

SALIVARY ALCOHOL TEST STRIP (2-27°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADALC1	50 Tests

Intended Use:

The One Step 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.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.

Test Principle:

It is well established that the concentration of alcohol in saliva is comparable to that of blood.^{2,3} The One Step 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 colours depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

Reagent Composition

Tetramethylbenzidine, Alcohol Oxidase (E.C.1.1.3.1.3), Peroxidase (E.C. 1.11.1.7)

Materials Provided

Individually pouched test strips
Instructions For Use sheet

Materials not provided:

Timer
Collection Cups

Reagent Preparation and Stability:

The One step Saliva Alcohol Test is to be stored at 2-27°C in its sealed pouch. If the storage temperature exceeds the acceptable range, the test performance may not be reliable. If the product is refrigerated, bring the one Step Saliva Alcohol test to room temperature prior to testing.

Assay Procedure:

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

1. 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.
2. Open the foil package and remove the test strip. Observe the reactive pad on the end of the test strip. If the reaction pad has a blue colour 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.

Read result at two (2) minutes. Compare the colour of the reaction pad with the chart on foil to determine the relative blood alcohol level.

Interpretation of Results:

Positive: The One Step Saliva Alcohol Test 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. Colour 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.

NOTE: The One Step Saliva Alcohol Test 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 One Step Saliva Alcohol Test 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.

NOTE: 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. 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 One Step Saliva Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapours in the air are sometimes detected by the One Step Saliva Alcohol Test. Alcohol vapours 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 vapours is suspected, the test should be performed in an area known to be free of vapours.

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

Assay Specificity:

This assay will react with methyl, ethyl and allyl alcohols.

Interfering Substances:

The following substances may interfere with the One Step 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.

A. Agents which enhance colour development

- Peroxidases
- Strong oxidizers

B. Agents which inhibit colour development

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

Controls:

The One Step 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 colour reaction on the pad. The colour reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution.

References:

1. Volpicelli, 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. MacCall, 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.

REF	Catalog number	LOT	Temperature limitation
1	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	Use by	
MA	Manufacturer		