

Oral Fluid Drug Test Package Insert

Package insert for testing of the following drugs:

Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Cotinine, Ecstasy, Fentanyl, Ketamine, Lysergic acid diethylamide, Marijuana, EDDP, Methadone, Methamphetamine, Methaqualone, Methylenedioxypyrovalerone, Heroin, Morphine, Opiate, Oxycodone, Phencyclidine, Propoxyphene, K2, Tramadol, Tricyclic Antidepressants and Alcohol.

INTENDED USE & SUMMARY

The Oral Fluid Drug And Alcohol Test is intended for screening for the presence of drugs and alcohol and their metabolites in oral fluid. For professional *in vitro* diagnostic use only.

The Oral Fluid Drug And Alcohol Test is a lateral flow chromatographic immunoassay for the qualitative 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	50/300
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine (BUP)	Buprenorphine	5/10
Cocaine (COC)	Benzoylcegonine	20
Cotinine (COT)	Cotinine	30/50
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	50
Fentanyl (FEN)	Norfentanyl	10
Ketamine (KET)	Ketamine	50/100
Lysergic acid diethylamide (LSD)	d-Lysergic acid diethylamide	25
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	12
Marijuana (THC)	Δ^9 -THC	25/50
Methadone Metabolite (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Methadone (MTD)	Methadone	30/75
Methamphetamine (MET)	D-Methamphetamine	50
Methaqualone (MQL)	Methaqualone	100/150
Methylenedioxypyrovalerone (MDPV)	Methylenedioxypyrovalerone	50/100
Heroin (6-MAM)	6-Monoacetylmorphine	10/15
Morphine (MOP)	Morphine	15
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	50/20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	5
Tramadol (TRA)	Tramadol	50
Tricyclic Antidepressants (TCA)	Nortriptyline	100
Alcohol (ALC)	Alcohol	> 0.02 % B.A.C

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. Benzodiazepines can be detected in oral fluid after use.

BUP: Buprenorphine is a semisynthetic opioid analgesic derived from thebain, 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

COT: 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.

MDMA: MDMA is an abbreviation for the chemical methylenedioxymethamphetamine. It has street many name 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 heart stroke. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the parent drug of MDMA, and MDEA (methylenedioxyethyl MDMA), 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 detectable in the saliva for up to 3 days after use.

FEN: Fentanyl, belongs to powerful narcotics analgesics, and is a special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain¹. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc^{2,3}, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

KET: Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained.

LSD: D-lysergic acid diethylamide (LSD) is the most potent hallucinogenic substance known to man. Dosages of LSD are measured in micrograms, or millionths of a gram. By comparison, dosages of cocaine and heroin are measured in milligrams, or thousandths of a gram. Compared to other hallucinogenic substances, LSD is 100 times more potent than psilocybin and psilocin and 4,000 times more potent than mescaline. The dosage level that will produce a hallucinogenic effect in humans generally is considered to be 25 micrograms.

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

EDDP: Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 16-50 hours. EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is formed by N-demethylation and cyclization of methadone in the liver. The detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

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. Based on the saliva/plasma ratio calculated over salivary pH ranges of 6.4-7.6 for therapeutic or recreational doses of methadone, a cut-off <50 ng/mL is suggested. 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 on countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule.

MDPV: "Bath salts", a form of designer drugs, also promoted as 'plant food' or 'research chemicals' and is sold mainly in head shops, on the Internet, and at other retail locations. Designer drugs were developed in recent years to subvert law enforcement and drug testing agencies and are advertised a 'legal' high. The technical term for 'bath salts' is substituted cathinone. Substituted cathinone is synthetic, concentrated version of the stimulant chemical in Khat. Khat is a plant that is cultivated and used in East Africa and the Middle East. It has a stimulant effect on the user and can be quite dangerous. The white crystals resemble legal bathing salts, thus the name of 'bath salts'.

Established as one of the main ingredients for 'bath salts' among other synthetic stimulants like Mephedrone, Methylone, Butylone and Methedrone, MDPV started appearing around 2004 when it was popularized as a club drug, often used in combination with alcohol, GHB, cannabis and other drugs of abuse, for its desired effects such as euphoria, alertness, talkativeness, and sexual arousal. There are currently no prescribed uses for the synthetic stimulants.

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.

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 being 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% B.A.C. or higher. At higher alcohol concentration near 0.30% B.A.C., the color may change to a dark blue-gray.

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 And Alcohol 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 gas chromatography/tandem mass spectrometry (GC/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

Analytical Sensitivity

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

Drug Conc. (Cut-off range)	AMP	BAR 50	BAR 300	BZO 10	BZO 50	BUP 5	BUP 10
	- +	- +	- +	- +	- +	- +	- +
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)	COC	COT 30	COT 50	MDMA	FEN	KET 50	KET 100
	- +	- +	- +	- +	- +	- +	- +
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)	LSD	THC 12	THC 25	THC 50	EDDP	MTD 30	MTD 75
	- +	- +	- +	- +	- +	- +	- +
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	1 29	0 30	0 30	0 30	0 30

Drug Conc. (Cut-off range)	MET	MLQ 100	MLQ 150	MDPV 50	MDPV 100	6-MAM 10	6-MAM 15	MOP
	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30 0	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	30 0
+50% Cut-off	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30

Drug Conc. (Cut-off range)	OPI	OXY 20	OXY 50	PCP	PPX	K2	TRA	TCA
	- +	- +	- +	- +	- +	- +	- +	- +
0% Cut-off	30 0	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	30 0
+50% Cut-off	0 30	0 30	0 30	0 30	0 30	0 30	0 30	0 30

Analytical Specificity

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

AMPHETAMINE (AMP)	
d-Amphetamine	50
d,l-Amphetamine	125
β -Phenylethylamine	4,000
Tryptamine	1,500
p-Hydroxyamphetamine	800
(+) 3,4-Methylenedioxymphetamine (MDA)	150
l-Amphetamine	4,000
COCAINE (COC)	
Benzoylcegonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgoninemethylester	12,500
N-Acetylprocainamide	12,500
Chlordiazepoxide	12,500
MARIJUANA (THC 25)	
Δ^9 -Tetrahydrocannabinol	25
11-nor- Δ^9 -THC-9 COOH	15
METHAQUALONE (MQL 150)	
Methaqualone	150
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
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
OPIATE (OPI 40)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3- β -d-glucuronide	50

METHADONE (MTD 75)	
Methadone	75
Doxylamine	100,000
Estrone-3-sulfate	100,000
Phencyclidine	100,000
METHADONE (MTD 30)	
Methadone	30
Doxylamine	50,000
Estrone-3-Sulfate	50,000
Phencyclidine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
OXYCODONE (OXY 20)	
Oxycodone	20
Hydrocodone	6,250
Hydromorphone	25,000
Levorphanol	12,500
Naloxone	12,500
Naltrexone	12,500
Oxymorphone	100
Secobarbital	50,000
OXYCODONE (OXY 50)	
Hydrocodone	12,500
Levorphanol	25,000
Naloxone	25,000
Naltrexone	50,000
Oxycodone	50
Secobarbital	100,000
Oxymorphone	200
Hydromorphone	50,000
BARBITURATE (BAR 300)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Bulabital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BARBITURATE (BAR 50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Bulabarbital	30
Butalbit	400

Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
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
($\pm$)-Lorazepam	1,000
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1,000
Nordiazepam	125
Temazepam	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
($\pm$)-Lorazepam	200
Midazolam	25
Nitrazepam	12
Norchlordiazepoxide	200
Nordiazepam	25
Temazepam	6
Triazolam	25

Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	30
COTININE (COT 50)	
(-) Cotinine	50
S(-)-Nicotine	5,000
EDDP (EDDP)	
EDDP	20
Meperidine	20,000
Methadone	20,000
Norfentanyl	20,000
Phencyclidine	20,000
Promazine	10,000
Promethazine	5,000
Prothipendyl	10,000
Prozine	2,500
6-MONOACETYLMORPHINE (6-MAM 15)	
6-Monoacetylmorphine (6-MAM)	15
Codeine	>600,000
Morphine	>600,000
FENTANYL (FEN)	
Norfentanyl	10
Fentanyl	50
Buspirone	12,500
COTININE (COT 30)	
(-) Cotinine	30
S(-)-Nicotine	3,000
ECSTASY (MDMA)	
Paramethoxyamphetamine (PMA)	1,600
Paramethoxymethamphetamine (PMMA)	160
3,4-Methylenedioxymphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
3,4-Methylenedioxymethamphetamine	50
PROPOXYPHENE (PPX)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
MORPHINE (MOP)	
Morphine	15
Codeine	15
Ethylmorphine	15
Hydromorphone	50
Hydrocodone	50
Morphine 3- β -d-glucuronide	30
Nalorphine	300
Oxymorphone	25,000
Thebaine	5,000