

Intended Use

Amnicator® is a rapid and simple method intended for detecting ruptured amniotic membrane in pregnant women. For professional use only.

Summary and Principles

Rupture of the amniotic membrane can result in the leaking of amniotic fluid into the vagina. The presence of amniotic fluid tends to elevate the pH of the upper vagina. Detection of this pH increase using a pH indicator dye has been shown to assist in determining the presence of amniotic fluid as an indirect indication of ruptured amniotic membrane.

Precautions

For professional use only.

Amnicator® is intended for in vitro use only.

Do not open the pouch until ready to use.

Do not use Amnicator® after expiry date shown on the product label.

Once used, Amnicator® swabs are considered potentially infectious and precautions appropriate for bio-hazards must be observed.

For single use only. Do not reuse swabs.

The swab is sterile in the unopened and undamaged pouch.

The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid information.

DO NOT USE IF PACKAGE SEAL IS BROKEN.

Material Safety Information

Amnicator® plastic components do not contain latex or PVC.

Storage

Amnicator® swabs in individually wrapped pouches should be stored at room temperature (5°C to 25°C) in the box. Do not expose the swabs to bright light.

Product stored under these conditions will be stable until the expiry date shown on the label. Do not open the pouch until ready to use.

Expiry Date

2 years from date of manufacture, expiration date is shown on the peel pouch, and box label.



Instructions for Use:

1. Cleanse the vulva and vaginal introitus.
2. Carefully insert a bi-value speculum (e.g., Cusco's speculum) into the vagina exposing the cervix.
3. Pass an Amnicator® swab into the vagina and sample for 10 to 15 seconds any liquid present at the external cervical os or in posterior fornix of the vagina.
4. Withdraw the Amnicator® swab and inspect the colour of the swab tip immediately.
5. Compare the colour of the Amnicator® swab with the colour chart.

INTERPRETATION OF RESULTS

Compare the colour of the Amnicator® swab tip with this colour chart*.

**Please note these colours are an approximate representation, and there can be small variations due to inks and printing processes, or screen colours if viewed on line.*

Intact Membranes**pH 5.0 Yellow****pH 5.5 Yellow/Olive****pH 6 Olive green****Ruptured Membranes****pH 6.5 Black/Dark green****pH 7.0 Blue-black****pH 7.5 Blue****Quality Control**

Laboratories wishing to perform optional in-house quality control may use buffers corresponding to the pH values listed on the Amnicator® colour chart

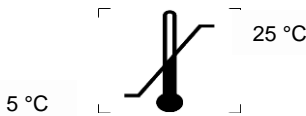
Limitations

1. Amnicator® test is designed to be used by qualified medical professional and is intended as an aid to professional diagnosis.
2. Amnicator® test can only indicate a change in pH value and should be used only as indicated in the Test Procedure described above.
3. Antibiotic therapy, the presence of creams, gels, semen, blood, or vaginal infection can alter the normal vaginal pH which may lead to false positive result.
4. If vaginal infection is suspected, microbiological testing should be used to exclude infection.



References

1. Abe T. The detection of the rupture of foetal membranes with the nitrazine indicator. Am J. Obst. & Gynec. 1940. 39:400-404.
2. Drife J. Preterm rupture of the membranes. Brit. Med. J. 1982; 285:583.
3. Mills A., Ganloch D. Use of the nitrazine yellow swab test in the diagnosis of the ruptured membranes. Brit. J. Obst. & Gynec. 1977; 84:138-140.
4. Pauersterin C. Premature rupture of the membranes. In; Clinical Obstetrics, Anonymous, ed. John Wiley & Sons and Churchill Livingston. 1987; 367-381.
5. Pritchard J, Macdonald P. Williams Obstetrics, anonymous, ed. New York: Appleton-Century-Crofts, 1960; 407-408.
6. Filet JP, More N, Librati C, Ruffie A, Delouis P, Cluzeau MH, Hocke C, and Lang JJ. Évaluation de trois méthodes diagnostiques dans la rupture prémature des membranes. Rev. Fr. Gynecol. Obstet. 1994; 89:123-128.
7. Dickinson, F., Soltani H. & Allsop J., 2005, Review of the Use of Nitrazine Yellow Swabs in Pre-Labour. 27th Triennial Congress International Confederation of Midwives, Brisbane, Australia.



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