Cod. 24502 One Step Saliva Alcohol Test

Package Insert

A rapid saliva test for the determination of relative blood alcohol concentration.

For medical or other professional in vitro diagnostic use only.

INTENDED USE

The Saliva Alcohol Test Strip (Saliva) is a rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration (BAC) at 0.02% or greater.

This test provides a preliminary result only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography (GC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any result, particularly when preliminary positive results are indicated.

SUMMARY

Two-thirds of all adults drink alcohol.[1] It has been well established that the concentration of alcohol in saliva is comparable to that in blood.[2,3] The blood alcohol concentration at which a person becomes impaired varies depending upon the individual. Each individual has specific parameters such as size, weight, eating habits and alcohol tolerance that affect the level of impairment. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

The Saliva Alcohol Test Strip (Saliva) is a rapid saliva test that can be performed without the use of an instrument. The test utilizes an enzyme system to detect alcohol in saliva at blood alcohol concentrations of 0.02% or greater.

PRINCIPLE

The Saliva Alcohol Test Strip (Saliva) is an chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the saliva specimen, reacts with chemicals on the reaction pad and causes a color change.

The Saliva Alcohol Test Strip (Saliva) consists of a plastic strip with a reaction pad attached at the tip. The reaction pad employs a solid-phase chemistry system which uses a highly specific enzyme reaction. On contact with solutions of alcohol, the reaction pad will rapidly change colors depending on the concentration of alcohol present. This color change is proportional to the concentration of alcohol in the saliva specimen. By comparing with the color blocks on the color chart printed on the pouch, an approximate blood alcohol concentration (BAC) can be determined.

REAGENTS

The test strip contains Tetramethylbenzidine, Alcohol Oxidase (EC 1.1.3.13), Peroxidase (EC 1.11.1.7) and other additives.

PRECAUTIONS

- For medical or other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- All specimens and test materials that have been exposed to saliva should be treated as potentially infectious.
- The used test strip and test materials should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-27°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Saliva specimens may be stored in a sealed container at 15-27°C for up to 4 hours prior to testing. Specimens may be refrigerated and stored at 2-8°C. Do not freeze saliva specimens. Refrigerated specimens should be brought to room temperature before testing.

MATERIALS

Materials Provided

- Test strips
- Collection cups
- Package insert

Materials Required But Not Provided

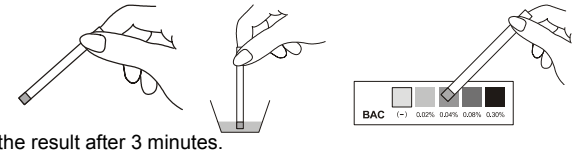
- Timer

DIRECTIONS FOR USE

Allow the test strip, specimens and/or controls to equilibrate to room temperature (15-27°C) prior to testing. Do not place anything in the mouth for 15 minutes before beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible after observing the reaction pad on the end of the test strip. The reaction pad should have a light cream color. Do not use the test strip if the reaction pad has a blue color before the saliva specimen is applied or is otherwise discolored.
2. **Saturate the reaction pad with saliva** from the collection cup or by applying saliva directly to the reaction pad. Saturating the reaction pad usually takes 6-8 seconds. Start the timer immediately after saturating the reaction pad with saliva.

   Note: For hygienic and sanitary reasons, placing the test strip in the mouth is not recommended.
3. **Read results at 2 minutes** by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the relative blood alcohol concentration. Do not interpret



the result after 3 minutes.

INTERPRETATION OF RESULTS

NEGATIVE: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

POSITIVE: A color change appears on the reaction pad. The BAC will range from 0.02% to 0.30%, with the color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.

NOTE: The test strip is very sensitive to the presence of alcohol. A blue color lighter than the 0.02% color pad should be interpreted as alcohol positive in saliva but less than 0.02% concentration of alcohol in blood.

INVALID: The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with saliva. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

The Saliva Alcohol Test Strip (Saliva) 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 color change on the reaction pad corresponding to a 0.02% or greater BAC. The color 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.

LIMITATIONS

1. The Saliva Alcohol Test Strip (Saliva) provides only a preliminary result for the relative BAC. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.
2. Failure to wait 15 minutes after smoking or placing food, drink, or other materials in the mouth before performing the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
3. Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.
4. The test strip should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
5. The test strip is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test strip. 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.
6. Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.

PERFORMANCE CHARACTERISTICS

The detection range of the Saliva Alcohol Test Strip (Saliva) is from 0.02% to 0.30% for the approximate relative blood alcohol concentration. The appropriate limit for determining sobriety varies depending on local regulations.

Assay Specificity

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

Interfering Substances

The following substances may interfere with the Saliva Alcohol Test Strip (Saliva). These substances do not normally appear in sufficient quantity in saliva to interfere with the test.

Peroxidases	Mercaptans	Bilirubin
Strong oxidizers	Tosylates	L-dopa
Ascorbic acid	Acido ossalico	L-methyldopa
Acido tannico	Acido urico	Methampyrone
Pyrogallol		

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2. Jones, A.W.: *Inter-and intra individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man*, Clin. Chem. 25,1394-1398, 1979.
3. McColl K.E., 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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