



SwabScreen Oral Fluid DrugTest Package Insert

Package insert for testing of the following drugs:

Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiate, Oxycodone, Phencyclidine and Alcohol.

For Forensic Use Only

INTENDED USE & SUMMARY

The SwabScreen Oral Fluid Drug And Alcohol Test is intended for screening for the presence of drugs and alcohol and their metabolites in oral fluid.

The SwabScreen Oral Fluid Drug And Alcohol 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
Barbiturate (BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	10
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylcegonine	20
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	12
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Alcohol (ALC)	Alcohol	> 0.02 % B.A.C

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.

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 just before FDA approval of Suboxone and Subutex.

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: 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.

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.

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

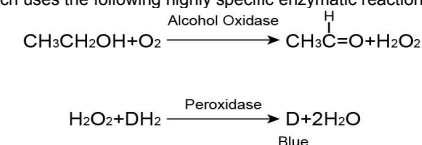
ALC: Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (20 mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

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

(1) The SwabScreen 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.

(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:



REAGENTS

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

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol Oxidase, Peroxidase, Buffer and Stabilizing Proteins.

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 cubes
- Security seal labels

Saliva collectors

• 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, 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 (**Do not bite, suck, or chew on the sponge**). Collect oral fluid for **7 minutes** or until sponge is soft and fully saturated. **No hard spots should be felt on the sponge when saturated.** (See illustration 1)

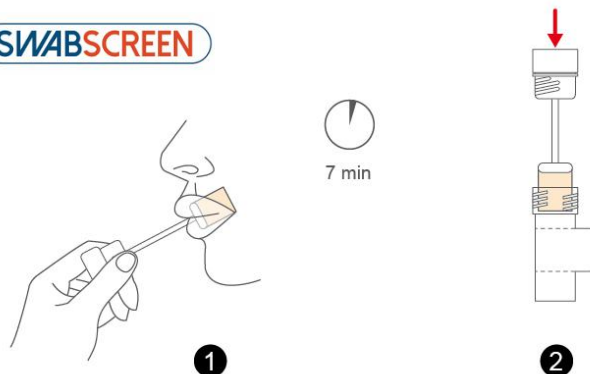
3. Place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge **gently** into the screening device, press until the collector cap sealed with the device tightly. **Keep upright when inserting and pressing the sponge.** (See illustration 2)

4. **Keep test device upright on flat surface and keep upright while test is running.** Wait for the colored signal to appear in test result area. Read saliva alcohol pad at 3 minutes, do not interpret saliva alcohol result after 4 minutes. Read drug results at 10 minutes, do not interpret drug results after 15 minutes.

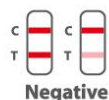
Note: 1. Once the collection sponge locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).

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

SWABSCREEN



Interpretation 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.

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream colored); it should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

Alcohol Presumptive Positive Result: The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02% B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

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 SwabScreen Oral Fluid Drug And Alcohol 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 \pm 50% cut-off and tested with the Oral Fluid Pipette Test. The results are summarized below.

Drug Conc. (Cut-off range)	AMP50		BAR 50		BZO 10		BUP 5		COC20	
	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	THC 12		MTD 30		MET50		OPI40		OXY 20		PCP10	
	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	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
+50% Cut-off	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 SwabScreen Oral Fluid Drug Test identified positive results at 10 minutes.

AMPHETAMINE (AMP50)		METHADONE (MTD 30)	
d-Amphetamine	50	Methadone	30
d,l-Amphetamine	125	Doxylamine	50,000
β -Phenylethylamine	4,000	Estrone-3-Sulfate	50,000
Tryptamine	1,500	Phencyclidine	50,000
p-Hydroxyamphetamine	800	PHENCYCLIDINE (PCP10)	
(+) 3,4-Methylenedioxamphetamine (MDA)	150	Phencyclidine	10
l-Amphetamine	4,000	Tetrahydrozoline	50,000
COCAINE (COC20)		OXYCODONE (OXY 20)	
Benzoylcegonine	20	Oxycodone	20
Cocaine	20	Hydrocodone	6,250
Cocaethylene	25	Hydromorphone	25,000
Ecgonine	1,500	Levorphanol	12,500
Ecgoninemethylester	12,500	Naloxone	12,500
N-Acetylprocainamide	12,500	Naltrexone	12,500
Chlordiazepoxide	12,500	Oxymorphone	100
MARIJUANA (THC 12)		Secobarbital	50,000
11-nor- Δ^9 -THC-9 COOH	12	BENZODIAZEPINES (BZO 10)	
Cannabinol	31,500	Oxazepam	10
11-nor- Δ^8 -THC-9 COOH	2	Alprazolam	6
Δ^8 -THC	6,000	Bromazepam	12
Δ^9 -THC	20,000	Chlordiazepoxide	12
METHAMPHETAMINE (MET50)		Clobazam	6
d-Methamphetamine	50	Clorazepate	25
Fenfluramine	60,000	Delorazepam	25
p-Hydroxymethamphetamine	400	Desalkylflurazepam	25
Methoxyphenamine	25,000	Diazepam	3
3,4-Methylenedioxymethamphetamine (MDMA)	50	Estazolam	3

I-Phenylephrine	4,000	Flunitrazepam	100
Procaine	2,000	α-Hydroxyalprazolam	200
(1R,2S)-(-) Ephedrine	400	(±)-Lorazepam	200
1-Ephedrine	400	Midazolam	25
Mephentermine	800	Nitrazepam	12
(-)Deoxyephedrine, L-Methamphetamine	3,000	Norchlordiazepoxide	200
Ephedrine	800	Nordiazepam	25
OPIATE (OPI 40)		Temazepam	6
Morphine	40	Triazolam	25
Codeine	10	BUPRENORPHINE (BUP 5)	
Ethylmorphine	24	Buprenorphine	5
Hydromorphone	100	Buprenorphine-3-D-Glucuronide	10
Hydrocodone	100	Norbuprenorphine	5
Levorphanol	400	Buprenorphine-3-D-Glucuronide	10
Oxycodone	25,000	Buprenorphine Glucuronide	20
Morphine 3-β-d-glucuronide	50	BARBITURATE (BAR 50)	
Norcodeine	1,500	Secobarbital	50
Normorphine	12,500	Amobarbital	100
Nalorphine	10,000	Alphenal	100
Oxymorphone	25,000	Aprobarbital	30
Thebaine	1,500	Butabarbital	30
Diacetylmorphine (Heroin)	50	Butalbital	400
6-Monoacetylmorphine(6-MAM)	25	Butethal	30
		Cyclopentobarbital	60
Bilirubin	3,500	Pentobarbital	150
		Phenobarbital	30

Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

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 SwabScreen Oral Fluid Drug Test when tested at concentrations up to 100 µg/mL.

Non Cross-Reacting Compounds

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

Alcohol Test

The following substances may interfere with the SwabScreen Oral Fluid Drug and Alcohol Screen Device when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers

(2) Agents which inhibit color development:

Reducing Agents: such as Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanals and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyldopa, L-dopa, L-methyldopa, and Methampyrone, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

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