

TECO DIAGNOSTICS

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BREAST MILK ALCOHOL TEST

Intended Use

The breast milk alcohol test is used to detect the presence of alcohol in breast milk and provides an estimate of the blood alcohol concentration. It is intended for over-the-counter use to detect alcohol intoxication. This test detects a breast milk alcohol level of 0.02% or higher.

Test Significance

Breastmilk alcohol levels closely parallel blood alcohol levels. The highest alcohol level in milk occurs 30 to 60 minutes after an alcoholic beverage, but food delays the peak time for milk alcohol levels. Nursing after 1 or 2 alcoholic drinks (including beer) can decrease the infant's milk intake by 20 to 23% and cause infant agitation and poor sleep patterns. Short-term alcohol consumption by nursing mothers has an immediate effect on the sensory characteristics (odor) of their milk and the feeding behavior of their infants^[1]. Alcohol consumption may adversely affect the infant's sleep and gross motor development and influence early learning about alcohol^[2]. The long-term effects of daily use of alcohol on the infant are unclear. Some evidence indicates that infant growth and motor function may be negatively affected by 1 alcoholic drink or more daily, but other studies have not confirmed these findings. Heavy maternal use may cause excessive sedation, fluid retention, and hormone imbalances in breastfed infants.

Test Principle

The alcohol strip test consists of a single reaction pad. When it contacts solutions containing alcohol, the reaction pad will rapidly turn pale blue to dark blue. The degree of color change depends on the concentration of alcohol present in sample.

The test is designed to provide a semi-quantitative measurement of alcohol in the breast milk specimen. This is done by comparing the color developed at the end of the reaction time with the color chart provided.

Warnings and Precaution

1. For *in vitro* diagnostic use only.
2. The strip test is moisture sensitive. It must be used at once after it is removed from the package. Do not use the strip if the pouch is damaged or if it has been opened.
3. Before testing a breast milk sample, the unused test strip's color pad should be compared to the negative (0.0% alcohol in the breast milk) color block. If the unused strip is darker than the negative color block, this may indicate that the product has deteriorated during storage and should not be used.
4. This test should not be interpreted by persons who are color-blind or visually impaired.
5. This test only provides an estimate of the Blood Alcohol Concentration. It should not be used as a tool to determine if it is safe for the user to operate machinery or a motor vehicle.
6. Use a new pipette for each sample to hold off on cross-contamination.
7. Results from this test may not be used for legal proceedings.
8. Results should not be read under sodium vapor lights as the lighting may cause false results.

Storage

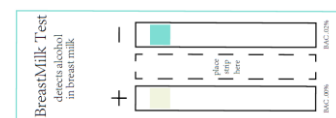
- Store the test strips in sealed pouches at 15-30°C.
- Store the strips in a dry place. Protect from humidity.
- Do not allow the strip test to freeze while in storage.
- Do not use the strip test beyond the expiration date.

Specimen Collection and Handling

Save breast milk samples in a clean collection cup. Collect enough so that a full drop can be applied to the strip. Test the samples at once to avoid alcohol evaporation which may result in a lower reading. Take care when dealing with human samples. They are considered to be possibly infectious. Be sure to minimize the air volume above the breast milk specimen. If the test subject ingests food or beverages, it is important to wait at least 10 minutes before collecting breast milk.

Assay Procedure

1. Take the strip test out of the sealed pouch.
2. Add one drop of breast milk sample to the pad on the strip.
3. Read the results at 2 min by matching the color on the test strip to the color chart on the pouch.



- **White or yellowish:** No alcohol or less than 0.02% alcohol in breast milk.
- **Pale blue** (second window in the color chart): 0.02% alcohol in the breast milk.

Quality Control

Before use, both negative and positive controls should be used to determine assay reliability and performance. Normal breast milk can be used for the negative control. Proper user technique can also be confirmed using positive and negative controls. If the expected results are not achieved with the controls, do not proceed with testing. Negative samples can be collected from any lactating woman who has not consumed any alcohol or products containing alcohol.

Limitation of Procedure

The breast milk alcohol test is a semi quantitative test for the detection of ethanol. Other alcohols may produce positive results if present in the breast milk sample.

REFERENCES

- [1] *Mennella JA, Beauchamp GK.*: The transfer of alcohol to human milk. Effects on flavor and the infant's behavior. *N Engl J Med.* 1991 Oct 3; 325(14):981-5.
- [2] *Julie Mennella.*: Alcohol's Effect on Lactation. *Alcohol Res Health.* 2001;25(3):230-4.

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Manufactured by:



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