Oral Fluid Drug Test
Package Insert

Package insert for testing of the following drugs:
Amphetamine,Cocaine,Marijuana,Methamphetamine,Opiate,Methadone, Phencyclidine,Oxycodone,Benzodiazepine,Buprenorphine,Barbiturates, Cotinine,EDDP,MDMA,6-MAM,Propoxyphene ,Fentanyl,ETG 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 Pipette 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)	Barbiturate	50/300
Benzodiazepine (BZO)	Oxazepam	10/50
Buprenorphine(BUP)	Buprenorphine	5/10
Cocaine (COC)	Cocaine	20
Cotinine(COT)	Cotinine	30/50
Ketamine(KET)	Ketamine	50
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Methadone (MTD)	Methadone	30/75
Methamphetamine (MET)	D-Methamphetamine	50
Ecstasy（MDMA）	3,4-Methylenedioxymethamphetamine	50
Heroin Test (6-MAM) **No cross with Morphine!**	6-Monoacetylmorphine	10
Opiates (OPI)	Morphine	40
Oxycodone(OXY)	Oxycodone	50/20
Morphine (MOP)	Morphine	15
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	4
Marijuana (THC)	Δ9-THC	50
Alcohol (ALC)	Alcohol	> 0.02 % B.A.C
Tramadol(TRA)	Tramadol	50
Fentanyl(FEN)	Norfentanyl	10
Ethyl Glucuronide(ETG)	Ethyl-β-D-glucuronide	150

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

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

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

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

OPI(MOP): 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 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

*The window of detection varies for different opiates. Codeine can be detected within one hour and up to 7-21 hours after a single oral dose. Morphine is detectable for several days after a dose.

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.

PCP: Phencyclidine is a hallucinogen and, can be detected in oral fluid as a result of the exchange of the drug between the circulatory system and the oral cavity.5

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. The approximate half- life in serum is averaged about 14 hours.

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 justbefore FDA approval of Suboxone and Subutex.

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. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days.

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.

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 excreted into the bile and urine together with the other metabolite EMDP (2-Ethyl-5-Methyl-3,3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value, dose and the patient's metabolism. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

MDMA:MDMA is an abbreviation for the chemical methylenedioxymethamphetamine MDMA. 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 stoke.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 know 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 50-100mg ; 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 saliva for up to 3 days after use.

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 excreted in the urine. Since 6-MAM is a unique metabolite to heroin, its presence in the urine confirms that heroin was the opioid used. This is significant because on a urine 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. 6-MAM remains in the urine for no more than 24 hours so a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually guarantees that heroin has recently been consumed.

Remark: Our 6MAM test had <u>no cross reactivity with morphine,</u>

PPX : Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. DarvocetTM, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. 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.

TRA: Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the

mu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.2 Large doses of Tramadol could developtolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. The major pathways appear to be N- and O- demethylation, glucoronidation or

sulfation in the liver.

The One Step Tramadol (TRA) Test Dipcard yields a positive result when the Tramadol in saliva exceeds 50 ng/ml

ALCOHOL(ACL)

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (20mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

***EtG*：** Ethyl Glucuronide (EtG) is a direct metabolite of ethanol alcohol. The presence of EtG in the urine can be used to detect recent alcohol consumption, even after the ethanol alcohol is no longer measurable. Consequently, Traditional laboratory practices typically measure the amount of alcohol present in the body.Depending on the amount of alcohol that has been consumed, this method usually reveals alcohol ingestion within the past few hours.

The One Step Ethyl Glucuronide (EtG) Test Dip Card yields a positive result when the Ethyl Glucuronide in urine exceeds 150ng/mL.

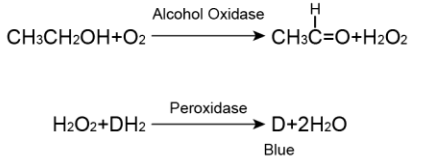
FEN（fentanyl）： Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, 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 etc2,3, 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

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.

PRINCIPLE

(1)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 coloured 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 coloured line will not form in the test line region.A drug-positive oral fluid specimen will not generate a coloured 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 coloured line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

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



REAGENTS

(1)The test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

(2) Alcohol Test: The alcohol pad contains Tetramethylbenzidine， Alcohol Oxidaze,Peroxidase，Buffer and Stabilizing Proteins

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date.
- 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 collector and device should be discarded according to local regulations.
- Safety data sheets available for professional user upon request

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 collector 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. If specimen cannot be tested immediately, it is recommended that specimen be stored at 2-8°C or -20°C for up to 72 hours. Specimen may also be stored at room temperature for up to 48 hours. For ideal shipment conditions, transport specimen using ice packs (2-8°C).

MATERIALS

Materials Provided

- Test devices
- Collectors
- Collection tubes
- Security seals
- Package insert

Materials Required But Not Provided

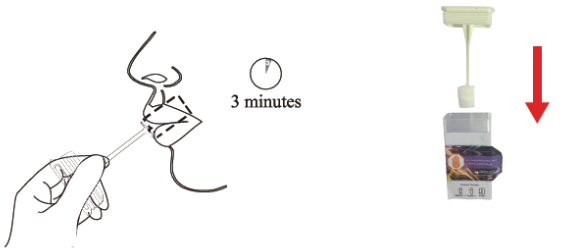
- Timer
- Gloves

DIRECTIONS FOR USE

Allow the test device, 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, 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.
2. Remove the collector from the sealed pouch. Take out of the collector cap ,Insert the sponge into the mouth.Close mouth and move the sponge around for oral fluid collection.Soak sponge in oral fluid and swab the inside of the mouth and tongue.Collect oral fluid for 3 minutes until sponge is soft and fully saturated, No hard spots should be felt on the sponge when saturated. (See illustration 1)
3. Place the test device on a clean and level surface. Remove the collection sponge from the mouth and insert it sponge first into the screening device,screw until the collector cap sealed with the device tightly.（See illustration 2）
4. Test device upright on flat surface and keep upright while test is running.Wait for the colored signal to appar in test results area. Read the results at 10 minutes.

Note: Once the collection sponge locks in place, the device is airtight,tamper evident,and ready to be disposed or sent to lab for comfimation(on presumptive positive result)



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

NEGATIVE:* A coloured line in the control line region (C) and a coloured line in the test line region (T) for a specific drug indicate 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 colour in the test line region (T) may vary, but it should be considered negative whenever there is even a faint coloured line.

POSITIVE: A coloured 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.

Alcohol Test Results

Alcohol Negative Result: The alcohol pad shows no color change (remains white or cream colored); it 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 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 coloured 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 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 ± 50% cut-off and tested with the Oral Fluid Pipette Test The results are summarized below.

Drug Conc.	AMP		COC		THC4		THC50		MET		OPI15/40		MTD30		MTD75		PCP		OXY20/50		TRA		FEN	
(Cut-off range)	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	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	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	0	30	0	**30**	0	30	0	30

Drug Conc.	BZO10/50		KET50/100		BUP5		BUP10		BAR50		BAR300		COT30/50		EDDP		PPX		MDMA		6-MAM		ETG	
(Cut-off range)	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	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	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	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-Methylenedioxyamphetamine (MDA)	150
l-Amphetamine	4,000
COCAINE (COC)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methylester	12,500
N-Acetylprocainamide	12,500
Chlordiazepoxide	12,500
MARIJUANA (THC)	
Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2,000

METHADONE (MTD)	
Methadone	75
Doxylamine	100,000
Estrone-3-sulfate	100,000
Phencyclidine	100,000
METHADONE (MTD)	
Methadone	30
Doxylamine	50,000
Estrone-3-Sulfate	50,000
Phencyclidine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
OXYCODONE (OXY)	
Oxycodone	20
Hydrocodone	6,250
Hydromorphone	25,000
Levorphanol	12,500
Naloxone	12,500
Naltrexone	6,250
Oxymorphone	100
Secobarbital	50,000

Cannabidiol	>10,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	4
Cannabinol	15000
11-nor-Δ^8-THC-9 COOH	2
Δ^8-THC	4000
Δ^9-THC	8000
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)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphine	100
Hydrocodone	100
Levorphanol	400

OXYCODONE (OXY)	
Hydrocodone	12,500
Levorphanol	25,000
Naloxone	25,000
Naltrexone	12,500
Oxycodone	50
Secorbarbital	100,000
Oxymorphone	200
Hydromorphone	50,000
Barbiturate(BAR)	
Secobarbital	300
Amobarbital	300
Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
Barbiturate(BAR)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30

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
6-Monoacetylmorphine (6-MAM)	15
Bilirubin	3,500
BENZODIAZEPINES (BZO)	
Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	12
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1000
(±)-Lorazepam	1000
Midazolam	125
Nitrazepam	60

Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	30
Cotinine (COT50)	
(-) 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
(6Monoacetylmorphine) 6-MAM	
6-Monoacetylmorphine (6-MAM)	20
6-Monoacetyl Codeine	5000
Diacetylmorphine (Heroin)	30
ETG	
Ethyl-β-D-glucuronide	150
Ethyl-β-D-glucuronide-	150

Norchlordiazepoxide	1000
Nordiazepam	125
Temazepam	30
BENZODIAZEPINES (BZO)	
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
Buprenorphine -3-D-Glucuronide	10
Buprenorphine Glucuronide	20
BUPRENORPHINE (BUP)	

D5	
FEN	
Norfentanly	10
Fentanly	50
Ecstasy(MDMA)	
Paramethoxyamphetamine (PMA)	1,600
Paramethoxymethamphetamine(PMMA)	160
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
3,4-Methylenedioxymethamphetamine	50
Propoxyphene(PPX)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
Morphine(MOP15)	
Morphine	15
Codeine	15
Ethylmorphine	15
Hydromorphine	50
Hydrocodone	50
Morphine 3-β-d-glucuronide	30
Nalorphine	300
Oxymorphone	25000
Thebaine	5000
Diacetylmorphine (Heroin)	15
6-Monoacetylmorphine (6-MAM)	15
Ketamine(KET100)	
Ketamine	100
norketamine	1000

Buprenorphine	5
Buprenorphine -3-D-Glucuronide	10
Norbuprenorphine	5
Ketamine(KET50)	
Ketamine	50
norketamine	500
Dextrolphorphan	25
Dextrolphantartratrate	25
D-Norpropxyphene	1560

Dextrolphorphan	70
Dextrolphantartratrate	70
D-Norpropxyphene	3000
TRAMADOL (TRA)	
Tramadol	50
N-desmethyl-tramadol	260
O-desmethyl-tramadol	12000
Cotinine (COT30)	
(-) Cotinine	30
S(-)-Nicotine	3000

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.

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 Test when tested at concentrations up to 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diclofenac		d,l-Propranolol
Acetophenetidine	Dicyclomine	Meperidine	
Acetylsalicylic acid	Diflunisal	Meprobamate	d-Pseudoephedrine
Aminopyrine	Digoxin	Methylphenidate	Quinacrine
Amoxicillin	Diphenhydramine	Nalidixic acid	Quinine
Ampicillin	l-Ψ-Ephedrine	Naproxen	Quindine
Amitryptyline	β-Estradiol	Niacinamide	Ranitidine
Amobarbital	Ethyl-p-aminobenzoate	Nifedipine	Salicylic acid
Ascorbic acid		Nimesulide	Sulfamethazine
Apomorphine	l-Epinephrine	Norethindrone	Sulindac
Aspartame	Erythromycin	d-Norpropoxyphene	
Atropine	Fenoprofen	Noscapine	Tetracycline

Benzilic acid	Furosemide	d,l-Octopamine	Tetrahydrocortisone
Benzoic acid	Gentisic acid	Oxalic acid	3-acetate
Benzphetamine	Hemoglobin		Tetrahydrocortisone
Buspirone	Hydralazine	Oxolinic acid	3(β-d-glucuronide)
d,l-Brompheniramine	Hydrochlorothiazide	Oxymetazoline	Theophylline
Caffeine	Hydrocortisone	Papaverine	Thiamine
Chloral hydrate	o-Hydroxyhippuric acid	Penicillin-G	Thioridazine
Chloramphenicol	β Hydroxynorephedrine	Pentazocine	d,l-Tyrosine
Chlorothiazide	5-Hydroxytryptamine		Tolbutamide
d,l-Chloropheniramine	(Serotonin)	Perphenazine	Trazodone
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Triamterene
Chloroquine	Ibuprofen	Trans-2-phenylcyclo-	Trifluoperazine
Cholesterol	Imipramine	propylamine	Trimethoprim
Clonidine	Iproniazid	Phentermine	Trimipramine
Cortisone	(-)Isoproterenol	Phenylpropanolamine	d,l-Tryptophan
	Isoxsuprine	Prednisolone	Tyramine
Creatinine	Ketamine	Phenolbarbital	Uric acid
Clomipramine	Ketoprofen	Prednisone	Verapamil
Deoxycorticosterone	Labetalol	Promazine	Zomepirac
Dextromethorphan	Loperamide	Promethazine	
	Maprotiline		

Alcohol Test

The following substances may interfere with the Oral Fluid Drug and Alcohol Screen Device when using samples other than oral fluid:

(1) Agents which enhance color development: Peroxides and strong oxidizers

(2) Agents which inhibit color development:

Reducing Agents: such as 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.

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