Oral Fluid Drug Test: Order Code 80712

For In Vitro Diagnostic Use Only

DrugCheck® SalivaScan™

INTENDED USE

The DrugCheck SalivaScan™ Oral Fluid Drug Test is a rapid visual immunoassay for the qualitative detection of multiple drugs and drug metabolites in human oral fluid at the following cutoffs:

Test	Calibrator	Cut-off (ng/ml)
Amphetamine (AMP)	D-Amphetamine	50
Benzodiazepine (BZO)	Oxazepam	10
Cocaine (COC)	Cocaine	20
Marijuana (THC) - Parent	Δ^9-THC	50
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Morphine	40
Oxycodone (OXY)	Oxycodone	20

The DrugCheck SalivaScan™ Oral Fluid Drug Test is used to obtain a visual, qualitative result and is intended for professional use only. This test provides only a preliminary result. Professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method.

SUMMARY AND EXPLANATION

Alcohol (ALC) Ethyl alcohol, or ethanol, is an intoxicating ingredient found in beer, wine, and liquor. It is a central nervous system depressant that is rapidly absorbed from the stomach and small intestine into the bloodstream. The intensity of the effect of alcohol on the body is directly related to the amount consumed.

Amphetamines (AMP) (amphetamine, methamphetamine) are sympathomimetic amines whose biological effects include potent central nervous system stimulation, anorectic, hyperthermic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines increase the heart rate and blood pressure and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structures in the brain.

Barbiturates (BAR) are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. Chronic use of Barbiturates leads to tolerance and physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Benzodiazepines (BZO) are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Buprenorphine (BUP) is a potent analgesic often used in the treatment of opioid addiction. 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. Concentrations of free Buprenorphine and Norbuprenorphine in saliva may be less than 1 ng/ml after therapeutic administration but can range up to 20 ng/ml in abuse situations.

Cocaine (COC) is derived from leaves of the coca plant, cocaine is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in saliva primarily as benzoylecgonine in a short period of time.

Cotinine (COT) 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.

EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. EDDP is formed by N-demethylation and cyclization of methadone in the liver. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

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

Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion.

Methamphetamine (MET) and its metabolites are potent sympathomimetic agents. Acute higher doses lead to enhanced stimulation of the central nervous system and symptoms include euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at high doses may be indistinguishable from schizophrenia.

Opiates (OPI) such as heroin, morphine, and codeine are derived from the resin of opium poppy. Heroin is quickly metabolized to morphine. Thus, morphine and morphine glucuronide might both be found in the saliva of a person who has taken only heroin. The body also changes codeine to morphine. Thus, the presence of morphine (or the metabolite, morphine glucuronide) in the saliva often indicates heroin, morphine and/or codeine use.

Oxycodone (OXY) 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. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

Phencyclidine (PCP) is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. Phencyclidine can be administered orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys.

Propoxyphene (PPX) 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). Norpropoxyphene demonstrates substantially less central nervous system depression than propoxyphene but shows a greater local anesthetic effect.

The length of time following drug use of which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity and diet.

PRINCIPLE

The Oral Fluid Drug Test 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 (T) 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 (C), indicating that proper volume of specimen has been added and membrane wicking has occurred.

The Saliva Alcohol Test consists of a strip with a reaction pad. 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.

PRECAUTIONS

- For In Vitro Diagnostic use.
- 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.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C (36-86°F) until the expiry date printed on the sealed pouch. Product containing alcohol should be stored at 2-27°C (36-81°F) Do not freeze. Kits should be kept out of direct sunlight.
- The test must remain in the sealed pouch until use.
- 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 HANDLING

- This device 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.

MATERIALS

Materials Provided

- 25 Individually packed screening devices and oral fluid collection swabs
- Product Insert
- Alcohol colour chart (if applicable)

Materials Required But Not Provided

- Timer
- Positive and negative controls

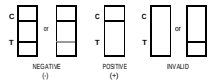
PROCEDURE

1. Bring tests, specimens, and/or controls to room temperature (15-30°C/60-86°F) before use. Donors should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 15 minutes prior to specimen collection.
2. Using the provided collection swab, have donor sweep inside of mouth (cheek, gums, tongue) several times, then hold swab in mouth until color on the saturation indicator strip appears in the indicator window of collection swab. Donor must leave swab in mouth until instructed to remove it. If at 7 minutes, color on the saturation indicator has not appeared, proceed with the test #3 below. Do not bite, suck, or chew on the sponge.
3. Remove collection swab from mouth and insert it sponge first into the screening device, pushing until the locking flange locks in place in the bottom of the device. 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.
4. Ensure that specimen is contacting all test strips. If not, rotate the device side to side / front to back to disperse the specimen within the chamber.
5. Set device upright on flat surface and keep upright while test is running. Wait for the coloured bands to appear in test results area. Negative results can be read as soon as two lines (both control and test) appear on any test strip (often within 2 minutes).
6. Read presumptive positive results at 10 minutes. Do not interpret results after 20 minutes.
7. For Alcohol, read results at 2 minutes. Compare the colour of the reaction pad with the chart provided to determine the relative blood alcohol level.

INTERPRETATION OF RESULTS

Positive: One coloured band appears, in the control region (C). No coloured 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 coloured 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 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 test immediately and contact your distributor.

The intensity of colour in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of colour in the test region (T) should be considered negative. Please note this is a qualitative test only and cannot determine the concentration of analytes in the specimen.

Insufficient specimen volume, incorrect operating procedure, air bubbles at the base of the test strip or expired tests are the most likely reasons for a control band failure.

ALCOHOL INTERPRETATION OF RESULTS

Positive: The alcohol strip will produce a colour change in the presence of saliva alcohol. The colour will range from light blue colour at 0.02% relative blood alcohol concentration to a dark blue colour 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 colours that appear to be between adjacent colour pads. The alcohol strip is very sensitive to the presence of alcohol. A blue colour that is lighter than the 0.02% colour 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 alcohol strip shows no colour change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the colour pad has a blue colour before applying saliva sample, do not use the test. A result where the outer edges of the colour pad produces a slight colour but the majority of the pad remains colourless the test should be repeated to ensure complete saturation of the pad with saliva.

LIMITATIONS OF TEST

- Should be only used for the qualitative detection of drugs of abuse in oral fluid. A positive result indicates the presence of a drug/metabolite only and does not indicate or measure intoxication. 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. This test does not distinguish between drugs of abuse and certain medications.
- 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. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.
- 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.
- 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.
- 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.
- Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

QUALITY CONTROL

An internal procedural control is included in the test device. A coloured 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.

The Alcohol Test Strip may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 30 ml of water. This solution should produce a colour change on the reaction pad. The colour reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution. Do not perform the control test with undiluted alcohol, as pure alcohol solutions will not produce a positive result.

PERFORMANCE CHARACTERISTICS

Sensitivity

A phosphate-buffered saline (PBS) pool was spiked with drugs to target concentrations of ± 50% cut-off and ± 25% cut-off. The results are summarized below:

Drug Conc. (Cut-off range)		AMP		BAR		BZO		BUP		COC		COT		EDDP		MTD	
	n	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	27	3	30	0	28	2	29	1	30	0	30	0	30	0
Cut-off	30	12	18	9	21	14	16	11	19	12	18	11	19	13	17	10	20
+25% Cut-off	30	2	28	3	27	4	26	8	22	2	28	1	29	2	28	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug Conc. (Cut-off range)		MET		OPI		OXY		PCP		PPX		THC (Parent)	
	n	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	28	2	28	2	30	0	30	0
Cut-off	30	13	17	10	20	10	20	11	19	10	20	10	20
+25% Cut-off	30	3	27	9	21	4	26	5	25	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Specificity

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

Compounds	ng/ml	Compounds	ng/ml	Compounds	ng/ml
Amphetamine Related Compounds					
D-Amphetamine	50	(+)-3,4-Methylene-dioxyamphetamine	150	PMA	125
L-Amphetamine	4,000	Phentermine	40,000	Tyramine	3,000
Barbiturate Related Compounds					
Secobarbital	50	Aprobarbital	30	Cyclopentobarbital	60
Allobarbital	200	Butabarbital	15	Pentobarbital	150
Alphenal	100	Butalbital	400	Phenobarbital	300
Amobarbital	100	Butethal	30		

Compounds	ng/ml	Compounds	ng/ml	Compounds	ng/ml
Benzodiazepine Related Compounds					
Oxazepam	10	Diazepam	15	Nitrazepam	10
Alprazolam	15	Estazolam	10	Nordiazepam	6
Bromazepam	8	Desalkylflurazepam	8	Prazepam	20
Chlordiazepoxide	10	Flunitrazepam	10	Temazepam	8
Clonazepam	40	Flurazepam	10	Triazolam	15
Clorazepate	20	Lorazepam	20		
Clobazam	6	Medazepam	10		
Buprenorphine Related Compounds					
Buprenorphine	5	Norbuprenorphine	10	Norbuprenorphine-3-β-D-Glucuronide	200
Buprenorphine Glucuronide	10	Buprenorphine-3-β-D-Glucuronide	5		
Cocaine Related Compounds					
Cocaine	20	Ecgonine	100,000	Ecgonine methyl ester	10,000
Benzoylecgonine	200	Prozine	2,500		
Cotinine Related Compounds					
Cotinine	50	Buprenorphine	>100,000		
EDDP Related Compounds					
EDDP	20	Norfentanyl	20,000	Promethazine	5,000
Meperidine	20,000	Phencyclidine	20,000	Prothipendyl	10,000
Methadone	20,000	Promazine	10,000		
Marijuana (Parent) Related Compounds					
Δ9-Tetrahydrocannabinol	50	11-nor-Δ9 -THC-9 COOH	12	Δ8-Tetrahydrocannabinol	75
11-hydroxy-Δ9-THC	300	Cannabinol	2,000	Cannabidiol	>10,000
Methadone Related Compounds					
Methadone	30	Doxylamine	12,500	2-Ethylidene-1,5-dimethyl-3,3-diphenyl pyrrolidine (EDDP)	10,000
Alpha-Methadol	125	Phencyclidine	12,500		
Biperiden	80,000	Pheniramine	25,000		
Methamphetamine Related Compounds					
D-Methamphetamine	50	MDEA	400	PMMA	50
Fenfluramine	3,000	3,4-Methylenedioxy-methamphetamine	75	Procaine	2,500
L-Methamphetamine	500				
L-Phenylephrine	2,500	Mephentermine	200		
Opiates Related Compounds					
Morphine	40	Meperidine	20,000	Oxycodone	25,000
Codeine	10	Hydrocodone	50	Oxymorphone	25,000
Diacetylmorphine (Heroin)	50	6-Monoacetylmorphine (6-MAM)	25	Morphine-3- β-d-glucuronide	50
Ethylmorphine	24	Hydromorphone	100	Thebaine	5,000
EDDP	20	Nalorphine	10,000		
Oxycodone Related Compounds					
Oxycodone	20	Hydromorphone	6,250	Oxymorphone	1,000
Hydrocodone	1,000	Naloxone	6,250		
Phencyclidine Related Compounds					
Phencyclidine (PCP)	10	Hydromorphone	2,000	Morphine-3- β-d-glucuronide	20,000
Hydrocodone	2,000	Nalorphine	10,000		
Propoxyphene - Related Compounds					
Propoxyphene (PPX)	50	D-Norpropoxyphene	200		

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 in device when tested at concentrations up to 100 ug/ml: 4-Dimethyllaminoantiyrine; Acetaminophen; Acetone; Albumin; Amitriptyline (Except TCA); Ampicillin; Aspartame; Aspirin; Benzocaine; Bilirubin; b-Phenylethyl-amine; Caffeine; Chloroquine (Except MET); Chlorpheniramine; Creatine; Dextromethorphan (Except KET); Dextrorphan tartrate (Except KET); Dopamine; (-)-Ephedrine (Except MET); (+/-)-Ephedrine (Except MET); Erythromycin; Ethanol; Furosemide; Glucose; Guaiacol Glyceryl Ether; Hemoglobin; Imipramine (Except TCA); (+/-)-Isoproterenol; Ibuprofen; Lidocaine; Methadone (Except MTD); (+)-Naproxen; Oxalic Acid; Penicillin-G; Pheniramine; Phenothiazine; Procaine; Protonix; Pseudoephedrine; Quinidine; Ranitidine; Sertraline; Tyramine; Trimeprazine; Venlafaxine; and Vitamin C (Ascorbic Acid).

Interference for Alcohol

The following substances may interfere with the 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. Agents which enhance color development: Peroxidases, strong oxidizers. Agents which inhibit color development: Reducing agents (Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid), Bilirubin, L-dopa, L-methyldopa, and Methampyrone.

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	Do not reuse		Medical device manufacturer		Use by YYYY-MM-DD		Do not use if package is damaged
REF	Catalog number	LOT	Batch code		Temperature limit	Σ	Contains sufficient <n>tests
	Refer to instructions for use		Consult instructions for use	IVD	In vitro diagnostic medical device	EC REP	Authorized representative in the European Community

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