A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana[1], Phencyclidine[2], Benzodiazepines[3], Oxycodone, Methadone[4] and their metabolites in human oral fluid.

The STAT™ Oral Fluid Drug Screen Device is a lateral flow chromogenic immunosay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone[4], Barbiturates and their metabolites in oral fluids at the following cut-off concentrations:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Assay</th>
<th>Cut-off (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amphetamine</td>
<td>AMP</td>
<td>50</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>BZO</td>
<td>50</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>BAR</td>
<td>300</td>
</tr>
<tr>
<td>Cocaine</td>
<td>COC</td>
<td>50</td>
</tr>
<tr>
<td>Methadone</td>
<td>MTD</td>
<td>75</td>
</tr>
<tr>
<td>Methamphetamine</td>
<td>mAMP</td>
<td>50</td>
</tr>
<tr>
<td>Opiates</td>
<td>OPI</td>
<td>40</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>OXY</td>
<td>50</td>
</tr>
<tr>
<td>Oxazepam</td>
<td>OXZ</td>
<td>50</td>
</tr>
<tr>
<td>Phencyclidine</td>
<td>PCP</td>
<td>15</td>
</tr>
<tr>
<td>Phenylisedone</td>
<td>DAP</td>
<td>10</td>
</tr>
<tr>
<td>Methadone (MTD)</td>
<td>MTD</td>
<td>50</td>
</tr>
<tr>
<td>Methadone (BAR)</td>
<td>BAR</td>
<td>300</td>
</tr>
</tbody>
</table>

This assay provides only a preliminary 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/therm mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. The presumptive judgment should be applied to any drug of abuse test result; particularly when preliminary positive results are indicated.

**INTENDED USE**

The oral fluid concentrations of the following drugs are detectable with the STAT™ Oral Fluid Drug Screen Device and have a positive test result when the concentration of the drug in oral fluids exceeds the specified cut-off level:

- **Amphetamines** (AMP) and Methamphetamine (mAMP) yield a positive result when the Methamphetamine concentration in oral fluids exceeds 50 ng/mL.
- **Cocaine** (COC) yields a positive result when the cocaine metabolite in oral fluids exceeds 20 ng/mL.
- **Opiates** (OPI) yield a positive result when the Opiate concentration in oral fluids exceeds 50 ng/mL.
- **Barbiturates** (BAR) yield a positive result when the Barbiturates concentration in oral fluids exceeds 300 ng/mL.

**PRINCIPLE**

The STAT™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/THC/PCP/BZO/OXY/MDD/MTD is an immunosay 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 the 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 a 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 test strip because of drug conjugate binding capacity. A negative oral fluid specimen will generate a line in the test line region because of the absence of drug conjugate.

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 applied and membrane wicking has occurred.

**SUMMARY AND EXPLANATION OF THE TEST**

The STAT™ Oral Fluid Drug Screen Device for AMP/mAMP/COC/THC/PCP/BZO/OXY/MDD/MTD and its metabolites is a rapid, oral fluid testing screen 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 abused by oral or intravenous injection and free-base smoking. Depending on the route of administration, cocaine metabolites in oral fluids at the following cut-off concentrations:

- **Amphetamine** (AMP) yields a positive result when the concentration of Amphetamine in oral fluids exceeds 50 ng/mL.

**OPIATE (OPI)**

The Opiate assay contained within the STAT™ Oral Fluid Drug Screen Device yields a positive result when the concentration of Morphine in oral fluids exceeds the 40 ng/mL cut-off level.

**APAP (METHAMPHETAMINE (mAMP))**

The Methamphetamine assay contained within the STAT™ Oral Fluid Drug Screen Device yields a positive result when the Methamphetamine concentration in oral fluids exceeds 50 ng/mL.

**COCAINE (COC)**

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the cola plant (erythroxylum coca). The drug is often abused by oral or intravenous injection and free-base smoking. Depending on the route of administration, cocaine metabolites in oral fluids at the following cut-off concentrations:

- **Cocaine** (COC) yields a positive result when the cocaine metabolite in oral fluids exceeds 20 ng/mL.

**BARBITURATES (BAR)**

Barbiturates are CNS depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and dependence. Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of physical abstinence can be severe enough to cause death.

**PRECAUTIONS**

- **For Forensic Use Only**
- **Do not use after the expiration date.**
- **The Oral Fluid Drug Screen Device should remain in the sealed pouch until use.**
- **Saliva is not classified as biological hazard unless derived from a dental procedure.**
- **The test device is for single use.**
- **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. A test device should remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.
**SPECMEN 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 Provided**
- Test device
- Package insert
- Procedure Card
- Timer

**Materials Required But Not Provided**

**DIRECTIONS FOR USE**

Allow the test device to reach room temperature [15-30 °C (59-86 °F)] prior to testing. Do not allow the test device to reach room temperature [15-30 °C (59-86 °F)].

1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and screw the Collector Cap counterclockwise to pull out the Collector Chamber. (Step 1)
2. Remove the sponge from the mouth. With gentle pressure, place the collection stick with the sponge end of the collection stick into the mouth. Close mouth and gently chew the sponge for saliva excretion. Soak sponge into saliva in mouth and swab the inside of the mouth and tongue to collect oral fluid specimen. (Step 2)
3. Insert the sponge end of the collection stick into the mouth. Close mouth and gently chew the soft and fully saturated with saliva. No hard spots should be felt on the sponge when saturated. (Step 3)
4. Remove the sponge from the mouth. With gentle pressure, place the collection stick with saturated sponge into Collection Chamber. (Step 4)
5. Screw the Collector Cap clockwise to secure the cap and start the timer. (Step 4)
6. Mark patient ID on the test device. Peel off the label to read test results. Wait for the color lines to appear on the test strips. Read results at 10 minutes. Do not read results after 1 hour. (Step 5)
7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.

**INTERPRETATION OF RESULTS**

(Please refer to the previous illustration)

**NEGATIVE**

Two 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.

**NOTE:** The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

**POSITIVE**

One color line appears in the control region (C). No line appears in the test region (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 device. If the problem persists, discontinue the test 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 procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

**LIMITATIONS**

1. The STAT™ 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.

A positive test result does not indicate the concentration of drug in the specimen or the route of administration.

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**

**Analytical Sensitivity**

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ±50% cut-off and 0% cut-off and tested with the STAT™ Oral Fluid Drug Screen Device. The results are summarized below.

**Analytical Specificity**

The following table lists the concentration of compounds (ng/ml) above which the STAT™ Oral Fluid Drug Screen Device for STAT™ Oral Fluid Drug Screen Device [15, 30 °C (59, 86 °F)] will report a positive result.
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 STAT™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 mg/mL.

**References:***


Distributed by:

Micro Distributing
620 Kennedy Court
Belton, TX 76513
866-933-0964
www.micro-distributing.com

Effective date: 10/29/2009

---

**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 STAT™ Oral Fluid Drug Screen Device when tested with concentrations up to 100 µg/mL.

**BIBLIOGRAPHY**


Distributed by:

Micro Distributing
620 Kennedy Court
Belton, TX 76513
866-933-0964
www.micro-distributing.com

Effective date: 10/29/2009