



4-Minute Saliva Test for Blood Alcohol

IVD

INTENDED USE

This product is for In-vitro use.

ALCO-SCREEN 02™, by Chematics is a saliva alcohol test intended for use as a rapid method to positively identify the presence of alcohol in saliva for blood alcohol concentrations (BAC) greater than 0.02%. The ALCO-SCREEN 02™ requires no special training provided that the instructions are followed carefully.

BACKGROUND AND HISTORY

Excessive or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of those who might be at risk due to alcohol use, and may serve as a deterrent against inappropriate alcohol consumption.

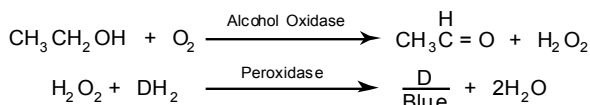
The BAC at which a person becomes impaired is variable, dependent upon the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment.

The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the level at which an individual is considered positive for the presence of alcohol.¹ DOT provides for the use of screening devices using bodily fluids, including saliva, to detect the presence of 0.02% (0.2‰) BAC or greater.¹ ALCO-SCREEN 02™ is a screening device designed to determine the presence of 0.02% (0.2‰) BAC or more in accordance with DOT regulations.

PRINCIPLE²

It is well established that the concentration of alcohol in saliva is comparable to that of blood^{3, 4, 5, 6}. The correlation between blood and saliva alcohol in concurrent samples taken between 60 and 360 minutes after alcohol ingestion have been shown to be r = 0.962 (p < 0.001)^{5, 6}. ALCO-SCREEN™ 02 exploits this relationship to allow a non-invasive method to screen for the presence of alcohol in saliva/blood.

The ALCO-SCREEN 02™ test consists of a plastic strip with a reactive pad applied at the tip. The tip, on contact with saliva samples with alcohol in excess of 0.02% (0.2‰) will produce a positive result after 4 minutes, which is indicated by the development of a distinct colored line across the pad. The reactive pad employs a solid phase chemistry that utilizes the following enzyme chemistry that is highly specific in this application.



ALCO-SCREEN 02™ will react with methyl, ethyl, and allyl alcohols. ALCO-SCREEN 02™ will not react with alcohols having 5 or more carbons, nor with glycine, glycerol, or serine. This property is a result of the specificity of the alcohol oxidase enzyme extracted from yeast.²

INTERFERENCES

The following substances may interfere with the ALCO-SCREEN 02™.

Peroxides	Uric Acid
Strong Oxidizers	Bilirubin
Ascorbic acid	L-dopa
Tannic Acid	L-methylidopa
Pyrogallol	Methamprone
Mercaptans and tosylates	Oxalic acid

The above-named substances do not normally appear in sufficient quantity in saliva to interfere with the test. However, care must be taken that they are not introduced into the mouth during the 15 minute period preceding the test.

REAGENT COMPOSITION: (per test unit)

Tetramethylbenzidine	0.027 mg
Alcohol Oxidase (EC 1.1.3.13) 0.	12 IU
Peroxidase (EC 1.11.1.7)	0.4 IU
Non-Reactive Ingredients	0.12 mg

LIMITATIONS

Failure to wait 15 minutes after placing food, drink, or other materials in the mouth before running the test can provide erroneous results due to possible contamination of the saliva by interfering substances.

ALCO-SCREEN 02™ is designed and calibrated to be interpreted four minutes after saturation of the reactive pad.

ALCO-SCREEN 02™ is sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the ALCO-SCREEN 02™. Alcohol vapors are often present in many institutions and homes. Alcohol is a component in many household products such as disinfectants, deodorizers, and glass cleaners. To determine if alcohol vapors are present in the air, refer to the TROUBLE SHOOTING section.

For questions regarding the validity of test results, refer to the TROUBLE SHOOTING section.

PRECAUTIONS

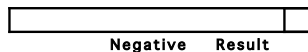
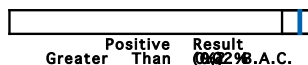
Test materials that have been exposed to saliva should be treated as potentially infective. These materials should be returned to the original foil package and disposed of in a sanitary manner.

Do not open test package until immediately before performing the test procedure.

Never use ALCO-SCREEN 02™ after the expiration date marked on the outside of each test package.

PROCEDURE

1. Abstain from placing anything in the subject's mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.
2. Open the foil package and remove the test strip. The preservative packet is not needed to perform the test and should be discarded. Observe the reactive pad on the end of the test strip. The pad should be a light cream color. A test strip with a reagent pad which has a colored line or is otherwise discolored must be discarded.
3. Saturate the reactive pad with saliva from a sputum cup or by applying saliva directly to the pad. Immediately start timer. After ten seconds, shake off excess saliva.
4. At four (4) minutes, observe the results on the reactive pad. Reading the results may be made easier by placing the test on a white background. The development of a distinct colored line across the reactive pad indicates the presence of alcohol greater than 0.02% (0.2‰) BAC. Results obtained after more than five (5) minutes may be erroneous.



Note: For questions regarding the validity of test results, refer the TROUBLE SHOOTING section.

RESULTS

ALCO-SCREEN 02™ produces a distinct colored line across the reactive pad in the presence of saliva greater than 0.02% (0.02g/dL) BAC. A reagent pad that shows no distinct line should be interpreted as less than 0.02% (0.2‰) BAC.

PERFORMANCE CHARACTERISTICS

In an independent study conducted by investigators at the US Department of Transportation Volpe National Transportation Systems Center, ALCO-SCREEN 02™ was found to be highly effective as an objective determinant for blood alcohol levels above or below the 0.02% (0,2‰) decision level.

The details and results of this study are summarized in the table below:

n	BAC	Challenge Condition	Results
20	0.000% (0,00‰)	Fluorescent light;; temp. 22°C	0 false positives
20	0.008% (0,08‰)	Fluorescent light;; temp. 22°C	0 false positives
20	0.032% (0,32‰)	Fluorescent light;; temp. 22°C	0 false negatives
20	0.000% (0,00‰)	Fluorescent light;; temp. 10°C	0 false positives
20	0.008% (0,08‰)	Fluorescent light;; temp. 10°C	0 false positives
20	0.032% (0,32‰)	Fluorescent light;; temp. 10°C	0 false negatives
20	0.000% (0,00‰)	Fluorescent light;; temp. 40°C	0 false positives
20	0.008% (0,08‰)	Fluorescent light;; temp. 40°C	0 false positives
20	0.032% (0,32‰)	Fluorescent light;; temp. 40°C	0 false negatives
20	0.000% (0,00‰)	Incandescent light; 22°C	0 false positives
20	0.008% (0,08‰)	Incandescent light; 22°C	0 false positives
20	0.032% (0,32‰)	Incandescent light; 22°C	0 false negatives
20	0.000% (0,00‰)	Mercury vapor light; 22°C	0 false positives
20	0.008% (0,08‰)	Mercury vapor light; 22°C	0 false positives
20	0.032% (0,32‰)	Mercury vapor light; 22°C	0 false negatives
20	0.000% (0,00‰)	Sodium vapor light; 22°C	0 false positives
20	0.008% (0,08‰)	Sodium vapor light; 22°C	0 false positives
20	0.032% (0,32‰)	Sodium vapor light; 22°C	0 false negatives
20	0.000% (0,00‰)	Daylight; 22°C	0 false positives
20	0.008% (0,08‰)	Daylight; 22°C	0 false positives
20	0.032% (0,32‰)	Daylight; 22°C	0 false negatives

STORAGE AND STABILITY

ALCO-SCREEN 02™ should be stored at room temperature, not to exceed 80°F (27°C). Under this condition, ALCO-SCREEN 02™ will perform according to specification until the expiration date stamped on the package. If storage temperature exceeds 80°F (27°C), degradation of the product and performance may occur.

If the product is refrigerated, the ALCO-SCREEN 02™ test must be brought to room temperature prior to opening the package.

Maximum performance is assured if the ALCO-SCREEN 02™ test is performed at room temperature, not to exceed 80°F (27°C). The ALCO-SCREEN 02™ can be used in environments above 80°F (27°C) if performed within ten minutes after removal from the specified storage temperature 80°F (27°C). Failure to perform the test within ten minutes upon exposure to temperatures above 80°F (27°C) could cause degradation of product performance.

CONTROLS

The color reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in aqueous solutions.

The ALCO-SCREEN 02™ may be qualitatively verified by using a test solution prepared by adding 10 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should provide a positive result (distinct colored line) across the reactive pad of the test.

Commercially available controls that contain preservatives cannot be used with the ALCO-SCREEN 02™.

TROUBLE SHOOTING

1. Nothing should be placed into the mouth of the subject for at least 15 minutes prior to saliva collection and testing with ALCO-SCREEN 02™. This prevents any foreign substance from interfering with the test.
2. Results must be determined four (4) minutes after saturation of the reactive pad with saliva. Any result determination made after five (5) minutes of saturation of the reactive pad may be erroneous.
3. Testing for alcohol vapors in the air can be performed by using tap water as a sample, and performing the test procedure as specified. The development of a distinct colored line indicates that alcohol vapors are present. Therefore the ALTERNATE PROCEDURE stated below must be used for subject testing.
4. Maximum performance of the ALCO-SCREEN 02™ test is obtained if performed at room temperature, not to exceed 80°F (27°C). For performing the test at temperatures over 80°F (27°C), see instructions stated in STORAGE AND STABILITY section.

ALTERNATE PROCEDURE

This procedure is to be employed if alcohol vapors are determined to be present, and/or alcohol vapors are suspected of interfering with the validity of the test results.

1. Abstain from placing anything in the subject's mouth for fifteen (15) minutes prior to beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.
2. Open the foil package and remove ALL contents (**paying special attention to removing the preservative packet**). Observe the reactive pad on the end of the test strip. The pad should be a white or cream color. A test strip with a reagent pad which has a colored line or is otherwise discolored must be discarded.
3. Saturate the reactive pad with saliva from a sputum cup or by applying saliva directly to the pad. Immediately replace ONLY the ALCO-SCREEN 02™ test stick into the foil package, and fold the package closed. Start timer.
4. At four (4) minutes, remove the test stick from the package and observe the results on the reactive pad. Reading of results may be made easier by placing the test on a white background. The development of a distinct colored line across the reactive pad indicates the presence of alcohol greater than 0.02% (0,2‰) BAC. Results obtained after more than five (5) minutes may be erroneous.

REFERENCES

- ¹National Highway Traffic Safety Administration (NHTSA), DOT. Federal Register. 59:147, August 2 1994, p. 39382-39390.
- ²Bergmeyer, H.U., Grabl, M & Walter, H. in Methods of Enzymatic Analysis, 3rd ed. Vol. II, ed. by Bergmeyer, H.U., Verlag Chemie, Weinheim, 1983, p. 143.
- ³Blanke, R.V. in Fundamentals of Clinical Chemistry, ed. by Tietz, N.W., W.B. Saunders Co., Philadelphia, 1970, p. 1114.
- ⁴McCall, K.E.L., Whiting, B., Moore, M.R. & Goldberg, A., CLIN.SCI., 56, 283-286, 1979.
- ⁵Jones, A.W., CLIN.EXP.PHARMACOL.PHYSIOL. 6, 53-59, 1979.
- ⁶Jones, A.W., CLIN.CHEM. 25, 1394-1398, 1979.