Amnicator®

Intended Use
Amnicator® is a simple swab screening system for the detection of the rupture of the amniotic membranes during pregnancy.

Background
Rupture of the amniotic membranes can result in the leakage of small amounts of amniotic fluid into the upper vagina. This causes any moisture or fluid in the upper vagina to become less acidic. This change can be detected by a change in colour of a pH indicator dye. The pH value is a simple measure of the acidity or alkalinity of a substance.

Principle
A swab impregnated with the pH indicator dye, nitrazine yellow, is brought into contact with the upper vagina. The swab absorbs any fluid, and the colour of the dye will change according to the pH value of the fluid.

Amniotic fluid has a neutral pH (pH around 7.0) while the normal moisture or fluid within the vagina is acidic (pH less than 6.0). If the fluid picked up by the swab is acidic (pH 6.0 or less) the swab bud will remain yellow, or yellow-blue, and indicates that there is no rupture. If the pH is greater than 6.0 the swab will turn blue-yellow or dark blue, indicating that amniotic fluid may be present due to ruptured membranes.

Reagents
Amnicators® consist of disposable swabs impregnated with nitrazine yellow dye. The swabs are packed within individual peel pouch sleeves. Swabs are sterilised by gamma irradiation and are sterile medical devices.

Precautions
1. Amnicator® is only intended for the detection of amniotic fluid, and should not be used for any other procedures.
2. Amnicator® should not be used after the expiry date shown on the product label and printed on the individual peel pouches.
3. Following contact with the vagina, swabs should be disposed of carefully.
4. Amnicators® should not be reused.

Storage
Amnicators® in their individual peel pouches should be stored at room temperature, and away from direct sunlight in the Ziplock bag. Under these conditions the product is stable until the expiry date shown.

Procedure
1. Remove Amnicator® swab from peel pouch. Take care not to touch the tip, or allow it to come into contact with other substances.
2. Part the labia exposing the cervix and carefully insert the swab into the vagina. Do not allow the swab to come into contact with vaginal tissue during entry.
3. Allow first and only contact of the Amnicator® swab bud to occur with the upper vaginal tissue, and allow bud to remain in contact for 15 seconds.
4. Carefully remove swab and examine the colour of the bud, according to the chart below.
5. If the colour indicates a pH of 6.0 or less, this indicates that the fluid which has been sampled is not amniotic fluid and that the amniotic membranes have not ruptured.
6. If the colour indicates a pH of greater than 6.0, it is possible that the fluid which has been sampled does contain amniotic fluid, and that the amniotic membranes may have ruptured. Further medical advice should be sought urgently.

Interpretation
The colour of the Amnicator® bud after use should be compared to the sample colours below.

Intact Membranes

pH 5.0 Yellow	pH 5.5 Yellow / Olive	pH 6.0 Olive Green
		

Ruptured Membranes

pH 6.5 Blue / Dark Green	pH 7.0 Blue	pH 7.5 Blue / Black
		

Quality Control
Routine quality control of Amnicator® swabs is **not** required. Laboratories which wish to perform optional in-house controls may use buffers corresponding to the pH values listed on the Amnicator® test colour chart above.

1. Remove one Amnicator® swab from its peel pouch.
2. Wet the bud with 3-4 drops of buffer solution.
3. Immediately compare the colour developed on the bud with the closest matching colour on the test card.
4. If the pH value written next to the colour selected on the card corresponds to the pH of the buffer solution, then the Amnicator® is performing correctly. If the pH indicated on the test card fails to match the pH of the buffer used, repeat the test with a fresh Amnicator®. If the pH values still do not match, the Amnicators® are not performing correctly and the remaining Amnicators® from the box should not be used.
5. Individual Amnicators® used for quality control should be discarded and are not to be used for clinical testing.

Limitations of the procedure
1. Amnicators® are intended to be used by qualified medical professionals such as midwives, nurses, and general practitioners.
2. Amnicator can only indicate a change in the acidity of vaginal moisture or fluid, and should be used only as described in the above procedure.
3. Antibiotic therapy or infections of the vagina can alter the acidity of vaginal fluid and may give a false indication of amniotic fluid.

Materials supplied
Each Amnicator® is contained in a single sterilized peel pouch. Amnicators® are supplied in packs of 20, 50 or 100 units.

References

1. Abe,T. The detection of the rupture of fetal membranes with the nitrazine indicator. *American Journal of Obstetrics and Gynaecology* 1940, **39:**400-404
2. Drife,J. Preterm rupture of the membranes. *British Medical Journal* 1982;**285:**583
3. Mills, A., Garrioch D., Use of the nitrazine yellow swab test in the diagnosis of ruptured membranes. *British Journal of Obstetrics and Gynaecology* 1977; **84:**138-140
4. Pauersterin, C., Premature rupture of the membranes. in: *Clinical Obstetrics,* Anonymous,ed., John Wiley & Sons and Churchill Livingstone, 1987; 367-381
5. Pritchard, J., Macdonald, P., *Williams Obstetrics* Anonymous,ed., New York: Appleton-Century-Crofts, 1980; 407-408
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