PRO-LAB DIAGNOSTICS

AMNIOTEST™

Nitrazine Yellow Swabs

(for in vitro diagnostic use)

PRODUCT CODE PL.901

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INTENDED USE

AmnioTest™ is a qualitative, pH-based, swab screening system intended as an aid in detecting rupture of amniotic membrane in pregnant women.

SUMMARY AND EXPLANATION

Rupture of the amniotic membrane can result in small volumes of amniotic fluid leaking into the upper 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[1,2,3].

PRINCIPLE OF THE PROCEDURE

A swab impregnated with nitrazine yellow dye is brought into contact with the upper vagina. The swab absorbs fluid associated with the tissue and the dye develops a colour which correlates with the pH of the absorbed fluid over the range pH 5.0 to pH 7.5.

Amniotic fluid has a neutral pH while the pH of the upper vagina is normally acidic. A pH of 6.5 or higher in the upper vagina is consistent with leakage of amniotic fluid [1,2,3].

REAGENTS

Pro-Lab AmnioTest™ consists of disposable swabs impregnated with nitrazine yellow dye. The swabs are packaged in individual sleeves. Swabs are sterilized by gamma radiation and are sterile until opened.

PRECAUTIONS

1. Pro-Lab AmnioTest™ is intended for In Vitro Diagnostic use only.
2. Do not use AmnioTest™ after expiry date shown on the product label.
3. Following contact with the vagina, swabs should be considered potentially infectious and precautions appropriate for microbiological hazards must be observed.
4. Do not reuse swabs.
5. The procedures, storage conditions, precautions and limitations specified in these directions must be adhered to in order to obtain valid information.

STORAGE

Sleeves should be stored at room temperature (15° to 30°C). Product stored under these conditions will be stable until the expiry date shown on the label.

PROCEDURE

1. Remove a swab from its protective sleeve. DO NOT touch the tip of the swab or allow it to come into contact with any liquid or other substance which might affect pH.
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 AmnioTest™ swab tip to occur with upper vaginal tissue (posterior vaginal fornix and external cervical os).
4. Allow the tip to remain in contact with upper vaginal tissue for about 15 seconds.
5. Carefully remove the swab and immediately examine the colour of the tip.

QUALITY CONTROL

Routine quality control of the swabs is **not** required when performing this test. Laboratories wishing to perform optional in-house quality control may employ buffers corresponding to the pH values listed on the AmnioTest™ Colour card.

1. Remove one AmnioTest™ swab from its sleeve.
2. Wet the swab's tip with 3 to 4 drops of buffer solution.
3. Immediately compare the colour developed on the swab tip to the closest matching colour on the AmnioTest™ Colour 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 swab is performing as expected. If the pH indicated on the Colour card fails to match the pH of the buffer used, repeat the test with a fresh swab. If the pHs still do not match, the swab is not performing as expected and the remaining kit should not be used to test clinical specimens.
5. Individual swabs tested in this manner should be discarded and must not be used for testing clinical samples.

INTERPRETATION OF RESULTS

The colour of the tip of the AmnioTest™ swab after use should be compared to the sample colours of the enclosed AmnioTest™ Colour Card.

Group	Colour	Approximate pH value	Indication Consistent with:
A	Yellow	not applicable	Fresh swabs
B	Yellow/Gold	5.0	Intact Amniotic Membrane
	Yellow/Olive	5.5	
	Olive	6.0	
C	Dark Green	6.5	Possible Ruptured Membrane
	Dark Blue/Green	7.0	
	Navy Blue	7.5 or higher	

LIMITATIONS OF THE PROCEDURE

1. PRO-LAB AmnioTest™ is designed to be used by qualified medical professionals and is intended as an aid to professional diagnosis.
2. AmnioTest™ can only indicate a change in pH value and should be used only as indicated in the Test Procedure described above.
3. Antibiotic therapy or infections of the vagina can lead to elevated vaginal pH resulting in a false interpretation of determin-ing the presence of amniotic fluid. Where doubt exists, standard microbiological testing should be employed to exclude infection.
4. False negative results may occur with tests of this nature. A negative test result does not preclude the possibility of rupture of the amniotic membrane in pregnant women. Other clinical findings should be considered when interpreting negative test results.
5. Sample colours on the Colour card are examples and should not be interpreted as an absolute match for actual test results.

MATERIALS SUPPLIED

Each PRO-LAB AmnioTest™ is contained in a single sterilized sleeve. One hundred such units are packed into a box containing an AmnioTest™ Colour Card (PL.902) and Product Instructions for Use.

PERFORMANCE CHARACTERISTICS

Method Comparison – Two Labour and Delivery Departments in the Eastern United States compared the performance of the Pro-Lab AmnioTest™ device with the accepted method of swab and nitrazine paper. 50 patients were tested by both methods during routine amniotic membrane status assessment.

Table 1: Method Comparison of AmnioTest™ and Swab-Nitrazine Paper

	Swab-nitrazine paper positive	Swab-nitrazine paper negative
AmnioTest™ positive	22	1
AmnioTest™ negative	0	27

Positive Agreement (23/22)* = 95.7%
Negative Agreement (27/28) = 96.4%
Overall Agreement (49/50) = 98.0%

Note* - Inverse value was taken here to give an appropriate percentage value

Conclusion – AmnioTest™ is a safe, effective, and convenient aid for detecting rupture of the amniotic membrane in pregnant women.

REFERENCES

1. Abe, T. 1940. Am. J. Obst. & Gynec. 39:400.
2. Sklovsky, E., MacLennan, A.H. 1976. Brit. M. J. 2:1014.
3. Mills, A., Garrioc, D.B. 1977. Brit. J. Obst. & Gynec. 84:138-140.

	= Use by
LOT	= Lot number
REF	= Catalogue number
	= Manufacturer
EC REP	= Authorized Representative in the European Community
Σ	= Contains sufficient for <n> tests
IVD	= In vitro diagnostic medical device
	= Temperature limitation
	= Consult instructions for use
STERILE R	=Sterilization using irradiation

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