**Intended Use**

The Oral Cube™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/PCLP/BUP/COY/DY/MTD/BAR/BZO/OXY/THC is a lateral flow chromatographic immun assay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodeine, Methadone, Barbiturates, Buprenorphine, Alcohol and their metabolites in oral fluids at the following cut-oﬀ concentrations:

- **Amphetamine (AMP)**: 50 ng/mL
- **Methamphetamine (mAMP)**: 50 ng/mL
- **Cocaine (COC)**: 50 ng/mL
- **Opiates (OPI)**: 40 ng/mL
- **Marijuana (THC)**: 1 ng/mL
- **Phencyclidine (PCP)**: 10 ng/mL
- **Benzodiazepines (BZO)**: 50 ng/mL
- **Oxycodone (OXY)**: 50 ng/mL
- **Methadone (MTD)**: 75 ng/mL
- **Barbiturates (BAR)**: 250 ng/mL
- **Buprenorphine (BUP)**: 10 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) is the preferred confirmatory method.

**Summary and Explanation of the Test**

The Oral Cube™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/PCLP/BUP/COY/DY/MTD/BAR/BZO/OXY/THC 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 psychomimetic 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 and up to 2 hours after use.

The Amphetamine assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol 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 and up to 2 hours after use.

The Methamphetamine assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol 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 can be detected in oral fluids by benzoylcegonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use. Cocaine and benzoylcegonine can be detected in oral fluids from 30 minutes to more than 2 hours after use.

The Cocaine assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the cocaine metabolite in oral fluid exceeds 20 ng/mL.

**Opiates (OPI)**

The term opiate 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 are typically metabolized by the liver and can be detected in oral fluids, even with low levels of consumption.

The Opiates assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the concentration of Morphine in oral fluid exceeds the 40 ng/mL.

**Marijuana (THC)**

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in oral fluid by capillary action. The detection of the drug is usually related to oral smoking, or the 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 saliva of up to 14 hours after drug use.

The Marijuana assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the concentration of Marijuana in oral fluid exceeds the 40 ng/mL.

**Phencyclidine (PCP)**

Phencyclidine, the hallucogen commonly referred to as Angel Dust, can be detected in saliva by capillary action. This is especially relevant because PCP has anxiolytic and sedative properties and has been abused orally for the purposes of sexual enhancement. PCP may also be detected in saliva up to 24 hours after use.

The Phencyclidine assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the concentration of Phencyclidine in oral fluid exceeds the 10 ng/mL.

**Methadone (MTD)**

Methadone is a synthetic opiate used in the maintenance treatment of heroin addiction. It acts as a partial agonist at opioid receptors in the brain. Methadone can be detected in oral fluids for long periods and at large doses, which is 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 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 Methadone assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the Methadone concentration in oral fluid exceeds 20 ng/mL.

**Oxycodone (OXY)**

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opioid agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and peripheral nervous system. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While use in the oral cavity, oxycodone is converted in the oral cavity to oxycodone hydrochloride combined with other analogues such as aspirin or acetaminophen. Oxycodone consists solely of oxycodone hydrochloride in a time-released formulation.

The Oxycodone assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the concentration of oxycodone in oral fluid exceeds 50 ng/mL.

**Buprenorphine (BUP)**

Buprenorphine HCI alone or in combination with Naloxone HCI. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primary heroin addicts) based on a similar or identical substance to the drug they were addicted to. Buprenorphine demonstrates a lower level of physical dependence. Subsequent use of Buprenorphine is not reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intraoral and intranasal administration.

The Buprenorphine assay contained within the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device yields a positive result when the Buprenorphine concentration in oral fluid exceeds 50 ng/mL.

**Buprenorphine (BUP)**

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade name of Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Oxycodone, Methadone and Buprenorphine.

**Principle**

(1) The Oral Cube™ Oral Fluid Drug and Alcohol Screen Device for AMP/mAMP/COC/PCLP/BUP/COY/DY/MTD/BAR/BZO/OXY/THC Device is a rapid oral fluid testing instrument designed specifically for the qualitative detection of the 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 color change, which can be seen 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 respective drug.
Allow the test device to reach room temperature (15-30°C [59-86°F]) prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

1. Remove the collection stick and test tube from the sealed pouch.
2. Tear off the package of the collection stick. (Step 1)
3. Insert the sponge end of the collection stick into mouth and soak sponge into saliva for 3 minutes. (Note: Time should be longer for people of little saliva. If the amount of saliva presser on the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.) (Step 2)
4. Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step 4)
6. Read results of alcohol test at 2 minutes and drug tests at 10 minutes.(If there is a label over reading window, peel off the label to read test results.) Do not read alcohol test result after 5 minutes and drug test results after 1 hour. (Step 5)
7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.

The following table lists the concentration of compounds (ng/mL) above which the Oral Cube® Oral Fluid Drug and Alcohol Screen Device provides a positive 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.

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various BAC. (0.02%, 0.08%, 0.15%, 0.30%). Negative salvia was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the Oral Cube® Oral Fluid Drug and Alcohol Screen Device are summarized below:

**ALCOHOL PREVALENT POSITIVE RESULT**: The alcohol test produces a color change to green in the presence of salivary alcohol 0.02 % BAC or higher. At higher alcohol concentration near 0.30% BAC, the color may change to a dark blue-gray.

**QUALITY CONTROL**

A procedural control is included in the test. A color 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 Cube® Oral Fluid Drug and Alcohol 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 cutoff level of the assay.
### OPIATES (OPI)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxymorphone</td>
<td>5.0</td>
</tr>
<tr>
<td>Normorphine</td>
<td>5.0</td>
</tr>
<tr>
<td>Morphine 3-ß-D-Glucuronide</td>
<td>5.0</td>
</tr>
<tr>
<td>6-Monoacetylmorphine</td>
<td>5.0</td>
</tr>
<tr>
<td>Levorphanol</td>
<td>1.0</td>
</tr>
<tr>
<td>Hydromorphine</td>
<td>1.0</td>
</tr>
<tr>
<td>Tapentadone</td>
<td>1.0</td>
</tr>
<tr>
<td>Thebaine</td>
<td>1.0</td>
</tr>
</tbody>
</table>

### OPIATES (OPI)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydromorphine</td>
<td>1.0</td>
</tr>
<tr>
<td>Metadone</td>
<td>1.0</td>
</tr>
<tr>
<td>Butylnorlaudanosine</td>
<td>1.0</td>
</tr>
<tr>
<td>Norbuprenorphine</td>
<td>1.0</td>
</tr>
</tbody>
</table>

### NON CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds spiked into oral fluid up to 100 µg/mL. The following compounds demonstrated no false positive results on the Oral Cube™ Oral Fluid Drug and Alcohol Screen Device when tested with concentrations up to 100 µg/mL.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (µg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>25.0</td>
</tr>
<tr>
<td>Dihydrocodeine</td>
<td>7.5</td>
</tr>
<tr>
<td>Ethylmorphine</td>
<td>15.0</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>12.500</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>12.500</td>
</tr>
<tr>
<td>Thebaine</td>
<td>12.500</td>
</tr>
</tbody>
</table>

### Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycerin, glycerol, and serine. This property is a result of specificity of the alcohol oxidase extracted from yeast.

### BIBLIOGRAPHY