iScreen OFD™

Oral Fluid Drug Screen Device

Package Insert for the 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

INTENDED USE

The iScreen OFD™ for AMP/mAMP/COC/OPI/THC/PCP is a lateral flow chromatographic immunoassay for the qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, phencyclidine and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	d-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	d-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	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) and gas chromatography/tandem mass spectrometry (GC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The iScreen OFD™ for AMP/mAMP/COC/OPI/THC/PCP and their metabolites is a rapid, oral fluid screening test that can be performed without the use of an instrument. The test utilizes 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 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 72 hours after use.[1]

The Amphetamine assay contained within the iScreen OFD™ 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 central nervous system (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 72 hours after use.[1]

The Methamphetamine assay contained within the iScreen OFD™ yields a positive result when the methamphetamine concentration in oral fluid exceeds 50 ng/mL.

Cocaine (COC)

Cocaine is a potent 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 and its metabolites, benzoylecgonine and ecgonine methylester, can be detected in oral fluid as early as 5-10 minutes and up to 24 hours after use.[1]

The Cocaine assay contained within the iScreen OFD™ yields a positive result when the cocaine metabolite concentration in oral fluid exceeds 20 ng/mL.

Opiates (OPI)

The drug class opiates 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 act to control pain by depressing the central nervous system. The drugs demonstrate addictive properties when used for sustained periods of time; symptoms of withdrawal may include sweating, shaking, nausea and irritability. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the drug intravenously or by nasal inhalation. Using an immunoassay cutoff level of 40 ng/mL, codeine can be detected in the oral fluid within 1 hour following a single oral dose and can remain detectable for 7-21 hours after the dose.[2] 6-Monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is a major metabolic product of codeine and heroin, and is detectable for 24-48 hours following an opiate dose.

The Opiates assay contained within the iScreen OFD™ yields a positive result when the morphine concentration in oral fluid exceeds 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.[3] Historical studies have shown a window of detection for THC in oral fluid of up to 14 hours after drug use.[3]

The THC assay contained within the iScreen OFD™ yields a positive result when the 11-nor-Δ^9-THC-9 COOH concentration in oral fluid exceeds 12 ng/mL.

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 sample collection 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 and as high as 600 ng/mL.[4]

The Phencyclidine assay contained within the iScreen OFD™ yields a positive result when the PCP concentration in oral fluid exceeds 10 ng/mL.

ASSAY PRINCIPLE

The iScreen OFD™ for AMP/mAMP/COC/OPI/THC/PCP is an immunoassay 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 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 colored line will show up 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 strip because of drug competition, while a drug-negative oral 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.

REAGENTS

The test contains membrane strips coated with drug-protein conjugates on the test line, polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with antibody specific to Amphetamine, Methamphetamine, Benzoylecgonine, Morphine, 11-nor-Δ^9-THC-9 COOH and Phencyclidine.

PRECAUTIONS

- The device is **for forensic use only**.
- Do not use after the expiration date.
- The oral fluid test device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- 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. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

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

Materials Provided

- Test devices
- Caps
- Sponge protectors
- Procedure cards
- Security seals
- Package insert

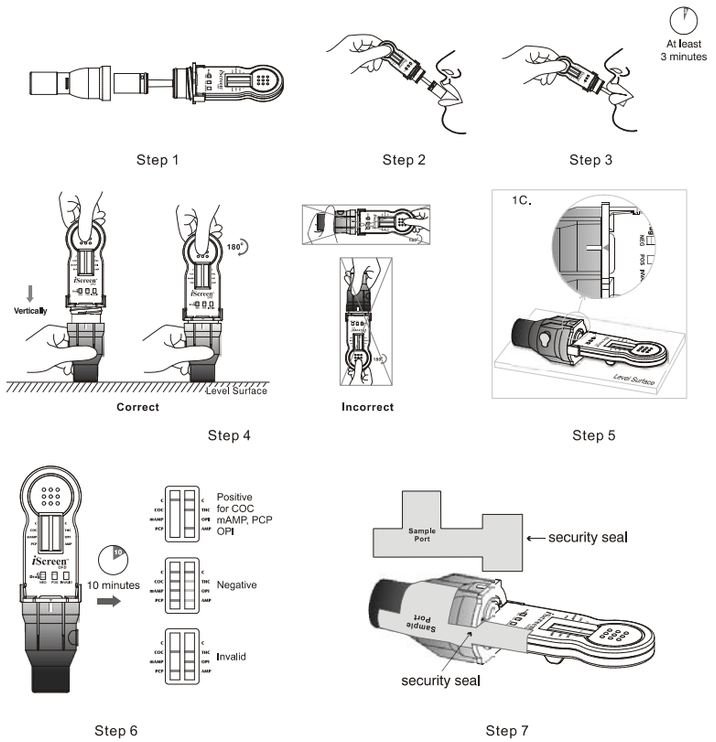
Materials Required but not Provided

- Timer

DIRECTIONS FOR USE

Allow the iScreen OFD™ to come to room temperature [15-30ºC (59-86ºF)] 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 Sample Collector Protector from the collection Sponge. Instruct the donor to insert the Sponge end of the collector into the mouth and actively swab 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 teeth to ensure **complete saturation**.
3. The Sponge is saturated when no hard spots can be felt. Collect for a total of at least three (3) minutes before removing the Sponge. Remove the collector from the mouth
4. Align the **Red Arrow** on the device with one of the **White Marks** on the Cap. Insert the collector **vertically** into the Cap and **press down firmly**. Twist the Cap clockwise 180° until the **Red Arrow** lines up with the other **White Mark**.
5. Place the test device horizontally on a clean and level surface with facing up.
6. **Read results at 10 minutes**. Do not read results after 1 hour.
7. If positive results are observed, secure Cap with security seal and send the device to a laboratory for confirmation. The laboratory can access the reservoir through the Sample Port.
8. For detailed operating instructions, please refer to the Procedure Card.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* All test lines appear. One colored line should be in the control region (C), and other 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 or drug free.

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

POSITIVE: One colored line appears in the control region (C). Any test line not 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.