The **Oral Fluid Drug Screen Device** can detect Opiate, Marijuana, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, 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>OPIATE (OPI)</td>
<td>10 ng/mL</td>
</tr>
<tr>
<td>BENZODIAZEPINES (BZD)</td>
<td>50 ng/mL</td>
</tr>
<tr>
<td>METHADONE (MDT)</td>
<td>30 ng/mL</td>
</tr>
<tr>
<td>OXOCODONE (OXO)</td>
<td>10 ng/mL</td>
</tr>
<tr>
<td>MARIJUANA (THC)</td>
<td>5 ng/mL</td>
</tr>
<tr>
<td>BARTITURATES (BAR)</td>
<td>100 ng/mL</td>
</tr>
<tr>
<td>BUPRENORPHINE (BUP)</td>
<td>10 ng/mL</td>
</tr>
</tbody>
</table>

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. Positive identification should be based on the pattern of detection of the specific drug metabolites in the oral fluid specimen when preliminary positive results are indicated.

**SUMMARY AND EXPLANATION OF THE TEST**


**INTENDED USE**


**FOR FEDERAL USE ONLY**

**PRINCIPLE**

The **Oral Cube™ Oral Fluid Drug Screen Device** for AMP/HAP/COC/OP/T/THC/OXO/OXY/MDT/BAR/BUP is an immunoassay based on the principle of competitive inhibition. The oral fluid specimen competes against their respective drug conjugate for binding sites on their specific antibody.

**DIRECTIONS FOR USE**

**SPECIMEN COLLECTION AND PREPARATION**

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.

**MATERIALS**

- **Materials Provided**
  - Test devices
  - Procedure card
- **Materials Required But Not Provided**
  - Timer

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place in any medium that alters the temperature of the mouth including foods, drinks, or tobacco products for at least 15 minutes prior to collection of oral fluid specimen.

**SAMPLE**

- **Oral Fluid**
  - Saliva
  - Saliva is not classified as biological hazard unless derived from a dental procedure.

**PRECAUTIONS**

- **For Federal Use Only.**
- Do not use after the expiration date.
- The oral fluid drug screen device should remain in the sealed pouch until use.
- The oral fluid drug screen device must be used in a laboratory or workplace setting.
- The test is for single use.
- The used collector and device should be discarded according to federal, state and local regulations.

**STORAGE AND STABILITY**

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.

**PROCEDURE**

1. **Materials Provided**
2. **Procedure Card**
3. **Materials Required But Not Provided**
4. **Timer**

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**Step 1**

**Step 2**

**Step 3**

**Step 4**

**Step 5**

**INTERPRETATION OF RESULTS**

(While referring to the previous illustration)

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

**VALID:**
Control lines are present in the control region (C) and test region (T). This negative result indicates that the drug concentration is above the detectable level.

**INVALID:**
Control line fails to appear. Insufficienct specimen volume or incorrect procedural techniques are the most likely reasons for contror line failure. Review the procedure and repeat the test using a new device. If the prolem persists, discontinue using the lot immediately and contact your supplier.

**QUALITY CONTROL**
A procedural control is included in the test. A color line appearing in the control region (C) is considered an internal control. The shade of color in the test line region (T) will vary, but it should persist, discontinue using the lot immediately and contact your supplier.

**LIMITATIONS**
Drug may be present in the specimen below the cut-off and tested with the Oral Cube™ Oral Fluid Drug Screen Device for AMP and MAR in buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off.

**INTERFERENCES**
A study was conducted to determine the cross-reactivity of the test with compounds applied into drug-free PBS stock. The following compounds demonstrated no false positive results on the Oral Cube™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

**Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Benzo diazepines, Oxycodone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are:**

- Parent compound only.

- Chloral hydrate
- Naloxone
- Chlorpromazine
- Naltrexone
- Chlorpromazine
- Naproxen
- Chlorpromazine
- Nalidixic acid
- Chlordiazepoxide
- Methylphenidate
- Clonazepam
- Loperamide
- Dilorazepam
- Labetalol
- Ecgonine
- Isoxsuprine
- Ecgonine HCl
- Meprobamate
- Cocaethylene
- Alphenol
- Cocaine HCl
- Chlormethiazole
- Dextromethorphan
- Alprazolam
- Doxylamine
- Hydroxyzine
- Alprazolam
- Diphenhydramine
- Alprazolam
- Digoxin
- Deoxycorticosterone
- Alprazolam
- Dextromethorphan
- Alprazolam
- Diphenhydramine
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