ONE SCREEN™

Rapid Saliva Alcohol Testing Strip

For Forensic and Research Use Only

INTENDED USE

Rapid Alcohol Test is intended for use as a rapid method to detect the presence of alcohol in saliva for blood alcohol concentration (BAC) greater than 0.02%. It has been published that the concentration of alcohol in saliva is almost equal to that in blood.[4]

The rapid test is intended for the semi-quantitation of ethyl alcohol in human saliva. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

EXPLANATION OF THE TEST

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol. [1-3]

Determination of ethyl alcohol in blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Rapid Alcohol Test is designed as the screen tool to rapidly determine if the BAC level is higher than 0.02% by testing saliva specimen.

PRINCIPLE OF THE PROCEDURE

Rapid Alcohol Test is based on the high specificity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$\text{EtOH} + \text{TMB} \xrightarrow{\text{ALOx/Peroxidase}} \text{CH}_3\text{CHO} + \text{Colored TMB}$$

The distinct color on reactive pad could be observed in less than 20 seconds after the tip was contacted with saliva samples with the ethyl alcohol concentration greater than 0.02%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in saliva.

MATERIALS PROVIDED

1. Instruction for use
2. Rapid Alcohol Test
   Each test contains these materials:

Tetramethylbenzidine (TMB)	0.1mg
Alcohol oxidase (EC)	0.5 IU
Peroxidase(EC)	0.35 IU
Proteins	0.15mg

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock

PRECAUTIONS

1. For in vitro use only.
2. Do not use the product beyond expiration date.
3. Handle all specimens as potentially infectious.
4. The product is sensitive to the presence of alcohol and moisture. After open the package, the test device should be used immediately.

SPECIMEN COLLECTION AND PREPARATION

1. Nothing should be placed into the mouth of the subject for at least 10 minutes prior to saliva collection. This includes food, drink, tobacco products or other materials.
2. Saliva specimen can be collected in a sputum cup or a clean container, or directly applied to the reaction pad of the test strip.
3. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with Rapid Alcohol Test.

Rapid Alcohol Test may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol alcohol into 8 oz of distill water. This solution should show a distinct positive result.

PROCEDURE

1. Open the foil package and remove the test strip.
2. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a sputum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
3. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart.
(Results after more than 2 minutes may be not accurate)

INTERPRETATION OF RESULTS

Negative: Almost no color change by comparing with the background. The negative result indicates that the BAC is less than 0.02%.
Positive: A distinct color developed all over the pad. The positive result indicates that the BAC is 0.02% or higher.
Invalid: The test should be considered invalid If only the edge of the reactive pad turned color that might be ascribed to insufficient sampling. The subject should be re-tested.

LIMITATIONS

1. Rapid Alcohol Test is designed for use with human saliva only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
2. There is a possibility that technical or procedure error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to " Interference" section for list of substances that will interfere the test results.
3. Stored at 2-30°C.
4. Do not place anything in mouth for at least 10 minutes prior to testing

EXPECTED RESULTS

Rapid Alcohol Test is a semi-quantitative assay. It identifies alcohol in human saliva at a concentration of 0.02% BAC.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The following data were obtained based on 86 clinical saliva samples.

	GC(+) (>0.02% BAC)	GC(-)	
Alcohol Test (+)	37	5*	
Alcohol Test (-)	1	43	
	98%	90%	93%
	Sensitivity	Specificity	Agreement

*The alcohol concentration was between 0.009-0.016g/dL

B. Detection Limit:
Detection limit at least at 10mg/dL (0.01g/dL)

C. Interference

The following substances may interfere with the Rapid Alcohol Test:

Tannic acid	Polyphenolic compopunds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds are not normally present in sufficient amount in saliva to interfere with the test. However, the precautious step must be taken so that these materials are not introduced into the mouth during the 10 minutes test period proceeding to the test.

REFERENCES;

1. National highway traffic safety administration NHTSA), DOT. Federal Register. 59:147, August 1994, pp 22382-90
2. Bergemeyer, H.U., et.al, Methods of Enzyme Analysis, 3rd ed. Vol. II, 1983, p143
3. Jones A.W., Clin. Exp. Pharmacol. Physiol. Vol. 6, 1979, pp 53-59
4. McCall K.E.L., et.al, Clin. Sce. Vol. 56, 1979, pp 283-286

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