

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

【INTENDED USE】

The Saliva Alcohol Rapid Test Cassette 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.

【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 Cassette consists of a plastic cassette 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 Cassette 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 Cassette after the expiration date marked on the foil package.

【STORAGE AND STABILITY】

The Saliva Alcohol Rapid Test Cassette is to be stored at 2-30°C (36-86°F) in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Saliva Alcohol Rapid Test Cassette must be brought to room temperature prior to opening the pouch.

【MATERIALS】
Materials Provided

- Test Cassettes
- Collection Tubes
- Package insert
- Collectors
- Security Seals

Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the pouched Cassette to equilibrate to room temperature (15-30°C) prior to testing.

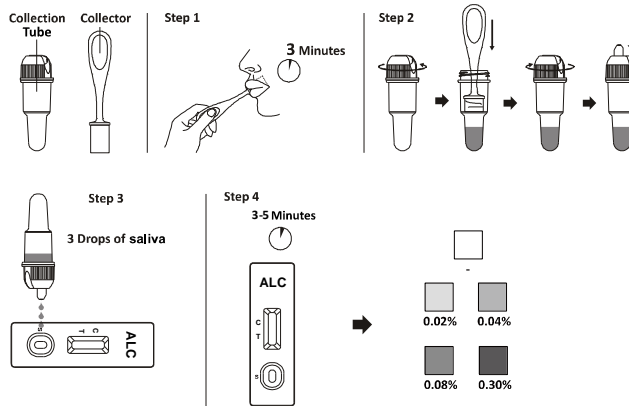
1. Bring the pouch to room temperature before opening it. Remove the test from the sealed pouch and use it within one hour.
2. Remove the collector from the sealed pouch and insert the sponge end of the collector into the mouth. Actively swab the inside of the mouth and tongue to collect saliva for a total of 3 minutes until the sponge becomes fully saturated. Gentle pressing the sponge between the tongue and teeth will assist saturation. No hard spots should be felt on the sponge when saturated.
3. Remove the collector from the mouth. Place saturated saliva collector into chamber and press sponge fully against the strainer to collect saliva. Discard the collector. Snap the cap shut on the collection tube.
4. Place the test cassette on a clean and level surface. Unscrew cap cover from the collection tube. Invert the collection tube and transfer 3 drops of saliva (approximately 120 µL) into specimen well of the test cassette and start the timer. Avoid trapping air bubbles in the specimen well. Place screw cap on the collection tube. See illustration below.
5. Read the results in 3-5 minutes. Compare the color of the reaction pad and standard color card to determine the relative blood alcohol concentration.

【INTERPRETATION OF RESULTS】

Positive: The Saliva Alcohol Rapid Test Cassette 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 Cassette 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 Cassette 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 Cassette is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Saliva Alcohol Rapid Test Cassette. 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】
Accuracy

A side-by-side comparison was conducted using the Alcohol Rapid Test Cassette (Saliva) and a commercially available Alcohol device (Saliva). Testing was performed on 78 clinical specimens previously collected from the volunteers of drinking different quantity of wine. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. The following results were tabulated:

Method	Other Alcohol Rapid Test (Saliva)		Total Result
	Results	Negative	
ALC Rapid Test Cassette (Saliva)	Positive	0	31
	Negative	47	47
Total Result		31	78
% Agreement		>99.9%	>99.9%

Analytical Sensitivity

Study to validate the sensitivity of the reagent pads on the Alcohol Rapid Test Cassette (Saliva) was conducted. The analytical sensitivity was determined by spiking water specimens with intact alcohol standard at 0, 0.01%, 0.02%, 0.04%, 0.08%, 0.15% and 0.3%. The alcohol standards were randomized and coded. The results were confirmed by commercial Alcohol Strip. A total of 30 replicates for each standard were tested. The specimens were visual compare the color of the reaction pad with the color chart at 2 minutes after specimen application. Results are presented in table below:

*The minimum sensitivity level for each analyte of the Alcohol Rapid Test Cassette (Saliva) is defined as the lowest level at which over 80% of the test results are positive when the diluted positive samples for an analyte of known concentrations were tested.

Alcohol Conc	n	Negative	Positive	% Positive
0%	30	30	0	0%
0.01%	30	29	1	3.33%
0.02%*	30	5	25	83.3%
0.04%	30	0	30	100%
0.08%	30	0	30	100%
0.15%	30	0	30	100%
0.30%	30	0	30	100%

* Lowest Positive Concentration

Assay Specificity

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

【INTERFERING SUBSTANCES】

The following substances may interfere with the Saliva Alcohol Rapid Test Cassette 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
- Methampyrone

【CONTROLS】

The Saliva Alcohol Rapid Test Cassette 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

	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		Catalog #
	Do not use if package is damaged		Manufacturer		Consult Instructions for Use

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