Oral Fluid Drug Test Mini Cube Package Insert

CE

Package insert for testing oral fluid forany combinationofthe following drugs: Amphetamine, Barbiturates, Benzodiazepine, Buprenorphine, Cocaine, Codeine, Cotinine, Ecstasy, EDDP, Fentanyl, Heroin (6-MAM), Ketamine, Kratom, Lysergic acid Methylenedioxypyrovalerone (MDPV), Morphine, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Synthetic Cannabinoid (K2), Tramadol, Tricyclic Antidepressants and Alcohol.

This device has various combinations. Please refer to product labeling for exact drug panels and cutoffs.

INTENDED USE & SUMMARY

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

The Oral Fluid Drug Test Mini Cube is a lateral flow chromatographic immunoassay for the qualitative and simultaneous detection of drugs and drug metabolites in human 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	20/50
Codeine (COD)	Codeine	10
Cotinine (COT)	Cotinine	30/50
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	50
Fentanyl (FEN)	Norfentanyl	10
Heroin (6-MAM)	6-Monoacetylmorphine	10/15
Ketamine (KET)	Ketamine	50/100
Kratom (KRA)	Mitragynine	100
Lysergic acid diethylamide (LSD)	d-Lysergic acid diethylamide	25
Marijuana Metabolite (THC)	11-nor-Δ^9-THC-9 COOH	3/12
Marijuana (THC)	Δ^9-THC	25/40/50
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
Morphine (MOP)	Morphine	15
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20/50
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	5/25
Tramadol (TRA)	Tramadol	50
Tricyclic Antidepressants (TCA)	Nortriptyline	100
Alcohol (ALC)	Alcohol	> 0.02 % B.A.C

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

OralFluidDrug TestMini Cubeshould only be performed by health professionals in a clinical/hospital setting to aid in screening of drug of abuse to determine the follow-up treatment measures in combination of clinical symptoms.

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.

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. 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 thebaine, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms.

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

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

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. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

MDMA: MDMA is an abbreviation for the chemical methylenedioxymethamphetamine. It has street many name including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, 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. MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), 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 pain.[1] After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc.[2,3]

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.

KRA: Kratom leaves produce narcotic-like effects when smoked, chewed, or drank as a suspension, which have recently attracted significant attention due to increased use in Western cultures as an alternative medicine. It is used in therapy for opiate addiction and chronic pain management. The addiction potential and adverse health consequences are becoming an important issue for health authorities. Extensive use of kratom results in prolonged sleep. The withdrawal symptoms include hostility, aggression, muscle pain and inability to work.

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.

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).[2]

EDDP: 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.

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).

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. The white crystals resemble legal bathing salts, thus the name of ‘bath salts’.

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: The drug class opiates refer to any drug that is derived from the opium poppy, including naturally occurring compounds such as morphine and codeine and semi-synthetic drugs such as heroin. Opiates control pain by depressing the CNS and demonstrate addictive properties when used for sustained periods of time. Opiates can be taken orally or by injection routes including intravenous, intramuscular and subcutaneous; illegal users may also take the intravenously or by nasal inhalation.[3]

*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.[5]

PPX: Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours).

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. 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 themuopioid receptors. It has been prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.[2]

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. Liquid chromatography/mass spectrometry (LC/MS) and liquid chromatography/tandem mass spectrometry (LC/MS/MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PRINCIPLE

(1) The Oral Fluid Drug Test Mini Cube 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. A procedural control, will appear as colored line 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 Oral Fluid Drug Test Mini Cube 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 oxidase, Peroxidase, Buffer and Stabilizing Proteins.

PRECAUTIONS

For professional *in vitro* diagnostic use only.
Do not use after the expiration date.
The test device should remain in the sealed pouch until use.
Do not reuse the test
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 are available 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 by the collection swab provided within 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). Perform testing immediately after collection.

MATERIALS

Materials Provided

- 25 Sealed pouches each containing:
  -Test cube
- 25 Plastic bags with saliva collector (with indicator)
- 1 Procedure card
- 25 Security seal labels
- 1 Package insert

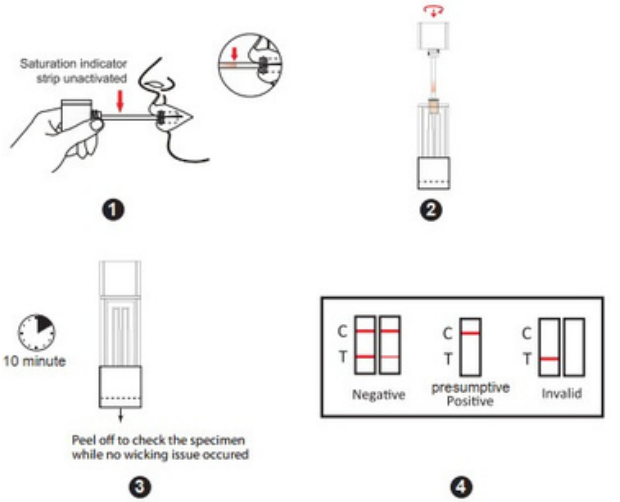
Materials Required but Not Provided

- 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 collection swab from packaging. Start Timer. Relax the mouth and insert the collection swab into the mouth. The collection swab must be horizontal throughout the collection process. Using a circular motion, gently swab both cheeks 5-10 times, gums 5-10 times, and surface of tongue 5-10 times, actively swab the inside the mouth, top of tongue, and between cheek and gum until a red color on the saturation indicator strip appears in the indicator window of collection swab.
   Important: Do not bite, suck or chew on the collection swab. It is critical that the collection swab is held horizontally during collection otherwise there will be insufficient saliva collected although the indicator turns red. During collection of the oral fluid, relax the mouth while swabbing the tongue and check as this will aid in the collection of the oral fluid.
   Note: Refer to Notes and Troubleshooting if the saturation indicator strip does not activate after 4 minutes. If after 7 minutes, color has not appeared, proceed with the test below. (See illustration 1)
   Remove test device from sealed pouch and place upright on a clean, flat surface.
3. Gently and slowly insert the collection swab into the test device, sponge first, until it reaches the bottom of the test device, then rotate until the collector cap sealed with the device tightly. (See illustration 2)
   Important: Keep test device upright while inserting collection swab. Once the collection swab is locked in place, the test device is airtight, tamper evident and ready to be shipped to a lab for confirmation if required. Alternatively, the test device can be disposed of.
   Keep test device upright on a flat surface until the test is complete. Start timer.
4. **Important:** If any test strips do not develop (invalid), peel away bottom of device label to inspect specimen volume. Refer to Notes and Troubleshooting.
   Interpret results at 10 minutes.
5. If positive results are observed, apply the security seal label from cap down to sides of the device, then send the device to a laboratory for confirmation. The laboratory can access the reservoir through the Sample Port.



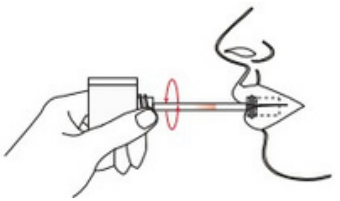
NOTES AND TROUBLESHOOTING

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

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

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

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



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)

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

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

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

INVALID: Control line (C) fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the

procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Alcohol TestResults

Alcohol Negative Result: The Alcohol test produces a 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

The colored line appearing in the control region (C) is considered the internal procedural control. It confirms sufficient specimen volume and adequate membrane wicking. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

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

PERFORMANCE CHARACTERISTICS

Accuracy

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

Specimen	AMP	BAR 50	BAR 300	BZO 10	BZO 50	BUP 5	BUP 10
Positive	100%	100%	100%	100%	100%	98.2%	100%
Negative	100%	100%	100%	100%	100%	100%	97.7%
Total	>99%	>99%	>99%	>99%	>99%	98.99%	98.99%

Specimen	COC 20	COC 50	COD	COT 30	COT 50	MDMA	FEN
Positive	100%	100%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	>99%	>99%	>99%	>99%	>99%	>99%	>99%

Specimen	KET 50	KET 100	KRA	LSD	THC 3	THC 12	THC 25
Positive	100%	100%	100%	100%	100%	100%	92.86%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	>99%	>99%	>99%	>99%	>99%	>99%	96%

Specimen	THC 40	THC 50	EDDP	MTD 30	MTD 75	MET	MQL 100
Positive	96%	96.4%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	100%	100%	100%
Total	98%	100%	>99%	>99%	>99%	100%	>99%

Specimen	MQL 150	MDPV 50	MDPV 100	6MAM 10	6MAM 15	MOP	OPI
Positive							100%
Negative	100%	100%	100%	100%	100%	100%	100%
	100%	97.7%	100%	100%	100%	100%	

Total	>99%	98.99%	>99%	>99%	>99%	>99%	>99%

Specimen	OXY 20	OXY 50	PCP	PPX	K2 5	K2 25	TRA
Positive	100%	100%	100%	100%	100%	100%	100%
Negative	100%	100%	100%	100%	97.7%	97.7%	100%
Total	>99%	>99%	>99%	>99%	98.99%	98.99%	>99%

Specimen	TCA
Positive	100%
Negative	98%
Total	99%

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of 50% cut-off and tested with the Oral Fluid Drug Test Mini Cube. 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	30	0	30	0	0	30	0	30	30	0	0	30	0	30

Drug Conc. (Cut-off range)	COC 20		COC 50		COD		COT 30		COT 50		MDMA		FEN	
	-	+	+	-	-	+	-	+	-	-	-	+	-	+
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	30	0	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	KET 50		KET 100		KRA		LSD		THC 3		THC 12		THC 25	
	+	-	+		-	+	+	-	+	-	-	+	-	+
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	30	0	30	0	0	30	30	0	30	0	0	30	1	29

Drug Conc. (Cut-off range)	THC 40		THC 50		EDDP		MTD 30		MTD 75		MET		MQL 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)	MQL 150		MDPV 50		MDPV 100		6-MAM 10		6-MAM 15		MOP		OPI	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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)	OXY 20		OXY 50		PCP		PPX		K2 5		K2 25		TRA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+
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)	TCA	
	-	+
0% Cut-off	30	0
-50% Cut-off	30	0
+50% Cut-off	0	30

Analytical Specificity

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

Drug Compound	Concentration (ng/mL)
AMPHETAMINE (AMP)	
d- Amphetamine	50
Phentermine	120,000
R(-)-Amphetamine	10,000
(±)-Amphetamine	50
Serotonin	500,000
Octopamine	60,000
(±)-Phenylpropanolamine hydrochloride	100,000
Tryptamine	1,500
BARBITURATE (BAR 50)	
Secobarbital	50
Amobarbital	100
Alphenal	100
Aprobarbital	30
Butabarbital	30
Butalbital	400
Butethal	30
Cyclopentobarbital Pentobarbital	60
Phenobarbital	150
BARBITURATE (BAR 300)	30
Secobarbital	
Amobarbital	
Alphenal	300
Aprobarbital	300
Butabarbital	150
Butalbital	200
Butethal	75
Cyclopentobarbital Pentobarbital	2,500
Phenobarbital	100
BENZODIAZEPINES (BZO 10)	600
Oxazepam	300
Alprazolam	100
Bromazepam	
Chlordiazepoxide	
Clobazam	10 6
Clorazepate	12
Delorazepam	12 6
Desalkylflurazepam	25
Diazepam	25
Estazolam	25 3
Flunitrazepam	3
α-Hydroxyalprazolam	100
(±)-Lorazepam	200
Midazolam	200
Nitrazepam	25
Norchlordiazepoxide	12
Nordiazepam	200
Temazepam	25
Triazolam	6
	25

Drug Compound	Concentration (ng/mL)
BENZODIAZEPINES (BZO 50)	
Oxazepam	50
Alprazolam	300
Bromazepam	60
Chlordiazepoxide	60
Clobazam	36
Clorazepate	125
Delorazepam	125
Desalkylflurazepam	125
Diazepam	15
Estazolam	15
Flunitrazepam	500
α-Hydroxyalprazolam	1,000
(±)-Lorazepam	1,000
Midazolam	125
Nitrazepam	60
Norchlordiazepoxide	1,000
Nordiazepam	125
Temazepam	30
Triazolam	125
BUPRENORPHINE (BUP 5)	
Buprenorphine	5 5
Norbuprenorphine	10
Buprenorphine-3-D-Glucuronide	20
Buprenorphine Glucuronide	
BUPRENORPHINE (BUP 10)	
Buprenorphine	10
Norbuprenorphine	20
Buprenorphine-3-D-Glucuronide	20
Buprenorphine Glucuronide	10
COCAINE (COC 20)	
Benzoylecgonine	20
Cocaine	20
Cocaethylene	25
Ecgonine	1,500
Ecgonine methyl ester	12,500
N-Acetylprocainamide	12,500
Norcocaine	500
COCAINE (COC 50)	
Benzoylecgonine	50
Cocaine	50
Cocaethylene	60
Ecgonine	2,500
Ecgonine methyl ester	25,000
N-Acetylprocainamide	25,000
Norcocaine	1,250
CODEINE (COD)	
Codeine	
Ranitidine	10
Heroin	6,250
	30

Drug Compound	Concentration (ng/mL)
Dihydrocodeine HCL	15
Ethyl Morphine	10
Hydrocodone	62.5
Hydromorphone	31.25
Levorphanol	250
6-acetylmorphine	25
Nalorphine	1,562.5
Normorphine	6,250
Norcodeine	2,000
COTININE (COT 30)	
(-) Cotinine	30
S(-)-Nicotine	3,000
Flephedrone(4-fluoromethcathinone)	50,000
N-Benzylisopropylamine	5,000
COTININE (COT 50)	
(-) Cotinine	50
S(-)-Nicotine	5,000
Flephedrone(4-fluoromethcathinone)	80,000
N-Benzylisopropylamine	8,000
ECSTASY (MDMA)	
3,4-Methylenedioxymethamphetamine	
Butylone HCl	50
Ephedrine HCL	6,250
Ethylone	12,500
Phentermine	12,500
l-Methamphetamine	12,500
Methylone HCL	1,562.5
3,4-Methylenedioxyamphetamine (MDA)	50,000
3,4-Methylenedioxyethylampheta mine (MDEA)	781.25
(1R,2S)- (-)-Ephedrine	97.7
FENTANYL(FEN)	3,125
Norfentanyl	
Fent a nyl	10
Buspirone	20
HEROIN(6-MAM 10)	12,500
6-Monoacetylmorphine (6-MAM)	
Codei ne	
Morphine	10
Heroin	>600,000
Diethylstilbestrol	>550,000
Trimethoprim	250
HEROIN (6-MAM 15)	70,000
6-Monoacetylmorphine(6-MAM)	50,000
Codeine	
Morphine	15
Heroin	>600,000
Diethylstilbestrol	>600,000
Trimethoprim	250
KETAMINE (KET 50)	75,000
Ketamine	52,000
Norketamine	
	50
	500

Drug Compound	Concentration (ng/mL)
Dextrolphorphan	25
Dextrolphantartratrate	25
D-Norprop xyp he ne	1,560
KETAMINE (KET100)	
Ketamine	100
Norketamine	1,000
Dextrolphorphan	70
Dextrolphantartratrate	70
D-Norpropxyphene	3,000
KRATOM (KRA 100)	
Mitragynine	100
Mitragynine Metabolite	100
7-Hydroxymitragynine	300
Bilirubin	35,000
11-Hydroxy-Δ^9-Tetrahydrocannabinol	35,000
LYSERGIC ACID DIETHYLAMIDE (LSD)	
D-lysergic acid diethylamide	
Fentanyl	25
Norfentanyl	40
Risperidone	150
Prilocaine	4,000
MARIJUANA (THC 3)	8,000
11-nor-Δ^9THC-9 COOH	3
Cannabinol 11-nor-Δ^8-	7,500
THC-9 COOH Δ8-THC	2
Δ9-THC	5,000
	4,500
MARIJUANA (THC 12)	
11-nor-Δ^9THC-9 COOH	12
Cannabinol 11-nor-Δ^8-	31,500
THC-9 COOH Δ8-THC	2
Δ9-THC	6,000
	20,000
MARIJUANA (THC 25) Δ^9-Tetrahydrocannabinol	
Δ8-Tetrahydrocannabinol	25
11-nor-Δ^9-THC-9 COOH	50
11-hydroxy-Δ^9-THC	3
Cannabinol	28
Cannabidiol (CBD)	125
11-Nor-Δ^9-THC-carboxy-glucuronide	1,400
(+)-11-nor-9-carboxy-Δ^9-THC	40
11-nor-Δ^8-THC-9-COOH	30
8-beta-11-dihydroxy-Δ^9-THC	12
8-beta-hydroxy-Δ^9-THC	125
Exo-THC	125
l-11-Nor-Δ^9-THC-9-Carboxylic Acyl-Glucuronide	50
Δ8-THC Carboxylic Acid	10
Δ9-THC Carboxylic Acid	12
MARIJUANA (THC 40)	2

Drug Compound	Concentration (ng/mL)
Δ9-Tetrahydrocannabinol	40
Δ8-Tetrahydrocannabinol	80
11-nor-Δ9-THC-9 COOH	4
11-hydroxy-Δ9-THC	45
Cannabinol	200
Cannabidiol (CBD)	2,200
11-Nor-Δ9-THC-carboxy-glucuronide	60
(+)-11-nor-9-carboxy-Δ9-THC	50
11-nor-Δ8-THC-9-COOH	20
8-beta-11-dihydroxy-Δ9-THC	200
8-beta-hydroxy-Δ9-THC	200
Exo-THC	75
l-11-Nor-Δ9-THC-9-Carboxylic Acyl-Glucuronide	15
Δ8-THC Carboxylic Acid	20
Δ9-THC Carboxylic Acid	4
MARIJUANA (THC 50)	
Δ9-Tetra hy droca nnabi nol	
Δ8-Tetra hy droca nnabi nol	
11-nor-Δ9-THC-9 COOH	
11-hydroxy-Δ9-THC	50
Cannabinol	100
Cannabidiol (CBD)	5
11-Nor-Δ9-THC-carboxy-glucuronide	55
(+)-11-nor-9-carboxy-Δ9-THC	250
11-nor-Δ8-THC-9-COOH	2,800
8-beta-11-dihydroxy-Δ9-THC	75
8-beta-hydroxy-Δ9-THC	60
Exo-THC	25
l-11-Nor-Δ9-THC-9-Carboxylic Acyl-Glucuronide	250
Δ8-THC Carboxylic Acid	250
Δ9-THC Carboxylic Acid	100
	20
	25
	4
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
METHADONE (MTD 30)	
Methadone	
Promethazine	30
PCP(Phencyclidine)	30,000
Levorphanol	5,000
Disopyramide	10,000
METHADONE (MTD 75)	1,000
Methadone	
Promethazine	75
	39,000

Drug Compound	Concentration (ng/mL)
PCP(Phencyclidine)	6,500
Levorphanol	13,000
Disopyramide	1,300
METHAMPHETAMINE (MET)	
d-Methamphetamine	50
Fenfluramine	60,000
p-Hydroxymethamphetamine	400
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine (MDMA)	50
l-Phenylephrine	4,000
Procaine	2,000
(1R,2S)- (-) Ephedrine	400
1-Ephedrine	400
Mephentermine	800
(-) Deoxyephedrine, L-Methamphetamine	3,000
Ephedrine	800
4-Methylethcathinone hydrochloride	25,000
Ethylone hydrochloride	25,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	100
(+/-)-Methylenedioxyamphetamine(MDA)	25,000
D,L-Methamphetamine	4,000
(±)-Amphetamine	10,000
Acetylsalicylic	4,000
Chlorothiazide	25,000
R(-)-Methamphetamine	400
METHAQUALONE (MQL 100)	
Methaqualone	
METHAQUALONE (MQL 150)	100
Methaqualone **METHYLENEDIOXYPYROVALERONE (MDPV 50)** Methylenedioxypyrovalerone	
Butylone	150
Ethylone	
Methylone	50
Brompheniramine	4,000
Methedrone	50 11,000
Naphyrone	800 5,000
Flephedrone	>100,000
METHYLENEDIOXYPYROVALERONE (MDPV 100)	>100,000
Methylenedioxypyrovalerone	
Butylone	
Ethylone	
Methylone	100 5,000
Brompheniramine	50 10,000
Methedro ne	1,000
Nap hyro ne	5,000
Fl ephedro ne	>100,000
MORPHINE(MOP)	>100,000
Morphine	
Codeine	
	15
	15

Drug Compound	Concentration (ng/mL)
Ethyl morphine	15
Hydromorphone	50
Hydrocodone	50
Morphine 3-β-d-glucuronide	30
Nalorphine	300
Oxymorphone	25,000
Thebaine	5,000
Diacetylmorphine (Heroin)	15
6-Monoacetylmorphine (6-MAM)	15
Oxycodone	12,500
OPIATE(OPI)	
Morphine	40
Codeine	10
Ethyl morphine	24
Hydromorphone	100
Hydrocodone	100
Levorphanol	400
Oxycodone	25,000
Morphine 3-β-d-glucuronide	50
Norcodeine	1,500
Normorphine	12,500
Nalorphine	10,000
Oxymorphone	25,000
Thebaine	1,500
Diacetylmorphine (Heroin)	50
6-Monoacetylmorphine (6-MAM)	25
Bilirubin	3,500
OXYCODONE (OXY 20)	
Oxycodone	
Dihydrocodeine HCL	20
Gatifloxacin	3,125
Hydrocodone	25,000
Hydromorphone	1,562.5
Heroin	781.25
Oxymorphone-D3	12,500
Oxymorphone	390.6
Naltrexone hydrochloride	48.8
OXYCODONE (OXY 50)	3,125
Oxycodone	
Dihydrocodeine HCL	50
Gatifloxacin	6,250
Hydrocodone	60,000
Hydromorphone	6,250
Heroin	1,562
Oxymorphone-D3	25,000
Oxymorphone	781
Naltrexone hydrochloride	100
PHENCYCLIDINE (PCP)	6,250
Phencyclidine	
Tetrahydrozoline	10
	50,000

Drug Compound	Concentration (ng/mL)
PROPOXYPHENE (PPX)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
SYNTHETIC CANNABINOID (K2 5)	
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
SYNTHETIC CANNABINOID (K2 25)	
JWH-018 5-Pentanoic acid metabolite	
JWH-073 4-butanoic acid metabolite	25
JWH-250 4-Hydroxypentyl metabolite	25
JWH-210 5-Hydroxypentyl metabolite	50,000
JWH-073 4-Hydroxybutyl metabolite	9,000
JWH-019 5-hydroxyhexyl metabolite	250
JWH-018 N-(4-hydroxypentyl) metabolite solution	800
JWH-019 6-Hydroxyhexyl	600
JWH-019 5-Hydroxyhexyl	125
MAM2201	1,000
JWH-122 5-Hydroxypentyl metabolite	50,000
APINACA 5-hydroxypentyl metabolite	1,000
JWH-122 4-Hydroxypentyl metabolite	50,000
	3,500
TRAMADOL (TRA)	
Tramadol	50
N-desmet hyl tramadol	260
O-desmet hyl tramadol	12,000
TRICYCLICANTIDEPRESSANTS (TCA)	
Nortri ptyli ne	100
Amitriptyline	250
Clomipramine	5,000
Desipramine	20
Doxepin	30
Imipramine	2,000
Maprotiline	10,000
Nordoxepin	1,500
Promazine	6,000
Promethazine	500
Trimipramine	5,000
Cyclobenzaprine Hydrochloride	500
Norclomipramine	5,000

Alcohol Test

TheAlcoholtest 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.

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 Mini Cube when tested at concentrations up to 100 g/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diclofenac	Loperamide	d-Pseudoephedrine
Acetophenetidin	Dicyclomine	Meprobamate	Quinacrine
Acetylsalicylic acid	Diflunisal	Methylphenidate	Quinine
Aminopyrine	Digoxin	Nalidixic acid	Quindine
Amoxicillin	Diphenhydramine	Naproxen	Ranitidine
Ampicillin	-Estradiol	Niacinamide	Salicylic acid
Amitriptyline	Ethyl-p-aminobenzoate	Nifedipine	Sulfamethazine
Ascorbic acid	l-Epinephrine	Nimesulide	Sulindac
Apomorphine	Erythromycin	Norethindrone	Tetracycline
Aspartame	Fenoprofen	Noscapine d,l-	Tetrahydrocortisone
Atropine	Furosemide	Octopamine	3-acetate
Benzilic acid	Gentisic acid	Oxalic acid	Tetrahydrocortisone
Benzoic acid	Hemoglobin	Oxolinic acid	3 (-d-glucuronide)
Benzphetamine	Hydralazine	Oxymetazoline	Theophylline
Caffeine	Hydrochlorothiazide	Papaverine	Thiamine
Chloral hydrate	Hydrocortisone	Penicillin-G	Thioridazine
Chloramphenicol	o-Hydroxyhippuric acid	Pentazocine	d,l-Tyrosine
Chlorothiazide	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 Test Mini Cube 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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2. Schramm W., *et al*. Drugs of Abuse in Saliva: A Review. *J Anal Tox*, 16 (1): 1-9, 1992. Kim L, *et al*. Plasma and oral fluid pharmacokinetics and pharmacodynamics after oral codeine administration. *ClinChem*, 48 (9): 1486-96, 2002.
3. Kang GI and Abbott FS. Analysis of methadone and metabolites in biological fluids with gas chromatography-mass spectrometry. *J Chromatogr*. 231 (2); 311-319. Sept 1982.
4. McCarron MM, *et al*. Detection of Phencyclidine Usage by Radioimmunoassay of Saliva. *J Anal Tox*. 8 (5):197-201, 1984.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EU REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2~30°C	LOT	Lot Number	REF	Catalog#
					Manufacturer

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