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, THC and PCP and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The 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, THC, PCP 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**
Marijuana (THC)	**THC-COOH**	**4 ng/mL**
Phencyclidine (PCP)	**Phencyclidine**	**10 ng/mL**
Cocaine (COC)	**Benzoylecgonine**	**20 ng/mL**
Opiates (OPI)	**Morphine**	**40 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 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 fluids for up to 72 hours after use[1].

The amphetamine assay contained within the 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 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[1]. Methamphetamine can be detected in oral fluids for up to 72 hours after use[1].

The Methamphetamine assay contained within the 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 central nervous system (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 metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

The cocaine assay contained within the Oral Fluid Drug Screen Device for cocaine and opiates yields a positive result when the cocaine metabolite 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 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]. Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The Oral Fluid Drug Screen Device yields a positive result when the concentration of opiates in the specimen exceeds the 40 ng/mL cut-off level.

Marijuana (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in saliva 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 saliva of up to 14 hours after drug use[3].

The THC assay contained within the Oral Fluid Drug Screen Device yields a positive result when the THC-COOH concentration exceeds 4 ng/mL.

Phencyclidine (PCP)

Phencyclidine, the hallucinogen commonly referred to as Angel Dust, can be detected in saliva as a result of the exchange of the drug between the circulatory system and the oral cavity. In a paired serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva of 79 patients at levels as low as 2 ng/mL and as high as 600 ng/mL[4].

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

ASSAY PRINCIPLE

The 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 conjugate 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, Benzoylecgonine, Morphine, THC-COOH and PCP.

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. Follow the detailed Directions for Use below. 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

- Oral Fluid Drug Screen Device for AMP/MAMP/COC/OPI/THC/PCP
- Collector
- Procedure Card
- Package insert

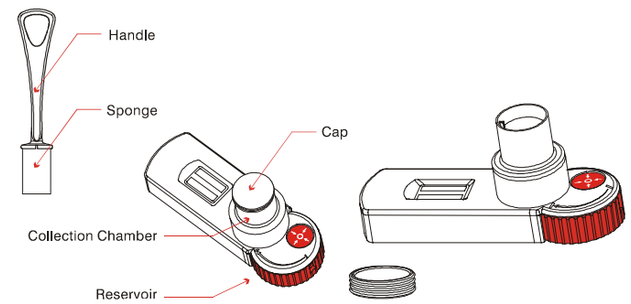
Materials Required but not Provided

- Timer

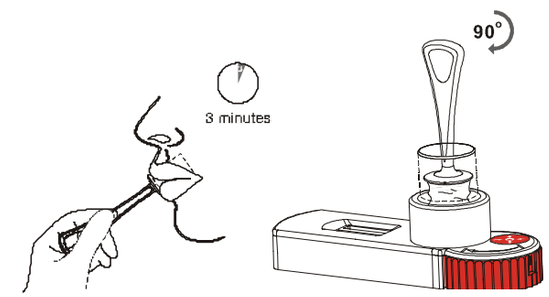
DIRECTIONS FOR USE

Allow the Oral Fluid Drug Screen Device to come to room temperature [15-30ºC (59-86ºF)] prior to testing.

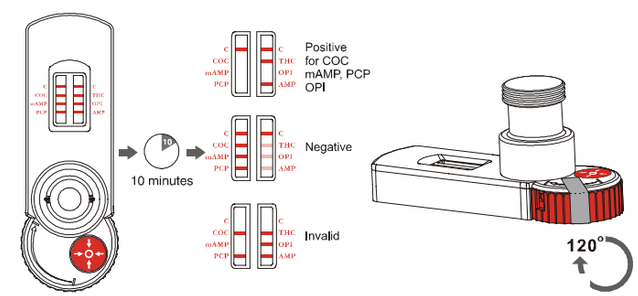
1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.
2. Remove the collector from the sealed pouch and give to donor. Remove the cap from the device.
3. Instruct donor to introduce collector into mouth and actively swab the inside of the mouth and the top of the tongue until the sponge becomes slightly moist.
4. Collect for a total of three (3) minutes making sure to frequently press the sponge between the tongue and teeth to ensure saturation. No hard spots should be felt on the sponge when full.
5. Remove the collector and introduce to the test device by pushing into the chamber and turning clockwise until engaged. Set the timer for 10 minutes.
6. At the end of 10 minutes, remove the collector from the device by turning counterclockwise and pulling. Discard the collector.
7. If positive results are observed, engage the red reservoir into locked position for shipping by turning clockwise as far as possible. Secure reservoir with tamper evident tape and send to the laboratory for confirmation.
8. For detailed operation instructions, please refer to the Procedure Card.



Step 1 **Step 2**



Steps 3 & 4 **Step 5**



Step 6 **Step 7**

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

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

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

POSITIVE: One red 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 red 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 Oral Fluid Drug Screen Device for cocaine and opiates 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 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 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		MOP		AMP	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	24	6	26	4	26	4
Cut-off	30	15	15	20	10	19	11
+25% Cut-off	30	11	19	5	25	7	23
+50% Cut-off	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 Screen device for AMP/MAMP/COC/OPI/THC/PCP identified positive results at a read time of 10 minutes.

COCAINE	
Benzoylecgonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine methylester	12,500
AMPHETAMINE	
D-amphetamine	50
DL-Amphetamine	125
ß-Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+)3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
METHAMPHETAMINE	
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
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	4
Cannabinol	12,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	10,000
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
Oxycodone	6,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine	25
Bilirubin	3,500
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 Oral Fluid Drug Screen Device when tested with at concentrations up to 10 μg/mL.

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloralhydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
L -Ψ-Ephedrine
Estrone-3-sulfate
[1R,2S] (-) Ephedrine
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
O-Hydroxyhippuric acid
p-Hydroxytyramine
Acetophenetidin
Acetylsalicylic acid
Amoxicillin
L-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine
D/L-Brompheniramine
Cannabidol
Chloramphenicol
D/L-Chlorophenirameine
Chloroquine
Clonidine
L-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
Ecgonine methyl ester
β-Estradiol
Ethyl-p-aminobenzoate
L(–)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxyamphetamine
Ibuprofen
Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Methylphenidate
Naloxone
Naproxen
Nifedipine
D-Norpropoxyphene
D/L-Octopamine
Oxolinic acid
Papaverine
Pentazocine hydrochloride
Phenelzine
L-Phenylephrine
Phenylpropanolamine
Prednisone
D-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Tetrahydrocortisone 3 (β-D-glucuronide)
Thiamine
D/L-Tyrosine
Triamterene
Trimethoprim
D/L-Tryptophan
Uric acid
Zomepirac
D/L-Isoproterenol
Ketamine
Labetalol
Meperidine
Methoxyphenamine
Nalidixic acid
Naltrexone
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclo-propylamine hydrochloride
β-Phenylethylamine
Prednisolone
D/L-Propranolol
D-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-acetate
Tetrahydrozoline
Thioridazine
Tolbutamide
Trifluoperazine
Tryptamine
Tyramine
Verapamil

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