

D-ALC-S11

One Step Urine Alcohol Test

INTENDED USE

The One Step Urine Alcohol Test is a rapid, highly sensitive method to detect the presence of alcohol in urine and provide an approximation of relative blood alcohol concentration. 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.

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

The Urine Alcohol Test is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the specimen, reacts with chemicals on the reaction pad and causes a color change. The One Step Urine Alcohol 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 colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

REAGENTS

Tetramethylbenzidine
Alcohol Oxidase
Peroxidase
Other additives

PRECAUTIONS

- The One Step Urine Alcohol Test is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration.
- Test materials that have been exposed to urine should be treated as potentially infectious.
- Do not use the One Step Urine Alcohol Test after the expiration date marked on the foil package.
- Limitations on compliance with appropriate preventive measures and local regulations.

STORAGE AND STABILITY

The One Step Urine Alcohol Test is to be stored at 2-27°C(36-80°F, long-term storage recommended 2-8°C(36-46°F)) in its sealed foil package. If storage temperatures exceed 27°C, the test performance may degrade. If the product is refrigerated, the One Step Urine Alcohol Test must be brought to room temperature prior to opening the pouch. Valid for 18 months.

MATERIALS PROVIDED

- Individually foil pouched test strips
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

DIRECTIONS FOR USE

Allow the pouched strip to equilibrate to room temperature (15-27°C) prior to testing.

1. Open the foil package and remove the test strip. Observe the reactive pad on the end of the test strip. If the reaction pad has a blue color before applying Urine sample, do not

use.

2. Saturate the reactive pad with Urine from collection cup or by applying urine directly to the pad. (It usually takes 6-8 seconds to be saturated.) Start timer immediately after urine application.
3. Read result at two (2) minutes. Compare the color of the reaction pad with the chart on foil to determine the relative blood alcohol level.

INTERPRETATION OF RESULTS

Positive: A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the color card.

Negative: No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

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

NOTE: If the test block becomes weak yellow, it does not affect the use of the product. Test strips are disposable and can not be reused.

LIMITATIONS

1. The One Step Urine Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the One Step Urine Alcohol 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.
2. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.
3. Alcohol concentration in human body slowly increases after the alcohol ingestion. Generally, the maximum of alcohol concentration in human urine, appears in the range from 30 minutes to 60 minutes after the last alcohol ingestion. After the maximum appearance, the alcohol concentration in human body reduces. How long the alcohol concentration reduces to zero depends on how much alcohol ingested.

PERFORMANCE CHARACTERISTICS

The detection limit on the One Step Urine Alcohol Test is from 0.02% to 0.30%. The cutoff level of the One Step Urine Alcohol Test can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the foil package.

Assay Specificity

The One Step Urine Alcohol Test will react with methyl, ethyl and allyl alcohols.

INTERFERING SUBSTANCES









The following substances may interfere with the One Step Urine Alcohol Test when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

- A. Agents which enhance color development
- Peroxidases
 - Strong oxidizers
- B. Agents which inhibit color development
- Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and tosylates, Oxalic acid, Uric Acid.
 - Bilirubin
 - L-dopa
 - L-methyldopa
 - Methampyrone

BIBLIOGRAPHY

1. 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.

GLOSSARY OF SYMBOLS

	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical device		Use by
	Manufacturer		Do not reuse
	Temperature limitation		CE making according to IVD Medical Directive 98/97/EC