



Urine Alcohol Rapid Test Dipstick Package Insert

REF DAL-101 English

A rapid, one step screening test for the semi-quantitative detection of Alcohol in urine.

For Forensic Use Only

【INTENDED USE】

The Urine Alcohol Rapid Test Dipstick 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】

It is well established that the concentration of alcohol in urine is comparable to that of blood.^{2,3} The Urine Alcohol Rapid Test Dipstick consists of a plastic dipstick with a reaction pad attached at the middle. 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 (EC 1.1.3.13)
Peroxidase (EC 1.11.1.7)
Other additives

【PRECAUTIONS】

The Urine Alcohol Rapid Test Dipstick 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 Urine Alcohol Rapid Test Dipstick after the expiration date marked on the foil package.

【STORAGE AND STABILITY】

The Urine Alcohol Rapid Test Dipstick is to be stored at 2-30°C (36-86°F) in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Urine Alcohol Rapid Test Dipstick must be brought to room temperature prior to opening the pouch.

【MATERIALS】

Materials Provided

- Test Dipsticks
- Package Insert

Materials Required But Not Provided

- Timer

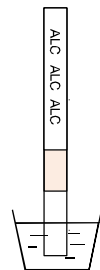
【DIRECTIONS FOR USE】

Allow the pouched dipstick to equilibrate to room temperature (15-30°C) prior to testing.

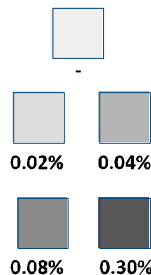
1. Collect the urine in the collection cup provided.

2. Open the foil package and remove the test dipstick. Observe the reactive pad on the middle of the test dipstick. If the reaction pad shows the blue color before applying urine sample, do not use.
3. Immerse the test dipstick vertically in the urine specimen for at least 15 seconds. Start timer immediately after urine application.
4. Read the result in 3-5 minutes. Compare the color of the reaction pad and standard color card to determine the relative blood alcohol concentration.

① Dip in the Urine for 15 seconds



② 3-5 Minutes



【INTERPRETATION OF RESULTS】

Positive: The Urine Alcohol Rapid Test Dipstick will produce a color change in the presence of urine alcohol. The color will range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Urine Alcohol Rapid Test Dipstick is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in urine but less than 0.02% relative blood alcohol.

Negative: When the Urine Alcohol Rapid Test Dipstick shows no color change this should be interpreted as a negative result indicating 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: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with urine. The test is not reusable.

【LIMITATIONS】

1. The Urine Alcohol Rapid Test Dipstick is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Urine Alcohol Rapid Test Dipstick. 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.

【PERFORMANCE CHARACTERISTICS】

The detection limit on the Urine Alcohol Rapid Test Dipstick is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Urine Alcohol Rapid Test Dipstick can vary based on local regulations and laws. Test results can be reference of the color table level standard than color card.

【ASSAY SPECIFICITY】

The Urine Alcohol Rapid Test Dipstick will react with methyl, ethyl and allyl alcohols.

【INTERFERING SUBSTANCES】

The following substances may interfere with the Urine Alcohol Rapid Test Dipstick 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-methyl dopa
- Methampyrone

【CONTROLS】

The Urine Alcohol Rapid Test Dipstick may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in urine is somewhat slower and less intense than with alcohol in an aqueous solution.

【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. Bendtsen p, Hultberg J, Carlsson M, Jones AW.: Monitoring Ethanol Exposure in a Clinical Setting by Analysis of Blood, Breath, Saliva, and Urine. Alcohol Clin Exp Res.1999 Sep;23(9):1446-51.
3. Jones AW, Kugelberg FC.: Relationship between blood and urine alcohol concentrations in apprehended drivers who claimed consumption of alcohol after driving with and without supporting evidence. Forensic Sci Int.2010 Jan 30;194(1-3):97-102.

Index of Symbols

	Attention, see 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				

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