Dry-veControl®

Alcohol
008A891GB

ultimed™

Rapid Saliva Test for Estimation of Blood Alcohol Level

INTENDED USE

The Dry-veControl® Screening Test is a rapid, highly sensitive method to detect the presence of alcohol in saliva and provide an approximation of relative blood alcohol concentration. This test device shows a high degree of sensitivity and can detect 0.02% to 0.3% alcohol concentration in saliva.
This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

Note: This test shall not be used to determine one's ability to legally operate a motor vehicle or heavy equipment. Any decision based on the results of this test will be the sole responsibility of the user.

SUMMARY

Two-thirds of all adults drink alcohol.[1] The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

PRINCIPLE

It is well established that the concentration of alcohol in saliva is comparable to that of blood.[2,3] The Dry-veControl® Screening Test consists of a plastic strip with a reaction pad attached at the tip. On contact with solutions of alcohol, the reaction pad will rapidly turn colours depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction. The reactions are as follows:

$$CH_3CH_2OH + O_2 \xrightarrow{\text{Alcohol Oxidase}} CH_3CHO + H_2O_2$$

$$H_2O_2 + \text{TMB} \xrightarrow{\text{Peroxidase}} \text{Blue colour} + 2H_2O$$

Reagent Composition:
Tetramethylbenzidine (TMB)
Alcohol Oxidase (EC 1.1.3.1.3)
Peroxidase (EC 1.11.1.7)
Other additives

PRECAUTIONS

- Do not use after the expiration date.
- Do not use the test if the foil pouch is damaged.
- The test should remain in the sealed foil pouch until use.
- Read the entire procedure carefully prior to testing.
- Do not reuse tests.
- Do not eat, drink or smoke in the area where specimens and kits are handled.
- Humidity and temperature can adversely affect results.
- The used test device should be discarded according to federal state and local regulations.

STORAGE AND STABILITY

The test kit is to be stored at 2 - 27°C in its sealed foil pouch. If storage temperatures exceed 27°C, the test performance may degrade. If the product is refrigerated, the Dry-veControl® Test must be brought to room temperature prior to opening the pouch.

MATERIALS PROVIDED

- Dry-veControl® -test strip in sealed pouch
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

SPECIMEN COLLECTION

Collect the saliva to a clean and dry tube.

PROCEDURE

1. Allow the pouched strip to equilibrate to room temperature (15-27°C) prior to testing.
2. 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 and food, etc.
3. 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 than in colour or otherwise coloured must be discarded.
4. Saturate the reactive pad with saliva from collection cup or by applying saliva directly to the pad. (It usually takes 6-8 seconds to be saturated.)
5. Start timer immediately after saliva application
6. Read result at two (2) minutes. Compare the colour of the reaction pad with the chart on foil to determine the relative blood alcohol level.

INTERPRETATION OF RESULTS

Positive: The test will produce a colour change in the presence of saliva alcohol. The colour will range from light blue colour at 0.02% (0.2 ‰) relative blood alcohol concentration to a dark blue colour near 0.3% (3.0‰) relative blood alcohol concentration. Colour pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colours that appear to be between adjacent colour pads.

Negative: When the test shows no colour change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the colour pad has a blue colour before applying saliva sample, do not use the test.

NOTE: The Dry-veControl® Test is very sensitive to the presence of alcohol. A blue colour that is lighter than the 0.02% (0.2 ‰) colour pad should be interpreted as being positive to the presence of alcohol in saliva but less than 0.02% (0.2 ‰) relative blood alcohol.
A result where the outer edges of the colour pad produces a slight colour but the majority of the pad remains colourless the test should be repeated to ensure complete saturation of the pad with saliva. The test is not reusable.

LIMITATIONS

1. Failure to wait 15 minutes after placing food, drink, or other materials (including smoking) in the mouth before running the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
2. The Dry-veControl® Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.
4. Waiting longer than 2 minutes and 30 seconds to interpret the test can result in erroneous or false positive results.
5. The test should not be used under sodium vapor lighting conditions

PERFORMANCE CHARACTERISTICS

Detection Limit

The detection limit of the Dry-veControl® Test is from 0.02% to 0.3% for approximate relative blood alcohol level. Test results can be compared with colour chart to reference levels.

Assay Specificity

The Dry-veControl® Test will react with the following substances:

- Methyl alcohol
- Ethyl alcohol
- Allyl alcohol

Interferences

The following substances may interfere with the Dry-veControl® Test when using samples other than saliva. The named substances do not normally appear in sufficient quantity in saliva to interfere with the test.

Agents which enhance colour development:
- Peroxides
- Strong oxidizers

Agents which inhibit colour development:
- Reducing agents:
  - Ascorbic acid
  - Tannic Acid
  - Pyrogallol
  - Mercaptans
  - Tosylates
  - Oxalic acid
  - Uric Acid
- Bilirubin
- L-dopa
- L-methyldopa
- Methampyrone

NOTE: However, care must be taken that they are not introduced into the mouth during the 15 minute period preceding the test.

WARNINGS

1. The Dry-veControl® Test 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.
2. 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.

QUALITY CONTROL

The integrity of the test may be qualitatively verified using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 glass approx. 235 ml) of water. This solution should produce a colour reaction on the pad. The colour reaction with alcohol in saliva is somewhat slower and less intense than with alcohol in an aqueous solution. Other commercially available controls should not be used with the test.

BIBLIOGRAPHY

1. Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes., Substance Abuse Library, University of Pennsylvania, 1997.
2. Jones, A.W.: Inter-and intra individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man., Clin. Chem. 25, 1394-1398, 1979.
3. MaCall, L.E.L., Whiting, B., Moore, M.R. and Goldberg, A.: Correlation of ethanol concentrations in blood and saliva., Clin.Sci., 56, 283-286, 1979.

	Manufacturer	Σn	Contents sufficient for <n> tests
		LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use		Store at
	Keep away from direct sunlight	REF	Ordering number

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