The STAT™ Oral Fluid Drug Screen Device for AMP/Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone is intended for the detection of the following drugs in oral fluid:

- **Amphetamine** and **Methamphetamine** for the detection of Amphetamine and Methamphetamine in oral fluid.
- **Cocaine** for the detection of Cocaine in oral fluid.
- **Opiates** for the detection of Opiates in oral fluid.
- **Phencyclidine** for the detection of PCP in oral fluid.
- **Benzodiazepines** for the detection of Benzodiazepines in oral fluid.
- **Morphine** for the detection of Morphine in oral fluid.
- **Oxazepam** for the detection of Oxazepam in oral fluid.
- **Barbiturates** for the detection of Barbiturates in oral fluid.
- **Marijuana** for the detection of Marijuana in oral fluid.
- **Oxycodone** for the detection of Oxycodone in oral fluid.
- **Phencyclidine** for the detection of Phencyclidine in oral fluid.
- **Benzodiazepines** and **Methadone** for the detection of Benzodiazepines and Methadone in oral fluid.

The device is intended to be used as a screening test to provide preliminary results regarding the presence or absence of the above-mentioned drugs in oral fluid. Positive results should be confirmed using appropriate third-party methods. Professional judgment should be applied to any drug of abuse test result, particularly when interpreting preliminary positive results.

**OPINATE (OP)**

The OPINATE strip indicates 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 demonstrated additive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, muscle rigidity, and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous. Illegal users may also take the injected route of use or nasal inhalation. The approximate detection limit of 40 ng/mL may be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for up to 2-3 days after use.

**PN (Phencyclidine)**

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 collection, Phencyclidine concentration in saliva is 3-4 times lower than in plasma. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use.

**Methamphetamine (MTD)**

Methamphetamine is a potent stimulant related to amphetamine but with greater CNS stimulatory properties. The drug is often self-administered by nasal inhalation, smoking, or ingestion. Depending on the route of administration, methamphetamine can be detected in oral fluid as early as 5-10 minutes and up to 72 hours after use.

**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 yields a positive result when the cocaine metabolite in oral fluid exceeds 20 ng/mL.

**Oxycodone (OXY)**

Oxycodone is an opiate analgesic prescribed for moderate to severe pain and for the treatment of opiate dependence (heroin, Vicon, Percocet, morphine). The pharmacology of oxycodone is different from that of heroin in the brain and liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or methadone maintenance clinic to be prescribed methadone.

**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 physical 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 a period of abstinence can be severe enough to cause death. Only a small amount (less than 3 mL) of barbiturates are excrated unchanged in the urine.

**Storage and Stability**

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 each drug of interest. Methamphetamine, Benzodiazepine, Morphine, Marijuana, Phencyclidine, Oxazepam, Oxycodone, Methadone and Barbiturates.

**Precautions**

For Oral Fluid 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.

**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 results remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

**PRINCIPLE**

The STAT™ Oral Fluid Drug Screen Device assay is an immunassay 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 on its 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 strip because by drug cut-off concentration, the drug of interest 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 colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.
**SPECIMEN 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**
- **Test Devices**
- **Package Insert**
- **Procedure Card**
- **Materials Required But Not Provided**
- **Timer**

**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].

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 whole piece of collection stick with Sponge from the Collection Chamber. (Step 1)
2. Insert 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 for a total of 3 minutes. (Step 2)
3. Remove the test device from the sealed pouch and screw the Collector Cap counterclockwise to secure the cap and start the timer. (Step 4)
4. Observe the control line(s) to determine the result. (Step 5)
5. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.

**INTERPRETATION OF RESULTS**

(If blank refers to the previous illustration)

**NEGATIVE**

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 below the detectable level.

**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 method.
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 drug-free specimen. Drug may be present in the specimen below the cutoff level of the device.

**PERFORMANCE CHARACTERISTICS**

**Analytical Sensitivity**

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% 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 AMP/HFA/PCP/MDMA/BZO/PCP/DXT/THC identified positive results at a read time of 10 minutes.

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- **Test Devices**
- **Package Insert**
- **Procedure Card**

**Materials Required But Not Provided**
- **Timer**

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- **Timer**
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.

### BIBLIOGRAPHY


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