### **Breastmilk Alcohol Test**

User Manual





#### **INTENDED USE**

The Breastmilk Alcohol Test is a fast, 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 screening only. An alternate method must be used in order to obtain a confirmative result. Consult your physician with any results that are concerning or you have questions, particularly when preliminary screen tests show positive.

#### **HOW DOES IT WORK**

It is well established that the concentration of alcohol in milk is comparable to that of blood. The Breastmilk Alcohol Test consists of a plastic strip with a reaction pad. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a chemical reaction which uses a highly specific reaction.



#### WHAT DO YOU NEED

#### Materials Provided

 Test strips Package insert

#### Materials Required but Not provided

Specimen collection container

Timer

#### **HOW TO PERFORM THE TEST**

Allow the pouched strip to adjust to room temperature (15-30°C / 59 - 86°F) prior to testing.

- 1. Remove the test strip from the sealed pouch and use it as soon as possible. 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 color chart to determine the relative blood alcohol level.

Do not interpret the result after 3 minutes.







#### **HOW TO READ THE RESULTS**

#### Positive:

The Breastmilk Alcohol Test will produce a color change in the presence of alcohol in 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.

#### Negative:

When the 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, it is void.

NEGATIVE POSITIVE AC 0.08% 20mg/dL 40ma/dL 80mg/dL 300mg/dL

NOTE: If the outer edges of the color pad produces a slight color, but the majority of the pad remains colorless at the read time, the test should be repeated to ensure complete

saturation of the pad with breast milk.

Disclaimer: The tests are not reusable.

#### STORAGE AND STABILITY

The Breastmilk Alcohol Test is to be stored at 4-30°C (39.2-86°F) in its sealed foil package. If storage temperatures exceed 30°C (86°F), the test performance may degrade. If the product is frozen during transition, the Breastmilk Alcohol Test must be brought to room temperature prior to opening the pouch.

#### SPECIMEN STORAGE

The breast milk specimens may be stored in a sealed container at 15-30°C (59 - 86°F) for up to 4 hours. Specimens maybe refrigerated and stored at 2-8°C (35.6 - 46.4°F), up to 2 days. Do not freeze the specimens. Refrigerated specimens should be brought to room temperature before testing.

#### **PRECAUTIONS**

- 1. The test strip is for external use only. Do not swallow.
- 2. Discard after first use. The test strip cannot be used more than once.
- 3. Do not use the test strip beyond the expiration date.

- **4.** Do not use the the test strip if the test pouch is punctured or not fully sealed.
- 5. Keep out of the reach of children.

#### LIMITATIONS OF THE TEST

- The Easy@Home Breastmilk Alcohol Test provides a preliminary result for detecting alcohol concentration in human breastmilk. A secondary analytical method must be used to obtain a confirmed result.
- 2. The Easy@Home Breastmilk Alcohol Test is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the 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.
- Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

#### TEST PERFORMANCE CHARACTERISTICS

The detection limit on the Breastmilk Alcohol Test ranges from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Breastmilk Alcohol Test can vary

based on local regulations and laws. Test results should be compared to reference levels with color chart.

#### Assay Specificity

The Breastmilk Alcohol Test will react with methyl, ethyl and allyl alcohols.

#### Interfering Substances

The following substances may interfere with the 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
- Peroxides
- 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

#### **QUESTIONS&ANSWERS**

Q1. What is the alcohol threshold for these tests? What level of alcohol does it detect?

The results of the easy@Home Breastmilk Alcohol Test will show the concentration of alcohol in breastmilk

in a scale from 0.02% (20mg/dL) to 0.30%(300mg/dL). This is represented by the intensity of the blue color. The darker the color, the higher concentration of alcohol in your breastmilk.

# Q2. Can you just drop a few drops on the test strip or do you have to dip the strip in it?

Yes, You can. For accurate results saturate the test pad completely. Either express a few drops of breastmilk directly onto the test strip OR dip the test pad in a small portion of freshly collected milk is OK. (Use a sterile and dry cup to collect. Test breastmilk right away.)

## Q3. What is the alcohol threshold for these tests? What level of alcohol does it detect?

The results of the easy@Home Breastmilk Alcohol Test will show the concentration of alcohol of breastmilk from a scale of 0.02% (20mg/dL) to 0.30%(300mg/dL) at the 2-3 minute read time. This is represented by the intensity of the blue color. The darker the color, the higher concentration of alcohol in your breastmilk. Please refer to the color chart.

# Q4. What does it mean if it appears clean at 2 minutes, but then change color at 5 minutes?

Results should be read at 2 minutes by visually comparing the color of the reaction pad with the color chart to determine the relative alcohol level. Chemicals on the strip can continue to activate past the read time. Always interpret the results at the read time for accuracy. DO NOT interpret the result after 3 minutes.

## Q5. Can I use the test strip with other liquids other than breastmilk?

The easy@Home Breastmilk Alcohol Test was designed exclusively to detect the alcohol presence in breast milk only. Please do not test with other liquids, like water, wine, beer or liquor. Testing with other liquids than breastmilk can result in inaccurate results.

## Q6. Can these be used on refrigerated milk while it's still cold? Or does that effect the results?

For the best results, breastmilk should be at room temperature, preferably - body temperature. However, it should be effective even when stored in the refrigerator. Make sure to bring it back to room temperature before testing.

#### **MEANING OF SYMBOLS ON PACKAGE**



Keep away from sunlight



Store between 39°F and 86°F



eep dry



Do not re-use

### **Jealthcare-Manager.com**

Questions or comments?

Please call toll-free:

1-855-822-6999 M-F 9 a.m.-5 p.m. CST

E-mail: service@healthcare-manager.com

Easy Healthcare Corporation

360 Shore Dr. Burr Ridge, IL USA 60527

To learn more, please visit us at www.healthcare-manager.com

Version No.: 01

Effective Date: 2019-06-12