

One Step Saliva Alcohol Test Strip

CLIA CATEGORIZATION: WAIVED

Intended Use

The saliva alcohol test is used to detect the presence of alcohol in saliva and provides an estimate of the blood alcohol concentration. It is intended for professional and over-the-counter use to diagnose alcohol intoxication. This test detects a blood alcohol level of 0.02% or higher.

Summary and Principle of Procedure

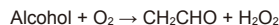
Alcohol is the most commonly abused drug. It is the leading cause of death in the 15 to 45 year old age group in North America. Alcohol abuse is also a contributing factor in most accidents and criminal violations in many cases. Studies have shown a strong correlation between saliva and blood ethanol concentrations.

The alcohol strip test consists of a single reaction pad. When it contacts solutions containing alcohol, the reaction pad will rapidly turn pale blue to dark blue. The degree of color change depends on the concentration of alcohol present in sample.

The test is designed to provide a semi-quantitative measurement of alcohol in saliva specimen. This is done by comparing the color developed at the end of the reaction time with the color chart provided.

Each reaction pad contains color indicator, alcohol oxidase and peroxidase. During the reaction with alcohol, alcohol oxidase generates hydrogen peroxide. In turn, hydrogen peroxide oxidizes the indicator, TMB (tetramethylbenzidine), in the presence of peroxidase. This produces a color that is proportional to the amount of alcohol in the sample.

The reactions are as follows:



Reagents

Alcohol Oxidase	Buffer
Horseradish Peroxidase	Protein Stabilizer
Tetramethylbenzidine (TMB)	Surfactant
Other Additives	

Warnings and Precaution

1. For in vitro diagnostic use only.

2. The strip test is moisture sensitive. It must be used at once after it is removed from the package. Do not use the strip if the pouch is damaged or if it has been opened.
3. Before testing a saliva sample, the unused test strip's color pad should be compared to the negative (0.0% BAC) color block. If the unused strip is darker than the negative color block, this may indicate that the product has deteriorated during storage and should not be used.
4. This test should not be interpreted by persons who are color-blind or visually impaired.
5. This test only provides an estimate of the Blood Alcohol Concentration. It should not be used as a tool to determine if it is safe for the user to operate machinery or a motor vehicle.
6. Use a new pipette for each sample to avoid cross-contamination.
7. Results from this test may not be used for legal proceedings.
8. Results should not be read under sodium vapor lights as the lighting may cause false results.
9. Do not consume anything or have anything in the mouth for at least 10 minutes prior to using the the test strip as it may cause false results.

Storage

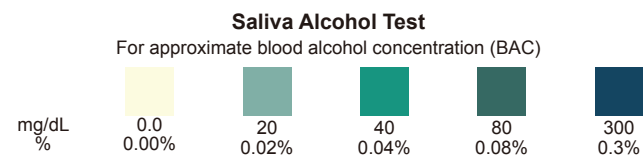
- Store the test strips in sealed pouches at 15°C-30°C (59°F-86°F).
- Store the strips in a dry place. Protect from humidity.
- Do not allow the strip test to freeze while in storage.
- Do not use the strip test beyond the expiration date.

Specimen Collection and Handling

Save saliva samples in a clean collection cup by expectorating the sample. Collect enough so that a full drop can be applied to the strip. Test the samples at once to avoid alcohol evaporation which may result in a lower reading. Take care when dealing with human samples. They are considered to be possibly infectious. Be sure to minimize the air volume above the saliva specimen. If the test subject ingests food or beverages, it is important to wait at least 10 minutes before collecting saliva.

Assay Procedure

1. Take the strip test out of the sealed pouch.
2. Add one drop of saliva sample to the pad on the strip.
3. Read the results at 2 min by matching the color on the test strip to the color chart as below.



Interpretation

Negative: No color change on reactive pad.

Positive: The color of the reactive pad changes in 2 minutes.

- **White or yellowish:** No alcohol or less than 0.02% alcohol in saliva sample;
- **Pale blue** (second window in the color chart): 0.02% alcohol in the saliva sample.
- **Dark blue:** (fourth window in the color chart): 0.08% alcohol in saliva sample.
- **Darker than the dark blue** (last window in the color chart): 0.3% alcohol in saliva sample.

Quality Control

Before use, both negative and positive controls should be used determine assay reliability and performance. Normal saliva can be used for the negative control. Proper user technique can also be confirmed using positive and negative controls.

If the expected results are not achieved with the controls, do not proceed with testing. Negative samples can be collected from any person who has not consumed any alcohol or products containing alcohol.

Limitation of Procedure

The saliva alcohol test is a semi quantitative test for the detection of ethanol. Other alcohols may produce positive results if present in saliva sample.

Specific Performance Characteristics

Four levels (0%, 0.02%, 0.08% and 0.30%) of saliva alcohol samples were prepared. 30 replicates were then run for each level. The test results were compared with the color chart. The levels of 0%, 0.02%, 0.08% and 0.30% matched 100% with the color chart. The legally allowable blood alcohol level for operating a motor vehicle may vary by jurisdiction. Test results should be compared with color chart to reference levels.

INDEX OF SYMBOLS

	Keep away from sunlight
	Store between 15°C - 30°C (59°F-86°F)
	Keep dry
	Do not re-use

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