DISCOVER OneStep Oral Fluid Tests and DISCOVER Oral Fluid Cassettes

Package Insert

For In Vitro Diagnostic Use

A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Alcohol and their metabolites in human oral fluid.

USA only: For Forensic Use Only. Note: "For Forensic Use Only" does not apply to any workplace testing or other non-law enforcement testing, regardless of whether or not that testing is conducted under other federal agency (e.g., Department of Transportation) authority.

Non-USA jurisdictions: For Laboratory Use Only

INTENDED USE

The ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** (Test/Cassette) are lateral flow chromatographic immunoassays for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiates, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Alcohol and their metabolites in oral fluids at the following cut-off concentrations:

Test Name	Calibrator	Cut-off
Amphetamine (AMP)	D -Amphetamine	50 ng/mL
Methamphetamine (mAMP/MET)	D-Methamphetamine	50 ng/mL
Cocaine (COC)	Cocaine	20 ng/mL
Opiates (OPI)	Morphine	40 ng/mL
Marijuana (THC)	THC-COOH	12 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	50 ng/mL
Oxycodone (OXY)	Oxycodone	50 ng/mL
Methadone (MTD)	Methadone	35 ng/mL
Barbiturates (BAR)	Secobarbital	50 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Alcohol (ALC)	Alcohol	>0.02% BAC*

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 AND EXPLANATION OF TEST

The ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** for AMP/(mAMP/MET)/COC/OPI/THC/PCP/BZO/OXY/MTD/ BAR /BUP/ALC and their metabolites are rapid, oral fluid screening tests that can be performed without the use of an instrument.

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.

The Amphetamine assay contained within the Test/Cassette yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

METHAMPHETAMINE (mAMP/MET)

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. The Methamphetamine assay contained within the Test/Cassette 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 metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use. The Cocaine assay contained within the Test/Cassette yields a positive result when the cocaine 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 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'. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid, and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin, and is detectable for 24-48 hours after an opiate dose. The Opiates assay contained within the Test/Cassette yields a positive result when the concentration of Morphine in oral fluid exceeds 40 ng/mL.

MARIJUANA (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (cannabis sativa), is detectable in saliva 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 saliva of up to 14 hours after drug use[3]. The Marijuana assay contained within the Test/Cassette yields a positive result when the THC-COOH concentration exceeds 12 ng/mL.

PHENCYCLIDINE (PCP)

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 serum and saliva sample collection of 100 patients in an Emergency Department, PCP was detected in the saliva 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 Test/Cassette yields a positive result when the Phencyclidine concentration in oral fluids exceeds 10 ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are frequently prescribed sedative and hypnotic drugs for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines. The Benzodiazepines assay contained within the Test/Cassette yields a positive result when the concentration of Oxazepam in oral fluids exceeds 50 ng/mL.

OXYCODONE (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. The Oxycodone assay contained within the Test/Cassette yields a positive result when the concentration of oxycodone in oral fluid exceeds 50 ng/mL.

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin®, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states one must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from 12-48 hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawal from methadone is more prolonged and troublesome than that provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists. The Methadone assay contained within the Test/Cassette yields a positive result when the Methadone concentration in oral fluids exceeds 35 ng/mL.

BARBITURATES (BAR)

Barbiturates are CNS depressants, 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 periods of drug abstinence can be severe enough to cause death. Only a small amount (< 5%) of most barbiturates are excreted unaltered in the urine. The Barbiturates assay contained within the Test/Cassette yields a positive result when the Barbiturates concentration in oral fluid exceeds 50 ng/mL.

BUPRENORPHINE (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCI. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes. The Buprenorphine assay contained within the Test/Cassette yields a positive result when the Buprenorphine concentration in oral fluid exceeds 10 ng/mL.

ALCOHOL (ALC)

Alcohol intoxication can lead to loss of alertness, coma, death as well as birth defects. The blood alcohol content* (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Other jurisdictions may have different regulations.

PRINCIPLE

① The ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** are competitive binding immunoassays in which drugs and drug metabolites in a oral fluid sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of oral fluid specimen is applied to the sample pad of the test device, the oral fluid specimen migrates through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the oral fluid specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

②Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue when contact with alcohol in the oral fluids. The alcohol pad employs a solid phase chemistry that uses the following highly specific enzymatic reaction:

$$CH_2CH_2OH + 0_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CH0 + H_20_2$$

$$H_20_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_20$$

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidase to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive positive result for alcohol.

REAGENTS

①The ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** contain membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Amphetamine, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Opiates , Oxycodone and Phencyclidine.

②Alcohol Test: The alcohol pad contains Tetramethylbenzidine, Alcohol Oxidase, Peroxidase, Buffer and Stabilizing Proteins.

MATERIALS PROVIDED

- Drug Test
- Package Insert
- Oral fluid Collector

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- External positive and negative controls

PRECAUTIONS

- USA only: For Forensic Use Only.
- Non-USA jurisdictions: For Laboratory Use only.
- Do not use after the expiration date.
- The Test Cassette 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 only. Do not re-use.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store the Test/Cassette 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.

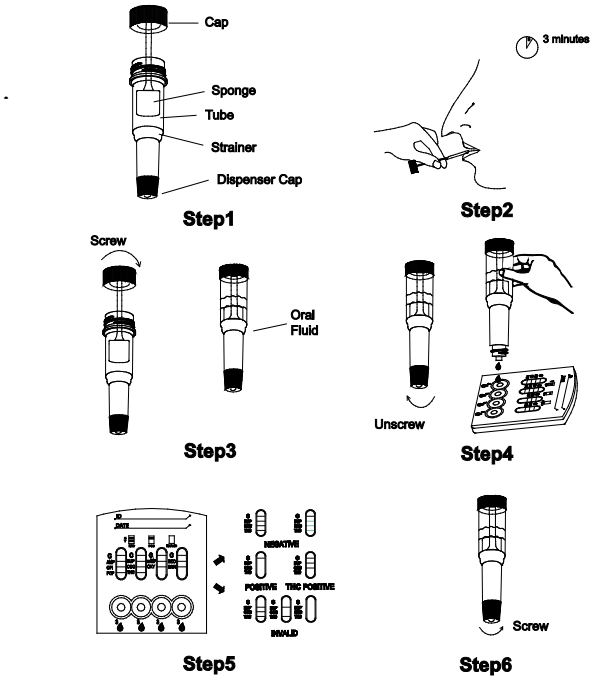
SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collector provided with the kit. Follow the detailed Test Procedures below. No other collection devices should be used with this assay. Oral fluid collected at any time of the day may be used.

TEST PROCEDURE – ORAL FLUID CASSETTE

Allow the test device, specimen and/or control to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

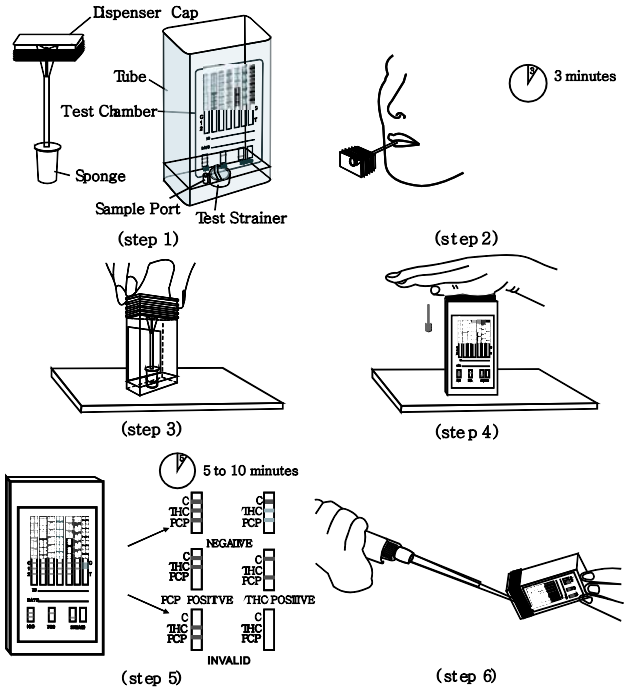
1. Remove the collector from the sealed pouch and remove the sponge from the Tube.
2. Insert the sponge into the mouth, actively swab the inside of the mouth and tongue to collect oral fluid for approximately 3 minutes until the sponge becomes soft and fully saturated. The sponge will be free from hard spots when fully saturated.
3. Remove the sponge from the mouth. Place the saturated oral fluid sponge into the Tube and screw the cap tightly.
4. Remove the test cassette from the sealed pouch and use it as soon as possible. Unscrew the dispenser cap, use the thumb and index finger to squeeze the tube and dispense 2 to 3 drops of the collected oral fluid into each sample well of test cassette and start the timer. Avoid trapping air bubbles in the specimen well.
5. Wait for the colored line(s) to appear. Read the results of drug tests at 5 to 10 minutes, read the alcohol test result at 2 to 5 minutes. DO NOT read the results of drug tests after 1 hour, DO NOT read the alcohol test result after 5 minutes
6. Screw the dispenser cap and send the collector with the collected oral fluid to a laboratory for confirmation if necessary.



TEST PROCEDURE - ONESTEP ORAL FLUID TEST

Allow the test device, specimen and/or control to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

1. Open the sealed pouch, then remove the saliva collector from the sealed plastic bag.
2. Insert the sponge into the mouth, actively swab the inside of the mouth and tongue to collect oral fluid for approximately 3 minutes until the sponge becomes soft and fully saturated. The sponge will be free from hard spots when fully saturated.
3. Remove the test Tube from the pouch, put the Tube on a flat surface. Remove the collector from the mouth and put the saturated oral fluid collector into the strainer of the Tube (on the center of the bottom).
4. Keep the Tube upright, push the Cap into the tube vertically and start the timer.
5. Wait for the colored line(s) to appear. Read the results of drug tests at 5 to 10 minutes, read the alcohol test result at 2 to 5 minutes. DO NOT read the results of drug tests after 1 hour, DO NOT read the alcohol test result after 5 minutes.
6. Use the pipette to collect the saliva sample from the sample port for confirmation testing if necessary.



INTERPRETATION OF RESULTS

Positive: One colored line appears in the Control zone (C). No line appears in the Test Zone (T). The absence of a line in the test region (T line) indicates a positive result. The positive result indicates that the drug level is above the detectable level.
Note: Samples with positive results should be confirmed with a more specific method.

Negative: One colored line appears in the Control zone, and another colored line appears in the Test zone. The negative result indicates the drug or its metabolite level is below the detectable level.

Invalid: No line appears in the Control zone. If no C line, or no C line or T line develop within 5 to 10 minutes, the test is invalid. The test should be repeated with a new test device. Insufficient specimen volume or the incorrect procedural techniques are the most likely reasons for invalid result. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the current lot and contact your supplier.

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream color), and should be interpreted as a negative result (no alcohol present). A result where the outer edges of the alcohol pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the alcohol pad with oral fluid. If the second result is the same, the results should be interpreted as negative (no alcohol present).

Alcohol Presumptive Positive Result: The Alcohol test produces a color change to green to blue in the presence of salivary alcohol 0.02 % BAC or higher. At higher alcohol concentration near 0.30% BAC, the color may change to a dark blue-gray.

QUALITY CONTROL

A procedure 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 ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** provide 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.
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 a drug-free specimen. Drug may be present in the specimen below the cutoff level of the assay.
4. There is a possibility that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.

PERFORMANCE CHAARACTERISTICS

Analytical Sensitivity

Sensitivity of the ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** was characterized by validating the test performance around the claimed cut-off concentration of each test. The cut-off of each test was determined by the lowest concentration of drug that produces at least 50% positive testing results in total numbers of determinations. 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 Test/Cassette. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		mAMP/MET		COC		OPI		THC		PCP	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0	20	0	20	0
-25% Cut-off	20	28	13	20	0	20	0	13	7	20	0	20	0
+25% Cut-off	20	4	26	0	20	7	13	0	20	2	18	5	15
+50% Cut-off	20	0	20	0	20	0	20	0	20	0	20	0	20

Drug concentration Cut-off Range	n	BZO		OXY		MTD		BAR		BUP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	20	20	0	20	0	20	0	20	0	20	0
-50% Cut-off	20	20	0	20	0	20	0	20	0	20	0
-25% Cut-off	20	20	0	20	0	20	0	20	0	19	1
+25% Cut-off	20	0	20	3	17	1	19	20	0	1	19
+50% Cut-off	20	0	20	0	20	0	20	0	20	0	20

For the alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various BAC (0.01%, 0.02%, 0.04%, 0.08%, 0.30%). Negative saliva was used to test at 0% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the ***Oral Fluid Drug Test Cassette*** and **OneStep Oral Fluid Drug Test Cassette** are summarized below:

Test	n	BAC (Concentration)									
		0%		0.02%		0.04%		0.08%		0.30%	
	15	-	+	-	+	-	+	-	+	-	+
Alcohol	15	15	0	1	14	0	15	0	15	0	15

Analytical Specificity

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into a Phosphate-buffered saline pool. Analyzing various concentration of each compound by using the ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test***, the concentration of the drug that produced a response approximately equivalent to the cut-off concentration of the assay was determined. Results of those studies appear in the table(s) below:

Drug Compound	**Concentration (ng/mL)**
AMPHETAMINE (AMP)	
D-Amphetamine	50
D,L-Amphetamine	125
L-Amphetamine	2500
(±)3,4-Methylenedioxyamphetamine (MDA)	100
Ephedrine	>10000
3,4-Methylenedioxythylamphetamine (MDEA)	>10000
METHAMPHETAMINE (mAMP/MET)	
+/-Methamphetamine	100
+Methamphetamine	50
3,4-Methylenedioxyethylamphetamine (MDEA)	1000
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100
Ranitidine (Zantac)	>10000
3,4-Methylenedioxyamphetamine (MDA)	>10000
D-Amphetamine	>10000
L-Amphetamine	>10000
Ephedrine	>10000
Procaine	2000
COCAINE (COC)	
Benzoylecogonine	20
Cocaine HCl	20
Cocaethylene	50
Ecgonine HCl	1500
OPIATES (OPI)	
Morphine	40
Codeine	40
Hydrocodone	250
Hydromorphone	250
Morphine 3-β-D-glucuronide	40
6-Monoacetylmorphine	80
Normorphone	10000
Oxycodone	1500
Oxymorphone	7500
Thebaine	2500
MARIJUANA (THC)	
11-nor-Δ8-THC-9-COOH	12
11-nor-Δ9-THC-9-COOH	12
Δ8 -THC	2000
Δ9 -THC	4000
Cannabinol	5000
Cannabidiol	10000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
4-Hydroxyphencyclidine	15000
Tetrahydrozoline	20000
BENZODIAZEPINES (BZO)	
Oxazepam	50
Alprazolam	40
α-Hydroxyalprazolam	250
Bromazepam	50
Chlordiazepoxide	500
Clobazam	20
Clonazepam	125
Clorazepate	50
Delorazepam	250
Diazepam	40
Estazolam	40
Flunitrazepam	50
Lorazepam	125
Midazolam	300
Nitrazepam	20
Nordiazepam	75
Temazepam	30
Triazolam	75
OXYCODONE (OXY)	
Oxycodone	50
Morphine	25000
Codeine	25000
Morphine 3-β-D-glucuronide	25000
Hydrocodone	1000
Hydromorphone	10000
Normorphone	10000
Oxymorphone	1000
METHADONE (MTD)	
Methadone	35
Doxylamine	25000
BARBITURATES (BAR)	
Secobarbital	50
Phenobarbital	500
Butalbital	100

Pentobarbital	250
Amobarbital	500
Cyclopentobarbital	100
Butethal	125
Barbital	50
Butabarbital	250
BUPRENORPHINE (BUP)	
Buprenorphine	10
Norbuprenorphine	15
Buprenorphine-3-D-glucuronide	12.5
Norbuprenorphine-3-D-glucuronide	175
Morphine-3-D-glucuronide	100000
Morphine	>100000
Oxymorphone	>100000
Hydromorphone	>100000

Alcohol Test

The Alcohol test will react with methyl, ethyl, and allyl alcohols, but it will not react with alcohols having 5 or more carbons, glycine, glycerol, and serine. This property is a result of specificity of the alcohol oxidase enzyme extracted from yeast.

Interfering Compounds

The following compounds in a Phosphate-buffered saline pool with Amphetamine, Cocaine, Barbiturate, Benzodiazepine, Buprenorphine, Marijuana, Methadone, Methamphetamine, Opiates, Oxycodone, Propoxyphene, show no cross-reactivity when tested with the ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** at a concentration of 100 μg/mL.

Common Substances:

Acetaminophen	Diphenhydramine	(+/-)-Norephedrine
Acetone	Dopamine	Oxalic Acid
Albumin	(+/-)-Epinephrine	Penicillin-G
Ampicillin	Erythromycin	Pheniramine
Ascorbic Acid	Ethanol	Phenothiazine
Aspartame	Furosemide	1-Phenylephrine
Aspirin	Glucose	β-Phenylethylamine
Atropine	Guaiacol Glyceryl Ether	Procaine
Benzocaine	Hemoglobin	Quinidine
Bilirubin	Ibuprofen	Ranitidine
Caffeine	(+/-)-Isoproterenol	Riboflavin
Chloroquine	Ketamine	Sodium Chloride
(+)-Chlorpheniramine	Levorphanol	Sulindac
(+/-)-Chlorpheniramine	Lidocaine	Theophylline
Creatine	(+)-Naproxen	Tyramine
Dexbrompheniramine	Niacinamide	4-Dimethylaminoantipyrine
Dextromethorphan	Nicotine	(1R,2S)-(-)-N-Methyl-Ephedrine

Alcohol Test

The following substances may interfere with the ***Oral Fluid Cassette*** and ***OneStep Oral Fluid Test*** when using samples other than oral fluid:

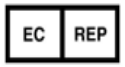
①Agents which enhance color development: Peroxides and strong oxidizers

②Agents which inhibit color development:

Reducing Agents: Ascorbic acid, Tannic Acid, Pyrogallol, Mercaptanalics and tosylates, Oxalic acid, Uric acid, Bilirubin, L-methyldopa, L-dopa, L-methyldopa, and Methampyrone, etc. The above-named substances do not normally appear in sufficient quantity in oral fluid to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 10 minutes period preceding the test.

SYMBOL GLOSSARY

The following symbols are found on the device and packaging:

Symbol	Description
	*In vitro* diagnostic medical device
	Caution Consult instructions for use.
	Temperature Limit Upper and lower storage temperatures
	Do not re-use
	Manufacturer
	CE mark
	Authorized representative in the European Community
	Use-by date
	Batch code Lot number
	Catalogue Number
	Consult instructions for use

BIBLIOGRAPHY

1. Moolchan, 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.
2. Kim, I, et al, "Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration", Clin Chem, 2002 Sept.; 48 (9), pp 1486-96.
3. Schramm, W. et al, "Drugs of Abuse in Saliva: A Review," J Anal Tox, 1992 Jan-Feb; 16 (1), pp 1-9
4. McCarron, MM, et al, "Detection of Phencyclidine Usage by Radioimmunoassay of Saliva," J Anal Tox.1984 Sep-Oct.; 8(5), pp 197-201.
5. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735

Revised: December 2013

For Laboratory Use Only

American Screening LLC
9742 St. Vincent AVE
Suite 100
Shreveport, LA 71105
1-318-798-3306

EC REP
EC REP Ltd
5 Fitzwilliam Square East
Dublin 2, Ireland
Tel: +353 1 2 544 944
Info@ecrep.ie
www.ecrep.ie

CE