CODE	DESCRIPTION	SPECIMEN/SAMPLE SITE
MWAM1/C	Amnicator® - Amniotic Fluid Test for the Detection of PROM	Obs & Gynae
MWAM1/B	Amnicator® - Amniotic Fluid Test for the Detection of PROM - Bulk packed 4x125	Obs & Gynae
MWAM2	Amnicator® - Amniotic Fluid Test for the Detection of PROM	Obs & Gynae
MWAM5	Amnicator® - Amniotic Fluid Test for the Detection of PROM	Obs & Gynae

MDD: European Medical Devices Directive 93/42/EEC

IVD: European In Vitro Diagnostic Medical Devices 98/79/EC

***For Tube Only IVD's, the Notified Body number for CE, and Approved Body number for UKCA do not appear on the markings.**

INTENDED USE

Amnicator® is a rapid and simple method intended for detecting ruptured amniotic membrane in pregnant women. This device is designed for **professional use only, following the recommend instructions for use.**

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.

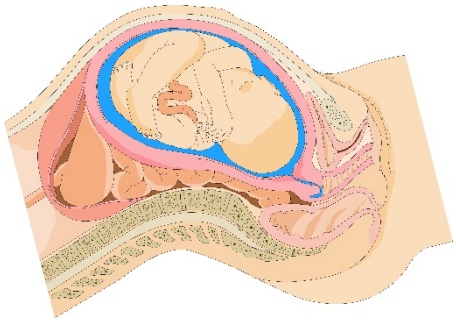
REAGENTS

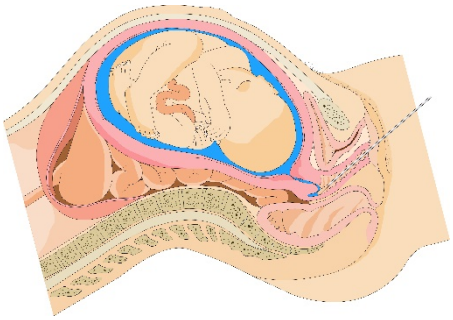
No dangerous components are defined by regulations.

Metolose

Nitrazine Yellow

INSTRUCTIONS FOR USE (FOR PROFESSIONAL USE ONLY)





1. In a Medical setting, Lay the patient on their back, 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. Remove the Amnicator® swab from the peel pouch taking care not to touch the tip, or allow it to come into contact with other substances.
4. Pass an Amnicator® swab into the vagina and sample for 10 to 15 seconds any liquid present at the external cervical or in posterior fornix of the vagina.
5. Withdraw the Amnicator® swab and inspect the color of the swab tip immediately.
6. Compare the color of the Amnicator® swab with the color chart*

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

Intact Membranes

Medical Wire & Equipment Co (Bath) Ltd
Leafield Industrial Estate, Corsham, Wiltshire,
England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

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

PRECAUTIONS

FOR PROFESSIONAL USE ONLY. NOT TO BE USE IN ANY OTHER WAY.

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 biohazards 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 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 (5ºC to 25ºC) 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.

QUALITY CONTROL

Laboratories wishing to perform optional in-house quality control may use buffers corresponding to the pH values listed on the Amnicator® color 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 results this can occur in 17% of cases.

Medical Wire & Equipment Co (Bath) Ltd
Leafield Industrial Estate, Corsham, Wiltshire,
England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

4. If vaginal infection is suspected, microbiological testing should be used to exclude infection.
5. False negatives may happen if the sample is insufficient or if the rupture of membranes is minor or intermittent. Additionally, the test does not provide information about the extent of the rupture or the amount of amniotic fluid remaining.

REFERENCES

1. Abe T. The detection of the rupture of fetal 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 prématurée 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.

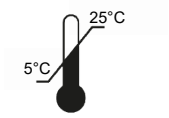
REGULATORY SYMBOLS APPLICABLE FOR FAMILY GROUP

5 °C 25 °C STERILE R MD CE 1639 UK CA 0120

EC REP Advena Ltd, Tower Business Centre, 2nd Fl., Tower Street, Swatar, BKR 4013, Malta

CH REP Swiss AR Services AG Industriestrasse 47 CH-6300 / Zug

SYMBOLS & DEFINITIONS



Temperature Limitation

Do Not Reuse

Do Not Use If Package Damaged

Manufacturer

CE 1639
CE Mark

IVD
In Vitro Diagnostic Medical Device

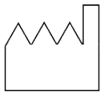
MD
Medical Device

STERILE R
Method of Sterilisation Using Irradiation

EC REP
Authorised Representative in the European Community

SGS UKAS
SGS Approval Mark

Use By (YYYY/MM)


Date of Manufacture

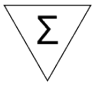
UK CA
UKCA Mark

REF
Catalogue Number

LOT
Batch Code

Consult Instructions for Use

Peel Here



Contains Sufficient for <n> Tests

CH REP
Swiss Representative

Medical Wire & Equipment Co (Bath) Ltd
Leafield Industrial Estate, Corsham, Wiltshire,
England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk

THINK BEFORE YOU PRINT

Medical Wire & Equipment Co (Bath) Ltd
Leafield Industrial Estate, Corsham, Wiltshire,
England SN13 9RT
Tel: +44 (0)1225 810 361 Fax: +44 (0)1225 810 153
info@mwe.co.uk www.mwe.co.uk