

TECO DIAGNOSTICS

1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

BREAST MILK TEST STRIPS

INTENDED USE

For the semi-quantitative determination of protein, calcium and zinc in breast milk samples. For *in vitro* use only. Read all instructions, precautions, and limitations carefully before performing this test.

SUMMARY AND EXPLANATION

Teco Breast Milk Test Strips (BMS) provide information regarding the status of the amount of Zinc, Calcium, and Protein in breast milk. These parameters are all important to test since they provide infants with a maintained immune system and rapid cell growth, strong muscles and bones, and healthy development, respectively.

Teco BMS strips are stable and ready to use upon removal from the bottle. The entire reagent strip is disposable. Results are obtained by direct comparison of the test strip with the color blocks printed on the bottle label. No calculations or laboratory instruments are required.

TEST PRINCIPLE

In general, all three tests are based on the chemical reactions of the indicator reagents on the pads with components in the breast milk sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the container color chart label.

STORAGE

1. Store at room temperature between 15°C – 30°C.
2. All test strips should be stored in the original container. Do not remove desiccant from bottle.
3. Do not expose to direct sunlight.
4. Do not open container until ready to use.
5. Remove only as many strips required for testing and immediately recap the container tightly.
6. Do not use after expiration date.

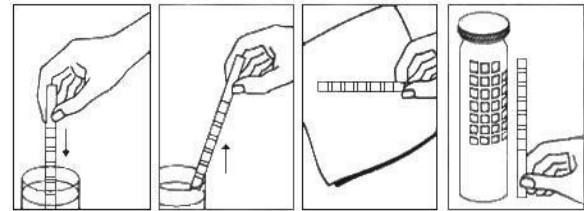
PRECAUTIONS

Breast Milk Test Strips are for *in vitro* diagnostic use. Do not touch test areas on the test strips.

SPECIMEN COLLECTION AND PROCEDURE

1. Collect breast milk in a clean glass or plastic container.
2. Test milk sample as soon as possible after collection. Refrigerate milk sample immediately if the sample cannot be tested within one hour. Bring refrigerated sample to room temperature and mix thoroughly before testing.
3. Do not centrifuge or add preservatives to the breast milk sample.
4. Aliquot a small portion of the breast milk sample into another container for testing in order to avoid contamination of the whole milk sample. Do not dip the test strips directly into the primary collection container.
5. Remove enough strips from the bottle for immediate use and replace cap tightly
6. Completely immerse reagent areas of the strip in fresh, well-mixed breast milk. Remove the strip immediately to avoid dissolving out the reagent areas.

7. While removing, touch the side of the strip against the rim of the milk container to remove excess breast milk. Blot the lengthwise edge of the strip on an absorbent paper towel to further remove excess liquid and avoid running over (contamination from adjacent reagent pads).
8. Obtain results by direct color chart comparison.



Note: All reagent areas may be read after 30 seconds for screening breast milk. Changes in color after 30 seconds are of no diagnostic value.

INTERPRETATION OF RESULTS

Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding test color block pictured on the container label. No equipment is required.

QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimens or controls whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance, and should not question handling and testing procedures if these standards are not met.

LIMITATIONS

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness.

As with the laboratory tests, definitive diagnostic or therapeutic decision should not be based on any single test result or method.

EXPECTED VALUES

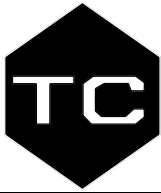
Protein: Total protein concentration in colostrum milk is around 17-45 g/L. The total protein level in mature milk is around 12-22 g/L¹.

Calcium: 200-400 mg/L throughout postpartum period².

Zinc: Zinc concentration begins around 4 mg/L at 2 week of lactation and drops to around 2 mg/L at 4 months postpartum³.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Teco Breast Milk Test Strips (BMS) have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy, and precision.



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For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for this reason that users are encouraged to develop their own standards of performance.

FREQUENTLY ASKED QUESTIONS

Why is it so important for my child to drink breast milk rather than formula?

Newborn infants are easily susceptible to contract an illness. Being breast fed decreases a baby's risk of contracting illnesses such as Type 1 and Type 2 diabetes⁴.

Human breast milk provides them with the nutrients they need in order to be healthy and strong. Breast milk provides natural antibodies to help fight infection, contributes to organ development, and is easy to digest⁵.

With the help of Teco Breast Milk Test Strips, mothers will be able to rest their breast milk in order to check if it has a sufficient amount of minerals that will fit their baby's needs.

Why is protein important in breast milk?

The proteins of human milk are divided into the whey and casein fractions or complexes. They are the sources for infant to build blocks of muscle and bone. Some proteins serve a wide range of other functions, including defense against pathogens.

Why is Calcium important in breast milk?

Calcium is important for infant's bone development. Some researches show that a very low calcium intake can contribute to the development of rickets in infants and children. Some studies also demonstrate that the bioavailability of calcium from human milk is greater than that from infant formulas or cow's milk.

Why is Zinc important in breast milk?

Zinc is a micronutrient which is critical to normal growth and development of the infant. The zinc in breast milk is well absorbed and utilized, or highly bioavailable to infant. Zinc level usually drops 4-6 months postpartum. The choice of complementary foods is important to maintain adequate zinc status in breastfed infants after 6 months.

Do these strips only work for breast milk?

Teco Breast Milk Test Strips test for quantities of Zinc, Calcium, and Protein in both human breast milk and cow's milk.

REFERENCES

1. Mladenović M, et al. Variations in the concentration of total human milk proteins in the first month of lactation. *Srp Arh Celok Lek.* 2007 Mar-Apr;135(3-4):163-6.
2. Jenness, R. (1979). The Composition of Human Milk. *Medline*,3(3), 225-239.
3. Yalcin, S. S., Yalcin, S., & Gucus, A. I. (2015). Zinc and Copper Concentrations in Breast Milk During the First Nine Months of Lactation: A Longitudinal Study. *Pediatrics*,135(Supplement).
4. Ballard, O., & Morrow, A. L. (2013). Human milk composition: nutrients and bioactive factors. *Pediatric Clinic of North America*, 60(1), 49-74.
5. Stuebe, A. (2009). The Risks of Not Breastfeeding for Mothers and Infants. *Reviews in Obstetrics and Gynecology*,2(4), 222-231.

BMS-3 Rev. 02/2021

Manufactured by:



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