

One + Step®

Saliva Alcohol Rapid Test Dipstick(Saliva) Package Insert

A rapid, one step screening test for the semi-quantitative detection of Alcohol in saliva.

For In-vitro Diagnostic Use Only

【INTENDED USE】

The Saliva Alcohol Rapid Test Dipstick 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 adult's drink alcohol¹ 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.^{2,3} The Saliva Alcohol Rapid Test Dipstick consists of a plastic dipstick 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 Rapid Test Dipstick 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 Saliva Alcohol Rapid Test Dipstick after the expiration date marked on the foil package.

【STORAGE AND STABILITY】

The Saliva Alcohol Rapid Test Dipstick 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 Rapid Test Dipstick must be brought to room temperature prior to opening the pouch.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Package Insert

Materials Required but not Provided

- Timer

【DIRECTIONS FOR USE】

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

1. Avoid from placing anything in the mouth for fifteen (15) minutes prior to beginning of the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints and food, etc.
2. Open the foil package and remove the test dipstick. Observe the reactive pad on the end of the test dipstick. If the reaction pad has a blue color before applying saliva sample, do not use.
3. Saturate the reactive pad with saliva from collection cup or by applying saliva directly to the pad. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application.
4. Read result at two (2) minutes. Compare the color of the reaction pad with the color chart on foil pouch to determine the relative blood alcohol level.

【INTERPRETATION OF RESULTS】

Positive: The Saliva Alcohol Rapid Test Dipstick 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 Rapid Test Dipstick 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 Rapid Test Dipstick 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】

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 Rapid Test Dipstick is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Rapid Test Dipstick. 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】

The detection limit on the Saliva Alcohol Rapid Test Dipstick is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Saliva Alcohol Rapid Test Dipstick 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 Rapid Test Dipstick will react with methyl, ethyl and allyl alcohols.

【INTERFERING SUBSTANCES】

The following substances may interfere with the Saliva Alcohol Rapid Test Dipstick 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
- Methamphetamine

【CONTROLS】

The Saliva Alcohol Rapid Test Dipstick 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】

1. Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes., Substance Abuse Library, University of Pennsylvania, 1997.
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. 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.

Index of Symbols

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| | Attention, see instructions for use | | Tests per kit | | Authorized Representative |
| | For in vitro diagnostic use only | | Use by | | Do not reuse |
| | Store between 2-30°C | | Lot Number | REF | Catalog # |
| | Do not use if package is damaged | | | | |

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