

OraLine® Saliva Drug Screen

One-Step, Rapid, Qualitative Drugs of Abuse Saliva Immunoassay Test Kit for Cannabinoids, Cocaine, Methamphetamine and Morphine.

Rapid, one-step screening tests for the simultaneous, qualitative detection of multiple drugs in human saliva.

The OraLine® IV is intended for forensic use only. The device is intended to be used in such facilities as court systems, police departments, probation/parole offices, juvenile detention centers, prisons, jails, and correction centers. This assay is not intended for sale to the general public.

For Forensic use only.

INTENDED USE

The OraLine® Saliva Drug Screen is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs in saliva at the following cut-off concentrations:

Test	Analyte Detected	Cut-off (ng/mL)
THC	Delta9-THC	4
COC	Cocaine	25
MET	Methamphetamine	3.75
OPI	Morphine, Heroin	2

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) or Liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods.

Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are read. Tests for Cannabinoids, Cocaine, Methamphetamine and Morphine cannot distinguish between abused drugs and certain prescription medications. Certain foods or medication may interfere with these tests and cause false positives.

SUMMARY

CANNABINOID (THC)

THC (Δ^9 -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use¹.

The OraLine® Saliva Drug Screen for Cannabinoids and yields a positive result when the concentration of THC-delta9 in saliva exceeds 4ng/mL.

COCAINE (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large doses, Cocaine causes fever, unresponsiveness, difficulty breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection or free-based smoking. Depending on administration, cocaine can be detected in saliva for up to 24 hours after use².

The OraLine® Saliva Drug Screen for Cocaine yields a positive result when the Cocaine in saliva exceeds 25ng/mL.

METHAMPHETAMINE (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is

made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased power and energy. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is detectable in saliva for up to 72 hours after use².

The OraLine® Saliva Drug Screen for Methamphetamine yields a positive result when the Methamphetamine in saliva exceeds 3.75ng/mL.

OPIATES/MORPHINE (OPI)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, Morphine and Codeine, and semi-synthetic drugs such as Heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances that control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Opiates can be detected in saliva for 7-21 hours after a dose¹.

The OraLine® Saliva Drug Screen for Morphine yields a positive result when the Morphine in saliva exceeds 2ng/mL.

REAGENTS

The OraLine® Saliva Drug Screen is an immunoassay test by visual color comparison. It is based on the principle of antigen-antibody complexation and is used for the analysis of Cannabinoids, Cocaine, Methamphetamine and Morphine in human saliva samples. The assay utilizes a competitive immunochromatographic technique involving a sample of test saliva delivered through a wicking action as the integrated collection spoon is filled with saliva. The drug sample competes for the limited antibody sites on the colored microspheres. When an adequate amount of drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored microspheres to the probe site on the membrane. Therefore, a positive saliva sample will inhibit the formation of precipitin at the probe site.

A reference or control line with a secondary antibody reaction is added to the membrane strip to check for proper sample migration on the membrane. This control line should always be present. A negative saliva sample will produce a colored line next to the indicated drug and a positive saliva sample will show no line (sometimes will appear white).

- Use a new test device for each saliva sample.
- For Forensic Use Only. Do not use after the expiration date.
- If the foil pouch is torn or perforated, the device should not be used.
- Open the sealed pouch containing the test device immediately prior to use. Prolonged exposure to ambient humidity will cause product deterioration.
- Always place OraLine® Saliva Drug Screen on a protected flat, level surface when running the test.
- Do not move the test device while the test is still running.
- Always read the test results under adequate lighting.
- Warning: Saliva and all materials coming in contact with them should be handled and disposed of as if infectious and capable of transmitting infection. Wear disposable gloves.**

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 36-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. The test device must be brought to room temperature prior to use.

SPECIMEN COLLECTION AND PREPARATION

The OraLine® Saliva Drug Screen is formulated for use with fresh saliva. Specimens are collected directly using the OraLine® Saliva Drug Screen test device. For normal application, do not collect or deliver samples using other means. Do not use any altered, processed, or aged saliva samples, as these samples may have inconsistent flow pattern and yield different results as compared with fresh samples. The amount of saliva collected using the OraLine® Saliva Drug Screen spoon is optimal for the test. Saliva specimens do not require any special pretreatment, but the samples should be free from gross debris from food, juices, or soft drinks.

Caution:

1. **If the test device is stored refrigerated, allow the test to come to room temperature prior to opening the pouch.**
The person being tested must be able to produce a sufficient saliva sample in order for the test to function properly. Frothy samples, and air-bubbles not only reduce the volume of sample delivered, but also may stop the capillary flow on the absorbent material.
3. **Make sure that the person being tested has had nothing in their mouth for at least five (5) minutes before saliva sample is collected; including food, chewing gum, and tobacco products, etc.**

Note: If the person being tested is experiencing dry mouth prior to sample collection, have the person drink a glass of water or have a piece of hard candy or sugarless gum, remove from mouth, wait five (5) minutes and then proceed with test. Alternatively, saliva could be collected in the provided sample collection cup. If using the cup, deliver a spoonful of saliva while holding the spoon in a horizontal position with the handle held in an upward position as shown in Procedure II below.

MATERIALS

Materials Provided

- One Package Insert and Instructions for Use
- One Kit of 25 sealed tests in foil pouches
- Collection Cups

Each Pouch Contains

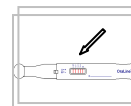
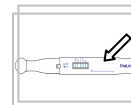
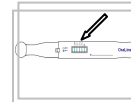
- One Test
- Desiccant

Materials Required But Not Provided

- Timer, Paper Towels, Disposable Gloves

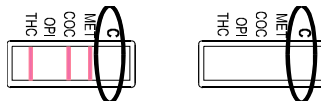
DIRECTIONS FOR USE

Test Procedure I



1. Remove the test device from the pouch. Verify that five (5) green lines are present in the test window. If the green lines are not present, a new device with five (5) visible green lines should be used.
2. Mark the device with the subject's name or ID number. Remove the cap.
3. Let the test subject accumulate sufficient saliva in the mouth first, then place the spoon end of the device into the subject's mouth and collect a spoonful of saliva sample. When collecting, the sample, make sure the spoon is in a horizontal position with the handle upward as illustrated.
4. Once the spoon is filled, do not replace the cap until the sample shows up in the view window. Place the device on a protected flat surface, and allow running for 10-12 minutes.

- The test results are read between 10-12 minutes in the viewing window. Make sure the control line (C) is clearly visible before reading and recording the results.



In both examples, the control line is absent. The test results are INVALID.

QUALITY CONTROL

Each time a new test kit lot number is received or a new operator is performing the test for the first time, an established positive control and a negative control should be tested. In regular operations, quality control of OraLine® Saliva Drug Screen should be performed periodically, as necessary depending on the frequency and the volume of tests used.

LIMITATIONS

The OraLine® Saliva Drug Screen assay is designed for use with human saliva samples only. The person being tested must be able to produce and deliver sufficient saliva in order for the test to function properly. A positive result with any of the tests may indicate only the presence of the parent drug or drug metabolite and does not indicate or measure level of drug present or intoxication. There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results, such as technical or procedural errors. See INTERFERENCE STUDY for lists of substances that are known to produce positive results and substances that do not interfere with test performance.

PERFORMANCE CHARACTERISTICS

Precision and Accuracy

Three lots of each drug were used to test 3 concentrations of artificial saliva samples for each drug. Sample 1 was drug free artificial saliva. Sample 2 was negative artificial saliva spiked with positive standards below cut off levels. Sample 3 was negative artificial saliva spiked with positive standards above cut off levels. The samples were analyzed in duplicate, twice daily for a period of 5 consecutive days. This was a blind study, with samples relabeled daily to randomly rotate the unknown samples.

The following lot-to-lot accuracies are tabulated from these studies:

THC (Cannabinoids)

Sample	Lot#OL-07-201-1-248		Lot#OL-07-216-1-10		Lot#OL-07-216-2-10		Precision
	+	-	+	-	+	-	
0 ng/mL	0	60	0	60	0	60	>99%
225ng/mL	5	55	5	55	4	56	>92%
562.5ng/mL	60	0	60	0	60	0	>99%

COC (Cocaine)

Sample	Lot#OL-07-201-1-248		Lot#OL-07-216-1-10		Lot#OL-07-216-2-10		Precision
	+	-	+	-	+	-	
0ng/mL	0	60	0	60	0	60	>99%
31.25ng/mL	0	60	0	60	0	60	>99%
78.125ng/mL	44	16	38	22	38	22	>66%

Analytical Sensitivity

Tests were run with spiked artificial saliva at the concentrations listed below.

The following analytical sensitivities are tabulated from these studies:

THC	112.5 ng/mL	225 ng/mL	337.5 ng/mL	450 ng/mL	562.5 ng/mL	675 ng/mL	787.5 ng/mL	0 ng/mL
		0	10%	43%	86%	100%	100%	100%

COC	15.625 ng/mL	31.25 ng/mL	46.875 ng/mL	62.5 ng/mL	78.125 ng/mL	93.75 ng/mL	109.375 ng/mL	0 ng/mL
		0	0	0	36%	53%	66%	100%

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in saliva by OraLine® Saliva Drug Screen at 10 minutes.

Compound	Concentration (ng/mL)
11-nor-delta-9-THC-COOH	40
Delta8-THC	10
Delta9-THC (native)	4

Compound	Concentration (ng/mL)
Benzoylecgonine	8
Cocaine	25

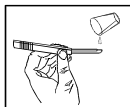
Compound	Concentration (ng/mL)
3,4-methylenedioxy-N-Methylamphetamine	5
(+)-3,4-Methylenedioxyamphetamine	1,000
d-Amphetamine	2,500
d-Methamphetamine	3.75
l-Methamphetamine	375
Pseudoephedrine	1,750

Compound	Concentration (ng/mL)
6-Acetylmorphine	2
Buprenorphine	No reaction at 100,000
Codeine	0.78125
Diacetylmorphine	1.875
Ethylmorphine	15
Hydrocodone	1.6875
Hydromorphone	1.75
Levorphanol	250
Meperidine	7,500
Morphine	2
Morphine-3β-D-glucuronide	2
Nalorphine	0.5
Naloxone	50
Naltrexone	250
Nor-Propoxyphene	No reaction at 100,000
Oxycodone	250
Oxymorphone	500
Ranitidine	17,500

Test Procedure II

Use this alternate procedure when direct collection and testing are difficult, due to the test environment or other medical conditions.

- Step 1 is the same as in Procedure I
- Step 2 is the same as in Procedure I
- Collect saliva in provided sample cup
- Fill the spoon by transferring the saliva into the spoon, by pouring from the cup. Make sure the spoon is held horizontally with the handle in an upward position, as shown, when filling the device.



Note: If the test is read before ten (10) minutes, the intensity of the colored lines may still change, or a new line may appear after ten (10) minutes. Thus, it is always important to record the results within 10-12 minutes for consistency.

INTERPRETATION OF RESULTS

The test results are determined by the presence or absence of red lines. With a POSITIVE sample, the drug from the sample solution blocks the limited antibody binding sites on the colored microspheres. This reaction prevents the attachment of the colored microspheres to the antigenic probe sites on the membrane. Therefore, a POSITIVE test results for one of the four (4) drugs is indicated by the absence of its corresponding red line. A NEGATIVE test result for all of the four (4) drugs is indicated by the presence of all five (5) red lines. Lines MET, OPI, COC and THC are the drug probe lines, and line C is the control or reference line (see diagrams). Line C is not related to the presence of any drug, but shows that the microsphere particles have completely traveled along the membrane and that the test is viable. The line intensity may vary for each drug. Do not compare intensities when interpreting results.

The OraLine® Saliva Drug Screen is a qualitative test and the intensity of the lines does not correspond to drug concentrations. The OraLine® Saliva Drug Screen only indicates the presumptive presence or absence of a specific drug in the saliva sample, and provides only preliminary qualitative test results.

Below are examples of a few possible test results (more variations are possible):

	Green lines indicate an intact test device before the test strip has been exposed to the sample solution.
	NEGATIVE tests results for all four drugs (THC, COC, OPI and MET) are indicated by the presence of all FIVE red lines.
	POSITIVE for OPI and NEGATIVE for THC, COC and MET.
	POSITIVE for THC & OPI and NEGATIVE for MET, and COC.
	POSITIVE for OPI, COC & MET and NEGATIVE for THC.

Note: Interpret the test results after the control line C is clearly defined in the test window. No test results should be interpreted until the control line C can be clearly identified in the viewing area. In the event that the control line C does not form, test results are inconclusive and the test should be repeated using a new OraLine® Saliva Drug Screen.

BIBLIOGRAPHY

1. Schramm, W. et al, "Drugs of Abuse in Saliva: A review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp1-9.
2. Moolachan, E., et al, "Saliva and Plasma Testing for Drugs of Abuse: Comparison of the Disposition and Pharmacological Effects of Cocaine", Addiction Research Center, IRP, NIDA, NIH, Baltimore, MD. As presented at the SOFT-TIAFT meeting October 1998.

PATENTS

- Patent Pending, Sun Biomedical Laboratories, Inc., 2007

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug free saliva or drug positive saliva containing Cannabinoids, Cocaine, Methamphetamine and Morphine. The following compounds show no cross-reactivity when tested with the OraLine® Saliva Drug Screen.

Non Cross-Reacting Compounds

Acetaminophen
Acetylsalicylic Acid
Albumin
Apple Juice
Ascorbic Acid
Biotin
Buprenorphine
Caffeine
Chloroquine
Dextromethorphan
Diazepam
Dimenhydrinate
Diphenhydramine
Doxepin
Doxylamine
Eclipse Gum
Equal
Ethanol
Flunitrazepam
Fluoxetine
Halls Lozenges
Haloperidol
Ibuprofen
Imipramine
Indomethacin
Keebler Crackers
Ketamine
L-Tryptophan
Listerine
Lysergic Acid Diethylamide
Mentos
Mescaline
Methadone
Norketamine
Norpropoxyphene
Oxazepam
Peaches
Pepsi Cola
Phencyclidine
Phenmetrazine
Phenobarbital
Pineapples
Propoxyphene
Pyroxidine
Scope
Secobarbital
Simethicone
Splenda
Sweet-n-Low
Temazepam
TicTac
Tropicana Orange Juice