EliteScreen Oral Cube™

Oral Fluid Drug and Alcohol Screen Device

Package insert for the AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2/MDMA/ALCO test for oral fluids. A rapid, screening test for the simultaneous, qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Synthetic Cannabinoid, Methylenedioxymethamphetamine, Alcohol and their metabolites in human oral fluid.

For Forensic Use Only

INTENDED USE

The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2/MDMA/ALCO is a lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates, Buprenorphine, Cotinine, Synthetic Cannabinoid, Methylenedioxymethamphetamine, Alcohol and their metabolites in oral fluids at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	50 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	50 ng/mL
Cocaine (COC)	Benzoylecgonine	20 ng/mL
Opiate (OPI)	Morphine	40 ng/mL
Marijuana (THC)	Δ^9-THC	50 ng/mL
Phencyclidine (PCP)	Phencyclidine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	10 ng/mL
Oxycodone (OXY)	Oxycodone	20 ng/mL
Methadone (MTD)	Methadone	30 ng/mL
Barbiturates (BAR)	Butalbital	50 ng/mL
Buprenorphine (BUP)	Buprenorphine	5 ng/mL
Cotinine (COT)	Cotinine	30 ng/mL
Synthetic Cannabinoid (K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	10 ng/mL
Methylenedioxymethamphetamine (MDMA)	(±)-3,4-Methylenedioxymethamphetamine	50 ng/mL
Alcohol (ALCO)	Alcohol	>0.02 % B.A.C.

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. "For Forensic Use Only" does not apply to any workplace testing or other non-law enforcement testing, regardless of whether or not that testing is conducted under other federal agency (e.g., Department of Transportation) authority.

SUMMARY AND EXPLANATION OF THE TEST

The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2/MDMA/ALCO and 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. 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 and up to 72 hours after use[1].

The Amphetamine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Amphetamine concentration in oral fluid exceeds 50 ng/mL.

METHAMPHETAMINE (mAMP)
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 and up to 72 hours after use[1].

The Methamphetamine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Methamphetamine concentration in oral fluid exceeds 50 ng/mL.

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[1]. Cocaine and benzoylecgonine can be detected in oral fluids for up to 24 hours after use[1].

The Cocaine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Benzoylecgonine concentration in oral fluid exceeds 20 ng/mL.

OPIATE (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. Opiate 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 cut-off 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[2]. 6-monoacetylmorphine (6-MAM) is found more prevalently in oral fluid and is a metabolic product of heroin. Morphine is the major metabolic product of codeine and heroin and is detectable for 24-48 hours after an opiate dose.

The Opiate assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Morphine concentration in oral fluid exceeds 40 ng/mL.

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[3]. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use[3].

The Marijuana assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Δ^9-THC concentration in oral fluid exceeds 50 ng/mL.

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].

The Phencyclidine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Phencyclidine concentration in oral fluids exceeds 10 ng/mL.

BENZODIAZEPINES (BZO)
Benzodiazepines are frequently prescribed sedative and hypnotic drug for the symptomatic treatment of anxiety, insomnia, sleep and seizure disorders. Most Benzodiazepines are extensively metabolized in the liver and excreted in the urine and saliva as metabolites. Chronic abuse may increase the risk of physical dependence and may result in intoxication, drowsiness and muscle relaxation. Oxazepam is the major metabolic product of Benzodiazepines.

The Benzodiazepines assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Oxazepam concentration in oral fluids exceeds 10 ng/mL.

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.

The Oxycodone assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Oxycodone concentration in oral fluid exceeds 20 ng/mL.

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). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone. Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight 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. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists[5].

The Methadone assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Methadone concentration in oral fluids exceeds 75 ng/mL.

BARBITURATES (BAR)
Barbiturates are CNS 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.
The approximate detection time limits for barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days
Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days[5]

The Barbiturates assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Butalbital concentration in oral fluid exceeds 50 ng/mL.

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.

The Buprenorphine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Buprenorphine concentration in oral fluid exceeds 5 ng/mL.

COTININE (COT)
Cotinine ((5S)-1-methyl-5-(3-pyridyl)pyrrolidin-2-one) is a first-stage metabolite of nicotine, an alkaloid that stimulates the autonomic ganglia and central nervous system 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. Aside from tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. Once converted from Nicotine, Cotinine has an in vivo half-life in human body for approximately 20 hours and is typically detectable for several days and up to one week after the use of tobacco. The level of cotinine in the blood, urine or saliva is proportionate to the amount of exposure to tobacco smoke. Cotinine, therefore, is a valuable indicator of tobacco smoke exposure, including secondary or passive smoke. People who smoke menthol cigarettes may retain cotinine in the blood for a longer period because menthol can compete with enzymatic metabolism of cotinine[7]. Genetic encoding of liver enzymes may also play a role, as people of African descent routinely register higher blood cotinine levels than Caucasians[8], Cotinine levels <10 ng/mL are considered to be consistent with no active smoking. Values of 10 ng/mL to 100 ng/mL are associated with light smoking or moderate passive exposure, and levels above 300 ng/mL are seen in heavy smokers who smoke more than 20 cigarettes a day. Values between 11 ng/mL and 30 ng/mL may be associated with light smoking or passive exposure, and levels in active smokers typically reach 500 ng/mL or more. Cotinine assays provide an objective quantitative measure that is more reliable than smoking histories or counting the number of Cotinine also permits the measurement of exposure to second-hand smoke or passive smoking. Various types of drug tests can detect cotinine in the blood, urine, or saliva. Cotinine level in saliva has been found to be the best marker for smoking status compared with saliva nicotine measurements, breath carbon monoxide testing and plasma thiocyanate testing[9].

The Cotinine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Cotinine concentration in oral fluid exceeds 30 ng/mL.

SYNTHETIC CANNABINOID (K2)
Synthetic Cannabinoid is a hallucinogen found as a mixture of herbs and spices that is typically sprayed with a synthetic compound chemically similar to THC, the psychoactive ingredient in marijuana. Since 2004, it has been sold in Switzerland, Austria, Germany and other European countries via internet shops without age restriction, attracting younger people. It is typically sold in small bags of dried leaves, resembling potpourri, and smoked in joints or pipes. Its psychological effects are similar to those of marijuana and include paranoia, panic attacks and giddiness. K2 can also cause an increased heart rate and increase of blood pressure. It appears to be stored in the body for long periods of time and the long-term effects on humans are not fully known.

The Synthetic Cannabinoid assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the concentration of JWH-018 Pentanoic Acid and JWH-073 Butanoic Acid in oral fluid exceeds 10 ng/mL.

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). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The Methylenedioxymethamphetamine assay contained within the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** yields a positive result when the Methylenedioxymethamphetamine concentration in oral fluid exceeds 50 ng/mL.

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

PRINCIPLE

(1) The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2/MDMA 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.

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

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3C = O + H_2O_2$$

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

During testing, oral fluid is collected on the alcohol pad and saturates the alcohol pad. If no alcohol is present in the oral fluid, the alcohol pad remains colorless (remains white or cream color) because there is no alcohol in the oral fluid to react with enzymes to start the color reaction. If alcohol is present in the oral fluid, the alcohol pad changes to green or blue color because the alcohol reacts with alcohol oxidase to produce aldehyde and peroxide. The peroxide reacts with peroxidase in the presence of hydrogen donor to produce a blue color. Therefore, the presence of green to blue color at the alcohol pad window indicates a presumptive result for alcohol.

REAGENT

(1) 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, Methamphetamine, Benzoylecgonine, Morphine, Marijuana, Phencyclidine, Oxazepam, Oxycodone, Methadone, Butalbital , Buprenorphine, Cotinine, Synthetic Cannabinoid and Methylenedioxymethamphetamine.

(2) The alcohol pad contains Tetramethylbenzidine, Alcohol Oxidase, Peroxidase, Buffer and Stabilizing Proteins.

PRECAUTIONS

- For Forensic Use Only.
- Do not use after the expiration date.
- The Oral Fluid Drug and Alcohol Screen Device should remain in the sealed pouch until use.
- Saliva is not classified as biological hazard unless derived from a dental procedure.
- The test device is for single use.
- The used collector and device should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test is stable through the expiration date printed on the sealed pouch. The test devices 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 assay. Oral fluid collected at any time of the day may be used.

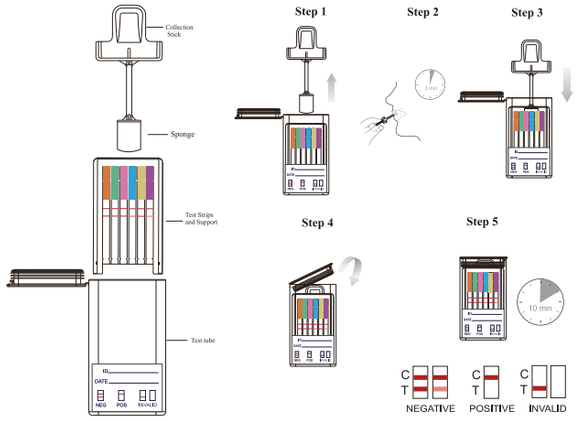
MATERIALS

Materials Provided
• Test devices • Package insert • Procedure card • Color chart card for alcohol interpretation (when applicable)
Materials Required But Not Provided
• Timer

DIRECTIONS FOR USE

Allow the test device to reach room temperature [15-30°C (59-86°F)] prior to testing. Do not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection of oral fluid specimen.

1. Remove the collection stick and test tube from the sealed pouch.
2. Tear off the package of the collection stick. (Step 1)
3. Insert the sponge end of the collection stick into mouth and soak sponge into saliva for 3 minutes. (Note: Time should be longer for people of little saliva. If the amount of saliva pressed into the test tube is not adequate for testing, collect more with another new collection stick and express the saliva into tube again.) (Step 2)
4. Hold the test tube vertically and place the collection stick with saturated sponge into the test tube. Make sure to fit the groove of collection stick onto the guide rail of test tube and press the collection stick to full extent. (Step 3)
5. Press down the lid to close the test tube. Keep the test tube vertically until you begin to read the test results. (Step 4)
6. Read results of alcohol test at 2 minutes and drug tests at 10 minutes. (If there is a label over reading window, peel off the label to read test results.) **Do not read alcohol test result after 5 minutes and drug tests results after 15 minutes.** (Step 5)
7. Send the collector with collected oral fluid to the laboratory for GC/MS confirmation if necessary.



INTERPRETATION OF RESULTS

(Please refer to the previous illustration)
NEGATIVE:
Two lines appear. * One color line should be in the control region (C), and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.
*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

POSITIVE:
One color line appears in the control region (C). No line appears in the test region (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 device. If the problem persists, discontinue using the lot immediately and contact your supplier.

ALCOHOL TEST RESULTS
(Please refer to the alcohol color chart)
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 most 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 result 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 color 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.

LIMITATIONS

1. The ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** 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 preferred confirmatory methods.
2. A positive test result does not indicate the concentration of drug in the specimen or the route of administration.
3. 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 assay.
4. The test has been developed for testing saliva samples only. No other fluids have been evaluated. Do NOT use this device to test anything else but saliva.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off and tested with the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device***. The results are summarized below.

Drug Concentration Cut-off Range	n	AMP		mAMP		COC		OPI		THC		PCP		BZO		OXY		MTD		BAR		BUP		COT		K2		MDMA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	10	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	10	0	30	0
-25% Cut-off	30	28	2	29	1	30	0	27	3	29	3	30	0	29	1	28	2	30	0	30	0	27	3	29	1	10	0	29	1
Cut-off	30	13	17	16	14	19	11	18	12	18	12	20	10	12	18	12	18	2	28	1	29	16	14	20	10	0	10	5	25
+25% Cut-off	30	4	36	7	23	5	25	3	37	0	30	7	23	1	29	3	27	0	30	0	30	7	23	7	23	0	10	0	30
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	10	0	30

For alcohol test, saliva was obtained by rinsing with positive ethanol control solutions at various B.A.C. (0.02 %, 0.08 %, 0.15 %, and 0.30 %). Negative saliva was used to test at 0.00% concentration. For each concentration, a total of 15 tests were performed to validate the test performance. The results of the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** are summarized below.

Test	Total # of Test/ Concentration	B.A.C.									
		0.00 %		0.02 %		0.08 %		0.15 %		0.30 %	
		-	+	-	+	-	+	-	+	-	+
Alcohol	15	15	0	1	14	0	15	0	15	0	15

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) above which the ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** for AMP/mAMP/COC/OPI/THC/PCP/BZO/OXY/MTD/BAR/BUP/COT/K2/MDMA identified positive results at a read time of 10 minutes.

Drug	Concentration (ng/mL)
AMPHETAMINE (AMP)	
D-Amphetamine	50
DL-Amphetamine	125
β-Phenylethylamine	4,000
(+)3,4-Methylenedioxyamphetamine (MDA)	150
L-Amphetamine	4,000
p-Hydroxyamphetamine	800
Tryptamine	1,500
Tyramine	1,000
METHAMPHETAMINE (mAMP)	
D-Methamphetamine	50
(1R,2S)-(-)-Ephedrine	400
Fenfluramine	60,000
Methoxyphenamine	25,000
3,4-Methylenedioxymethamphetamine	50
p-Hydroxymethamphetamine	400
L-Phenylephrine	4,000
Procaine	2,000
COCAINE (COC)	
Benzoylecgonine	20
Cocaine HCl	20
Cocaethylene	25
Ecgonine HCl	1,500
Ecgonine Methyl Ester	12,500
OPIATE (OPI)	
Morphine	40
Bilirubin	3,500
Codeine	10

Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	100
Hydromorphone	100
Levorphanol	400
6-Monoacetylmorphine	25
Morphine 3-β-D-Glucuronide	50
Nalorphine	10,000
Normorphine	12,500
Norcodeine	1,500
Oxycodone	25,000
Oxymorphone	25,000
Thebaine	1,500
PHENCYCLIDINE (PCP)	
Phencyclidine	10
Tetrahydrozoline	50,000
BENZODIAZEPINES (BZO)	
Oxazepam	10
Alprazolam	40
Bromazepam	400
Chlordiazepoxide	780
Chlordiazepoxide HCl	390
Clobazam	100
Clonazepam	785
Clorazepate Dipotassium	195
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	385
(±) Lorazepam	1,560
RS-Lorazepam Glucuronide	160
Midazolam	12,500
Nitrazepam	95
Norchlordiazepoxide	200
Nordiazepam	390
Oxazepam	50
Temazepam	20
Triazolam	2,500
α-Hydroxyalprazolam	1,260
OXYCODONE (OXY)	
Oxycodone	20
Codeine	25,000
Dihydrocodeine	6,250
Ethylmorphine	12,500
Hydrocodone	1,000
Hydromorphone	6,250
Oxymorphone	1,000
Thebaine	25,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9-COOH	12
Cannabinol	3,000
Δ^8-THC	50
Δ^9-THC	50
METHADONE (MTD)	
Methadone	30
Doxylamine	12,000
BARBITURATES (BAR)	
Butalbital	50
Alphenal	100
Amobarbital	150
Aprobarbital	100
Butabarbital	75
Secobarbital	50
Butethal	100
Cyclopentobarbital	500
Pentobarbital	300
Phenobarbital	100
BUPRENORPHINE (BUP)	
Buprenorphine	5
Norbuprenorphine	20
Buprenorphine 3-D-Glucuronide	15
Norbuprenorphine 3-D-Glucuronide	200
COTININE (COT)	
(-)-Cotinine	30
S-(-)-Nicotine	6,250
L-Glutathione Reduced	40,000
SYNTHETIC CANNABINOID (K2)	
JWH-018 5-Pentanoic Acid Metabolite	10
JWH-073 4-Butanoic Acid Metabolite	10
MAM2201 N-Pentanoic Acid Metabolite	200
JWH-398 N-Pentanoic Acid Metabolite	400
JWH-210 N-(5-Carboxypentyl) Metabolite	2,500
JWH-073 3-Hydroxybutyl Metabolite	2,500
JWH-018 N-4-Hydroxypentyl	8,000
JWH-073 4-Hydroxybutyl Metabolite	40,000
JWH-019 5-Hydroxyhexyl Metabolite	40,000
JWH-018 5-Hydroxypentyl Metabolite	45,000
JWH-122 5-Hydroxypentyl Metabolite	50,000
JWH-122 4-Hydroxypentyl Metabolite	50,000
JWH-019 6-Hydroxyhexyl Metabolite	50,000
RCS-4 N-(5-Carboxypentyl) Metabolite	50,000
Trifluoperazine Dihydrochloride	50,000
Trifluoperazine Hydrochloride	70,000
2,4,6-Trimethylbenzamide	100,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
(±)-3,4-Methylenedioxymethamphetamine	50
Dobutamine Hydrochloride	60,000
p-Hydroxymethamphetamine	15,000
(+)3,4-Methylenedioxyamphetamine	1,500

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.

INTERFERENCE

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 Cube™ Oral Fluid Drug and Alcohol Screen Device*** when tested with concentrations up to 100 µg/mL.

Amphetamine, Methamphetamine, Cocaine, Opiate, Marijuana, Phencyclidine, Benzodiazepines, Oxycodone, Methadone, Barbiturates and Buprenorphine Non-Cross-Reacting Compounds Are:
*Parent compound only:

Chlorothiazide
DL-Chlorpheniramine
Chlorpromazine
Chloroquine
Chlorothiazide
Norethindrone
D-Norpropoxyphene
Noscapine
DL-Octopamine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
L-Ψ-Ephedrine
β-Estradiol
Estrone-3-Sulfate
Ethyl-p-Aminobenzoate
L-(-)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic Acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
o-Hydroxyhippuric Acid
p-Hydroxytyramine
Ibuprofen
Iproniazid
DL-Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Meperidine
Methylphenidate
Nalidixic Acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Oxalic Acid
Oxolinic Acid
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine Hydrochloride
Perphenazine
Phenelzine
Trans-2-Phenylcyclopropylamine Hydrochloride
Phenylpropanolamine
Prednisolone
Prednisone
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinine
Quinidine
Ranitidine
Salicylic Acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Tetrahydrocortisone 3-Acetate
Tetrahydrocortisone 3 (β-D-Glucuronide)
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
DL-Tryptophan
Uric Acid
Verapamil
Zomepirac

Cotinine Non-Cross-Reacting Compounds Are:
*Parent compound only:

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic Acid
Amoxicillin
Amphetamine Sulfate
Ampicillin
L-Ascorbic Acid
Apomorphine
Aspartame
Atropine
Cholesterol
Clonidine
Codeine
Cortisone
Benzoylecgonine
Benzoic Acid
Benzphetamine
Caffeine
Chloramphenicol
Chlorothiazide
Chlorpromazine
Chloroquine
Cocaine Hydrochloride
Norethindrone
D-Norpropoxyphene
Noscapine
DL-Octopamine
Creatinine
Dextromethorphan
Diflunisal
Digoxin
L-Ψ-Ephedrine
β-Estradiol
Estrone-3-Sulfate
Ethyl-p-Aminobenzoate
L-(-)-Epinephrine
Erythromycin
Fenoprofen
Furosemide
Gentisic Acid
Hemoglobin
Heroin
Hydralazine
Hydrochlorothiazide
Hydrocortisone
Ibuprofen
Isoxsuprine
Ketamine
Labetalol
Loperamide
Methadone
Methamphetamine
Meperidine
Meprobamate
Methylphenidate
Morphine
Nalidixic Acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Oxymetazoline
Papaverine
Penicillin-G
Perphenazine
Phencyclidine
Phenelzine Hydrochloride
Phenylpropanolamine
Prednisolone
Prednisone
DL-Propranolol
D-Propoxyphene
D-Pseudoephedrine
Quinacrine
Quinine
Oxycodone
Ranitidine
Secobarbital
Salicylic Acid
Serotonin
Sulfamethazine
Sulindac
Tetracycline
Thiamine
Thioridazine
DL-Tyrosine
Tolbutamide
Trifluoperazine
Trimethoprim
DL-Tryptophan
Tyramine
Uric Acid
Verapamil
Zomepirac

Synthetic Cannabinoid Non-Cross-Reacting Compounds Are:
*Parent compound only:

Acebutolol Hydrochloride
Acepromazine-d6 Hydrochloride
Acetylcysteine Effervescent Tablets
Acetaminophen
o6-Acetylmorphine
Acetazolamide Tablets
N-Acetylprocainamide
Acetone
Acetophenetidin
Alprenolol Hydrochloride
Alprazolam
Allopurinol Tablets
Alphenal
Amiloride Hydrochloride Tablets
Amiodarone Hydrochloride Tablets
Amoxicillin Capsule
Ampicillin Caps (Ampicinine)
Amitriptyline Hydrochloride Tablets
Aminophylline Tablets
Amantadine Hydrochloride Tablets
Amphotericin B
Ammonium Chloride

PN:Y0311133904

Amobarbital
Amphetamine Sulfate
Amikacin Hydrate
Amikacin Sulfate Injection
4-Aminobenzoic Acid
DL-Aminoglutethimide
Aniline Hydrochloride
Antipyrine
Aprobarbital
Aspartame
L-Ascorbic Acid
L-Aspartic Acid
D-Aspartic Acid
DL-Aspartic Acid
Atropine Sulfate Injection
Baclofen Tablets
Benzphetamine
Barbituric Acid
Betamethasone Injection
Berberine Hydrochloride Tablets
Benzilic Acid
Benzocaine
Benzyl Alcohol
Benzoylecgonine
Bendroflumethiazide
Benzylamine Hydrochloride
Benzoic Acid
Bisacodyl
Bromazepam
Bromocriptine Mesylate Tablets
Bupivacaine Hydrochloride
Buprenorphine
Buspirone Hydrochloride
Butacaine
Butalbital
Butabarbital
Butyrophenone
Butethal
Cannabidiol
Caffeine
Carbamazepine Tablets
Carisoprodol
Cefaclor
Cefradine Capsules
Ceftriaxone Sodium for Injection
Cefotaxime Sodium for Injection
Cefoxitin
Cefadroxil Capsule
Cephradine
Chlordiazepoxide HCL
Chloroquine Phosphate
Chlorpheniramine Maleate Tablets
Chlorpromazine Hydrochloride Tablets
Chlorpropamide
Chlorprothixene Hydrochloride
Chlorthalidone
Chlorzoxazone Tablets
Cimetidine (Tablets)
(-)-Cinchonidine
Cinoxacin
Ciclosporin Soft Capsule
Citric Acid
Clenbuterol Hydrochloride
Clindamycin
Clobetasone Butyrate
Clomipramine Hydrochloride Tablets
Clorazepate Dipotassium
Kanamycin Sulfate

Methylenedioxymethamphetamine
Non-Cross-Reacting Compounds are:
*Parent compound only:

Acebutolol Hydrochloride
Acetopromazine-d6 Hydrochloride
Acetylcysteine
Acetylsalicylic Acid (Aspirin)
Acetaminophen
o6-Acetylmorphine
Acetazolamide
N-Acetylprocainamide
Acetone
Acetophenetidin
Alprenolol Hydrochloride
Alprazolam
Allopurinol
Alphenal
Amiloride Hydrochloride
Aminophenazone (4-Dimethylaminoantipyrine)
Amiodarone Hydrochloride
Amoxicillin
Ampicillin (Ampicinine)
Amitriptyline Hydrochloride
Aminophylline
Amantadine Hydrochloride
Amphotericin B
Ammonium
Amobarbital
Amikacin Hydrate
Amikacin Sulfate
4-Aminobenzoic Acid
DL-Aminoglutethimide
Kanamycin Sulfate
Aniline Hydrochloride
Antipyrine
R-(-)-Apomorphine Hydrochloride Hemihydrate
Aprobarbital
Aspartame
L-Ascorbic Acid
L-Aspartic Acid
D-Aspartic Acid
DL-Aspartic Acid
Atropine Sulfate
Baclofen
Benzphetamine
Barbituric Acid
Betamethasone
Berberine Hydrochloride
Beclomethasone Dipropionate Aerosol
Benzilic Acid
Benzocaine
Benzyl Alcohol
Benzoylecgonine
Bendroflumethiazide
Benzylamine Hydrochloride
Benzoic Acid
Bisacodyl
Bromazepam
Bromocriptine Mesylate
Bupivacaine Hydrochloride
Buprenorphine
Buspirone Hydrochloride
Butacaine
Butalbital
Butabarbital
Buprenorphine-3-β-D-Glucuronide
Butyrophenone
Butethal
Cannabidiol
Caffeine
Carbamazepine
Carisoprodol
Cefaclor
Cefradine
Ceftriaxone Sodium
Cefotaxime Sodium
Cefoxitin
Cefuroxime Axetil (Zinnat)
Cefadroxil
Cephradine
Chlordiazepoxide HCL
Chloroquine Phosphate
Chlorpheniramine Maleate
Chlorpromazine Hydrochloride
Chlorpropamide
Chlorprothixene Hydrochloride
Chlorthalidone
Chlorzoxazone
Chloral Hydrate (Trichloroacetaldehyde Hydrate)
Cimetidine
(-)-Cinchonidine
Cinoxacin
Cyclosporine
Citric Acid
Clenbuterol Hydrochloride
Clindamycin
Clobetasone Butyrate
Clomipramine Hydrochloride
Clorazepate Dipotassium
Clonazepam
Clobazam
Cloxacillin
Colchicine
Cholesterol
(-)-Cotinine
Cocaethylene
Cocaine Hydrochloride
Codeine
Creatinine
Cyclobenzaprine Hydrochloride
Cyclophosphamide
L-Cystine
Cyproheptadine Hydrochloride
Cyclopentobarbital
Dantrolene Sodium Salt
Dextromethorphan Hydrobromide
Dexamethasone Acetate
Deoxyepinephrine
Deferoxamine Mesylate
Desipramine Hydrochloride
Dimethyl Isosorbide
(Isosorbide Dimethyl Ether)
Diazepam
Diflorasone Diacetate
Digoxin
Diazoxide
Dieldrin
Dipyrone
Dimethyl Sulfoxide
5,5-Diphenylhydantoin
DL-3,4-Dihydroxymandelic Acid
Dihydralazine
Hemoglobin
Disopyramide
Dopamine Hydrochloride
Doxepin Hydrochloride
Doxycycline Hyclate
Doxylamine Succinate Salt
Droperidol
Ecgonine Methyl Ester
(±)-Ephedrine Hydrochloride
Erythromycin Enteric
Eserine
Estazolam
β-Estradiol
Estriol
Estrone
Estrone-3-Sulfate Potassium Salt
Etoposide
Ethacrynic Acid
Ethambutol Hydrochloride
Ethyl-p-Aminobenzoate
Ethylenediaminetetraacetic Acid
Etodolac
Ethyl Morphine
Famotidine
Fenfluramine
Ferrous(II) Sulfate Heptahydrate
Fenoprofen Calcium Salt Hydrate
Flufenamic Acid
Flunitrazepam
Flunisolide
Flurandrenolide
Flurazepam Dihydrochloride
Furosemide
Gemfibrozil
Gentamicin Sulfate Granules
Gentisic Acid
Glutathione Reduced
Glybenclamide
Glucose
Griseofulvin
Halcinonide
Heroin Hydrochloride
Hexachlorophene
Hypnovel (Cyclobarbital)
Hippuric Acid
Histamine
Hydralazine Hydrochloride
(1R,9S)-(-)-β-Hydrastine
Hydroflumethiazide
Hydromorphone
Hydrocodone
Hydroxocobalamin Hydrochloride
α-Hydroxyhippuric Acid
Hydroxyzine Dihydrochloride
α-Hydroxyalprazolam
17α-Hydroxyprogesterone
Hydrocortisone
Hydrochlorothiazide
Hypoxanthine
Triamcinolone Acetonide Ointment
Zinc Undecylenate

Alcohol Test
The following substances may interfere with ***Oral Cube™ Oral Fluid Drug and Alcohol Screen Device*** when using samples other than oral fluid:
(1) Agents which enhance color development: peroxides and strong oxidizers
(2) Agents which inhibit color development:
Reducing agents such as ascorbic acid, tannic acid, pyrogallol, mercaptans, tosylates, oxalic acid, uric acid, bilirubin, L-dopa, L-methyldopa, and methampyrone
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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