

Breast milk Alcohol Rapid Test Panel

(Breast Milk)

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 Panel 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 Panel consists of a plastic Panel 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
Alcohol Oxidase (EC 1.1.3.13)
Peroxidase (EC 1.11.1.7)
Other additives

【PRECAUTIONS】

The breast milk Alcohol Rapid Test Panel 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 Panel after the expiration date marked on the foil package.

【TEST PROCEDURE】

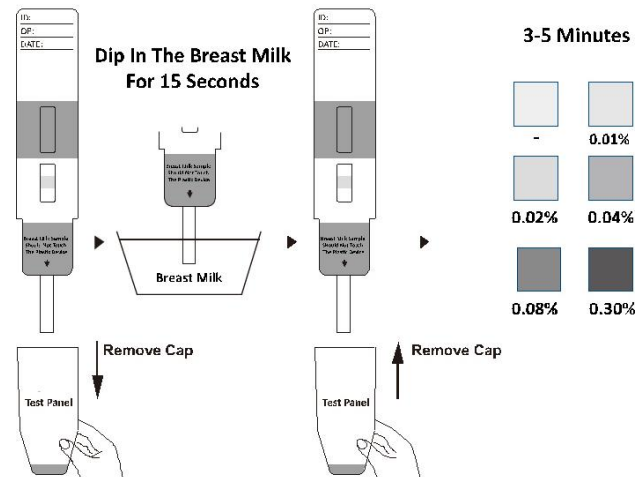
The breast milk Alcohol Rapid Test Panel is to be stored at 2-30°C (36-86°F) in its sealed foil package. *Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.*

1. Remove the cap.
2. With the arrow pointing toward the specimen, immerse the test panel vertically in the specimen for at least 10 to 15 seconds. Immerse at least half of the absorption pad of the test panel, but not beyond the arrow on the test panel.
3. Replace the cap and place the test panel on a non-absorbent flat surface.
4. Start the timer and wait for the results within 3-5 minutes to read. Compare the color of the reaction pad with color card to determine the relative alcohol concentration.

【INTERPRETATION OF RESULTS】

Positive: The breast milk Alcohol Rapid Test Panel 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 Panel 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 Panel 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 Panel is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Breast milk Alcohol Rapid Test Panel. 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 Panel is from 0.01% to 0.30% for approximate alcohol level.

【ASSAY SPECIFICITY】

The breast milk Alcohol Rapid Test Panel will react with methyl, ethyl and allyl alcohols.

【INTERFERING SUBSTANCES】

The following substances may interfere with the breast milk Alcohol Rapid Test Panel 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 Panel 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.

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