One Step Oral Fluid Drug Test Package Insert

Package insert for testing of the following drugs:
Amphetamine 50, Cocaine 20, Marijuana 12, Methamphetamine 50, Opiate 40, Methadone 75, Phencyclidine 10, Oxycodone 50, Buprenorphine 10，BAR300 and Benzodiazepines50.

INTENDED USE & SUMMARY

The Oral Fluid Drug Test is intended for screening for the presence of drugs and drug metabolites in oral fluid. For professional *in vitro* diagnostic use only.
The Oral Fluid Pipette 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)	Detection Time
Amphetamine (AMP)	d-Amphetamine	50	10 min - 72 hrs
Cocaine (COC)	Benzoylecgonine	20	10 min - 24 hrs
Marijuana (THC)	11-nor-Δ⁹-THC-9 COOH	12	Up to 14 hrs
Methamphetamine (MET)	d-Methamphetamine	50	10 min - 72 hrs
Opiate (OPI)	Morphine	40	1 hr - several days*
Methadone (MTD)	Methadone	**75**	Up to 2 days
Phencyclidine (PCP)	Phencyclidine	10	/
Oxycodone (OXY)	Oxycodone	**50**	Up to 14 hrs
Benzodiazepines (BZO)	Oxazepam	**50**	/
Buprenorphine(BUP)	Buprenorphine	**10**	/
Barbiturates (BAR)	Secobarbital	**300**	/

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]
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]
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: 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.
MTD: Methadone is an analgesic compound most frequently used for the treatment of opiate addiction. One clinical study suggested that the ratio of methadone to plasma was approximately 0.51.[4] Using known half life data for plasma, the detection window in saliva is expected to be up to 2 days after use.
PCP: Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.[5]
OXY: Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain. The approximate half- life in serum is averaged about 14 hours.
BZO: Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders.
The Benzodiazepines assay contained within the Oral Fluid Drug Screen Device yields a positive result when the oxazepam concentration in oral fluid exceeds 10 ng/mL.
BUP: Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence.Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction,and side effects compared to full opioid agonists because of the "ceiling effect", which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses.However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Buprenorphine was rescheduled from Schedule V to Schedule III drug justbefore FDA approval of Suboxone and Subutex.

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. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.
The approximate detection time limits for Barbiturates are:
Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.
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 coloured 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 coloured line will not form in the test line region.
A drug-positive oral fluid specimen will not generate a coloured 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 coloured 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 test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. 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 devices
- Collectors
- Collection tubes
- Security seals
- Package insert

Materials Required But Not Provided

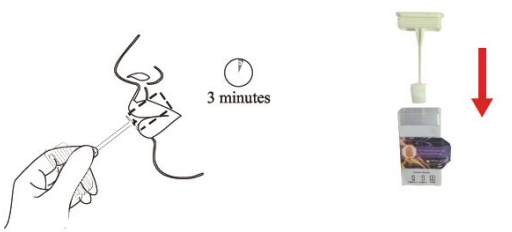
- Timer
- Gloves

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. Remove the collector from the sealed pouch. Take out of the collector cap ,Insert the sponge into the mouth.Close mouth and move the sponge around for oral fluid collection.Soak sponge in oral fluid and swab the inside of the mouth and tongue.Collect oral fluid for 3 minutes until sponge is soft and fully saturated, No hard spots should be felt on the sponge when saturated. (See illustration 1)
3. Place the test device on a clean and level surface. Remove the collection sponge from the mouth and insert it sponge first into the screening device,screw until the collector cap sealed with the device tightly.（See illustration 2）
4. Test device upright on flat surface and keep upright while test is running.Wait for the colored signal to appar in test results area. Read the results at 10 minutes.

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



Interpretation results:

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* A coloured line in the control line region (C) and a coloured 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 colour in the test line region (T) may vary, but it should be considered negative whenever there is even a faint coloured line.

POSITIVE: A coloured 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 coloured 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 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 Pipette Test The results are summarized below.

Drug Conc. (Cut-off range)	AMP		COC		THC		MET		OPI		MTD		PCP		OXY		BZO		BUP		BAR	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	87	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	87	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	87	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)	
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)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
N-Acetylprocainamide	12,500
Chlordiazepoxide	12,500
MARIJUANA (THC)	
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
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
METHADONE (MTD)	
Methadone	75
Doxylamine	100,000
Estrone-3-sulfate	100,000
Phencyclidine	100,000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
Barbiturate(BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2500
Butethal	100

OXYCODONE (OXY)	
Hydrocodone	12,500
Levorphanol	25,000
Naloxone	25,000
Naltrexone	12,500
Oxycodone	50
Secorbarbital	100,00
	0
Oxymorphone	200
Hydromorphone	50,000
OPIATE (OPI)	
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
BENZODIAZEPINES (BZO)	
Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	12
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1000
(±)-Lorazepam	1000
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1000
Nordiazepam	125
Temazepam	30
BUPRENORPHINE (BUP)	
Buprenorphine	10
Buprenorphine -3-D-Glucuronide	10
Norbuprenorphine	20
Norbuprenorphine-3-D-Glucuronide	400
Buprenorphine Glucuronide	20

Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100

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

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