Rapid Response™

Alcohol Test Strip (Saliva)

REF AST-2S50 Product Insert

A rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration.

For forensic use only.

Intended Use

The Rapid Response™ 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. 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.

Introduction

Two-thirds of all adults drink alcohol.[1] 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 Rapid Response™ Alcohol Test Strip (Saliva) consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly change color 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

- Read the entire procedure carefully prior to testing.
- Test materials that have been exposed to saliva should be treated as potentially infectious.
- Do not use the Rapid Response™ Alcohol Test Strip (Saliva) after the expiration date marked on the foil pouch.
- Do not eat, drink or smoke in the area where specimens and kits are handled. 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

Materials

Materials provided

- 50 Individually packaged test strips
- 50 collection cups
- Product insert

Materials required but not provided

- Timer

Storage and Stability

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

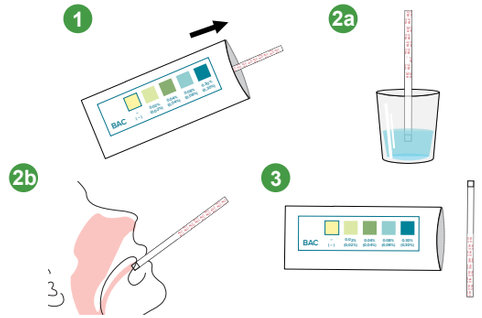
Collection and Storage of Specimens

- The Rapid Response™ Alcohol Test Strip (Saliva) 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.

Test Procedure

Bring tests, specimens, and/or controls to room temperature (59-80.6°F (15-27°C)) before use.

Donor should avoid placing anything (including food, drink, gum and tobacco products) in their mouth for at least 15 minutes prior to specimen collection.



1. Remove the test from its sealed pouch and use it as soon as possible. (See illustration 1.) 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.
2. Saturate the reactive pad with saliva from collection cup (See illustration **2a**.) or from mouth by applying saliva directly to the pad (See illustration **2b**). (It usually takes 6-8 seconds to be saturated.) Start timer immediately after saliva application.
3. **2 minutes after collection:** Read result at 2 minutes. Compare the color of the reaction pad with the chart on the pouch to determine the relative blood alcohol level. (See illustration 3.)

Results Interpretation

Positive: The Rapid Response™ Alcohol Test Strip (Saliva) 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 Rapid Response™ Alcohol Test Strip (Saliva) 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 Rapid Response™ Alcohol Test Strip (Saliva) 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 produce 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. The color change of the color band is considered an internal 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.
- For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls whenever a new test is performed, or whenever a new canister is first opened. Each laboratory should establish its own goals for adequate standards of performance.

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 Rapid Response™ Alcohol Test Strip (Saliva) is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Rapid Response™ Alcohol Test Strip (Saliva). Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectants, 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 Rapid Response™ Alcohol Test Strip (Saliva) is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Rapid Response™ Alcohol Test Strip (Saliva) can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil pouch.

Interfering Substances

The following substances may interfere with the Rapid Response™ Alcohol Test Strip (Saliva) 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

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- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

Controls

The Rapid Response™ Alcohol Test Strip (Saliva) 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.

Glossary of Symbols

Consult instructions for use

Test per Kit

Do Not Reuse

86°F 30°C / 36°F 2°C Store between 35°F to 80°F (2-27°C)

Use by

REF Catalogue #

LOT Lot Number

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