Oral Fluid Drug Test
Package Insert
For Use in Employment and Insurance (E&I) Testing

Package insert for testing of the following drugs:
Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Codeine, Ecstasy, Fentanyl, Heroin (6-MAM), Marijuana, Methadone, Methamphetamine, Methaqualone, Opiates, Oxycodone, Propoxyphene and Tricyclic Antidepressants

INTENDED USE & SUMMARY

The Oral Fluid Drug Test is intended for screening for the presence of drugs and their metabolites in oral fluid.
The Oral Fluid Drug Test is a lateral flow chromatographic immunoassay for the qualitative and simultaneous detection of drugs and drug metabolites in oral fluid at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	50
Barbiturate (BAR)	Secobarbital	50
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine (BUP)	Buprenorphine	5/10
Cocaine (COC)	Benzoylecgonine	20
Codeine (COD)	Codeine	10
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	50
Fentanyl (FEN)	Norfentanyl	10
Heroin (6-MAM)	6-Monoacetylmorphine	10/15
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	12
Marijuana (THC)	Δ^9-THC	25/40
Methadone (MTD)	Methadone	30/75
Methamphetamine (MET)	d-Methamphetamine	50
Methaqualone (MQL)	Methaqualone	100/150
Opiates (OPI)	Morphine	15/40
Oxycodone (OXY)	Oxycodone	50/20
Propoxyphene (PPX)	Propoxyphene	50
Tricyclic Antidepressants (TCA)	Nortriptyline	100

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

AMP: Amphetamine is a sympathomimetic amine with therapeutic indications. The drug is often self-administered by nasal inhalation or oral ingestion.[1]

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 can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

BZO: Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection and are extensively oxidized in the liver to metabolites.

BUP: Buprenorphine is a semisynthetic opioid analgesic derived from Thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the “ceiling effect”, which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

COC: Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic derived from the coca plant (erythroxylum coca).[1]

COD: Codeine is an opiate used to treat pain, as a cough medicine, and for diarrhea. It is typically used to treat mild to moderate degrees of pain. Greater benefit may occur when combined with paracetamol (acetaminophen) or a nonsteroidal anti-inflammatory drug (NSAID) such as aspirin or ibuprofen. Evidence does not support its use for acute cough suppression in children or adults. In Europe it is not recommended as a cough medicine in those under twelve years of age. It is generally taken by mouth. It typically starts working after half an hour with maximum effect at two hours. The total duration of its effects last for about four to six hours.

MDMA: Abbreviated for the chemical 3, 4- methylenedioxymethamphetamine, MDMA has many street names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. It is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or stoke. MDMA belongs to a family of man-made drugs; its relatives include MDA (3, 4- methylenedioxymethamphetamine), the parent drug of MDMA, and MDEA (3, 4-Methylenedioxy-N-ethylamphetamine), also known as EVE. They all share the MDMA-like effects. MDMA is administered either by oral ingestion or intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100 mg; the threshold toxic dose is 500mg. The effects of MDMA begin 30 minutes after intake. They peak in an hour and last for 2-3 hours. it is detectible in the oral fluid for up to 3 days after use.
THC: Tetrahydrocannabinol, 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.[2]

FEN: Fentanyl is a power narcotic analgesic and is a special opiate receptor stimulant. Fentanyl is one of many substances listed in the United Nations “Single Convention on Narcotic Drugs” of 1961. Among the various opiate agents under international control, fentanyl is commonly used to treat moderate to severe pain.[1] Side effects of Fentanyl use include ataxia and irritability.

6-MAM： 6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excrete. Since 6-MAM is a unique metabolite to heroin, its presence in the saliva confirms that heroin was the opioid used. This is significant because on a saliva immunoassay drug screen, the test typically tests for morphine, which is a metabolite of a number of legal and illegal opiates/opioids such as codeine, morphine sulfate, and heroin.

MTD: Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. In addition to use as a narcotic agonist, methadone is being used more frequently as a pain management agent. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression.as. Due to this recommendation, the cut-off level of the methadone test was calibrated to 30 ng/mL.

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.[1]

MQL: Methaqualone is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form and is also available in Europe and other countries in combination with diphenhydramine (Mandrax).

OPI: The drug class opiates refer 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 control pain by depressing the CNS and demonstrate addictive properties when used for sustained periods of time. 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.[3]

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.

PPX: Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene but shows a greater local anesthetic effect.

TCA: TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver.

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 liquid chromatography/tandem mass spectrometry (LC-/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.

PRINCIPLE

The Oral Fluid Drug Test 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 along the test strip 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 Oral Fluid Drug Test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- *For Use in Employment and Insurance (E&I) Testing.*
- Do not use after the expiration date.
- The device and collection swab are single use only
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used collection swab and device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device 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.

SPECIMEN COLLECTION AND PREPARATION

The oral fluid specimen should be collected using the collection swab provided with the kit. Follow the detailed Directions for Use below. No other collection devices should be used with this test. Oral fluid collected at any time of the day may be used. Perform testing immediately after collection.

MATERIALS

Materials Provided

- Individually sealed test devices
- Collection swab (with indicator)
- Security seal labels
- Package insert

Materials Required but Not Provided

- Timer
- Gloves

DIRECTIONS FOR USE

Allow the test device, and/or controls to reach room temperature (59-86°F) prior to testing. Instruct the donor not to place anything in the mouth including food, drink, gum, tobacco products for at least 10 minutes prior to collection.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.

   Remove the collection swab from packaging. Start Timer. Relax the mouth and insert the collection swab into the mouth. The collection swab must be horizontal throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum until a red color on the saturation indicator strip appears in the indicator window of collection swab.

   Important: Do not bite, suck or chew on the collection swab. It is critical that the collection swab is held horizontally during collection otherwise there will be insufficient saliva collected although the indicator turns red. During collection of the oral fluid, relax the mouth while swabbing the tongue and check as this will aid in the collection of the oral fluid.

   Note: Refer to Notes and Troubleshooting if the saturation indicator strip does not activate after 4 minutes. If after 7 minutes, color has not appeared, proceed with the test below. (See illustration 1)
2. Remove test device from sealed pouch and place upright on a clean, flat surface. **Gently and slowly** insert the collection swab into the test device, sponge first, until it reaches the bottom of the test device. Push the cap until it locks in place and is secure. (See illustration 2)

   Important: Keep test device upright while inserting collection swab. Once the collection swab is locked in place, the test device is airtight, tamper evident and ready to be shipped to a lab for confirmation if required. Alternatively, the test device can be disposed of.
3. Keep test device upright on a flat surface until the test is complete. Start timer. **Important: If any test strips do not develop (invalid), peel away bottom of device label to inspect specimen volume. Refer to Notes and Troubleshooting.**
4. Interpret results at 10 minutes.

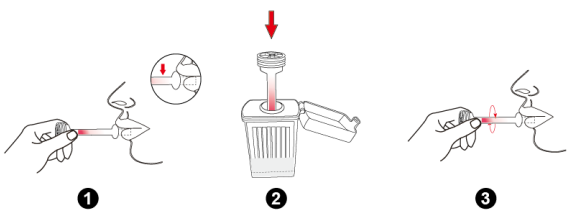
Notes and Troubleshooting

1. Invalid results may occur, if the strips do not wick, peel off the label at the bottom of the device as marked to check if either there is enough specimen, or the oral fluid is too thick or viscous to run.

a.) If strips do not appear to flow when there is enough oral fluid, or the oral fluid is too thick to run move the device back and forth several times across a flat, clean surface. Ensure the device remains upright. Do not tilt the device when the test is running before reading results.

b.) Oral fluid tends to form air bubbles which sit at the bottom of the strip and prevent the strip from running. Gently tap the device on the table or counter surface popping the air bubble allowing capillary action to begin, thus initiating the test.

2. The indicator strip has not turned red after 4 minutes. Some donors may have a dry mouth. Nerves may contribute to this. Rotate the swab in a circular motion while swabbing each area of the oral cavity until the saturation indicator activates. (See illustration 3)



Interpretation results:

INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE: * A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicates a negative result. This indicates that the drug concentration in the oral fluid specimen is below the designated cut-off level for that specific drug.

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

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the oral fluid specimen exceeds the designated cut-off for that specific drug.

INVALID: Control line (C) 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 device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

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 sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Oral Fluid Drug Test provides 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 liquid chromatography/tandem mass spectrometry (LC-MS/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the oral fluid specimen may cause erroneous results.
3. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
4. A negative result may not necessarily indicate a drug-free specimen. Drug may be present in the specimen below the cut-off level of the test.
5. The test does not distinguish between drugs of abuse and certain medications.
6. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

100 clinical spiked oral fluid specimens were tested using the Oral Fluid Drug Test were compared to a commercial oral fluid kit. Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Specimen	AMP	BAR 50	BZO 10	BZO 50	BUP 5	BUP 10	COC
Positive	100%	100%	100%	100%	98.20%	100%	100%
Negative	100%	100%	100%	100%	100%	97.70%	100%
Total	>99%	>99%	>99%	>99%	98.99%	98.99%	>99%

Specimen	COD	FEN	MDMA	MET	MQL 150	MQL 100	MTD 30
Positive	100%	100%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	>99%	>99%	>99%	>99%	>99%	>99%	>99%

Specimen	MTD 75	6-MAM 10	6-MAM 15	OPI 15	OPI 40	OXY 50	OXY 20
Positive	100%	100%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	>99%	>99%	>99%	>99%	>99%	>99%	>99%

Specimen	PPX	TCA	THC 12	THC 25	THC 40
Positive	100%	100%	100%	92.86%	96%
Negative	100%	97.70%	100%	100%	100%
Total	>99%	98.99%	>99%	96%	98%

Analytical Sensitivity

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

Drug Conc. (Cut-off range)	AMP		BAR 50		BZO 10		BZO 50		BUP 5		BUP 10		COC	
	-	+	-	+	-	-	+	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	COD		FEN		MDMA		MET		MQL 100		MQL 150		MTD 30	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	MTD 75		6-MAM 10		6-MAM 15		OPI 15		OPI 40		OXY 20		OXY 50	
	-	+	-	+	-	+	-	+	-	-	+	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	0	30	0	0	0	30	0	30

Drug Conc. (Cut-off range)	PPX		TCA		THC 12		THC 25		THC 40	
	-	+	-	+	-	+	-	-	+	-
0% Cut-off	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0
+50% Cut-off	0	30	0	30	0	30	1	29	0	30

Analytical Specificity and Cross Reactivity

The following table lists the concentration of compounds (ng/mL) above which the Oral Fluid Drug Test identified positive results at 10 minutes.

Drug Compound	Concentration (ng/mL)
AMPHETAMINE (AMP)	
d- Amphetamine	50
Phentermine	120,000
R(-)-Amphetamine	10,000
(±)-Amphetamine	50
Serotonin	500,000
Octopamine	60,000
(±)-Phenylpropanolamine hydrochloride	100,000
Tryptamine	1,500
BARBITURATE (BAR 50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30
Butalbital	400
Butethal	30
Cyclopentobarbital	60

Drug Compound	Concentration (ng/mL)
Pentobarbital	150
Phenobarbital	30
BENZODIAZEPINES (BZO 10)	
Oxazepam	10
Alprazolam	6
Bromazepam	12
Chlordiazepoxide	12
Clobazam	6
Clorazepate	25
Delorazepam	25
Desalkylflurazepam	25
Diazepam	3
Estazolam	3
Flunitrazepam	100
α-Hydroxyalprazolam	200
(±)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25
BENZODIAZEPINES (BZO 50)	
Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	12
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1,000
(±)-Lorazepam	1,000
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1,000
Nordiazepam	125
Temazepam	30
BUPRENORPHINE (BUP 5)	
Buprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Buprenorphine Glucuronide	20
BUPRENORPHINE (BUP 10)	
Buprenorphine	10
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	20
Buprenorphine-3-D-Glucuronide	200
Buprenorphine Glucuronide	10
COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25

Drug Compound	Concentration (ng/mL)
Ecgonine	1,500
Ecgonine methyl ester	12,500
N-Acetylprocainamide	12,500
Norcocaine	500
CODEINE (COD)	
Codeine	10
Ranitidine	6,250
Heroin	30
Dihydrocodeine HCL	15
Ethyl Morphine	10
Hydrocodone	62.5
Hydromorphone	31.25
Levorphanol	250
6-acetylmorphine	25
Nalorphine	1,562.5
Normorphine	6,250
Norcodeine	2,000
FENTANYL (FEN)	
Norfentanyl	10
Fentanyl	20
Buspirone	12,500
ECSTASY (MDMA)	
3,4-Methylenedioxymethamphetamine	50
Butylone HCl	6,250
Ephedrine HCL	12,500
Ethylone	12,500
Phentermine	12,500
l-Methamphetamine	1,562.5
Methylone HCL	50,000
3,4-Methylenedioxyamphetamine (MDA)	781.25
3,4-Methylenedioxyethylampheta mine (MDEA)	97.7
(1R,2S)- (-)-Ephedrine	3,125
METHAMPHETAMINE (MET)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)- (-) Ephedrine	400
1-Ephedrine	400
Mephentermine	800
(-) Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
4-Methylethcathinone hydrochloride	25,000
Ethylone hydrochloride	25,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	100
(+/-)-Methylenedioxyamphetamine(MDA)	25,000
D,L-Methamphetamine	4,000
(±)-Amphetamine	10,000
Acetylsalicylic	4,000
Chlorothiazide	25,000
R(-)-Methamphetamine	400
METHAQUALONE (MQL 150)	
Methaqualone	150
METHAQUALONE (MQL 100)	

Drug Compound	Concentration (ng/mL)
Methaqualone	100
METHADONE (MTD 30)	
Methadone	30
Promethazine	30,000
PCP(Phencyclidine)	5,000
Levorphanol	10,000
Disopyramide	1,000
METHADONE (MTD 75)	
Methadone	75
Promethazine	39,000
PCP(Phencyclidine)	6,500
Levorphanol	13,000
Disopyramide	1,300
HEROIN (6-MAM 10)	
6-Monoacetylmorphine (6-MAM)	10
Codeine	>600,000
Morphine	>550,000
Heroin	250
Diethylstilbestrol	70,000
Trimethoprim	50,000
HEROIN (6-MAM 15)	
6-Monoacetylmorphine (6-MAM)	15
Codeine	>600,000
Morphine	>600,000
Heroin	250
Diethylstilbestrol	75,000
Trimethoprim	52,000
OPIATE (OPI 15)	
Morphine	15
Codeine	15
Ethyl morphine	15
Hydromorphone	50
Hydrocodone	50
Morphine 3-β-d-glucuronide	30
Nalorphine	300
Oxymorphone	25,000
Thebaine	5,000
Diacetylmorphine (Heroin)	15
6-Monoacetylmorphine (6-MAM)	15
OPIATE (OPI 40)	
Morphine	40
Codeine	10
Ethyl morphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-d-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50

Drug Compound	Concentration (ng/mL)
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
OXYCODONE (OXY 20)	
Oxycodone	20
Dihydrocodeine HCL	3,125
Gatifloxacin	25,000
Hydrocodone	1,562.5
Hydromorphone	781.25
Heroin	12,500
Oxymorphone-D3	390.6
Oxymorphone	48.8
Naltrexone hydrochloride	3,125
OXYCODONE (OXY 50)	
Oxycodone	50
Dihydrocodeine HCL	6,250
Gatifloxacin	60,000
Hydrocodone	6,250
Hydromorphone	1,562
Heroin	25,000
Oxymorphone-D3	781
Oxymorphone	100
Naltrexone hydrochloride	6,250
PROPOXYPHENE (PPX)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	100
Amitriptyline	250
Clomipramine	5,000
Desipramine	20
Doxepin	30
Imipramine	2,000
Maprotiline	10,000
Nordoxepin	1,500
Promazine	6,000
Promethazine	500
Trimipramine	5,000
Cyclobenzaprine Hydrochloride	500
Norclomipramine	5,000
MARIJUANA (THC 12)	
11-nor-Δ^9-THC-9 COOH	12
Cannabinol	31,500
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	6,000
Δ^9-THC	20,000
MARIJUANA (THC 25)	
Δ^9-Tetrahydrocannabinol	25
11-nor-Δ^9 -THC-9 COOH	15
MARIJUANA (THC 40)	
Δ^9-Tetrahydrocannabinol	40
Δ^8-Tetrahydrocannabinol	80
11-nor-Δ^9-THC-9 COOH	4
11-hydroxy-Δ^9-THC	45
Cannabinol	200
Cannabidiol	2,200
Desloratadine Citrate Disodium	35,000
Phenethylamine	20,000

Drug Compound	Concentration (ng/mL)
p-Hydroxymethamphetamine	70,000
Cefuroxime Axetil	40,000
Norbuprenorphine	40,000
Dexamethasone acetate	65,000

Interference

A study was conducted to determine the cross-reactivity of the Oral Fluid Drug Test with compounds spiked into drug-free PBS stock. The following compounds demonstrated no false positive results on the Oral Fluid Drug Test when tested at concentrations up to 100 μg/mL.

Non-Cross-Reacting Compounds

Acetaminophen	Diclofenac	Loperamide	d-Pseudoephedrine
Acetophenetidin	Dicyclomine	Meprobamate	Quinacrine
Acetylsalicylic acid	Diflunisal	Methylphenidate	Quinine
Aminopyrine	Digoxin	Naproxen	Quinidine
Amoxicillin	Diphenhydramine	Niacinamide	Salicylic acid
Ampicillin	β-Estradiol	Nifedipine	Sulfamethazine
Ascorbic acid	Ethyl-p-aminobenzoate	Nimesulide	Sulindac
Apomorphine	Erythromycin	Norethindrone	Tetracycline
Aspartame	Fenoprofen	Noscapine	Tetrahydrocortisone
Atropine	Furosemide	d, l-Octopamine	3-acetate
Benzilic acid	Gentisic acid	Oxalic acid	3 (β-d-glucuronide)
Benzoic acid	Hemoglobin	Oxolinic acid	Theophylline
Benzphetamine	Hydralazine	Oxymetazoline	Thiamine
Caffeine	Hydrochlorothiazide	Papaverine	Thioridazine
Chloral hydrate	Hydrocortisone	Penicillin-G	d, l-Tyrosine
Chloramphenicol	o-Hydroxyhippuric acid	Pentazocine	Tolbutamide
Chlorothiazide	βHydroxynorephedrine	Perphenazine	Trazodone
d, l-Chlorpheniramine	5-Hydroxytryptamine	Phenelzine	Triamterene
Chlorpromazine	3-Hydroxytyramine	Trans-2-phenylcyclo-	Trifluoperazine
Chloroquine	Ibuprofen	propylamine	d, l-Tryptophan
Cholesterol	Iproniazid	Labetalol	Tyramine
Clonidine	(-) Isoproterenol	Phenylpropanolamine	Uric acid
Creatinine	Isoxsuprine	Prednisolone	Verapamil
Deoxycorticosterone	Ketoprofen	d, l-Propranolol	Zolpidem
Dextromethorphan	Nalidixic acid	Prednisone	

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. Schramm W., *et al*. Drugs of Abuse in Saliva: A Review. *J Anal Tox*, 16 (1): 1-9, 1992.
3. Kim L, *et al*. Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration. *ClinChem*, 48 (9): 1486-96, 2002.
4. Kang GI and Abbott FS. Analysis of methadone and metabolites in biological fluids with gas chromatography-mass spectrometry. *J Chromatogr*. 231 (2); 311-319. Sept 1982.
5. McCarron MM, *et al*. Detection of Phencyclidine Usage by Radioimmunoassay of Saliva. *J Anal Tox*. 8 (5):197-201, 1984

Manufactured for:
Healgen Scientific, LLC.
Address: 3818 Fuqua Street, Houston, TX 77047, USA
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

Revised Date：2021-12-22
B21969-03