Identify Health® Oral Fluid Drug Screen Test

Package Insert

A rapid test for the simultaneous, qualitative detection of multiple drugs or drug metabolites in human oral fluid. For in vitro diagnostic use by healthcare professionals including professionals at point of care sites. Also applicable for workplace safety and law enforcement use.

【INTENDED USE】

The Oral Fluid Drug Screen Test for AMP/MET/COC/OPI/THC/PCP/MTD/MDMA/OXY /COT/BAR/BZO/BUP/PPX is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs or metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Methamphetamine (MET)	d-Methamphetamine	50
Marijuana (THC)	THC-COOH	12
Phencyclidine (PCP)	Phencyclidine	10
Cocaine (COC)	Benzoylecgonine	20
Opiates (OPI)	Morphine	40
Methadone (MTD)	Methadone	30
Oxycodone (OXY)	Oxycodone	20
Cotinine(COT)	Cotinine	30
Cotinine(COT)	Cotinine	50
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Barbiturates(BAR)	Secobarbital	50
Benzodiazepines(BZO)	Oxazepam	10
Buprenorphine（BUP）	Buprenorphine	5
Propoxyphene (PPX)	d-Propoxyphene	50

This assay provides only a preliminary analytical test result. A more specific alternate chemical method should be used to confirm a preliminary positive analytical result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse screen test result, particularly when preliminary positive results are indicated.

【SUMMARY】

The Oral Fluid Drug Screen Test for AMP/MET/COC/OPI/THC/PCP/MTD/MDMA/OXY/COT/ BAR/BZO/BUP/PPX or their metabolites is a rapid, oral fluid 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 oral fluid.

Amphetamine (AMP)

Amphetamine is a sympathomimetic amine with therapeutic indications, especially for use in treating Attention Deficit Disorders. 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 following use and for as long as 72 hours after use. [1]

The amphetamine assay contained within the Oral Fluid Drug Screen Test yields a positive result when the amphetamine concentration in oral fluid exceeds 50ng/mL.

Methamphetamine (MET)

Methamphetamine is a potent stimulant chemically related to amphetamine but with greater 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 following use and for as long as 72 hours after use. [1]

The Methamphetamine assay contained within the Oral Fluid Drug Screen Test yields a positive result when the methamphetamine concentration in oral fluid exceeds 50ng/mL.

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 and metabolites benzoylecgonine and ecgonine methyl ester can be detected in oral fluid as early as 5-10 minutes following use.[2] Cocaine and benzoylecgonine can be detected in oral fluids for up to 48 hours after use.[2]

The cocaine assay contained within the Oral Fluid Drug Screen Test for cocaine and opiates yields a positive result when the cocaine metabolite in oral fluid exceeds 20ng/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.[3] Heroin metabolite 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid than urine.

The opiates assay contained within the Oral Fluid Drug Screen Test yields a positive result when the opiates concentration in oral fluid exceeds 40ng/mL.

Marijuana (THC)

THC (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.

11-nor-9-tetrahydrocannabinol-9-carboxylic acid, also known as 11-nor-9-THC-9 COOH and THC-COOH, is the main metabolite of THC which is formed in the body after cannabis is consumed, and is present in oral fluid after use.

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 PCP assay contained within the Oral Fluid Drug Screen Test yields a positive result when the PCP concentration in oral fluids exceeds 10ng/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).

Methadone is a long acting pain reliever producing effects that last from 12-48hours. 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. A study 414 specimens collected from 16 donors taking therapeutic methadone at doses between 30-100 mg/day all showed saliva methadone concentrations exceeding 20 ng/mL.[5]

The MTD assay contained within the Oral Fluid Drug Screen Test yields a positive result when the MTD concentration in saliva exceeds 30ng/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. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

The OXY assay contained within the Oral Fluid Drug Screen Test yields a positive result when the OXY concentration in saliva exceeds 20ng/mL.

Cotinine (COT 30)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Although nicotine is excreted in saliva, the relatively short half-life of the drug makes it an unreliable maker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine bears a high correlation with plasma cotinine levels and has been found to be the best maker for smoking status compared with saliva nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing.

The window of detection for cotinine in saliva at a cutoff level of 30 ng/mL is expected to be up to 1-2 days after nicotine use.

Cotinine (COT 50)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

Although nicotine is excreted in saliva, the relatively short half-life of the drug makes it an unreliable maker for tobacco use. Cotinine, however, demonstrates a substantially longer half-life than nicotine bears a high correlation with plasma cotinine levels and has been found to be the best maker for smoking status compared with saliva nicotine measurement, breath carbon monoxide testing and plasma thiocyanate testing.

The window of detection for cotinine in saliva at a cutoff level of 50 ng/mL is expected to be up to 1-2 days after nicotine use.

Methylenedioxymethamphetamine (MDMA)

Methylenedioxymethamphetamine (ecstasy) 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 Oberlender, 1990.

The MDMA assay contained within the Oral Fluid Drug Screen Test yields a positive result when the MDMA concentration in saliva exceeds 50ng/mL.

Barbiturates(BAR)

Barbiturates are central nervous system 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 produce a clinically significant degree of physical dependence. A study of a single oral dose of one barbiturate: butalbital, phenobarbital or secobarbital showed the drug is detectable in oral fluid with 15-60 minutes of dosing and remained detectable in oral fluid for 52 hours. [6]

The Barbiturates(BAR) assay contained within the Oral Fluid Drug Screen Test yields a positive result when the Secobarbital concentration in saliva exceeds 50ng/mL.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g.,daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, and loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

The BZO assay contained within the Oral Fluid Drug Screen Test yields a positive result when the Oxazepam concentration in saliva exceeds 10ng/mL.

Buprenorphine(Buprenorphine)

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 HCl. 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 BUP assay contained within the Oral Fluid Drug Screen Test yields a positive result when Buprenorphine in saliva exceeds 5 ng/mL.

Propoxyphene (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yieldnorpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours).The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The PPX assay contained within the Oral Fluid Drug Screen Test yields a positive result when propoxyphene in saliva exceeds 50ng/mL.

【ASSAY PRINCIPLE】

The Oral Fluid Drug Screen Test for AMP/MET /COC/OPI/THC/PCP /MTD /MDMA /OXY /COT/BZO/BUP/PPX 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, Morphine, THC-COOH, Phencyclidine, Methadone, Oxycodone,Cotinine, Methylenedioxymethamphetamine, Oxazepam, Secobarbital, Buprenorphine and Propoxyphene, respectively.

【PRECAUTIONS】

1. Do not use after the expiration date.
2. The test should remain in the sealed pouch until use.
3. Saliva is not classified as biological hazard unless derived from a dental procedure.
4. The used collector and cup 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 cups 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 cups should be used with this assay. Oral fluid collected at any time of the day may be used.

【MATERIALS】

Materials Provided

Test cups　　Collectors　　Package insert
Procedure Card

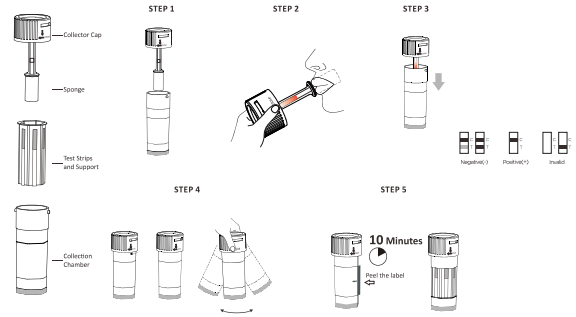
Materials Required but Not Provided

Timer

【DIRECTIONS FOR USE】

Allow the test cup, 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 of opening.
2. Remove the test cup from the sealed pouch and insert the sponge end of the collector into the mouth. Actively swab the inside of the mouth and tongue to collect oral fluid for approximately 3 minutes until the sponge becomes fully saturated. At the same time, the color of indicator will be changed from colorless to pink. Gentle pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
3. Remove the collector from the mouth. Place saturated oral fluid collector into chamber and press sponge fully against the strainer to collect oral fluid.
4. Secure the cap, shake three times, and start the timer. See illustration below.
5. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not read results after 20 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the previous illustration)

NEGATIVE:* Two lines appear. One colored line should be in the control region (C), and another

apparent colored line adjacent should be in the test region (Drug/T). This negative result indicates that the drug concentration is below the detectable level.

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

POSITIVE: One colored line appears in the control region (C). No line 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.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

【LIMITATIONS】

1. The Oral Fluid Drug Screen Test provides only a qualitative, preliminary analytical result. A secondary analytical method should be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS), gas chromatography/tandem mass spectrometry (GC/MS/MS), liquid chromatography/mass spectrometry (LC/MS) or liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
2. 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.

【EXPECTED VALUES】

This negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERISTICS】

Accuracy

Assemble each single test into the cup before testing, and evaluate the cup with approximately 210-280 specimens per drug type previously collected from subjects presenting for Drug Screen Testing which were confirmed by GC/MS. These specimens were randomized and tested using the Multi-Drug Rapid Test. Specimens were rated as either positive or negative at 10 minutes. The test results are shown in table below.

Table: Specimen Correlation

Method		GC/MS		% agreement with GC/MS	% Total agreement with GC/MS
Oral Fluid Drug Screen Test		Positive	Negative		
AMP50	Positive	90	6	94.7%	94.8%
	Negative	5	109	94.8%	
BAR50	Positive	80	6	96.4%	95.7%
	Negative	3	121	95.3%	
BUP5	Positive	86	5	95.6%	95.7%
	Negative	4	115	95.8%	
COC20	Positive	91	7	93.8%	93.8%
	Negative	6	106	93.8%	
THC12	Positive	75	5	96.2%	96.8%
	Negative	3	167	97.1%	
MET50	Positive	126	4	99.2%	98.2%
	Negative	1	149	97.4%	
MDMA50	Positive	96	1	97.0%	98.3%
	Negative	3	130	99.2%	
OPI40	Positive	89	7	93.7%	93.8%
	Negative	6	108	93.9%	
BZO10	Positive	94	5	94.0%	94.8%
	Negative	6	105	95.5%	
PCP 10	Positive	107	2	96.4%	97.4%
	Negative	4	117	98.3%	
MTD 30	Positive	116	3	97.5%	97.4%
	Negative	3	108	97.3%	
OXY 20	Positive	91	1	97.8%	98.7%
	Negative	2	136	99.3%	
COT30	Positive	131	2	99.2%	98.7%
	Negative	1	96	98.0%	
COT50	Positive	131	2	99.2%	98.7%
	Negative	1	96	98.0%	
PPX 50	Positive	92	3	95.8%	96.7%
	Negative	4	111	97.4%	

Analytical Sensitivity

A Phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off, ± 25% cut-off and +300% cut-off and tested with the Oral Fluid Drug Screen Test. The results are summarized below.

Drug conc. (Cut-off range)	n	AMP		MET		THC		PCP	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	28	2	26	4	26	4
+25% Cut-off	30	7	23	6	24	8	22	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	COC		OPI		MTD		OXY	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	25	5	27	3	27	3	25	5
+25% Cut-off	30	10	20	8	22	7	23	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	COT(50)		MDMA		BAR		BZO	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	25	5	26	4	27	3
+25% Cut-off	30	6	24	7	23	6	24	7	23
+50% Cut-off	30	0	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30	0	30

Drug conc. (Cut-off range)	n	BUP		PPX		COT(30)	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	27	3	25	5	27	3
+25% Cut-off	30	7	23	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30
+300% Cut-off	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the cutoff concentration of compounds (ng/mL) above which will be detected by the Oral Fluid Drug Screen Test for AMP/MET/COC/OPI/THC/PCP/MTD/OXY/COT/MDMA/BAR/BZO/BUP/PPX at a read time of 10 minutes, respectively.

Compound	ng/mL	Compound	ng/mL
AMPHETAMINE (AMP)			
d-Amphetamine	50	p-Hydroxyamphetamine	800
d,l-Amphetamine	125	(+)3,4-Methylenedioxyamphetamine (MDA)	150
ß-Phenylethylamine	5,000	l-Amphetamine	4,000
Tryptamine	1,500	Noscapine	10000
Trimethoprim	10000		
METHAMPHETAMINE (MET)			
d-Methamphetamine	50	(1R,2S) - (-) Ephedrine	400
Fenfluramine	60,000	Procaine	2,000
p-Hydroxymethamphetamine	400	L-Phenylephrine	6,250
Methoxyphenamine	25,000	Ephedrine	400
Mephentermine	1,500	Benzphetamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	500		
MARIJUANA (THC)			
11- nor -Δ9-THC-9 COOH	12	Δ9- THC	10,000
Cannabinol	12,500	11- nor -Δ8-THC-9 COOH	2
Δ8 -THC	6,000		
COCAINE (COC)			
Benzoylecgonine	20	Ecgonine HCl	1,500
Cocaine HCl	20	Ecgonine methyl ester	12,500
Cocaethylene	30		
OPIATES (OPI)			
Morphine	40	Norcodeine	1,500
Codeine	10	Normorphine	12,500
Ethylmorphine	25	Nalorphine	10,000
Hydromorphine	100	Oxymorphone	25,000
Hydrocodone	100	Thebaine	2,000
Levorphanol	400	Diacetylmorphine (Heroin)	50
Oxycodone	25,000	6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50		
Noscapine	10,000		
METHADONE(MTD)			
Methadone	30	(+)-Chlorpheniramine	6,250
Disopyramide	400	LAAM	200
Doxylamine	12,500	Nor-LAAM	12,500
PHENCYCLIDINE(PCP)			
Phencyclidine	10	Tetrahydrozoline	50,000
OXYCODONE (OXY)			
Oxycodone	20	Codeine	25,000
Oxymorphone	40	Dihydrocodeine	6,250
Levorphanol	10,000	Naloxone	5,000
Hydrocodone	1,500	Naltrexone	5,000
Hydromorphone	10,000	Thebaine	25,000
COTININE (COT 30)			
(-)-Cotinine	30	(-)-Nicotine	450
COTININE (COT 50)			
(-)-Cotinine	50	(-)-Nicotine	750
METHYLENEDIOXYMETHAMPHETAMINE(MDMA)			
(±) 3,4-Methylenedioxymethamphetamine HCl (MDMA)			50
(±) 3,4-Methylenedioxyamphetamine HCl (MDA)			200
3,4-Methylenedioxyethylamphetamine (MDE)			30
L-Methamphetamine			25,000
BARBITURATES(BAR)			
Alphenol	30	Butethal	80
Amobarbital	100	Cyclopentobarbital	200
Aprobarbital	80	Pentobarbital	100
Butabarbital	50	Phenobarbital	50
Butalbital	500	Secobarbital	50
BENZODIAZEPINES(BZO)			
Alprazolam	10	Flunitrazepam	100
α -hydroxyalprazolam	400	(±) Lorazepam	1,000
Bromazepam	150	RS-Lorazepamglucuronide	50
Chlordiazepoxide	200	Midazolam	3,500
Clobazam	40	Nitrazepam	50
Clonazepam	300	Norchlordiazepoxide	100
Clorazepate dipotassium	50	Nordiazepam	200
Delorazepam	900	Oxazepam	10
Desalkylflurazepam	100	Temazepam	20
Diazepam	50	Triazolam	1,000
Estazolam	1,250	Noscapine	10000
Trimethoprim	10000		
BUPRENORPHINE(BUP)			
Norbuprenorphine	25	Buprenorphine	5
Buprenorphine-3-β-D-glucuronide	10	Norbuprenorphine-3-β-D-glucuronide	100
PROPOXYPHENE(PPX)			
D-Propoxyphene	50	D-Norpropoxyphene	50

Cross-Reactivity

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 Oral Fluid Drug Screen Test when tested with at concentrations up to 10 μg/mL.

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Caffeine
Chloramphenicol
Cortisone
Chloroquine
Creatinine
Diclofenac
Digoxin
l -Ψ-Ephedrine
Estrone-3-sulfate
l(–)-Epinephrine
Fenoprofen
Gentisic acid
Hydrochlorothiazide
o-Hydroxyhippuric acid
Ibuprofen
d/l-Isoproterenol
Ketoprofen
Loperamide
Methylphenidate
Naproxen
Nifedipine
Oxalic acid
Oxymetazoline
Penicillin-G
Phenelzine
hydrochloride
Prednisolone
d/l-Propranolol
d-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-acetate
Tetrahydrocortisone 3 (β-D-glucuronide)
Tolbutamide
Trifluoperazine
d/l-Tryptophan
Uric acid
Acetophenetidin
Acetylsalicylic acid
Amoxicillin
l-Ascorbic acid
Aspartame
Benzilic acid
d/l-Brompheniramine
Chloral-hydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Deoxycorticosterone
Diflunisal
Diphenhydramine
β-Estradiol
Ethyl-p-aminobenzoate
Erythromycin
Furosemide
Hydralazine
Hydrocortisone
p-Hydroxytyramine
Iproniazid
Isoxsuprine
Labetalol
Meprobamate
Nalidixic acid
Niacinamide
Norethindrone
Oxolinic acid
Papaverine
Perphenazine
Trans-2-phenylcyclopropylamine
Phenylpropanolamine
Prednisone
Zomepirac
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Thiamine
d/l-Tyrosine
Triamterene
d/l-Octopamine
Tyramine
Verapamil

【BIBLIOGRAPHY】

1. Schramm, W. et al, “Drugs of Abuse in Saliva: A Review,” *J Anal Tox*, 1992 Jan-Feb; 16 (1), pp 1-9
2. Scheidweiler, K, et al, “Pharmacokinetics of Cocaine and Metabolites in Human Oral Fluid and Correlation with Plasma Concentrations following Controlled Administration,” *Ther Drug Monit* 2010 October; 32 (5) 628-637.
3. Kim, I, et al, “Plasma and Oral Fluid Pharmacokinetics and Pharmacodynamics after Oral Codeine Administration,” *Clin Chem, 48:9, 1486-1496, 2002.*
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. Gray, T, et al, “Methadone Disposition in Oral Fluid during Pharmacotherapy for Opioid-Dependence,” *Forensic Sci Int*, 2011, March 20; 206(1-3): 98-102.
6. Fritch, D, et al, “Barbiturate Detection in Oral Fluid, Plasma and Urine.” *Ther Drug Monit* 201 Feb; 33(1): 72-79.
7. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735
8. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982;488
9. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA),Research Monograph 73, 1986

Medical Distribution Group Inc
6771 Whitfield Industrial Ave, Suite A,
Sarasota, FL 34243