19
+25% Cutoff	30	2	28	8	22	4	26	2	28	1	29
+50% Cutoff	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cutoff range)	n	KET		MET		MOR		MTD		OXY		PCP	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0
-50%Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0
-25%Cutoff	30	27	3	30	0	28	2	30	0	28	2	28	2
Cutoff	30	9	21	13	17	10	20	10	20	10	20	11	19
+25%Cutoff	30	3	27	3	27	9	21	2	28	4	26	5	25
+50%Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cutoff range)	n	THC		THC parent		BAR		FYL		TML		K2 30	
		-	+	-	+	-	+	-	+	-	+	-	+
0%Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0
-50%Cutoff	30	30	0	30	0	30	0	30	0	30	0	30	0
-25%Cutoff	30	30	0	30	0	27	3	22	8	24	6	26	4
Cutoff	30	10	20	10	20	9	21	12	18	9	21	10	20
+25%Cutoff	30	5	25	4	26	3	27	2	28	3	27	4	26
+50%Cutoff	30	0	30	0	30	0	30	0	30	0	30	0	30

B. Specificity

The following table lists the concentrations of compounds in (ng/mL) above which OralTox Oral Fluid Drug Test identified positive results at 10 minutes

Amphetamine-Related Compounds	
D-Amphetamine	50
L-Amphetamine	4000
(+)-3,4-Methylenedioxyamphetamine	150
Phentermine	40000
PMA	125
Tyramine	3000
Barbiturate -Related Compounds	
Secobarbital	50
Allobarbital	200
Alphenal	100
Amobarbital	100
Aprobarbital	30
Butabarbital	15
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	300
Benzodiazepine-Related Compounds	
Oxazepam	10
Alprazolam	15
Bromazepam	8
Chlordiazepoxide	10
Clonazepam	40
Clorazepate	20
Clobazam	6
Diazepam	15
Estazolam	10
Desalkyflurazepam	8
Flunitrazepam	10
Flurazepam	10
Lorazepam	20
Medazepam	10
Nitrazepam	10

Fentanyl Related Compounds	
Fentanyl	10
Norfentanyl	50
K2(Spice) - Related	
JWH-018 5-pentanoic	50
JWH-073 4-Butanoic	50
Ketamine-Related Compounds	
Ketamine(KET)	50
Norketamine	50
Dextromethorphan	25
Dextrorphan tartrate	25
D-Norpropoxyphene	1560
Meperidine	750
Mephentermine hemisulfate salt	1000
D-Methamphetamine	750
3,4-Methylenedioxyethylamphetamine	1500
Nordoxepin hydrochloride	1500
Phencyclidine	250
Promazine	400
Promethazine	1250
Marijuana -Related Compounds	
11-nor-Δ9 -THC-9 COOH	12
Δ8-Tetrahydrocannabinol	2000
Δ9-Tetrahydrocannabinol	4000
11-hydroxy-Δ9 -THC	300
Marijuana parent-Related Compounds	
Δ9-Tetrahydrocannabinol	40
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2000
Cannabidiol	>10000
Methadone -Related Compounds	
Methadone	30
Alpha-Methadol	125

Nordiazepam	6
Prazepam	20
Temazepam	8
Triazola	15
Buprenorphine -Related Compounds	
Buprenorphine	5
Buprenorphine Glucuronide	10
Buprenorphine-3-β-D-Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine-3-β-D-Glucuronide	200
Cocaine-Related Compounds	
Cocaine	20
Benzoylecgonine	200
Ecgonine	100000
Ecgonine methyl ester	10000
Prozine	2500
Opiates -Related Compounds	
Morphine	40
Codeine	10
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
EDDP	20
Meperidine	20000
Hydrocodone	50
Desalkyflurazepam	8
Flunitrazepam	10
Flurazepam	10
Lorazepam	20
Medazepam	10
Nitrazepam	10
Nordiazepam	6
Prazepam	20
Temazepam	8
Triazola	15

Biperiden	80000
Doxylamine	12500
2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrolidine (EDDP)	10000
Phencyclidine	12500
Pheniramine	25000
Methamphetamine-Related Compounds	
D-Methamphetamine	50
Fenfluramine	3000
L-Methamphetamine	500
L-Phenylephrine	2500
MDEA	400
3,4-Methylenedioxymethamphetamine	75
Mephentermine	200
PMMA	50
Procaine	2500
Oxycodone-Related Compounds	
Oxycodone	20
Hydrocodone	1000
Hydromorphone	6250
Naloxone	6250
Oxymorphone	1000
Phencyclidine-Related Compounds	
Phencyclidine (PCP)	10
Hydrocodone	2000
Hydromorphone	2000
Morphine-3- β-d-glucuronide	20000
Nalorphine	10000
Tramadol Related Compounds	
Tramadol	30
(+/-) Chlorpheniramine	50,000
Dimenhydrinate	50,000
Diphenhydramine	50,000
Phencyclidine	50,000

C. Interference

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

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	

LITERATURE REFERENCES

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