

# SCREEN

## DROGA TEST

### Screen Drug Test Oral Fluid 6

Cocaine - Amphetamine - Marijuana - Methamphetamine - Opiates - Ecstasy (Oral Fluid) Package Insert

REF: 911151645

English

Screening rapid test for the simultaneous qualitative detection of amphetamine, methamphetamine, cocaine, opiates, marijuana, ecstasy and their metabolites in human saliva.

#### PRECAUTIONS

- **Not for medical or diagnostic use.**
- Do not use after expiration date.
- Test device should remain sealed until ready for use.
- Saliva is not classified as biological hazard substance if not deriving from dental procedure.
- Used test container and card should be discarded in accordance with local regulations.

#### INTENDED USE AND SUMMARY

Saliva SCREEN DROGA TEST for AMP/MAMP/MET/COC/OPI/THC/MDMA and their metabolites is a rapid, saliva 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 saliva at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	40
Methamphetamine (MET)	d-Methamphetamine	40
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9 COOH	10
Cocaine (COC)	Benzoylcegonine	30
Opiates (OPI/MOP)	Morphine	40
Ecstasy(MDMA)	d,l-Methylenedioxyamphetamine	50

This assay provides only a preliminary result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) and Tandem Gas Chromatography/Mass Spectroscopy are the preferred confirmation methods. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The Saliva SCREEN DROGA TEST for **AMP/MAMP/MET/COC/OPI/THC/MDMA** and their metabolites is a rapid saliva assay not requiring any particular equipment. The assay uses antibodies to selectively determine high levels of specific substances in the human urine.

The permanence times are approximated for each substance, as they vary based on the frequency of usage, body mass, age, health, tolerance to drugs and narcotic substances.

#### AMPHETAMINE (AMP)

Amphetamine is a substance often used for therapeutic use. It is often self-administered through inhalation or ingestion. Depending on the way of administration the substance can be detected in saliva already after 5-10 minutes and up to 72 hours after use<sup>1</sup>. The amphetamine analysis contained in the Saliva SCREEN DROGA TEST produces positive results when amphetamine concentration in saliva exceeds 40 ng/ml.

#### METHAMPHETAMINE (mAMP)

Methamphetamine is a potent stimulant, chemically linked to amphetamine, but with a major

capability of stimulating the central nervous system (CNS). The substance is often self-administered through inhalation, smoking or ingestion.

Depending on the way of administration the substance can be detected in saliva already after 5-10 minutes and up to 72 hours after use<sup>1</sup>. The methamphetamine analysis contained in the Saliva SCREEN DROGA TEST produces positive results when methamphetamine concentration in saliva exceeds 40 ng/ml.

#### COCAINE (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant (erythroxylum coca). It is often self-administered through inhalation or intravenous injection or by base-smoking. Depending on the way of administration cocaine and its metabolites can be detected in saliva already after 5-10 minutes and up to 24 hours after use<sup>1</sup>. The cocaine analysis contained in the Saliva SCREEN DROGA TEST produces positive results when cocaine concentration in saliva exceeds 30 ng/ml.

#### OPIATES (OPI)

Opiates include any of the substances deriving from the opium poppy, included natural products as morphine, codeine, and semi-synthetic substances as heroin. Opiates act on pain control depressing the central nervous system. Opiates show addictive characteristics if used for long periods of time. Dependence symptoms can include sweating, shakings, nausea, and irritability. Opiates can be taken orally or through intravenous, intramuscular, or subcutaneous injection. Users can also take the substance intravenously or through inhalation. With a cut-off level of 40 ng/ml it is possible to detect traces of codeine in saliva during 1 hour from oral use up to 7-21 hours after use<sup>2</sup>. 6-Monoacetylmorphine, a metabolic product of heroin, is detected mainly in saliva. Morphine is one of the main metabolic products of heroin and codeine and can be detected in the 24-48 hours subsequent to a dose of opiate.

The opiates analysis contained in the Saliva SCREEN DROGA TEST produces positive results when morphine concentration in saliva exceeds 40 ng/ml.

#### MARIJUANA (THC)

Tetrahydrocannabinol (THC) is the active component of marijuana (cannabis sativa) detectable in saliva a short time after assumption. This is mainly due to its direct contact with the mouth (oral administration or smoking) and the following permanence of the substance in the oral cavity<sup>3</sup>. A series of studies showed a detection window of THC in saliva for a period of 14 hours after use<sup>3</sup>. The THC analysis contained in the Saliva SCREEN DROGA TEST produces positive results when 11-nor- $\Delta^9$ -THC-9-COOH concentration in saliva exceeds 10 ng/ml.

#### ECSTASY (MDMA)

Ecstasy (MDMA) is a designer drug first synthesized in 1914 by a German drug company for the treatment of Obesity. Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The MDMA assay contained within the saliva screen droga test yields a positive result when the MDMA concentration in saliva exceeds 50ng/ml.

#### ANALYSIS PRINCIPLE

Saliva SCREEN DROGA TEST for AMP/MAMP/MET/COC/OPI/THC/MDMA 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 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 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 (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 amphetamine, methamphetamine, cocaine, opiates,  $\Delta^9$ -THC-COOH, methadone, ecstasy and synthetic marijuana.

#### 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 saliva SCREEN DROGA TEST 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. Follow the detailed directions for use below. No other collection the saliva SCREEN DROGA TEST should be used with this assay. Oral fluid collected at any time of the day may be used.

#### PACKAGE COMPOSITION

Saliva SCREEN DROGA TEST, directions for use.

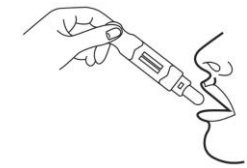
#### DIRECTIONS FOR USE

Allow the saliva SCREEN DROGA TEST, specimen, and/or controls to reach room temperature (15-30°C) prior to testing. Instruct the donor to not 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 from the sealed pouch and use it within one hour.
2. Take off the saliva SCREEN DROGA TEST cap and insert the absorbent wick to the mouth. Put it under the tongue to collect saliva until the control line appears and then take out the saliva SCREEN DROGA TEST.

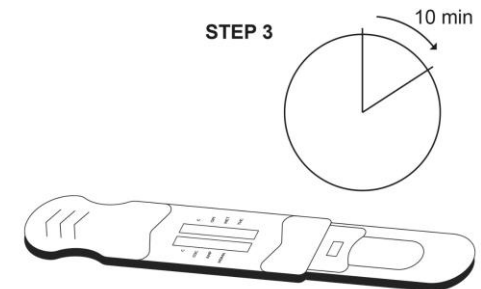


**STEP 1**  
REMOVE  
THE CAP

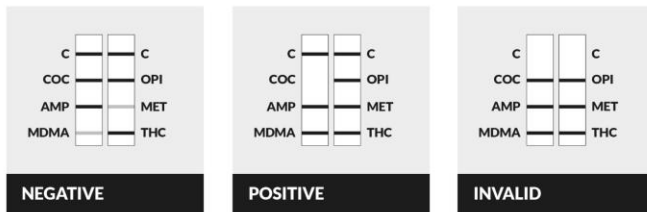


**STEP 2**  
UNTIL BOTH  
CONTROL  
LINES  
APPEAR

3. Place the saliva screen droga test on a clean and level surface. See illustration below.



4. Read the result after 10 minutes. Do not interpret the result after 1 hour.



## INTERPRETATION OF RESULTS

**Negative: \* All the test lines appear.** A colored line must appear in the control region (C), while the other must be near the test region (Substance/T). The negative result indicates that the drug concentration in the urine is under the cut-off level or absent.

**\*NOTE:** The intensity of the color in the test region (Substance/T) may vary, but any shade of color in the test region should be considered negative.

**Positive: A single colored line appears in the control region (C).** No colored line appears in the test region (Substance/T). A positive result indicates that the concentration of that substance is above the cut-off level.

**Invalid: No control line appears.** Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure. Please review the procedure and repeat with a new card.

**In case the test result is positive, please avoid aggressive behavior and reason any search for dialogue with the tested subject. Ask for advice to your physician, a psychologist, or the competent service in your area.**

## QUALITY CONTROL

The test includes an internal procedural control, the red band appearing in the control region (C). The appearance of this band confirms the test has been carried out correctly with a sufficient specimen volume, membrane wicking and correct procedural technique.

## LIMITATIONS

1. The Saliva SCREEN DROGA TEST only provides a preliminary qualitative analytic result. A more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) and Tandem Gas Chromatography/Mass Spectroscopy (GC/MS/MS) are the preferred confirmation methods, particularly when the preliminary result is positive.
2. A positive result does not indicate level of intoxication or administration route.
3. A negative result may not necessarily indicate a drug-free sample. Negative results can be obtained when drug is present but below the cut-off level of the test.
4. It is possible that technical or procedural errors, as well as other interfering substances in the saliva specimen may cause erroneous results.
5. Test does not distinguish between drugs of abuse and certain medications containing the same substance. False positive results can be caused by some medications.

Distributed by:

**Screen Italia Srl**

Via dell'Artigianato, 16

06089 - Torgiano - Perugia - Italia

[www.screenpharma.it](http://www.screenpharma.it) - [info@screenpharma.it](mailto:info@screenpharma.it)