

SCREEN[®]

SCREEN ETIL PROFESSIONAL (Saliva) Package Insert

REF: SC-1002-40 English

INTENDED USE

The Etil Pro CE rapid test is a chemical method test for the rapid and sensitive detection of alcohol (alc) (ethyl alcohol/ethanol) in saliva and other liquid specimen. By examination of saliva specimen you can estimate the blood alcohol concentration.

ABSTRACT

This chemical method gives a qualitative result, i.e. the test shows if specimens e.g. saliva contain alcohol or not.

The assay detects ethanol at concentration of 0.1‰ or 10 mg/dL respectively by colour change of the reaction or test pad. The blue colour intensity increases with the alcohol concentration in the sample. Thus, Etil Pro CE produces a colour change in the presence of alcohol in specimen ranging from light yellow at negative specimens via a light blue, middle blue to a dark bluegrey colour at high alcohol concentration.

BASICS

Ethanol for use in alcoholic beverages, is produced by fermentation: when certain species of yeast metabolize sugar (wine, mead), cereal starch (beer) or rice starch (sake). The fermentation stops at certain alcohol concentrations, because concentrated ethanol solutions are toxic to yeast. By distillation the concentration of ethanol in beverages can be higher like it is in liquors. Alcohol can be found in medicine and diverse chocolate candy. Reasons of acute intoxication are mostly abuse by drinking alcoholic beverages or at working places alcohol vapour inhalation.

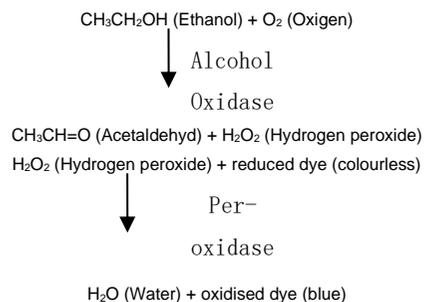
High intake of alcohol is a wide spreading social issue. The consumption can lead to accidents in traffic and at working environment. It can cause diseases and social problems like shattered partnerships or psychological problems in the social environment of alcohol consumers.

The controlling of people for consumption of alcohol is an important method, to discover persons which are influenced by alcohol. This people might endanger themselves as well as their surrounding. Even in the medicine of working space the alcohol test Etil Pro CE gives you a brought awareness which can be used

- to increase occupational health and safety,
- to ensure the product quality,
- to optimize soft skills and to improve the working atmosphere,
- and to reduce absence from work.

TEST PRINCIPLE

The Etil Pro CE test consists of a plastic strip with a reactive pad applied at the tip detecting ethanol at concentration of 0.1‰ or 10 mg/dL by a highly specific chemical method. The tip, on contact with solutions of alcohol will rapidly turn shades of green to dark blue depending on the amount of alcohol present. The reactive pad employs a solid phase chemistry which uses the following highly specific enzyme reaction.



STORAGE AND STABILITY

The test kit is to be stored refrigerated or at room temperature (2-30°C) in the sealed pouch for the duration of the shelf life.

Bring the strip to room temperature to avoid condensation of moisture on the reaction pad. Humidity and high temperature can adversely affect results.

WARNINGS AND PRECAUTIONS

1. For professional use only
2. Use only once
3. Do not use after the expiration date
4. The test strip should remain in the sealed pouch until use.
5. Soak the reaction pad with enough liquid to ensure that it is totally wet.
6. Do not use test if pouch is damaged.
7. Do not touch the reaction pad of the strip to avoid contamination
8. Handle all specimens as if they contain infectious agents. Proper handling and disposal methods should be established
9. Do not perform test in alcohol containing atmosphere.
10. Pure alcohol can lead to false results.
11. Be aware of the mentioned cross-reactivities.
12. The person who will read the color results can not be color blind.

REAGENTS AND MATERIALS SUPPLIED

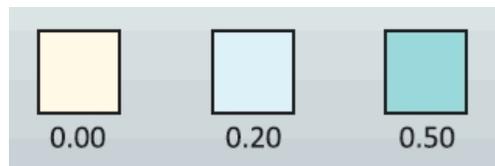
1. Individually wrapped test devices
2. One instruction sheet.

SPECIMEN COLLECTION AND TEST 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. Bring the sealed pouch to room temperature (15-30°C), to avoid condensation of moisture on the reaction pad.
3. If you analyse other samples than fresh saliva be aware to bring them to room temperature before proceeding.
4. Open the foil package and remove the test strip. Don't touch the reactive pad on the end of the test strip. The pad should be a light cream colour. A test strip with a reagent pad which is dark tan in colour or otherwise discoloured must be discarded.
5. Saturate the reactive pad with liquid or saliva from mouth or sputum cup. Immediately start timer.
6. At two (2) minutes observe the colour change (if any) in the reactive pad. A colour change of green or dark green-grey indicates the presence of alcohol and a positive result. Results obtained after more than 3 minutes may be erroneous.

INTERPRETATION OF RESULTS

After 2 minutes the colour of the reaction pad must be evaluated.



Please do not compare the result of the test strip with the above colours due to colour variations caused by different printers. Please only use the colour-chart of the foil package.

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.

If you test pure alcohol the test could effect a negative result due to the absence of water, which is required for the colour change reaction.

Etil Pro CE is designed and calibrated to be interpreted 2 minutes after saturation of the reactive pad. Waiting longer than two minutes may result in erroneous results or false positive results.

Etil Pro CE is highly sensitive to the presence of alcohol. Alcohol vapours in the air are sometimes detected by the Etil Pro CE. Alcohol vapours 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 vapours is suspected, the test should be performed in an area known to be free of these vapours (such as outside).

NOTES: The person who will read the color results can not be color blind.

PERFORMANCE CHARACTERISTICS

Specificity

The Etil Pro CE will react with methyl, ethyl, and n-propanyl (allyl) alcohols. Etil Pro CE will not react with alcohols having 5 or more carbons, nor with glycine, glycerol, or amino acids (serine). This property is a result of the specificity of the alcohol oxidase chemical method.

INTERFERENCES

The following substances may interfere with the Etil Pro CE stick when using samples other than saliva:

Agents which enhance colour development:

- Peroxides
- Strong Oxidizers (common in detergents, cleaning agents and bleaches)

Agents which inhibit colour development:

1. Reducing Agents:
 - Ascorbic acid
 - Tannic Acid
 - Pyrogallol
 - Mercaptans
 - Tosylates
 - Oxalic acid
 - Uric acid
2. Bilirubin
3. L-Dopamine
4. L-Methyldopamine
5. Methamphetamine

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. Therefore the proband does not eat, drink or smoke 15 minutes before starting the test.

LITERATURE

- Bergmeyer, 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
1. Blanke, R. V. in Fundamentals of Clinical Chemistry, ed. by Tietz, N.W., W.B. Saunders Co., Philadelphia, 1970, p.1114
 2. McCall, K.E.L., Whiting, B. Moore, M.R., Goldberg, A., CLIN. SCI., 56, 283-286, 1979
 3. Jones, A. W., CLIN. EXP. PHARMACOL.PHYSIOL. 6, 53-59, 1979
 4. Jones, A. W., CLIN. CHEM., 25, 1394-1398, 1979
 5. Aktories, K., Förstermann, U., Hofmann, F., Starke, K., Allgemeine und spezielle Pharmakologie und Toxikologie, 9th ed. Elsevier Urban Fischer Verlag, München, 2005
 6. Thomas L. eds., Labor und Diagnose, 6. ed., TH-Books Verlagsgesellschaft, Frankfurt, 2005

INDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

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