

AlcoQuick™ Saliva Alcohol Screening Test

INTENDED USE

AlcoQuick™ Saliva Alcohol Screening test is for the rapid semi-quantitative detection of alcohol in saliva. This test is for laboratory use only. This test detects an alcohol level of 0.02% or higher.

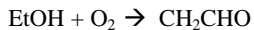
SUMMARY AND EXPLANATION

Alcohol is the most commonly abused drug, and the leading killer of the 15 to 45 years old age group in North America. Alcohol abuse is also a frequent contributing factor in all types of accidents, and criminal violations. Studies have shown a significant correlation between saliva and blood ethanol concentrations. The saliva/blood ratio is approximately 1.07 when both fluids are collected simultaneously. However, due to metabolic and physiologic variables, this correlation is not always constant. Saliva alcohol has long been used to determine blood alcohol, but the saliva/blood ratio may vary widely. To determine accurate blood alcohol concentrations, it is recommended that results of the AlcoQuick™ Saliva Alcohol Screening test be confirmed using gas chromatography on blood.

PRINCIPLE OF PROCEDURE

AlcoQuick™ Saliva Alcohol Screening test strips are disposable plastic strips, which consist of a single reagent pad. The test is designed to provide a qualitative measurement of alcohol in urine specimen by comparing the colour developed at the end of the reaction period with the colour chart provided. Each reagent pad contains the colour indicator substrate and the enzymes alcohol oxidase and peroxidase. During the reaction with alcohol, hydrogen peroxide will be generated by alcohol oxidase. In turn, horseradish peroxidase oxidizes the colour indicator (3, 3', 5, 5'-tetramethyl-benzidine) in the presence of peroxidase, producing a colour that is proportional to the concentration of alcohol in the sample.

The reactions are as follows:



REAGENTS

Each reagent pad contains the following reagents in a homogenous dried format: Alcohol Oxidase; Horseradish Peroxidase; substrate tetramethylbenzidine (TMB) and a buffer with protein stabilizer.

WARNINGS AND PRECAUTION

1. For In Vitro Diagnostic Use Only. For professional use only.
2. For testing human saliva specimen only. Other body fluid is not suitable for testing with this test.
3. The test strip is moisture sensitive and must be used immediately after it is removed from the package.
4. Avoid cross-contamination by using a new pipette for each specimen.
5. DO NOT place test strip inside mouth.

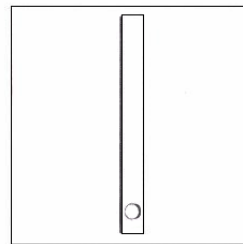
STORAGE

1. Store the test strips in the sealed pouches at 2° to 27°C. Keep refrigerated (2° to 8°C) for long term storage.
2. Do not allow test strips to freeze or subject to elevated temperature during storage.
3. Do not use test strips beyond the expiration date.

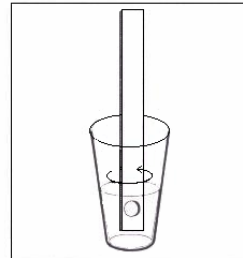
SPECIMEN COLLECTION AND HANDLING

Collect saliva specimens in clean dry sealable containers. Do not add any preservative. Use the specimen immediately for testing to avoid alcohol evaporation that may result in lower reading. Human specimen should be handled with caution and considered potentially infectious. Be sure to minimize the air volume above the saliva specimen. One can split directly into the reagent pad of the test strip. **Never** place the strip inside the mouth.

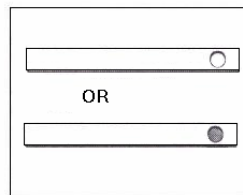
ASSAY PROCEDURE



1. Take out the test strip from sealed pouch just before testing.



2. Dip the test strip with round window end into saliva sample and swirl for 5 seconds. Remove the strip from the sample cup, then lay it flat on a piece of clean dry paper towel with the round window side up.



3. Read results in 2 minutes. Match the colour on the round window with the concentration on the colour chart provided. Record the result.

QUALITY CONTROL

For each clinical run, both negative and positive controls should be used to ensure proper user technique and determine assay reliability and performance. Normal saliva sample can be used for the negative control.

If the expected results are not achieved with the controls, do not proceed with testing.

LIMITATION OF PROCEDURE

1. AlcoQuick™ Saliva Alcohol Screening test is a semi-quantitative test for the detection of ethanol, methanol, and isopropanol. Some other alcohols may produce positive results if present in saliva.
2. Normal concentrations of reducing substances, such as uric acid and ascorbic acid, will not affect the test.

SPECIFIC PERFORMANCE CHARACTERISTICS

Four levels (0%, 0.02%, 0.05% and 0.08%) of alcohol samples were prepared and 15 replicates were run for each level. The results were compared with the colour chart. The levels of 0%, 0.02%, 0.05% and 0.08% were 100% matched with the colour chart and were readily distinguishable.

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