ALCO SCREEN®

2-Minute Saliva Test
for Blood Alcohol

IVD

INTENDED USE

This product is for in-vitro use.

ALCO-SCREEN™, by Chematics, is a saliva alcohol test intended for use as a rapid, highly sensitive non-invasive method for the objective determination of alcohol ingestion. With positive results, relative blood alcohol concentration may be approximated by colorimetric visual observation. For applications requiring a quantitative determination of blood alcohol concentration, a positive ALCO-SCREEN™ result must be verified using an acceptable quantitative alcohol procedure. ALCO-SCREEN™ requires no special training provided that instructions are followed carefully. However, quantitative follow-up testing should be performed by a qualified professional.

ALCO-SCREEN™ may also be used to qualitatively detect the presence of alcohol in many other fluids, such as drinks, blood serum etc. See Limitations for further information.

SUMMARY

Excess 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 individuals who might be at risk due to alcohol use or intoxication. Screening is also an important deterrent against inappropriate alcohol consumption.

The blood alcohol concentration at which a person becomes impaired is variable dependent on 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.

PRINCIPLE[1]

It is well established that the concentration of alcohol in saliva is comparable to that of blood[2,3,4,5]. The correlation between blood and saliva alcohol in concurrent samples taken between 60 and 360 minutes after alcohol ingestion have been shown to be $r = 0.962$ ($p<0.001$)[4, 5]. ALCO-SCREEN™ exploits this relationship to allow a non-invasive method to screen for the presence of alcohol in saliva/blood.

The ALCO-SCREEN™ test consists of a plastic strip with a reactive pad applied at the tip. The tip, on contact with solutions of alcohol, will rapidly turn shades of green to blue to gray depending on the amount of alcohol present. The reactive pad employs a solid phase chemistry that utilizes the following enzyme chemistry that is highly specific in this application.

The ALCO-SCREEN™ will react with methyl, ethyl, and allyl alcohols. ALCO-SCREEN™ will not react with alcohols having 5 or more carbons, nor with glycine, glycerol, or

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3\overset{H}{C}=O + H_2O_2$$

$$H_2O_2 + DH_2 \xrightarrow{\text{Peroxidase}} \underset{\text{Blue}}{D} + 2H_2O$$

serine. This property is a result of the specificity of the alcohol oxidase enzyme extracted from yeast.[1]

REAGENT COMPOSITION: (per test unit)

Tetramethylbenzidine	0.176 mg
Alcohol Oxidase (EC 1.1.3.13)	0. 5 IU
Peroxidase (EC 1.11.1.7)	30 IU
Buffer	0.747 mg
Stabilizing Proteins	0.190 mg

INTERFERENCES

The following substances may interfere with the ALCO-SCREEN™ stick when using samples other than saliva:

- Agents that may enhance color development:
  - Peroxides
  - Strong Oxidizers
- Agents that may inhibit color development:
  - Reducing Agents:
    - Ascorbic acid
    - Tannic Acid
    - Pyrogallol
    - Mercaptans and tosylates
  - Bilirubin
  - L-dopa
  - L-methyldopa
  - Methampyrone

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.

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™ is designed and calibrated to be interpreted two minutes after saturation of the reactive pad. Waiting longer than two minutes may result in erroneous results or false positive results.

ALCO-SCREEN™ may be used to detect the presence of alcohol in fluids other than saliva. However, when used in this manner, the color chart on the package does not apply. If alcohol is present in the fluid, a color change ranging from a light green-gray to black to brown will occur as the alcohol concentration increases. Little or no color change may occur with pure alcohol due to the absence of water which is required for the color change reaction. When testing beverages to determine whether they contain an intoxicating amount of alcohol, a result should not be considered positive unless the pad changes to a very dark brown or black.

ALCO-SCREEN™ is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the ALCO-SCREEN™. 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. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of these vapors (such as outside).

PRECAUTIONS

ALCO-SCREEN™ is a visually interpreted test where observation of color development is used to detect the presence of alcohol and color matching may be used to provide an approximation of blood alcohol concentration. As such, exact interpretation of results is not required in most cases. However, persons who are color blind or visually impaired may experience difficulty when a more specific interpretation is required.

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

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.

Never use ALCO-SCREEN™ after the expiration date marked on the outside of each test package, or if the test package appears damaged or otherwise compromised.

STORAGE AND STABILITY

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

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

PROCEDURE

1. Abstain from placing anything in the 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. 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 is dark tan in color or otherwise discolored must be discarded.
3. Saturate the reactive pad with saliva from mouth or sputum cup. Immediately start timer.
4. At two (2) minutes observe the color change (if any) in the reactive pad. A color change of green or blue indicates the presence of alcohol and a positive result. Results obtained after more than 2 minutes and 30 seconds may be erroneous.
5. Estimate the approximate blood alcohol concentration by comparing the color of the reagent pad with the color chart appearing on the test package.

RESULTS

ALCO-SCREEN™ produces a color change in the presence of saliva alcohol ranging from a light green-gray color at 0.02% (0,20‰) blood alcohol concentration to a dark blue-gray color near 0.30% (3,0‰) blood alcohol concentration. Color blocks are provided within this range to allow an approximation of blood alcohol concentration to be made. ALCO-SCREEN™ may produce colors that appear to be between adjacent color blocks.

ALCO-SCREEN™ is very sensitive to the presence of alcohol. A green color that is lighter than the 0.02% color block should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% (0,20‰) blood alcohol.

A result where the reagent pad shows no color change (remains white or cream colored) should be interpreted as a negative result (no alcohol present).

A result where the outer edges of the reagent pad produces a slight color but the majority of the pad remains colorless should be repeated to ensure complete saturation of the reagent pad with saliva. If the second result is the same, the results should be interpreted as being negative (no alcohol present).

PERFORMANCE CHARACTERISTICS

ALCO-SCREEN™ is highly effective as an objective determinant for alcohol ingestion. In a clinical study involving 230 subjects ALCO-SCREEN™ demonstrated an accuracy of greater than 95% in correctly identifying the presence or absence of measurable alcohol in blood. The following table summarizes the results of this study:

n	230
Sensitivity	0.983
Specificity	0.843
Positive Predictive Value	0.956
Negative Predictive Value	0.935
Accuracy	0.952

ALCO-SCREEN™ has been shown to be highly sensitive, having a lower detection limit of less than 0.009% (0,09‰) BAC.

CONTROLS

The integrity of ALCO-SCREEN™ may be qualitatively verified using a test solution prepared by adding 4 drops of 80 proof distilled spirits to 8oz. (1 glass) of water. This solution should provide a color reaction equal to or higher (darker) than the 0.04% (0,4‰) color block.

The color reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in aqueous solutions. For additional information regarding controls, please contact Chematics, Inc. Other commercially available controls should not be used with ALCO-SCREEN™

REFERENCES

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