



Chuangxingwell



Breast Milk Alcohol Rapid Test kit Package Insert



A rapid, one step screening test for the semi-quantitative detection of Alcohol in breast milk.
For Self test Use Only.

[INTENDED USE]

The Breast Milk Alcohol Rapid Test kit is a rapid, highly sensitive method to detect the presence of alcohol in breast milk and provide an approximation of relative 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 screening 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 breast milk is comparable to that of blood.² The Breast Milk Alcohol Rapid Test Kit consists of a plastic Dipstick with a reaction pad attached at the middle. On contact with 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
- Tetramethylbenzidine
- Alcohol Oxidase (EC 1.1.3.13)
- Peroxidase (EC 1.11.1.7)
- Other additives

[PRECAUTIONS]

The Breast Milk Alcohol Rapid Test Kit 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 breast milk should be treated as potentially infectious. Do not use the Breast Milk Alcohol Rapid Test Kit after the expiration date marked on the foil package.

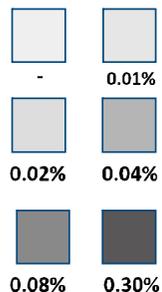
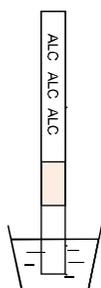
[STORAGE AND STABILITY]

The Breast Milk Alcohol Rapid Test Kit is to be stored at 2-30°C in its sealed foil package. Avoid hot and sunshine, in a dry place, for a period of 24 months. DO NOT FREEZE. Do not open the inner packaging until ready, it must be used within an hour if opened.

[TEST PROCEDURE]

- Bring the pouch to room temperature before opening it.
- By collecting cup collect a cup of Breast Milk.
- Open the foil package and remove the test dipstick. Observe the reactive pad on the middle of the test dipstick. If the reaction pad has a blue color before applying Breast Milk sample, do not use.
- Saturate the reactive pad with Breast Milk from collection cup or by applying Breast Milk directly to the pad. (It usually takes 15 seconds to be saturated.) Start timer immediately after Breast Milk application.
- The results within 3-5 minutes to read. Compare the color of the reaction pad and standard than color card to determine the relative Breast Milk alcohol concentration.

① Dip in the Breast Milk for 15 seconds ② 3-5 Minutes



[INTERPRETATION OF RESULTS]

Positive: The Breast Milk Alcohol Rapid Test Dipstick will produce a color change in the presence of alcohol in breast milk. The color will range from light blue color at 0.01% 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 alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Breast Milk Alcohol Rapid Test Dipstick is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.01% color pad should be interpreted as being positive to the presence of alcohol in breast milk but less than 0.01% relative blood alcohol.

Negative: When the Breast Milk 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 breast milk 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 breast milk. The test is not reusable.

[LIMITATIONS]

1.The Breast Milk Alcohol Rapid Test Kit is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Breast Milk Alcohol Rapid Test Kit. 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 Breast Milk Alcohol Rapid Test Kit is from 0.01% to 0.30% for approximate alcohol level.

[ASSAY SPECIFICITY]

The Breast Milk Alcohol Rapid Test Kit will react with methyl, ethyl and alcohols.

[INTERFERING SUBSTANCES]

The following substances may interfere with the Breast Milk Alcohol Rapid Test Kit when using samples other than breast milk. The named substances do not normally appear in sufficient quantity in breast milk 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 Breast Milk Alcohol Rapid Test Kit 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 breast milk 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. Margaret E. Lawton, PhD : Alcohol In Breast Milk. Ausr NZ J ObsreiGynaec(1985) 25: 71-73.

[Index of Symbols]

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Authorized representative in the European Community		



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