

## GLOSSARY OF SYMBOLS

- Catalog number
- Consult instructions for use
- Manufacturer
- Temperature limitation
- Batch code
- Use by
- Do not reuse
- Do not use if package is damaged
- Sufficient for (quantity)
- Authorized representative in the European Community

**NOTE: The following instructions pertain only to devices that contain an alcohol test strip.**

## Saliva Alcohol Test

### Intended Use

The Saliva Alcohol Test is a rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration. This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

### Summary

Two-thirds of all adults drink alcohol.<sup>1</sup> The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

### Principle

It is well established that the concentration of alcohol in saliva is comparable to that of blood.<sup>2,3</sup> The 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.

### Reagents

- Tetramethylbenzidine
- Alcohol Oxidase (EC 1.1.3.13)
- Peroxidase (EC 1.11.1.7)
- Other additives

### Precautions

The Saliva Alcohol Test is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration. Test materials that have been exposed to saliva should be treated as potentially infectious. Do not use the One Step Saliva Alcohol Test after the expiration date marked on the foil package.

### Storage and Stability

The Saliva Alcohol Test is to be stored at 2-27°C (36-80°F) in its sealed foil package. If storage temperatures exceed 27°C, the test performance may degrade. If the product is refrigerated, the Saliva Alcohol Test must be brought to room temperature prior to opening the pouch.

### Materials Provided

- 25 Individually foil pouched test devices
- Package insert

### Materials Required But Not Provided

- Timer

### Directions For Use

Allow the pouched strip to equilibrate to room temperature (15-27°C) prior to testing.

- Abstain from placing anything in the mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints and food, etc.
- Open the foil package and remove the device. Observe the reactive pad on the end of the test strip. If the reaction pad has a blue color before applying saliva sample, do not use.
- For specimen collection, follow Procedure instructions on page 2 of this package insert.
- Saturate the reactive pad with saliva. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application. Read result at two (2) minutes. Compare the color of the reaction pad with the color chart provided to determine the relative blood alcohol level.

### Interpretation of Results

Positive: The 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 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 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.

### Limitations

- 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.

### Performance Characteristics

The detection limit on the Saliva Alcohol Test is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Saliva Alcohol Test can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

### Assay Specificity

The Saliva Alcohol Test will react with methyl, ethyl and allyl alcohols.

### Interfering Substances

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.

- 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
  - Methamprone

### Controls

The Saliva Alcohol Test may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution.

### Bibliography

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- MaCall, L.E.L., Whiting, B., Moore, M.R. and Goldberg, A.: Correlation of ethanol concentrations in blood and saliva., Clin.Sci., 56, 283-286, 1979.



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### For International Market

### INTENDED USE

The DrugCheck® SalivaScan™ Oral Fluid Drug Test is a rapid visual immunoassay for the qualitative, presumptive detection of drugs of abuse in human oral fluid specimens. The test system consists of one or two membrane strips mounted in a plastic cassette.

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
Benzodiazepine (BZO)	Oxazepam	10
Buprenorphine (BUP)	Buprenorphine	5
Cocaine (COC)	Benzoylcocaine	20
Cotinine (COT)	Cotinine	50
EDDP (EDDP)	2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine	20
Ketamine (KET)	Ketamine	50
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	12
Marijuana (THC)	Δ9-THC	50
Methadone (MTD)	Methadone	30
Methamphetamine (MET)	D-Methamphetamine	50
Opiates (OPI)	Opiates	40
Oxycodone (OXY)	Oxycodone	40
Phencyclidine (PCP)	Phencyclidine	10
Propoxyphene (PPX)	Propoxyphene	50
Barbiturate (BAR)	Barbiturate	50

### PRINCIPLE

The DrugCheck SalivaScan 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.

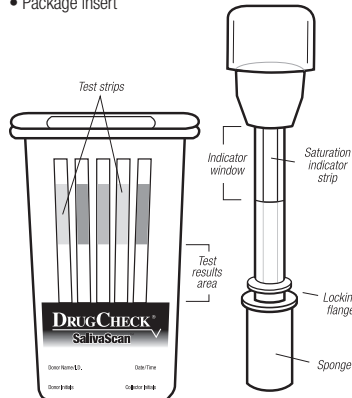
During testing, a portion of the oral fluid specimen migrates upward by capillary action. A drug, if present in the oral fluid specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible 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.

### MATERIALS

#### Materials Provided

- Individually packed screening devices and oral fluid collection swabs
- Combined Test Procedure/Results Record sheet
- Package insert



#### Materials Required but Not provided

- Timer
- Positive and negative controls

### INTRODUCTION

The DrugCheck SalivaScan for AMP/BAR/BUP/BZO/COC/COT/EDDP/KET/MET/MOR/MTD/OXY/PCP/PPX/THC parent/THC and 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):** Amphetamines (amphetamine, methamphetamine, and the structurally related "designer" drugs, e.g., "Ecstasy") are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthermic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver. 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.

**Benzodiazepine(BZO):** Benzodiazepines 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). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

**Benzoylcocaine/Cocaine(COC):** 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.

**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. 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. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

**Cotinine(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.

**EDDP(EDDP):** Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 16-50 hours. EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMPD (2-Ethyl-5-Methyl-3,3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value, dose, and the patient's metabolism. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

**Ketamine (KET):** Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anesthetic since 1970. About 90 percent of the ketamine legally sold is intended for veterinary use. It can be injected or snorted, but is sometimes sprinkled on tobacco or marijuana and smoked. Ketamine is frequently used in combination with other drugs, such as ecstasy, heroin or cocaine. Ketamine is also known as "special K" or "vitamin K." Certain doses of Ketamine can cause dream-like states and hallucinations. In high dose, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney.

**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<sup>3</sup>. Historical studies have shown a window of detection for THC in saliva of up to 14 hours after drug use<sup>3</sup>. The Marijuana THC 12 assay yields a positive result when the THC-COOH concentration exceeds 12 ng/mL. The Marijuana THC 50 assay yields a positive result when the Δ9-THC concentration exceeds 50 ng/mL.

**Methadone(MTD):** 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. 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.

