SlivaScreen Test Cup
Catalogue No.: See Box Label

For forensic use only

INTENDED USE & SUMMARY

MD SalivaScreen is a rapid visual immunoassay for the qualitative detection of drugs of abuse in human oral fluid specimens. The test system consists of up to 16 membrane strips mounted in a plastic device. This test detects combinations of the following drugs at the concentrations listed below. Specific combinations will vary according to the test in question:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	50
Barbiturate(BAR)	Secobarbital	50
Buprenorphine(BUP)	Buprenorphine	5
Benzodiazepine (BZO)	Oxazepam	10
Cocaine (COC)	Cocaine	20
Cotinine(COT)	Cotinine	50
EDDP(EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Fentanyl(FYL)	Fentanyl	10
K2	JWH-018-5 pentanoic	50
K2	JWH-018-5 pentanoic	30
Ketamine (KET)	Ketamine	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine	50
Mephedrone（MEP）	Mephedrone	100
Opiates (OPI)	Morphine	40
Opiates (OPI)	Morphine	25
Oxycodone(OXY)	Oxycodone	20
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene(PPX)	Propoxyphene	50
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	12
Marijuana (THC parent)	Δ9-THC	30/50
Alcohol（ALC）	Alcohol	0.02%/0.04% 0.08%/0.30%

AMP: Amphetamines are a class of potent sympathominetic agents with therapeutic applications. The most common amphetamines are d-amphetamine and d, l-amphetamine. Amphetamines are central nervous stimulants that cause the neurotransmitters epinephrine, norepinephrine and dopamine to be released into the brain and body giving users feelings of euphoria, alertness, and increased energy. Chronic abuse of amphetamine leads to tolerance and drug reinforcement effect. Cardiovascular responses to amphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations and psychotic behavior. Amphetamine is metabolised by a number of pathways. In general, acid urine promotes excretion whereas alkaline urine retards it. In 24 hours, approximately 79% of the amphetamine dose is excreted in acid urine and about 45% in alkaline urine. Typically, about 20% is excreted as unchanged amphetamine. Unchanged amphetamine can be detected up to 1 –2 days after use.

BAR: Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects of short-acting barbiturates, such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives and glucuronide conjugates.

BUP: Buprenorphine, a derivative of the baine, is an opioid that has been marketed in the United States as the Schedule V parenteral analgesic Buprenex. In 2003, based on a reevaluation of available evidence regarding the potential for abuse, addiction, and side effects, DEA reclassified buprenorphine from a Schedule V to a Schedule III narcotic. Buprenorphine resembles morphine structurally but has a longer duration of action than morphine and can be administrated sublingually as an analgesic. In October 2002, FDA approved the use of a buprenorphine monotherapy product, Subutex, and a buprenorphine/naloxone combination product, Suboxone, for the treatment of opioid addiction. Subutex and Suboxone are the first narcotic drugs available under the US Drug Act (DATA) of 2003 for the treatment of opiate dependence that can be prescribed in the US in a physician's work place. It has also been shown that buprenorphine has abuse potential and may itself cause dependency. In addition, a number of deaths have been recorded as a result of overdose with intravenously injected buprenorphine in conjunction with other psychotropic drugs such as benzodiazepines. Buprenorphine is metabolised primarily by n-dealkylation to form glucuronide-buprenorphine and glucuronide-norbuprenorphine.

BZO: Benzodiazepines are a class of widely prescribed central nervous system depressants which have anxiolytic, hypnotic, anticonvulsant and muscle relaxant effects. Chronic abuse can result in addiction and tardive dyskinnesia. Acute higher doses lead to drowsiness, dizziness, muscle relaxation, lethargy, coma and possible death. The effects of benzodiazepines use last 4 – 8 hours. Many of the benzodiazepines share a common metabolic route and are excreted as oxazepam and its glucuronide in urine. Oxazepam is detectable in the urine for up to 7 days after drug use.

COC: Cocaine derived from the leaves of cocoa plant, is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by cocaine are: euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of cocaine could induce tolerances and physiological dependency which leads to its abuse. Cocaine is used by smoking, intravenous, intransal or oral administration and excreted in the urine primarily as benzoylecgonine in a short period. Benzoylecgonine has a biological half-life of 5 – 8 hours, which is much longer than that of cocaine (0.5 – 1.5 hours), and can be generally detected for 12 – 72 hours after cocaine use or exposure.

COT: Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, it's elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

EDDP: EDDP 2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, because EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

FYL: Fentanyl is a synthetic opioid related to the phenylpiperidines.Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly cross the blood-brain barrier. This is reflected in the half-life for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl. The levels in plasma and cerebrospinal fluid decline rapidly owing to redistribution of fentanyl from highly perfused tissue groups to other tissues, such as muscle and fat. As saturation of less well-perfused tissue occurs, the duration of effect of fentanyl and sufentanil approaches the length of their elimination half-lives of between 3 and 4 hours. Fentanyl undergoes hepatic metabolism and renal excretion. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

K2: Synthetic cannabis is a psychoactive designer drug derived from natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis. 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 cannabis product. Studies suggest that synthetic cannabinoid 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. When synthetic cannabis blends first went on sale in the early 2000s (decade), it was thought that they achieved an effect through a mixture of legal herbs. Laboratory analysis in 2008 showed that this is not the case, and that they in fact contain synthetic cannabinoids that act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabinoids, most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug. It has been sold under various brand names, online, in head shops, and at some gas stations.

KET: Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic. Certain doses of ketamine can cause dream-like states and hallucinatioins. In high doses, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolised in the liver and excreted through the kidney. The half-life of ketamine in the body is around three hours.

MDMA: MDMA Methylenedioxymethamphetamine (Ecstasy) is a designer drug first synthesised 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. The most pervasive effect of MDMA, occurring in almost all people who have taken a reasonable dose of the drug, is to produce a clenching of the jaws.

MET: Methamphetamine is the most popular synthetic derivative of the amphetamines. It is a potent sympathomimetic agent with therapeutic applications. Acute large doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. More acute response produces anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. Methamphetamine is excreted in the urine as amphetamine and oxized and deaminated derivatives. However, 10-40% of methamphetamine is excreted unchanged. Methamphetamine is generally detectable in the urine for 3 to 5 days after use.

MTD: Methadone is a synthetic opioid, clinically available. It is used clinically for the treatment of severe pain and in maintenance programs for morphine and heroine addicts. Methadone acts on the central nervous and cardiovascular systems to produce respiratory and circulatory depression. Methadone also produces miosis and increases the tone of smooth muscle in the lower gastrointestinal tract while decreasing the amplitude of contractions. Acute higher doses induce analgesia, sedation, respiratory depression and coma. After methadone administration, the major urinary excretion products are methadone and its metabolites, EDDP and EMDP. Large individual variations in the urine excretion of methadone are output of methadone from 5-22%. Typically, following a 5 mg oral dose, methadone and EDDP account for 5% of the dose in the 24-hour urine. In those individuals on maintenance therapy, methadone may account for 5 to 50% of the dose in the 24-hour urine and EDDP may account for 3 to 25% of the dose.

MEP: Mephedrone, also known as 4-methylmethcathinone (4-MMC) or 4-methylephedrone is a synthetic stimulant drug of the amphetamine and cathinone classes. Slang names include drone, M-CAT, White Magic and meow meow. It is chemically similar to the cathinone compounds found in the khat plant of eastern Africa. Mephedrone comes in the form of tablets or a powder, which users can swallow, snort or inject, producing similar effects to MDMA, amphetamines and cocaine. In addition to its stimulant effects, Mephedrone produces side effects, of which teeth grinding are the most common. A number of metabolites are possible, however the n-demethyl metabolite of Mephedrone will be 4-Methylcathinone. This metabolite appears to be nearly inactive as a Monoamine Oxydase Inhibitor .On further metabolism of this metabolite one of the possible metabolites is 4-Methylnorephedrine, caused by the reduction of the Keto.A dose of 150mg-250mg is the average, giving a duration of around 2 hours.the duration will lengthen in larger 250mg+ dosages .

OPI: Opioid analgesics comprise of a large group of substances that control pain by depressing the central nervous system. Acute high dose used by abusers or addicts can cause depressed coordination, disrupted decision, decreased respiration, hypothermia and coma. Morphine is excreted unmetabolised and is the marker metabolic product of opiates. Morphine and morphine glucuronide is detectable in urine for several days after an opiate dose.

OXY: Oxycodone is known as Oxycontin, Roxicodone and is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiate derived from opium. Like other opiates, oxycodone is characterised by its analgestic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and stripiac arrest. Oxycodone is metabolised by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of oxycodone is excreted in a 24 hour urine collection and consists of 13-19% free oxycodone, 7-29% glucuronide conjugated oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of oxycodone is 1-3 days following use.

PCP: Phencyclidine commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even a moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high does, from 100 to500 ng/ml, PCP can cause convulsions, hypertion, prolonged coma, absent peripheral sensation, and even death. PCP is metabolised via hydroxylation, oxidation, and conjugation with glucuronic acid in the liver. About 10% of the does is excreted in urine as unchanged drug. For chronic users, PCP can be detected in the urine for 7 to 8 days after drug administration.

PPX: Propoxyphene is a prescription drug for the relief of pain. Although slightly less selective than morphine, Propoxyphene binds primarily to opioid receptors and produces analgesia and other CNS effects that are similar to those seen with morphine-like opioids. It is likely that at equianalgesic doses the incidence of side effects such as nausea, anorexia, constipation, abdominal pain, and drowsiness are similar to those of codeine. After oral administration, concentrations of Propoxyphene in plasma reach their highest values at 1 to 2 hours. There is great variability between subjects in the rate of clearance and the plasma concentrations that are achieved. The percentage of excreted unchanged Propoxyphene in urine is less than 1%. In humans, the major route of metabolism is N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent Propoxyphene (6 to 12 hours), and its accumulation with repeated doses may be responsible for some of the observed toxicity.

THC: THC The agents of Marijuana that cause various biological effects in humans are called cannabinoids. Cannabinoid is a central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short term memory, and produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increased heart rate. Large doses of cannabinoids could cause the development of tolerances and physiological dependency and lead to abuse. A tolerance to the cardiac and psychotropic effects can occur and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea. Δ^9-THC is the primary active ingredient in cannabinoids. The main metabolite excreted in the urine is 11-nor-Δ^9-THC-9-COOH, which are found within hours of exposure and remain detectable in the urine for 3-10 days after smoking.

ALC

: Acute alcohol intoxication can lead to loss of alertness, coma, and even death. Long term effects include internal organ damage and birth defects. The blood alcohol concentration (BAC) at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. Since urine alcohol concentration is normally higher than that in saliva and blood, the cutoff concentration for alcohol in urine is set at 0.04%.

PRINCIPLE

MD SalivaScreen 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.

Saliva Alcohol Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

MATERIALS

Materials Provided

- Individually packed screening devices
- Oral fluid collection swabs
- Package insert

Materials Required but Not provided

- Timer
- Positive and negative controls

PRECAUTIONS

- For forensic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore, recommended that these products be treated as potentially infectious, and handled by observing usual safety precautions (e.g., do not ingest or inhale).
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in the area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

STORAGE AND STABILITY

- The kit should be stored at 36-86°F (2-30°C) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Kits should be kept out of direct sunlight.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

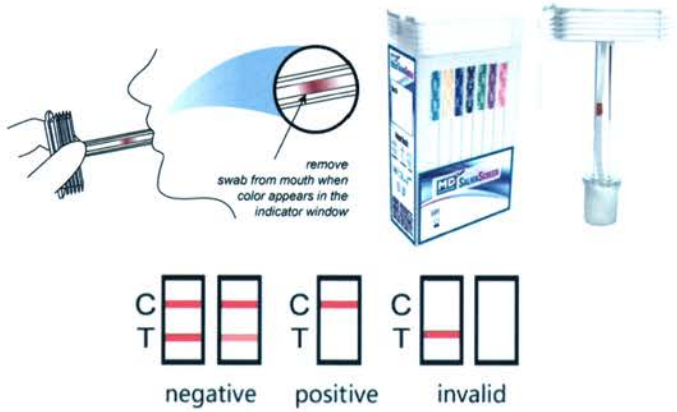
SPECIMEN COLLECTION AND STORAGE

- MD SalivaScreen Test Cup is intended for use with human oral fluid specimens only.
- Oral fluid specimens must be collected according to the directions in the Procedure section of this package insert.
- Perform testing immediately after specimen collection.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

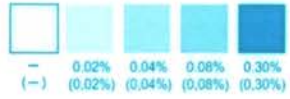
DIRECTIONS FOR USE

Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) 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 assay.
- Instruct the donor to not place anything in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.
- Bring tests, specimens, and/or controls to room temperature (60-86°F or 15-30°C) before use.
- Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, and tongue) several times, and 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: After 7 minutes, proceed with the test below, even if color on the saturation indicator strip has not appeared in the indicator window
- Remove the collection swab from the mouth and insert it, sponge first, into the screening device. Press cap down tightly until fully locked.
- Test device upright on flat surface and keep upright while test is running. Wait for the colored bands to appear in test results area. Read results at 10 minutes. Do not interpret the result after 20 minutes.
- NOTE: Once the collection swab locks in place, the device is airtight, tamper evident, and ready to be disposed or sent to lab for confirmation (on presumptive positive result).



For ALC, read result at 3min ,



Other Drug Tests , read result at 10min

INTERPRETATION OF RESULTS

(See previous illustration)

POSITIVE: Only one colored band appears, in the control region (C). No colored band appears in the test region (T) for the drug in question. A positive result indicates that the drug concentration exceeds the detectable level.

NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T) for the drug in question. A negative result indicates that the drug concentration is below the detectable level.

INVALID: Control band fails to appear. Results from any test which has not produced a control band (C) at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region (T) should be considered negative. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

Alcohol Test Results

Positive: The One Step Saliva Alcohol Test will produce a color change in the presence of saliva alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The One Step Saliva Alcohol Test is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% relative blood alcohol.

Negative: When the One Step Saliva Alcohol Test shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying saliva sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. 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. MD SalivaScreen is for forensic use, and should be only used for the qualitative detection of drugs of abuse in oral fluid.
2. This assay provides a preliminary analytical test result only. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
3. There is a possibility that technical or procedural errors as well as other substances and factors may interfere with the test and cause false results.
4. A positive result indicates the presence of a drug/metabolite only, and does not indicate or measure intoxication.
5. A negative result does not at any time rule out the presence of drugs/metabolites in saliva, as they may be present below the minimum detection level of the test.
6. This test does not distinguish between drugs of abuse and certain medications.

Limitation of ALC test:

1. Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
2. The Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

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 MD SalivaScreen. The results are summarized below.

Drug Conc. (Cut-off range)	n	AMP		BAR		BUP		BZO		COC	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	27	3	28	2	30	0	29	1
Cut-off	30	12	18	9	21	11	19	14	16	12	18
+25% Cut-off	30	2	28	3	27	8	22	4	26	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	COT		EDDP		FYL		K2 50		K2 30	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	22	8	26	4	26	4
Cut-off	30	11	19	13	17	12	18	10	20	10	20
+25% Cut-off	30	1	29	2	28	2	28	3	27	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	KET		MTD		MET		MDMA		MEP	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	30	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	30	30	0
-25% Cut-off	30	27	3	30	0	30	0	25	5	20	10
Cut-off	30	9	21	10	20	13	17	14	16	8	22
+25% Cut-off	30	3	27	2	28	3	27	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	0	0	30

Drug Conc. (Cut-off range)	n	OPI 40		OPI 25		OXY		PCP		PPX	
		-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	28	2	26	4	28	2	28	2	30	0
Cut-off	30	10	20	13	17	10	20	11	19	10	20
+25% Cut-off	30	9	21	9	21	4	26	5	25	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)	n	THC 12		THC parent30		THC parent50	
		-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	30	0
Cut-off	30	10	20	10	20	10	20
+25% Cut-off	30	5	25	5	25	4	26
+50% Cut-off	30	0	30	0	30	0	30

Analytical-Specificity

The following table lists the concentrations of compounds (in ng/ml) above which MD SalivaScreen Test Cup identified positive results at 10 minutes.

Amphetamine (AMP 50)	
D-Amphetamine	50
L-Amphetamine	4000
(+)-3,4-Methylenedioxyamphetamine (MDA)	150
Phentermine	40000
PMA	125
Tyramine	3000
Barbiturate (BAR 50)	
Secobarbital	50
Allobarbital	200
Alphenal	100
Amobarbital	100
Aprobarbital	30
Butabarbital	15
Butalbital	400
Butethal	30
Cyclopentobarbital	60
Pentobarbital	150
Phenobarbital	300
Buprenorphine (BUP 5)	
Buprenorphine	5
Buprenorphine Glucuronide	10
Buprenorphine–3–β–D–Glucuronide	5
Norbuprenorphine	10
Norbuprenorphine–3–β–D–Glucuronide	200
Benzodiazepine (BZO 10)	
Oxacepam	10
Alprazolam	15
Bromazepam	8
Chlordiazepoxide	10
Clonazepam	40
Clorazepate	20
Clbazam	6
Diazepam	15
Estazolam	10
Desalkyflurazepam	8
Flunitrazepam	10
Flurazepam	10
Lorazepam	20
Medazepam	10
Nitrazepam	10
Nordiazepam	6
Prazepam	20
Temazepam	8
Triazola	15
Cocaine (COC 20)	
Cocaine	20
Benzoylecgonine	200
Ecgonine	100000
Ecgonine methyl ester	10000
Cotinine (COT 50)	
Cotinine	50
Buprenorphine	>100,000
EDDP (EDDP 20)	
EDDP	20
Meperidine	20000
Methadone	20000
Norfentanyl	20000
Phencyclidine	20000
Promazine	10000
Promethazine	5000
Prothipendyl	10000
Fentanyl (FYL 10)	
Fentanyl	10
K2 50	
JWH-018 5-pentanoic	50
JWH-073 4-Butanoic	50
K2 30	
JWH-018-5 pentanoic	30
JWH-073-4 Butanoic	30
JWH-250 5-Hydroxypentyl	>10,000
Ketamine (KET 50)	
Ketamine(KET)	50
Norketamine	50

Methadone (MTD 30)	
Methadone	30
Alpha-Methadol	125
Biperiden	80000
Doxylamine	12500
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrolidin e (EDDP)	10000
Phencyclidine	12500
Pheniramine	25000
MET (MET 50)	
D-Methamphetamine	50
Fenfluramine	3000
L-Methamphetamine	500
L-Phenylephrine	2500
MDEA	400
3,4-Methylenedioxymethamphetamine (MDMA)	75
Mephentermine	200
PMMA	50
Procaine	2500
Ecstasy (MDMA 50)	
3,4-Methylenedioxymethamphetamine(MDMA)	50
3,4-Methylenedioxyamphetamine (MDA)	250
3,4-Methylenedioxyethylamphetamine (MDEA)	60
Paramethoxyamphetamine (PMA)	1600
Paramethoxymethamphetamine(PMMA)	160
MEP (MEP 100)	
Mephedrone	100
Opiates (OPI 40)	
Morphine	40
Codeine	50
Diacetylmorphine (Heroin)	50
Ethylmorphine	24
Hydrocodone	50
Hydromorphone	100
6-Monoacetylmorphine (6-MAM)	25
Morphine-3- β-d-glucuronide	50
Nalorphine	10000
Oxycodone	25000
Oxymorphone	25000
Thebaine	5000
Opiates(OPI 25)	
Morphine	25
Codeine	8
Diacetylmorphine (Heroin)	30
Ethylmorphine	15
Hydrocodone	25
Hydromorphone	80
6-Monoacetylmorphine (6-MAM)	15
Morphine-3- β-d-glucuronide	40
Nalorphine	8000
Oxycodone	15000
Oxymorphone	15000
Thebaine	3000
Oxycodone (OXY 20)	
Oxycodone	20
Hydrocodone	500
Hydromorphone	3000
Naloxone	3000
Oxymorphone	20
Phencyclidine (PCP 10)	
Phencyclidine (PCP)	10
Hydrocodone	2000
Hydromorphone	2000
Morphine-3- β-d-glucuronide	20000
Nalorphine	10000
Propoxyphene (PPX 50)	
Propoxyphene (PPX)	50
D-Norpropoxyphene	200
Marijuana (THC 12)	
11-nor-Δ9 -THC-9 COOH	12
Δ8-Tetrahydrocannabinol	2000
Δ9-Tetrahydrocannabinol	4000
11-hydroxy-Δ9 -THC	300
Marijuana (THC parent30)	
Δ9-Tetrahydrocannabinol	30

Dextromethorphan	25
Dextrorphan tartrate	25
D-Norpropoxyphene	1560
Meperidine	750
Mephentermine hemisulfate salt	1000
D-Methamphetamine	750
3,4-Methylenedioxyethylamphetamine (MDEA)	1500
Nordoxepin hydrochloride	1500
Phencyclidine	250
Promazine	400
Promethazine	1250

Δ8-Tetrahydrocannabinol	40
11-nor-Δ9-THC-9 COOH	8
11-hydroxy-Δ9 -THC	150
Cannabinol	1000
Cannabidiol	>10,000
Marijuana (THC parent50)	
Δ9-Tetrahydrocannabinol	50
Δ8-Tetrahydrocannabinol	75
11-nor-Δ9 -THC-9 COOH	12
11-hydroxy-Δ9 -THC	300
Cannabinol	2000
Cannabidiol	>10,000

For ALC test:
The following substances may interfere with the Saliva Alcohol Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

A. Agents which enhance color development
- Peroxidases
- Strong oxidizers

B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

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 MD SalivaScreen when tested at concentrations up to 100 ug/ml.

Non Cross-Reacting Compounds

(-)-Ephedrine (Except MET)	Chlorpheniramine	Oxalic Acid
(+)-Naproxen	Creatine	Penicillin-G
(+/-)-Ephedrine (Except MET)	Dextromethorphan (Except KET)	Pheniramine
4-Dimethyllaminoantiyrine	Dextrorphan tartrate (Except KET)	Phenothiazine
Acetaminophen	Dopamine	Procaine
Acetone	Erythromycin	Protonix
Albumin	Ethanol	Pseudoephedrine
Amitriptyline	Furosemide	Quinidine
Ampicillin	Glucose	Ranitidine
Aspartame	Guaiacol Glyceryl Ether	Sertraline
Aspirin	Hemoglobin	Tyramine
Benzocaine	Imipramine	Trimeprazine
Bilirubin	(+/-)-Isoproterenol	Venlafaxine
b-Phenylethyl-amine	Methadone	Ibuprofen
Caffeine	Vitamin C (Ascorbic Acid)	Lidocaine
Chloroquine (Except MET)		

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GLOSSARY OF SYMBOLS

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

Manufactured for:
Medical Disposables
4854 Distribution Court Ste 8 Orlando, FL 32822

Customer Service Phone: 888-863-1112
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