Dry-veControl®

Alcohol
008A850

ultimed™

Rapid Saliva Test for Estimation of Blood Alcohol Levels

Intended use

The Dry-veControl® saliva alcohol test is intended for use as a rapid, highly sensitive method to detect the presence of alcohol in saliva and to provide a semi-quantitative approximation of blood alcohol concentration. For applications where a quantitative determination of blood alcohol concentration required, a positive Dry-veControl® result must be verified using an acceptable quantitative alcohol procedure. Dry-veControl® requires no special training provided that instructions are followed carefully. However, quantitative follow-up testing should be performed by a qualified professional.

Dry-veControl® may also be used to non-quantitatively detect the presence of alcohol in many other fluids, such as soft drinks, blood serum, etc. (see limitations for further information).

Summary

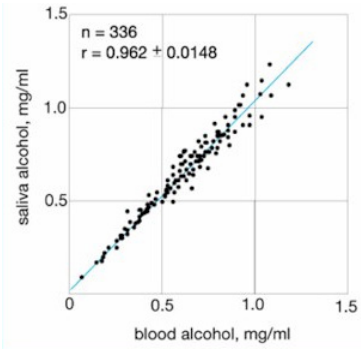
Excessive or inappropriate consumption of alcohol is one of the most common and pervasive social problems in our society. It is a contributory factor to many accidents, injuries and medical conditions. Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol intoxication. Screening also provides additional benefit as a deterrent against inappropriate alcohol consumption.

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

Principle

It is well established that the concentration of alcohol in saliva is comparable to that of blood. The following figure shows the correlation between saliva and blood alcohol. The regression line equation was:

$$y = 0.003 + 1.075x$$



Correlation beween blood and saliva alcohol in concurrent samples
taken between 60 and 360 minutes after alcohol ingestion

The Dry-veControl® 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 depending on the amount of alcohol present. The reactive pad employs a solid phase chemistry which uses the following highly specific enzyme reaction:

$CH_3CH_2O + O_2$ => Alkoholoxidase => $CH_3CH = O + H_2O_2$

$H_2O_2 + D_{ye}H_2$ => Peroxidase => D_{ye}/Blue + $2H_2O$

Specificity

The Dry-veControl® will react with methyl, ethyl, and allyl alcohols. Dry-veControl® 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.

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Reagent Composition (per test unit):

Tetramethylbenzidine	0,176 mg
Alcohol Oxidase (EC 1.1.3.1.3)	0,5 IU
Peroxidase (EC 1.11.1.7)	30 IU
Buffer	0,747 mg
Stabilizing Proteins	0,19 µg

Interferences

The following substances may interfere with the Dry-veControl® stick when using samples other than saliva:

Agents which enhance colour development:

- Peroxides
- Strong oxidizers

Agents which inhibit colour development:

Reducing agents:

- Ascorbic acid
- Tannic Acid
- Pyrogallol
- Mercaptans and tosylates
- Oxalic acid
- Uric acid

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.

Dry-veControl® 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.

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

Dry-veControl® is highly sensitive to the presence of alcohol. Alcohol vapours in the air are sometimes detected by the Dry-veControl®. 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).

Precautions

Dry-veControl® is a visually interpreted test where colour matching is 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 colour blind or visually impaired may experience difficulty when a more specific interpretation is required.

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 properly.

Never use Dry-veControl® after the expiration date marked on the outside of each test package.

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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 have a light cream colour. A test strip with a reagent pad which is dark tan in colour or otherwise coloured must be discarded.
3. Saturate the reactive pad with saliva from the sputum cup. Immediately start timer.
4. After two (2) minutes observe the colour change (if any) in the reactive pad. A colour change of green or blue indicates the presence of alcohol and a positive result. Results obtained after more than 3 minutes may be erroneous.
5. Estimate the approximate blood alcohol concentration by comparing the colour of the reagent pad with the colour chart appearing on the test package.

Results

Dry-veControl® produces a colour change in the presence of saliva alcohol ranging from a light green-grey colour at 0.02% blood alcohol concentration to a dark blue-grey colour near 0,30 % blood alcohol concentration. Colour blocks are provided within this range to allow an approximation of blood alcohol concentration to be made. Dry-veControl® may produce colours that appear to be between adjacent colour blocks.

Dry-veControl® is very sensitive to the presence of alcohol. A green colour that is lighter than the 0.02% colour block should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% blood alcohol.

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

A result where the outer edges of the reagent pad produces a slight colour but the majority of the pad remains colourless 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).

Storage and stability

Dry-veControl® should be stored at room temperature, not to exceed 27°C. Under this condition, Dry-veControl® will perform according to specification until the expiration date stamped on the package. If storage temperature exceeds 27°C, degradation of the product and performance may occur.

If the product is refrigerated, the Dry-veControl® test must be brought to room temperature prior to opening the package.

Controls

The integrity of Dry-veControl® may be qualitatively verified using a test solution prepared by adding 4 drops of 80 proof distilled spirits to 8 oz. (1 glass) of water. This solution should provide a colour reaction equal to or higher (darker) than the 0.04% colour block.
The colour reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in aqueous solutions. For additional information regarding controls, please contact ulti med Products. Other commercially available controls should not be used with Dry-veControl®.

Technical assistance

For technical assistance or further information, please contact ulti med Products (Deutschland) GmbH

Materials Provided

- Dry-veControl® -test strip in sealed pouch
- sputum cup
- instructions

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