Oral Fluid Drug Screen Test

Package Insert

English

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/BAR/BUP/BZO/COT/COC/MDMA/MET/MTD/OPI/OXY/PCP/PPX/PGB/KET/K2/K2+/LSD/6-AM/THC/TML 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
Barbiturates(BAR)	Secobarbital	50
Buprenorphine（BUP）	Buprenorphine	5
Buprenorphine（BUP）	Buprenorphine	10
Benzodiazepines(BZO)	Oxazepam	5
Benzodiazepines(BZO)	Oxazepam	10
Cotinine(COT)	Cotinine	30
Cotinine(COT)	Cotinine	50
Cocaine (COC)	Benzoylecgonine	20
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	50
Methamphetamine (MET)	d-Methamphetamine	50
Methadone (MTD)	Methadone	30
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	d-Propoxyphene	30
Propoxyphene (PPX)	d-Propoxyphene	50
Pregabalin(PGB)	Pregabalin	2,000
Ketamine (KET)	Ketamine	50
Synthetic Marijuana (K2-30)	JWH-018、JWH-073	30
Synthetic Marijuana (K2--50)	JWH-018、JWH-073	50
AB-PINACA pentanoic acid metabolite (K2+)	AB-PINACA pentanoic acid metabolite	10
Lysergic acid diethylamide (LSD)	Lysergic acid diethylamide	50
6-Monoacetylmorphine (6-AM)	6-Monoacetylmorphine	10
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	12
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50
Tramadol (TML)	Tramadol	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/BAR/BUP/BZO/COT/COC/MDMA/MET/MTD/OPI/OXY/PCP/PPX/PGB/KET/K2/K2+/LSD/6-AM/THC/TML 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]

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]

Buprenorphine(BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™, and Suboxone™ which contain Buprenorphine HCl alone or in combination with Naloxone 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.

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.

Cotinine (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.

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.

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]

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.

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]

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 12-48 hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. 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]

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.

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.

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]

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 norpropoxypheneseen with repeated doses may be largely responsible for resultant toxicity.

Pregabalin(PGB)

Pregabalin, sold under the trade name Lyrica®, an analog of the inhibitory neurotransmitter gamma-aminobutyric acid and also of gabapentin, has been used clinically since 2002 as an analgesic, anticonvulsant and anxiolytic agent. It is supplied as the free drug in 25-300mg capsules for oral administration. Adult dose are normally within a range of 50-200mg thrice daily.

Ketamine (KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamineis still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a streetdrug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss ofcoordination, sense of invulnerability, muscle rigidity, aggressive /violent behavior, slurred or blockedspeech, exaggerated sense of strength, and a blank stare.There is depression of respiratory function butnot of the central nervous system, and cardiovascular function is maintained.The effects of Ketaminegenerally last 4-6 hours following use..

Synthetic Marijuana (K2)

Synthetic Marijuana or K2 is a psychoactive herbal and chemical product that, when consumed, mimics the effects of Marijuana. It is best known by the brand names K2 and Spice, both of which have largely become genericized trademarks used to refer to any synthetic Marijuana product. The studies suggest that synthetic marijuana intoxication is associated with acute psychosis, worsening of previously stable psychotic disorders, and also may have the ability to trigger a chronic (long-term) psychotic disorder among vulnerable individuals such as those with a family history of mental illness.

As of March 1, 2011, five cannabinoids, JWH -018, JWH- 073, CP- 47, JWH- 200 and cannabicyclo hexanol are now illegal in the US because these substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

AB-PINACA pentanoic acid metabolite (K2+)

Synthetic cannabinoids are designer drugs that are structurally different from THC (the active component of cannabis) but act in similar ways to affect the cannabinoid receptor system in the brain. Over the past few years, this class of designer drugs has mainstreamed to become globally popular and increasingly problematic. Synthetic cannabinoids fall into seven major structural groups:

1 .Naphthoylindoles (e.g. JWH-018, JWH-073)
2. Naphthylmethylindoles (JWH-175, JWH-184, JWH-185, JWH-199)
3 .Naphthoylpyrroles (JWH-145, JWH-146, JWH-147, etc)
4. Naphthylmethylindenes (JWH-176)
5. Phenylacetylindoles (JWH-250, JWH-251, JWH-302)
6. Cyclohexylphenols (e.g. CP 47,497)
7. Dibenzopyrans (classic cannabinoid structure such as. HU-210 and HU-211)

New structural group: Aminoalkylindazoles (AB-PINACA, AB-FUBINACA, AB-CHMINACA, etc).

In their original, chemical state, synthetic cannabinoids are liquid. The drugs are usually sold combined with dried herbs that emulate marijuana and are intended for smoking althoughpowdered versions are also available. As laws are written to control these drugs with each new synthetic cannabinoid class as they are introduced to the market, the older versions (JWH-018,JWH-073) are seen less frequently than years past. The current trend shows the aminoalkylindazole based drugs such as AB-PINACA, AB-FUBINACA and AB-CHMINACA.

Lysergic acid diethylamide (LSD)

LSD (Lysergic acid diethylamide), which is one of the most effective hallucinogens, but non-addictive, is used mainly as an entheogen and recreational drug. LSD is very potent, with 20–30 µg being the threshold dose. After taking it 30 to 120 minutes, the effects are realized, which can normally last from 8–12 hours. However, acute adverse psychiatric reactions such as anxiety, paranoia, and delusions are possible. The metabolize of LSD is very widely and rapidly, which taking 24 hours to discharge 90%, part of metabolism through the liver is 2-Oxo-3-hydroxy-LSD.

6-AM

6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) 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. 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

Marijuana (THC)

Tetrahydrocannabinol, the active ingredient in the marijuana plant (*cannabis sativa*), is detectable in saliva shortly after use. The detection of the drug is thought to be primarily due to the direct exposure of the drug to the mouth (oral and smoking administrations) and the subsequent sequestering of the drug in the buccal cavity.[1] Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use.[1]

Tramadol (TML)

Tramadol(TML) is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is asynthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. Large doses oftramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. Approximately 30% of the dose is excreted in theurine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O- demethylation, glucoronidation or sulfation in the liver.

【ASSAY PRINCIPLE】

The Oral Fluid Drug Screen Test for AMP/BAR/BUP/BZO/COT/COC/MDMA/MET/MTD/OPI/OXY/PCP/PPX/PGB/KET/K2/K2+/LSD/6-AM/THC/TML 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, Secobarbital, Buprenorphine, Oxazepam,

Cotinine,Benzoylecgonine, Methylenedioxymethamphetamine, Methamphetamine,Methadone, Morphine, Oxycodone, Phencyclidine, Propoxyphene, Pregabalin, Ketamine, AB-PINACA pentanoic acid metabolite, Synthetic Marijuana, Lysergic acid diethylamide, 6-Monoacetylmorphine, 11-nor-Δ9-THC-9 COOH, Tramadol and 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

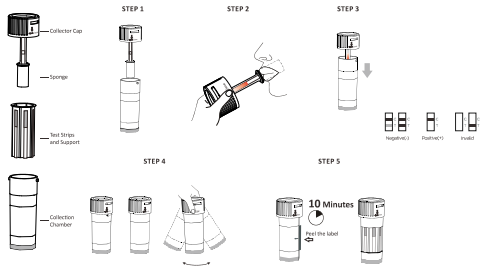
Materials Required but Not Provided

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 sufficient specimen volume, 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.

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