**OrALert™ Oral Fluid Drug Screen Device**

**OrALert™ Oral Fluid Drug Screen Device for 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**

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

- **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)**
  - 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.

  - Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.

- **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 study 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, as high as 600 ng/mL.

  - The Phencyclidine assay contained within the OrALert™ Oral Fluid Drug Screen Device yields a positive result when the 9-THC concentration in oral fluid exceeds 100 ng/mL.

**ASSAY PRINCIPLE**

The OrALert™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/OPi/THC/PCP is an immunoblot assay 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, will displace the drug conjugate and bind to the control line. A drug-negative oral fluid specimen will generate a line in the test line region of the assay strip.

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 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.
- The test device should not be exposed to direct light or exposed to a temperature range below 4°C or above 40°C.
- The used collector and device should be discarded according to local, state and national 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 not be exposed to temperatures above 50°C or below 4°C.

**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 PROVIDER**

**MATERIALS**

- Test devices
- Caps
- Collectors
- Procedure cards
- Tamper evident tape
- Package insert

**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 not to 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 swish and actively swirl 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 the buccal pouch and keep in the mouth for 4-6 minutes.
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 devices by pushing it into the chamber and turning the collector clockwise and set the timer for 9 minutes.
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 hopper.
9. For detailed operation instructions, please refer to the Procedure Card.
INTERPRETATION OF RESULTS

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 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 techniques.

LIMITATIONS

1. The OralAlert™ 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 level of the test system.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

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

<table>
<thead>
<tr>
<th>Drug conc. (Cut-off range)</th>
<th>n</th>
<th>COC</th>
<th>mAMP</th>
<th>OPC</th>
<th>PCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
<td></td>
<td>30</td>
<td>0</td>
<td>30</td>
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</tr>
<tr>
<td>-50% Cut-off</td>
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<td>0</td>
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<tr>
<td>-25% Cut-off</td>
<td></td>
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<tr>
<td>&lt;25% Cut-off</td>
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<tr>
<td>&gt;25% Cut-off</td>
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</tbody>
</table>

The following table lists the concentration of compounds (ng/mL) above which the OralAlert™ Oral Fluid Drug Screen Device identified positive results at a read time of 10 minutes.

COCAINE (COC)

<table>
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<tr>
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<td>0</td>
</tr>
<tr>
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<td>30</td>
<td>0</td>
<td>30</td>
<td>0</td>
</tr>
</tbody>
</table>

METHAMPHETAMINE (mAMP)

<table>
<thead>
<tr>
<th>Drug conc. (Cut-off range)</th>
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<th>mAMP</th>
<th>OPC</th>
<th>PCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Cut-off</td>
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<td>0</td>
<td>30</td>
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<tr>
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<td>&lt;25% Cut-off</td>
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<td>30</td>
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</tbody>
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ANALYTICAL SPECIFICITY

The following compounds demonstrated no false positive results on the OralAlert™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL:

- Acetylaminophen
- Acetaminophen
- Aflatoxin B1
- Aflatoxin B2
- Acetophenetidin
- Acenaphthene
- Acenaphthylene
- Acenaphthylene naphthenic

BIBLIOGRAPHY


