

HEALTH-CHEM DIAGNOSTICS LLC

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ORAL FLUID DRUG SCREEN DEVICE

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 | 12 ng/mL |
| Phencyclidine (PCP) | Phencyclidine | 10 ng/mL |
| Cocaine (COC) | Benzoyllecgonine | 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/MSIMS) 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 use¹. Amphetamine can be detected in oral fluids for up to 72 hours after use.

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. Methamphetamine can be detected in oral fluids for up to 72 hours after use. 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. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use.

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 dose². 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 cavity³. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use. The THC assay contained within the Oral Fluid Drug Screen Device yields a positive result when the THC-COOH concentration exceeds 12 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/mL⁴. 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, Benzoylcegonine, 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 SaniSal®, Saliva Collection Device. 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

Material Provided: • Drug Test device • SaniSal® - Saliva Collection Device • Package inserts

Materials Required but Not Provided: • Timer

DIRECTIONS FOR USE

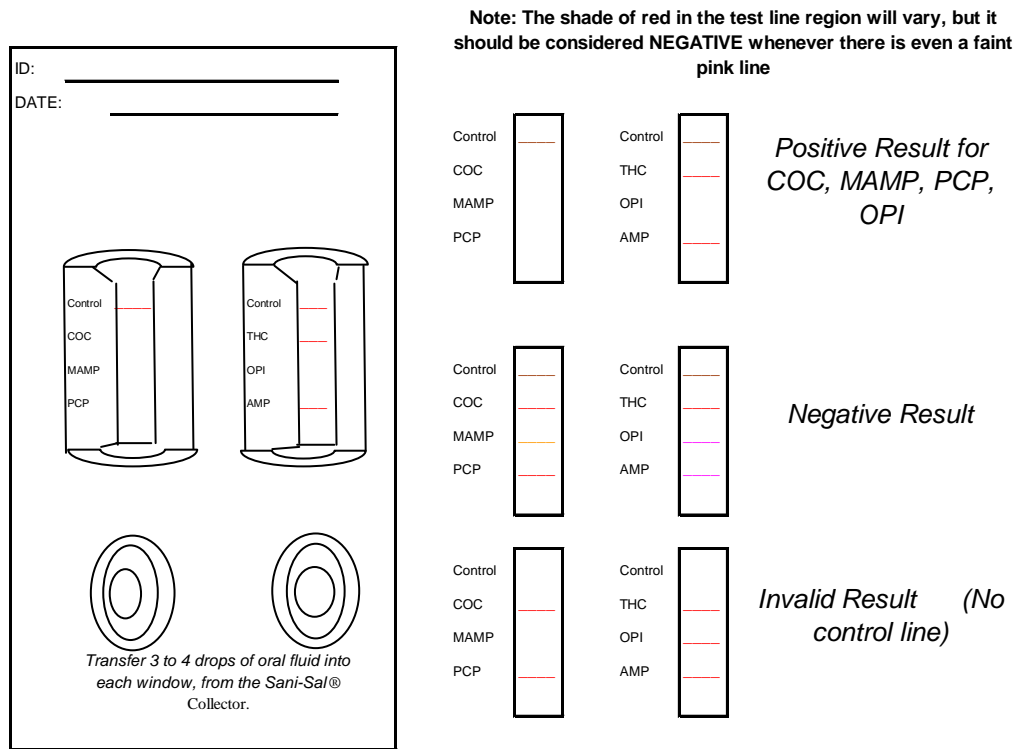
1. Allow the test device, specimen and/or controls to reach room temperature (15-30°C) prior to testing.
2. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it as soon as possible.
3. Open foil pouch holding the Sani-Sal® Saliva Collection Device by the cap, and place between the cheek and gum until the foam sponge has expanded and thoroughly wetted (usually about two to four minutes).

After removing the Sani-Sal® Saliva Collection Device from the mouth (again handling only by the plastic cap), the Sani-Sal® Saliva Collection Device should be assembled into its flexible plastic tube holder by twisting gently to insert the wet sponge.

4. Squeeze the flexible plastic tube to extract the saliva sample. Drops may be added directly to the test or may be collected in the bottom of the test tube. This will normally yield a sufficient quantity of concentrated saliva for the test. If necessary, centrifugation can improve the yield.
5. Wait for the colored line(s) to appear. Usually, within 5 minutes (a line appearing within 5 minutes usually signify the test completion). The test results should be read at 10 minutes to make sure that no visible line formation has occurred. The test results are not stable and therefore, should not be read after 1 hour.

Illustration

READ YOUR RESULTS AFTER 10 MINUTES



INTERPRETATION OF RESULTS

NEGATIVE:

Four lines appear for each panel. 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 test line). This negative result indicates that the drug concentration is below the detectable level.

**NOTE: The shade of red in the test line region 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 for a specific drug. 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. Test panels are sensitive to high temperature storage (above 56°C - 140°F) 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 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 cut-off level of the assay.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity:

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of $\pm 50\%$ cut-off and $\pm 25\%$ cut-off and tested with the Oral Fluid Drug Screen Device. The results are summarized below.

| Drug Concentration (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 Concentration (Cut-off range) | n | THC | | OPI | | 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 | 47 | 26 | 4 |
| Cut-off | 30 | 15 | 15 | 20 | 10 | 19 | 11 |
| +25% cut-off | 30 | 11 | 19 | 5 | 15 | 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 | |
|---|--------|
| Benzolecgonine | 20 |
| Cocaine HCl | 20 |
| Cocaethylene | 25 |
| Ecgonine HCl | 1,500 |
| Ecgonine Methyl ester | 12,500 |
| AMPHETAMINE | |
| D-Amphetamine | 50 |
| DL-Amphetamine | 125 |
| β -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-Methylenedioxyamphetamine (MDMA) | 50 |
| L-Phenylephrine | 4,000 |
| Procaine | 2,000 |
| (1R,2S) – (-) Ephedrine | 400 |
| MARIJUANA (THC) | |
| 11-nor- Δ 9-THC-9-COOH | 12 |
| Cannabinol | 12,500 |
| 11-nor- Δ 8-THC-9-COOH | 2 |
| Δ 8-THC | 6,000 |
| Δ 9-THC | 10,000 |
| OPIATES | |
| 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 |
| 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 | Acetophenetidin |
| N-Acetylprocainamide | Acetylsalicylic acid |
| Arminopyrine | Amoxicillin |
| Ampicillin | L-Ascorbic acid |
| Apomorphine | Aspartame |
| Atropine | Benzilic acid |
| Benzoic acid | Benzphetamine |
| D/L-Brompheniramine | Caffeine |
| Cannabidol | Chloralhydrate |
| Chloramphenicol | Chlorothiazide |
| D/L-Chloropheniramine | Chlorpromazine |
| Chloroquine | Cholesterol |
| Clonidine | Cortisone |
| L-Cotinine | Creatinine |
| Deoxycorticosterone | Dextromethorphan |
| Diclofenac | Diflunisal |
| Digoxin | Diphenhydramine |
| L-ψ-Ephedrine | β-Estradiol |
| Estrone-3-sulfate | Ethyl-p-aminobenzoate |
| L(-)-Epinephrine | Erythromycin |
| Fenoprofen | Furosemide |
| Gentisic acid | Hemoglobin |
| Hydralazine | Hydrochlorothiazide |
| Hydrocortisone | O-Hydroxyhippuric acid |
| p-Hydroxytyramine | Ibuprofen |
| Iproniazid | D/L-Isoproterenol |
| Isoxsuprine | Ketamine |
| Ketoprofen | Labetalol |
| Loperamide | Meperidine |
| Meprobamate | Methylphenidate |
| Nalidixic acid | Naloxone |
| Naltrexone | Naproxen |
| Niacinamide | Nifedipine |
| Norethindrone | D-Norpropoxyphene |
| Noscapine | D/L-Octopamine |

| | |
|--|---|
| Oxalic acid | Oxolinic acid |
| Oxymetazoline | Papaverine |
| Penicillin-G | Pentazocine hydrochloride |
| Perphenazine | Phenelzine |
| Trans-2-phenylcyclopropylamine hydrochloride | Phenylpropanolamine |
| Prednisolone | Prednisone |
| D/L-Propranolol | D-Propoxyphene |
| D-Pseudoephedrine | Quinacrine |
| Quinine | Quindine |
| Ranitidine | Salicylic acid |
| Serotonin | Sulfamethazine |
| Sulindac | Tetracycline |
| Tetrahydrocortisone 3-acetate | Tetrahydrocortisone 3 (β -D-glucuronide) |
| Thiamine | Thioridazine |
| D/L-Tyrosine | Tolbutamide |
| Triamterene | Trifluoperazine |
| Trimethoprim | D/L-Tryptophan |
| Tyramine | Uric acid |
| Verapamil | Zomepirac |

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