

One Step Breast Milk Alcohol Test Strip

Cat. No.: ALC 712

INTENDED USE

The One Step BreastMilk Alcohol Test is a rapid, highly sensitive method to detect the presence of alcohol in milk 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 milk is comparable to that of blood.^{2,3} The One Step BreastMilk 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 (EC 1.1.3.13)
Peroxidase (EC 1.11.1.7)
Other additives

PRECAUTIONS

- The One Step BreastMilk 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 milk should be treated as potentially infectious. Do not use the One Step BreastMilk Alcohol Test after the expiration date marked on the foil package.

STORAGE AND STABILITY

The One Step BreastMilk Alcohol Test is to be stored at 2-27°C (36-80°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 BreastMilk Alcohol Test must be brought to room temperature prior to opening the pouch.

MATERIALS PROVIDED

- 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. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible after observing the reaction pad on the end of the test strip. The reaction pad should have a light cream color. Do not use the test strip if the reaction pad has a blue color before the breast milk is applied or is otherwise discolored.
2. Saturate the reaction pad with breast milk from the collection container or by applying the breast milk directly to the reaction pad. (It usually takes 6-8 seconds to be saturated.)

3. Read results at 2 minutes by visually comparing the color of the reaction pad with the chart on foil to determine the relative blood alcohol level.
4. Do not interpret the result after 3 minutes.

INTERPRETATION OF RESULTS

Positive: The One Step BreastMilk Alcohol Test will produce a color change in the presence of breast milk. 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 One Step BreastMilk Alcohol Test 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 milk but less than 0.02% relative blood alcohol.

Negative: When the One Step BreastMilk Alcohol Test 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 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 saliva. The test is not reusable.

LIMITATIONS

1. The One Step BreastMilk Alcohol Test provides only a preliminary result for detection alcohol concentration in human breast milk. A secondary analytical method must be used to obtain a confirmed result.
2. The One Step BreastMilk Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the One Step BreastMilk 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.
3. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

PERFORMANCE CHARACTERISTICS

The detection limit on the One Step BreastMilk Alcohol Test is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the One Step BreastMilk 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 BreastMilk Alcohol Test will react with methyl, ethyl and allyl alcohols.

INTERFERING SUBSTANCES

The following substances may interfere with the One Step BreastMilk Alcohol Test 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-methyldopa
 - Methampyrone

CONTROLS

The One Step BreastMilk Alcohol Test 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

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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

REF	Catalog number	1	Temperature limitation
1	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	2	Use by
3	Manufacturer	2	Do not reuse

MANUFACTURER

Atlas Link Technology Co., Ltd

Website: <https://www.invitro-test.com>

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