Oral Fluid Drug Test
Package Insert

Package insert for testing of the following drugs:
Amphetamine, Barbiturates, Benzodiazepine, Cocaine, Marijuana, Methadone, Methamphetamine, Morphine, Opiate and Propoxyphene.

For employment and insurance use.
For forensic use.

INTENDED USE & SUMMARY

The Oral Fluid Drug Test is intended for screening for the presence of drugs and their metabolites in oral fluid. For professional *in vitro* diagnostic use only.

The Oral Fluid Drug Test is a lateral flow chromatographic immunoassay for the qualitative detection of drugs and drug metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50/80
Barbiturate (BAR)	Secobarbital	50/300
Benzodiazepine (BZO)	Oxazepam	5/10/20/50
Cocaine (COC)	Benzoylecgonine	20/40
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12
Marijuana (THC)	Δ^9-THC	25/50/75/100
Methadone (MTD)	Methadone	30/75
Methamphetamine (MET)	D-Methamphetamine	50
Morphine (MOP)	Morphine	15
Opiates (OPI)	Morphine	40
Propoxyphene (PPX)	Propoxyphene	50

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

AMP: Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion.[1]

BAR: Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

BZO: Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites. Benzodiazepines can be detected in oral fluid after use.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca).[1]

THC: Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[2]

MTD: Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. In addition to use as a narcotic agonist, methadone is being used more frequently as a pain management agent. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression. Based on the saliva/plasma ratio calculated over salivary pH ranges of 6.4-7.6 for therapeutic or recreational doses of methadone, a cut-off <50 ng/mL is suggested. Due to this recommendation, the cut-off level of the methadone test was calibrated to 30 ng/mL.

MET: Methamphetamine is a potent stimulant chemically related to amphetamine but with greater CNS stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion.[1]

OPI (MOP): The drug class opiates refers to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates control pain by depressing the CNS, and demonstrate addictive properties when used for sustained periods of time. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation.[3]
*The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Morphine is detectable for several days after a dose.

PPX: Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene, but shows a greater local anesthetic effect.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

The Oral Fluid Drug Test is an immunoassay based on the principle of competitive binding. 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 the oral fluid specimen migrates along the test strip by capillary action. A drug, if present in the oral fluid specimen below its cut-off 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 line region of the specific drug strip. The presence of drug above the cut-off 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 drug competition, while a drug-negative oral fluid specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The Oral Fluid Drug Test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For employment and insurance use. For forensic use.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used collector and device should be discarded according to local regulations.
- Safety data sheets available for professional user upon request

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this test. Oral fluid collected at any time of the day may be used. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8°C or -20°C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8°C).

MATERIALS

Materials Provided

- Test cups
- Saliva collectors
- Security seal labels
- Package insert

Materials Required But Not Provided

- Timer
- Gloves

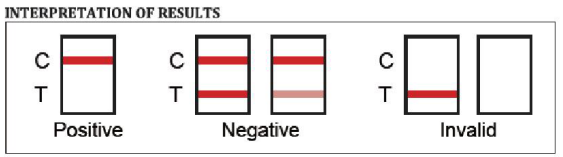
DIRECTIONS FOR USE

Allow the test device, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Using the provided collection swab, remove the collector from the sealed pouch, have donor sweep inside of mouth (cheek, gum, tongue) several times, 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.
   Note: If after 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with the test below. (See illustration 1)
3. Open the cap and place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge first into the screening device until touch the bottom of the saliva cup, pushing the cap until it locked in place of the saliva cup. **Keep upright when insert the sponge.** (See illustration 2)
4. **Test device upright on flat surface and keep upright while test is running.** Wait for the colored signal to appear in test results area. Read the results at 10 minutes.

Note: 1, Once the collection sponge locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).

2, In the case of no flowing even with enough saliva specimen, or the saliva is too thick to run, please move the device but don't tilt and keep upright back and forth on a flat and clean surface for several times. Do not tilt the device when the test is running before reading results.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Oral Fluid Drug Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) or gas chromatography/tandem mass spectrometry (GC/MS/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
3. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
4. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the test.
5. The test does not distinguish between drugs of abuse and certain medications.
6. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

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

Drug Conc. (Cut-off range)	AMP 50		AMP 80		BAR 50		BAR 300		BZO 5		BZO 10		BZO 20	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	14	16	14	16	14	16	16	14	15	15	17	13
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
3X Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	BZO 50		COC 20		COC 40		THC 12		THC 25		THC 50		THC 75	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	14	16	14	16	14	16	16	14	17	13	15	15	14	16
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
3X Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	THC 100		MTD 30		MTD 75		MET		MOP		OPI		PPX	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
Cut-off	15	15	14	16	15	15	14	16	14	16	15	15	15	15
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30
3X Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

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

AMPHETAMINE (AMP 50)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
AMPHETAMINE (AMP 80)	
d-Amphetamine	50
d,l-Amphetamine	125
β-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
COCAINE (COC 40)	
Benzoylecgonine	40
Cocaine	40
Cocaethylene	50
Ecgonine	2,000

METHADONE (MTD 75)	
Methadone	75
Doxylamine	100,000
Estrone-3-sulfate	100,000
Phencyclidine	100,000
METHADONE (MTD 30)	
Methadone	30
Doxylamine	50,00
Estrone-3-sulfate	50,00
Phencyclidine	50,00
MARIJUANA (THC 12)	
11-nor-Δ^9-THC-9 COOH	12
Cannabinol	31,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	20,000
METHAMPHETAMINE (MET)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000

Ecgoninemethylester	25,000
N-Acetylprocainamide	18,000
Chlordiazepoxide	18,000
COCAINE (COC 40)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgoninemethylester	12,500
N-Acetylprocainamide	12,500
Chlordiazepoxide	12,500
MARIJUANA (THC 25)	
Δ^9-Tetrahydrocannabinol	25
11-nor-Δ^9 -THC-9 COOH	15
MARIJUANA (THC 50)	
Δ^9-Tetrahydrocannabinol	50
Δ^8-Tetrahydrocannabinol	75
11-nor-Δ^9-THC-9 COOH	15
11-hydroxy-Δ^9-THC	300
Cannabinol	2,000
Cannabidiol	>10,000
MARIJUANA (THC 75)	
Δ^9-Tetrahydrocannabinol	75
Δ^8-Tetrahydrocannabinol	150
11-nor-Δ^9-THC-9 COOH	15
11-hydroxy-Δ^9-THC	300
Cannabinol	1,500
Cannabidiol	>10,000
MARIJUANA (THC 100)	
Δ^9-Tetrahydrocannabinol	100
Δ^8-Tetrahydrocannabinol	250
11-nor-Δ^9-THC-9 COOH	25
11-hydroxy-Δ^9-THC	500
Cannabinol	2,500
Cannabidiol	>10,000
BARBITURATE (BAR 50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	30
BARBITURATE (BAR 300)	
Secobarbital	300
Amobarbital	300

3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)-(-) Ephedrine	400
1-Ephedrine	400
Mephentermine	800
(-)Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
BENZODIAZEPINES (BZO 5)	
Oxazepam	5
Alprazolam	5
Bromazepam	10
Chlordiazepoxide	10
Clobazam	4
Clorazepate	15
Delorazepam	15
Desalkylflurazepam	15
Diazepam	3
Estazolam	3
Flunitrazepam	60
α-Hydroxyalprazolam	120
(±)-Lorazepam	120
Midazolam	15
Nitrazepam	8
Norchlordiazepoxide	120
Nordiazepam	15
Temazepam	5
Triazolam	15
BENZODIAZEPINES (BZO 10)	
Oxazepam	10
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
α-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
BENZODIAZEPINES (BZO 50)	

Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
OPIATE (OPI 40)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphine	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-d-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
PROPOXYPHENE (PPX)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200

Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	12
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1,000
(±)-Lorazepam	1,000
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1,000
Nordiazepam	125
Temazepam	30
Triazolam	40
MORPHINE (MOP)	
Morphine	15
Codeine	15
Ethylmorphine	15
Hydromorphine	50
Hydrocodone	50
Morphine 3-β-d-glucuronide	30
Nalorphine	300
Oxymorphone	25,000
Thebaine	5,000
Diacetylmorphine (Heroin)	15
6-Monoacetylmorphine (6-MAM)	15

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Oral Fluid Drug Test when tested at concentrations up to 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen
Acetophenetidine
Acetylsalicylic acid
Aminopyrine
Amoxicillin
Ampicillin
Amitryptyline
Ascorbic acid
Apomorphine
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzphetamine
Caffeine
Chloral hydrate
Chloramphenicol
Chlorothiazide
d,l-Chloropheniramine
Chlorpromazine
Chloroquine
Cholesterol
Clonidine
Cortisone
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Dicyclomine
Diflunisal
Digoxin
Diphenhydramine
β-Estradiol
Ethyl-p-aminobenzoate
l-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric acid
βHydroxynorephedrine
5-Hydroxytryptamine
(Serotonin)
3-Hydroxytyramine
Ibuprofen
Iproniazid
(-)Isoproterenol
Isoxsuprine
Ketoprofen
Labetalol
Loperamide
Meprobamate
Methylphenidate
Nalidixic acid
Naproxen
Niacinamide
Nifedipine
Nimesulide
Norethindrone
Noscapine
d,l-Octopamine
Oxalic acid
Oxolinic acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine
Perphenazine
Phenelzine
Trans-2-phenylcyclo-propylamine
Phentermine
Phenylpropanolamine
Prednisolone
Phenolbarbital
Prednisone
d,l-Propranolol
d-Pseudoephedrine
Quinacrine
Quinine
Quindine
Ranitidine
Salicylic acid
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone3-acetate
Tetrahydrocortisone
3 (β-d-glucuronide)
Theophylline
Thiamine
Thioridazine
d,l-Tyrosine
Tolbutamide
Trazodone
Triamterene
Trifluoperazine
Trimethoprim
d,l-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

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