Ref: 0524

AMNIOQUICK®

Rapid test for detection of IGFBP-1 (Insulin Growth Factor Binding Protein 1)

CE

INTENDED USE

AMNIOQUICK® is a simple and rapid test that allows *in vitro* detection of IGFBP-1 (Insulin Growth Factor Binding Protein 1) from a vaginal swab sample. AMNIOQUICK® test is intended to detect the rupture of fetal membranes in pregnant woman with suspected rupture from a vaginal swab sample. Each test is used to obtain a visual result.
The AMNIOQUICK® Test Device can be used as an aid to initiate or attend therapeutic treatments by physicians. Each device is designed for professional and *in-vitro* diagnostic.

INTRODUCTION

The **P**remature **R**upture of **M**embranes or **PROM** is relatively frequent and concerns 5 to 10 % of pregnancy cases. It might lead to preterm delivery and fetal infection. The leakage of amniotic liquid is not always detectable by conventional clinical examination and therefore confirmatory biological test is sometimes useful. Biological tests are based on detection of alkalinization of vaginal fluid (easy to proceed, sensitive, inexpensive but poorly specific) or presence of a molecule which is physiologically present in high concentration in amniotic fluid (diamine oxidase, alpha feto protein, fibronectin, IGFBP-1).

TEST PRINCIPLE

A pair of monoclonal antibodies anti-IGFBP-1 is used for the IGFBP-1 detection. One is immobilized on the nitrocellulose membrane at the level of the test line: it corresponds to the capture antibody. Another one is labelled with colloidal gold for the subsequent revelation.
During the sample migration, IGFBP-1, if present in the sample, will form antigen-antibody complexes with the labelled antibodies. These complexes will be captured by the capture antibodies on the test line, creating one purple coloured line generated by gold nanoparticles.
The presence of a purple internal control line in the upper part of the membrane indicates that the result is valid and that the followed procedure is correct.

MATERIAL PROVIDED

- Test strips individually pouched with a desiccant.
- Sterile Dacron vaginal swab.
- Unit dose vial of Diluent.
- Workstation (or rack tube).
- Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

- Stop watch or timer.

STORAGE AND STABILITY

AMNIOQUICK® test is packed in aluminium pouch with desiccant bag. The kit should be stored in a dry area at 2-30°C.

Under these conditions the strip is stable until the indicated expiry date. The strip must be protected from humidity. Once the pouch is open, the test should be performed within 1 hour maximum.

PRECAUTIONS

- For diagnostic *in vitro* use only.
- For best results, strictly follow the test procedure and storage instructions.
- Do not open the foil pouch until it reaches room temperature to prevent formation of condensation. Humidity and high temperature can affect results.
- Do not use the kit beyond the expiration date.
- Do not to eat, drink or smoke during the handling of the samples and the test.
- Do not pipet by mouth. Use white coat, disposable gloves and ocular protections while handling potentially infectious material and performing the assay.
- All patient samples should be handled as potentially infectious. When performing the test, all materials used should be treated as if they were potentially infectious. Then, eliminate the components of the test and the sample according to the suitable procedure for potentially infectious waste.
- Avoid splashes and aerosol formation. Clean up spills thoroughly using an appropriate disinfectant.
- Test strips provided in the kit are intended for single use. Do not re-use.
- Do not interchange or mix reagents from different kits and lots.
- Do not use a strip if the foil pouch is opened or damaged.

SPECIMEN COLLECTION AND HANDLING

Use the sterile Dacron swab to collect secretions on the vaginal wall. Open the swab bag and place the swab into the vagina (5 cm depth) for 1 minute.
Alternatively, speculum may be used and vaginal secretion may be collected by leaving the swab into the vagina (5cm depth) for 15 seconds.
Collection of sample from the cervix or from the posterior fornix should be avoided. The epithelial cells located in those zones may contain elevated levels of phosphorylated IGFBP-1 that may cross react with the test.

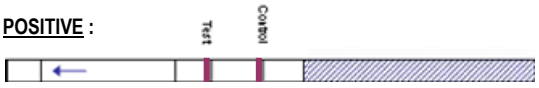
TEST PROCEDURE

1) Bring the complete kit and samples to be tested to room temperature prior to testing.
2) Open the unit dose vial and lay it vertically on a flat and horizontal surface.
3) Dip the swab into the unit dose vial and rotate for 10 seconds. Then discard the swab.
4) Dip the strip into the vial with arrows pointing downwards. Gently hit the dipstick on the bottom of the tube to enhance migration. Keep the strip in the tube in vertical position for 10 minutes.
5) Read the result after 10 minutes from the time the strip is dipped in the tube. **Do not interpret any Test band appearing 15 minutes after the strip is dipped in the vial.**
6) Then, eliminate the components of the test and the sample according to the suitable procedure for potentially infectious waste

RESULTS INTERPRETATION

A proper reading requires:
- A minimum visual acuity,
- Good lighting conditions.

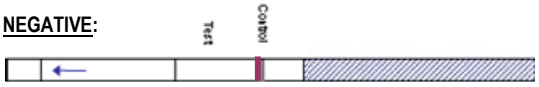
POSITIVE :



Presence of two distinct bands:
- A purple control line appears at the control line level.
- A purple test line appears (even if intensity is weak) at the test line level.

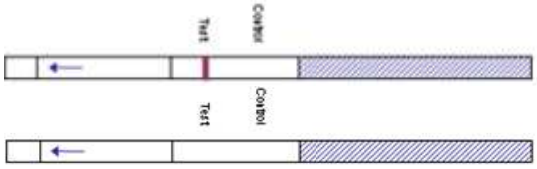
Presence of amniotic fluid in the sample.

NEGATIVE:



Only one band appears at the level of the control line C.
No band appears at the level of test line T.
Amniotic fluid is not present in the sample.

INVALID:



Absence of control line C.
Results from a test with no control line must be discarded.

BIOSYNEX
12, rue Ettoré Bugatti – CS28006
67038 STRASBOURG Cedex – France
Tél. : +33 3 88 77 57 00
Fax : +33 3 59 81 21 74
info@biosynex.com
www.biosynex.com

Review the procedure and repeat it with a new test device and a new tube. If the problem persists, contact your local distributor.

QUALITY CONTROL

- Internal procedural controls are included in the test. A coloured line appearing in the control zone (C) ensures that sufficient specimen volume has been loaded and that the correct procedure has been followed.
- Good Laboratory Practices recommend the use of positive and negative controls to check the correct test operating.
  Control samples specific for this product are available separately.

LIMITATIONS OF PROCEDURE

- As with all diagnostic tests, the test result must be consistent with clinical findings.
- False positive results might be linked to presence of IGFBP-1 coming from important bleeding or from decidual cells of the cervix when cervix is mature enough.
- False negative results might appear when test is performed more than 12 hours after the leakage of amniotic fluid has stopped.
- The swab has to be diluted in extraction tube immediately after collection of sample. Then the tube can be kept for 6 hours maximum at room temperature or 4°C before running the test as proteases in vaginal secretions may alter IGFBP1 if stored longer than 6 hours.

PERFORMANCES

Detection limit:
Detection limit of the AMNIOQUICK® test determined using a native IGFPB-1 control prepared in the test dilution buffer is **5 ng/ml**.

Clinical studies:
Different evaluations were achieved in a hospital environment to determine diagnostic efficacy of the AMNIOQUICK® test:

1-Evaluation in the Estaing University Hospital, Clermont Ferrand, France
The test was compared with another premature rupture of fetal membranes test.

2-Evaluation in the Chao-Yang hospital gynecologic-obstetric clinic, Beijing, China
The test was compared with another premature rupture of fetal membranes test and with traditional methods for premature rupture of fetal membranes detection (pH test, crystallization and ultrasound).
In the absence of a "gold standard", the performance test results from each study must be interpreted in relation of comparative method or methods chosen.

Evaluation results are available upon request.

Literature

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SYMBOLS:

	Attention, see instructions for use	LOT	Lot number
IVD	For *in vitro* diagnostic use only		Manufacturer
2°C 30°C	Store between 2-30°C		Do not reuse
Σ	Tests per kit	REF	Catalog number
	Expiry		

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BIOSYNEX
12, rue Ettoré Bugatti – CS28006
67038 STRASBOURG Cedex – France
Tél. : +33 3 88 77 57 00
Fax : +33 3 59 81 21 74
info@biosynex.com
www.biosynex.com