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 oral fluids at the following cut-off concentrations:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Cut-off</th>
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</thead>
<tbody>
<tr>
<td>Amphetamine (AMP)</td>
<td>50 ng/mL</td>
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<tr>
<td>Methamphetamine (MAMP)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>Marijuana (THC)</td>
<td>THC-COOH 4 ng/mL</td>
</tr>
<tr>
<td>Phencyclidine (PCP)</td>
<td>10 ng/mL</td>
</tr>
<tr>
<td>Cocaine (COC)</td>
<td>Benzoylecgonine 20 ng/mL</td>
</tr>
<tr>
<td>Opiates (OPI)</td>
<td>Morphine 40 ng/mL</td>
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</tbody>
</table>

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to confirm a definitive analytical result. Gas chromatography/mass spectrometry (GC/MS) and gas chromatography/mass spectrometry tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any test 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. 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 50 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 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. Heroin metabolite 6-monooacetylmorphine (6-MAM) is found more prevalently in excoriated 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 cutoff level.

Marijuana (THC)

Totally psychoactive, 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 sequestration of the drug in the buccal cavity. 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 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.

The PCP assay contained within the Oral Fluid Drug Screen Device for oral fluids exceeds 15 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. Also, if present in the oral fluid specimen before its cut-off concentration, will not saturate the binding sites of the specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will arise 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 test line will not form in the test line region.

A drug-positive oral fluid specimen will 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 colorless line appears on the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

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.

PROCEDURE 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 Required but not Provided:

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

DIRECTIONS FOR USE

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

1. Bring the potch 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 swish inside of the mouth and the top of the tongue until the substance 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.

For Forensic Use Only

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- 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.

Materials Provided:

- Collector
- Procedure Card
- Package insert

PRECAUTIONS

For forensic use only.

- Do not use past the expiration date.
- The Oral Fluid test device should remain in the sealed pouch until use.
- If tested for biological hazard unless derived from a dental procedure.

For forensic use only.

- 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.
**INTERPRETATION OF RESULTS**

**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**

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.

**BIBLIOGRAPHY**

