MD Saliva Screen Test Cup

Procedure Card

- Bring tests and specimens to room temperature (15-30°C/59-86°F) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 10 minutes prior to specimen collection.
- The oral fluid specimen should be collected using the collector provided with the kit. No other collection devices should be used with this drug test.

A

Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, tongue) several times, then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. ***Important*: *Do not bite, suck, or chew on the sponge.***

NOTE: If after 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with step B of the test.

B

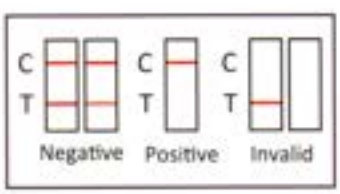
Open the cap and place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge into the screening device **gently and slowly** until touch the bottom of the saliva cup, pushing the cap until it locked in place of the saliva cup. **Keep upright on flat surface when inserting the sponge.**

C

Keep upright while test is running. Wait for the colored signal to appear in test result area.

D

Read the results **at 10 minutes**. Read saliva alcohol pads **at 3 minutes**.



Note: 1, Once the collection sponge locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).
2, If no wicking issue occurred, please peel off the label at the bottom of the device as marked to check if there is enough specimen (obviously specimen residue) or the saliva is too thick or viscous to run.
3, In the case of no flowing even with enough saliva specimen, or the saliva is too thick to run, please move the device but don't tilt and keep upright back and forth on a flat and clean surface for several times until the saliva flows up (please peel off the specimen label to easily check and make sure the oral fluid can touch the strips to run). Do not tilt the device when the test is running before reading results.

SalivaScreen Test Cup

Catalogue NO.See Box Label

For Forensic Use Only

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 Multi-Saliva Drugs of Abuse 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 Multi-Saliva Drugs of Abuse 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)	Benzoylecgonine	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 ssociety 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 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 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 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.

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.[1]
*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.

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.

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.[1]

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. Darvocet™, 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.

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 cannabicyclohexanol 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. JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", K3" and others. These products may be smoked for their psychoactive effects.

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 themu-opioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2] Large doses of Tramadol could develop tolerances 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.

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.

ALC: 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% (20 mg/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

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 Multi-Saliva Drugs of Abuse And Alcohol 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.

(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:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3\overset{H}{\underset{|}{C}}=O + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} D + 2H_2O$$

Blue

REAGENTS

(1) The Multi-Saliva Drugs of Abuse And Alcohol 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 cups
- Saliva collectors
- Security seal labels
- Package insert

Materials Required But Not Provided

- Timer
- Gloves

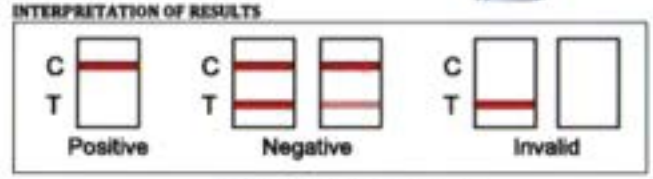
DIRECTIONS FOR USE

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. Using the provided collection swab, remove the collector from the sealed pouch, have donor sweep inside of mouth (cheek, gum, tongue) several times, then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. **Important:** Do not bite, suck, or chew on the sponge.
   Note: If after 7 minutes, color on the saturation indicator has not appeared in the indicator window, proceed with the test below. (See illustration 1)
3. Open the cap and place the test device on a clean and flat surface. Remove the collection sponge from the mouth and insert the sponge first into the screening device until touch the bottom of the saliva cup, pushing the cap until it locked in place of the saliva cup. **Keep upright when insert the sponge.** (See illustration 2)
4. **Test device upright on flat surface and keep upright while test is running.** Wait for the colored signal to appear in test results area. Read the results at 10 minutes. Read saliva alcohol pads at 3 minutes.

Note: 1, Once the collection sponge locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).
2, In the case of no flowing even with enough saliva specimen, or the saliva is too thick to run, please move the device but don't tilt and keep upright back and forth on a flat and clean surface for several times. Do not tilt the device when the test is running before reading results.

INTERPRETATION OF 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 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 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.

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 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 Multi-Saliva Drugs of Abuse 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 ± 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		MQL 100		MQL 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 Multi-Saliva Drugs of Abuse And Alcohol 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
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

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
Secorbarbital	100,000
Oxymorphone	200
Hydromorphone	50,000
BARBITURATE (BAR 300)	
Secobarbital	300
Amobarbital	300

Procaine	2,000
(1R,2S)-(-) Ephedrine	400
l-Ephedrine	400
Mephentermine	800
(-)Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
OPIATE (OPI 40)	
Morphine	40
Codeine	10
Ethylmorphine	24
Hydromorphine	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
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
(±)-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

Alphenal	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BARBITURATE (BAR 50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30
Butalbital	400
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)	
Norfentanly	10
Fentanly	50
Buspirone	12,500
COTININE (COT 30)	
(-) Cotinine	30
S(-)-Nicotine	3,000
ECSTASY (MDMA)	
Paramethoxyamphetamine (PMA)	1,600
Paramethoxymethamphetamine (PMMA)	160
3,4-Methylenedioxyamphetamine (MDA)	250

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 (BUP 5)	
Buprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	5
Buprenorphine-3-D-Glucuronide	10
Buprenorphine Glucuronide	20
KETAMINE (KET 50)	
Ketamine	50
norketamine	500
Dextrolphorphan	25
Dextrolphantartratrate	25
D-Norpropxyphene	1,560
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	100
Amitriptyline	250
Clomipramine	5,000
Desipramine	20
Doxepine	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 50)	

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
Hydromorphine	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
KETAMINE (KET 100)	
Ketamine	100
norketamine	1,000
Dextrolphorphan	70
Dextrolphantartratrate	70
D-Norpropxyphene	3,000
TRAMADOL (TRA)	
Tramadol	50
N-desmethyl-tramadol	260
O-desmethyl-tramadol	12,000
SYNTHETIC CANNABINOID (K2)	
JWH-018 5-Pentanoic acid metabolite	5
JWH-073 4-butanoic acid metabolite	5
JWH-250 4-Hydroxypentyl metabolite	25,000
JWH-210 5-Hydroxypentyl metabolite	50,000
JWH-073 4-Hydroxybutyl metabolite	250
JWH-019 5-hydroxyhexyl metabolite	5,000
JWH-018 N-(4-hydroxypentyl) metabolite solution	500
JWH-019 6-Hydroxyhexyl	700
JWH-019 5-Hydroxyhexyl	400
MAM2201	40,000
JWH-122 5-Hydroxypentyl metabolite	700
APINACA 5-hydroxypentyl metabolite	50,000
BUPRENORPHINE (BUP 10)	
Buprenorphine	10

Δ^8-Tetrahydrocannabinol	50
Δ^9-Tetrahydrocannabinol	75
11-nor-Δ^9-THC-9 COOH	15
11-hydroxy-Δ^9-THC	300
Cannabinol	2,000
Cannabidiol	>10,000
6-MONOACETYLMORPHINE (6-MAM 10)	
6-Monoacetylmorphine (6-MAM)	10
Codeine	>600,000
Morphine	>550,000
METHYLENEDIOXYPYROVALERONE (MDPV 50)	
Methylenedioxypyrovalerone	50
Butylone	4,000
Ethylone	50
Methylone	11,000
Brompheniramine	800
Methedrone	5,000
Naphyrone	>100,000
Flephedrone	>100,000

Buprenorphine-3-D-Glucuronide	10
Norbuprenorphine	20
Buprenorphine-3-D-Glucuronide	200
Buprenorphine Glucuronide	10
LYSERGIC ACID DIETHYLAMIDE (LSD)	
D-lysergic acid diethylamide	25
METHAQUALONE (MQL 100)	
Methaqualone	100
METHYLENEDIOXYPYROVALERONE (MDPV 100)	
Methylenedioxypyrovalerone	100
Butylone	5,000
Ethylone	50
Methylone	10,000
Brompheniramine	1,000
Methedrone	5,000
Naphyrone	>100,000
Flephedrone	>100,000

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 Multi-Saliva Drugs of Abuse And Alcohol when tested at concentrations up to 100 µg/mL.

Non Cross-Reacting Compounds

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

Alcohol Test
The following substances may interfere with the Oral Fluid Drug andAlcohol 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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