

OrALert™

Oral Fluid Drug Screen Device

Package Insert for the AMP/mAMP/COC/OPI/THC/PCP

Test for Oral Fluids

A rapid, screening test for the simultaneous, qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana and phencyclidine and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylcegonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	Δ ⁹ - THC	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL

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.

SUMMARY

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in human oral fluid.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion. Depending on the route of administration, amphetamine can be detected in oral fluid as early as 5-10 minutes following use.¹ Amphetamine can be detected in oral fluid for up to 72 hours after use.

The Amphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the amphetamine concentration in oral fluid exceeds 50 ng/mL.

Methamphetamine (mAMP)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater central nervous system (CNS) stimulation properties. The drug is often self-administered by nasal inhalation, smoking or oral ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes following use.² Methamphetamine can be detected in oral fluid for up to 72 hours after use.¹

The Methamphetamine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/mL.

Cocaine (COC)

Cocaine is a potent CNS stimulant and a local anesthetic derived from the coca plant (erythroxylum coca). The drug is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Depending on the route of administration, cocaine and its metabolites, benzoylcegonine and ecgonine methylester, can be detected in oral fluid as early as 5-10 minutes following use.¹ Cocaine and benzoylcegonine can be detected in oral fluid for up to 24 hours after use.¹

The Cocaine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

Opiates (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 act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.² 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the morphine concentration in oral fluid exceeds 40 ng/mL.

Marijuana (THC)

Tetrahydrocannabinol (THC), 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.³ Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.³

The THC assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the Δ⁹-THC concentration in oral fluid exceeds 100 ng/mL.

Phencyclidine (PCP)

Phencyclidine (PCP), the hallucinogen commonly referred to as Angel Dust, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and oral fluid sample collection of 100 patients in a hospital emergency department, PCP was detected in the oral fluid of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL.⁴

The Phencyclidine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP 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 conjugates for binding sites on their specific antibody.

During testing, a portion of the oral fluid specimen migrates upward 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 test contains membrane strips coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Methamphetamine, Benzoylcegonine, Morphine, Δ⁹- THC and Phencyclidine.

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- The Oral Fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

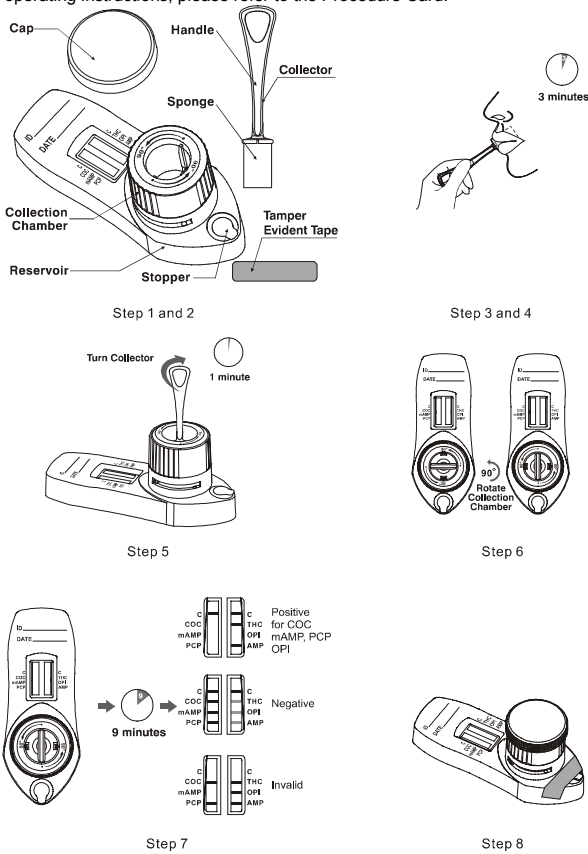
The oral fluid specimen should be collected using the collector provided with the kit, following the detailed instructions under Directions for Use. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

- MATERIALS
- Materials Provided
- Test devices
 - Caps
 - Collectors
 - Procedure cards
 - Tamper evident tape
 - Package insert
- Materials Required but not Provided
- Timer

DIRECTIONS FOR USE

Allow the OrALert™ Oral Fluid Drug Screen Device to come to room temperature [15-30°C (59-86°F)] prior to testing. Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test and cap from the sealed pouch and use the test as soon as possible.
2. Remove the collector from the sealed pouch and give it to the donor.
3. Instruct the donor to insert the sponge end of the collector into the mouth and actively swab the inside of the mouth and the top of the tongue. As soon as the sponge softens slightly, the donor should gently press the sponge between the tongue and teeth to ensure complete saturation.
4. The sponge is saturated when no hard spots can be detected. Collect for a total of three (3) minutes before removing the sponge.
5. Remove the collector from the mouth. With the test device on a flat surface, insert the collector into the test device by aligning the notches on the collector with the tracks on the inside of the collection chamber. Push the collector into the chamber and turn the collector clockwise until it is engaged.
6. After 1 minute, rotate the collection chamber counterclockwise and set the timer for 9 minutes.
7. Read results at 9 minutes.
8. If positive results are observed, remove the collector by turning it counterclockwise and pulling. Secure the cap over the collection chamber, seal the reservoir with tamper evident tape and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the stopper.
9. For detailed operating instructions, please refer to the Procedure Card.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* **Two lines appear.** One colored line should be in the control region (C), and another apparent colored line should be adjacent in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

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

POSITIVE: **One colored line appears in the control region (C). No line appears in the test region (Drug/T).** This positive result indicates that the drug concentration is above the detectable level.

INVALID: **Control line 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 panel. If the problem persists, discontinue using the lot immediately and contact the manufacturer.

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.

LIMITATIONS

1. The OrALert™ Oral Fluid Drug Screen Device 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) are preferred confirmatory methods.

2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.

3. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A PBS pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the OrALert™ Oral Fluid Drug Screen Device. The results are summarized below.

Drug conc. (Cut-off range)	n	COC		mAMP		PCP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	30	0
Cut-off	30	20	10	23	7	22	8
+25% Cut-off	30	6	24	7	23	8	22
+50% Cut-off	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	THC		OPI		AMP	
		-	+	-	+	-	+
0% Cut-off	120	120	0	120	0	120	0
-50% Cut-off	120	120	0	120	0	120	0
-25% Cut-off	120	108	12	108	12	109	11
Cut-off	120	60	60	60	60	60	60
+25% Cut-off	120	12	108	10	110	10	110
+50% Cut-off	120	3	117	0	120	0	120

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPI/THC/PCP identified positive results at a read time of 10 minutes.

COCAINE (COC)	
Benzoylcegonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
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

METHAMPHETAMINE (mAMP)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxy-methamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S) - (-) Ephedrine	400
MARIJUANA (THC)	
Δ ⁹ -THC	100
11-nor-Δ ⁹ -THC -9 COOH	12
Cannabinol	3,000
Δ ⁸ -THC	100
OPIATES (OPI)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	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
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000

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 OrALert™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

Acetaminophen

N-Acetylprocainamide

Aminopyrine

Ampicillin

Apomorphine

Atropine

Benzoic acid

d,l-Brompheniramine

Cannabidiol

Chloramphenicol

d,l-Chloropheniramine

Chloroquine

Clonidine

l-Cotinine

Deoxycorticosterone

Diclofenac

Digoxin

l-ψ-Ephedrine

Estrone-3-sulfate

l-(-)-Epinephrine

Fenoprofen

Gentisic acid

Hydralazine

Hydrocortisone

p-Hydroxytyramine

Iproniazid

Isoxsuprine

Ketoprofen

Loperamide

Meprobamate

Nalidixic acid

Naltrexone

Acetophenetidin

Acetylsalicylic acid

Amoxicillin

l-Ascorbic acid

Aspartame

Benzilic acid

Benzphetamine

Caffeine

Chloralhydrate

Chlorothiazide

Chlorpromazine

Cholesterol

Cortisone

Creatinine

Dextromethorphan

Diflunisal

Diphenhydramine

β-Estradiol

Ethyl-p-aminobenzoate

Erythromycin

Furosemide

Hemoglobin

Hydrochlorothiazide

o-Hydroxyhippuric acid

Ibuprofen

d,l-Isoproterenol

Ketamine

Labetalol

Meperidine

Methylphenidate

Naloxone

Naproxen

Niacinamide

Norethindrone

Noscapine

Oxalic acid

Oxymetazoline

Penicillin-G

Perphenazine

Trans-2-phenylcyclopropylamine

Prednisolone

d,l-Propranolol

d-Pseudoephedrine

Quinine

Ranitidine

Serotonin

Sulindac

Tetrahydrocortisone 3-Acetate

Thioridazine

Tolbutamide

Trifluoperazine

d,l-Tryptophan

Uric acid

Zomepirac

Nifedipine

d-Norpropoxyphene

d,l-Octopamine

Oxolinic acid

Papaverine

Pentazocine

Phenelzine

Phenylpropanolamine

Prednisone

d-Propoxyphene

Quinacrine

Quindine

Salicylic acid

Sulfamethazine

Tetracycline

Thiamine

d,l-Tyrosine

Triamterene

Trimethoprim

Tyramine

Verapamil

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