BIOSYNEX

AMNIOQUICK® CARD

Ref: 1090005

EN

RAPID IGFBP-1 (INSULIN-LIKE GROWTH FACTOR-BINDING PROTEIN 1) PROM TEST

For professional in vitro diagnostic use only.

CE

1 I OBJECTIVES

AMNIOQUICK® CARD is a simple and rapid immunochromatographic test that detects IGFBP-1 (Insulin-like Growth Factor-Binding Protein 1) *in vitro* based on a vaginal swab. The AMNIOQUICK® CARD test is designed to detect foetal membrane rupture in pregnant women using a vaginal swab sample. The test gives a qualitative result.
The AMNIOQUICK® CARD test can be used by health professionals in the event of suspected premature rupture of membranes (PROM). Every test device is intended for professional *in vitro* diagnostic use only.

2 I INTRODUCTION

Premature Rupture of Membranes (PROM) is relatively common and occurs in 5 to 10% of pregnancies. It can lead to premature births and foetal infections. Amniotic fluid leakage cannot always be detected through a physical examination and confirmatory blood tests are often useful. The blood tests involve detecting, in the vagina, either alkaline secretions (a simple and low-cost method, but insufficiently sensitive and specific) or the presence of proteins that can be found in high concentrations in amniotic fluid (diamine-oxidase, alpha-fetoprotein, foetal fibronectin, IGFBP-1).

3 I TEST PRINCIPLE

A pair of anti-IGFBP-1 monoclonal antibodies is used to detect IGFBP-1. One is immobilised on the nitrocellulose membrane in the test area and acts as a capture antibody. The other antibody is first coupled with colloidal gold nanoparticles and acts as the as a revelation reagent. When a sample positive for IGFBP-1 migrates, antigen-antibody complexes form and can be captured by antigens in the test area, thereby creating a visible purple line in the T test area on account of the gold nanoparticles.
A purple strip in the C control area means that the test results are valid and that the procedure has been followed correctly.

4 I EQUIPMENT

Equipment provided

- Cassettes, individually packaged in an aluminium pouch with a desiccant.
- CE 0123 or CE 0197 sterile nylon vaginal swabs.
- Diluent, in single-dose vials (dropper).
- Patient form.
- Directions for use.

Equipment required but not supplied

- Stopwatch.

5 I STORAGE AND STABILITY

AMNIOQUICK® CARD tests are individually wrapped in aluminium packaging with a desiccant. The tests should be stored in a dry place at a temperature of between 2 and 30°C.
This test is stable until the expiry date printed on the aluminium packaging. The cassette should be kept away from damp. Once the pouch has been opened, the test must be performed within an hour.

6 I PRECAUTIONS

- For *in vitro* diagnostic use only.
- For best results, carefully follow the procedure and the storage instructions.
- Do not open the aluminium packaging until it is at room temperature to prevent condensation. Damp and high temperatures may affect results.
- Do not use the kit after the expiry date.
- Do not eat, drink or smoke while handling the samples and the test.
- Wear a lab coat, disposable gloves and protective glasses when handling potentially infectious materials and when taking the test.
- The samples and the equipment used when performing the test must be considered as potentially infectious and treated as such. Dispose of the test components and the swab according to the procedure applicable to potentially infectious waste.
- Avoid splatters and formation of aerosols. Clean all spilled liquid with an appropriate disinfectant.
- The tests and tubes provided are intended for single use. Do not re-use the cassettes, swabs or diluent tubes.
- Do not combine or mix up the reagents of kits or different batches.
- Do not use a test if the aluminium packaging is open or damaged.
- Carefully read the AMNIOQUICK® CARD instructions for use before performing the test.

7 I SAMPLE COLLECTION AND STORAGE

Collection without speculum

Use the sterile swab provided to collect secretions on the surface of the vagina. Remove the swab from its packaging. Insert the swab into the vagina (5 cm deep) and soak for 1 minute.

Collection with speculum

Alternatively, a speculum can be used. Collect vaginal secretions after 15 seconds of contact with the vaginal walls in the posterior fornix.

Sample storage

The swab must be diluted in the extraction buffer tube immediately after sampling. The tube can then be stored for 6 hours at most at room temperature or at 4°C before performing the test, given that proteases found in vaginal secretions may degrade IGFBP-1.

8 I TEST PROCEDURE

1. Bring the complete kit and the samples to room temperature (15-30°C) before performing the test.
2. Open the aluminium pouch, remove the cassette from its packaging and place it on a horizontal and flat surface.
3. Open the single-dose vial and place it on a horizontal and flat surface.
4. Immerse the swab into the vial and rotate for a dozen or so seconds. Press the sides of the tube to extract the most liquid possible from the swab. Remove the swab or break the end of it off in the vial.
5. Close the vial and shake. Open the upper part of the cap to access the drops. Hold the vial vertically and add 3 drops of the diluted sample into the sample well (S) of the cassette by applying slight pressure to the sides of the tube. Avoid adding air bubbles to the cassette sample well and tipping the liquid into the result reading window.
6. Start the stopwatch and read the result at 10 minutes. A positive result can appear in the first minutes. No T test line at 10 minutes means that the result is negative. Do not interpret after 15 minutes.
7. Dispose of the components of the test and the swab according to the procedure applicable to potentially infectious waste.

9 I INTERPRETATION OF THE RESULTS

Results are interpreted as negative, positive or invalid depending on the coloured lines that appear in the C control area and T test area:

POSITIVE

Two distinct purple lines: a control line appears in the C control area and a purple line (even of weak intensity) appears in the T test area.

NEGATIVE

A single purple line appears in the C control area. No line appears in the T test area.

INVALID

No purple line in the C control area, regardless of the configuration in the T test area. The results of a test without a control line must be discarded. Review the procedure and repeat it with a new test device. If the problem persists, contact the local distributor.

NB: If the migration front does not reach the C control area in 10 minutes, add an additional sample drop and read the result at 15 minutes. If the C control line does not appear at 15 minutes, take a new sample and repeat the procedure using a new test device.

10 I QUALITY CONTROL

Internal control:

A control line is used as an internal control of the procedure. Its apparition indicates that the volume of the sample used is sufficient and the procedure has been followed correctly.

External control:

Good Laboratory Practices recommend using controls to ensure that the kit works correctly. A positive control for this product is available separately under reference 6090001.

11 I LIMITATIONS

1. As for any diagnostic test, the test result must be correlated with clinical results.
2. If there is a lot of blood (head of the swab is noticeably red) in the vaginal secretion sample, a positive result must be interpreted with caution.

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3. False negative results may occur if the test is performed 12 hours after stopping amniotic fluid leakage due to membrane rupture.
4. Collecting a sample incorrectly may lead to false negative results.
5. AMNIOQUICK® CARD is a qualitative test. No quantitative interpretation can be made based on the test result.

12 I PERFORMANCE

Detection limit:

The detection limit for the AMNIOQUICK® CARD test is based on a native IGFBP-1 control prepared in the dilution buffer is **5 ng/mL**.

Clinical studies:

Test performance was determined based on 4 clinical studies.

	Study No. 1 Li Yanfang *et al.*	*Study No. 2* Newcomb *et al.*	*Study No. 3* Wang *et al.*	*Study No. 4* Aryati *et al.*
Place	Beijing, China	Rochester, United States	Chengdu, China	Surabaya, Indonesia
Year	2010	2011	2012	2013
No. of patients	200	272	200	52
Sensitivity	98.5%	91.2%	100%*	85%
Specificity	100%	84.8%	100%	95%
PPV	100%	81.3%	100%	97%
PNV	97.1%	93.1%	83.3%	78%

*Before 37 WA

Hook effect:

The AMNIOQUICK® CARD test has a hook effect for concentrations greater than 250 µg/mL of native IGFBP-1 diluted in the extraction tube (the reference ranges for the concentration of IGFBP-1 in amniotic fluid range from 10.5 to 350 µg/mL).

Reproducibility:

Inter-day**:** An inter-day variation study was performed by the same technician testing 6 samples over 2 days. Positive and negative samples gave correct results in all cases.

Inter-batch: An inter-batch variation study was performed by the same technician testing 19 samples across 2 different batches of tests. Positive and negative samples gave correct results in all cases.

Inter-operator: An inter-operator variation study was performed by 3 different technicians testing 6 samples in triplicate. Positive and negative samples gave correct results in all cases.

Interference:

The following substances were added to the diluent, then tested:

- Capillary blood (10 and 20 µL)
- EFS serum (10 and 50 µL)
- Urine of pregnant women (50 and 100 µL)
- Sperm (10 and 20 ng/mL)

Capillary blood and urine of pregnant women do not lead to false positives. EFS blood may lead to false positives from 100 µL/mL. Sperm does not lead to interference up to 100 µL/mL.

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SYMBOLS

	Caution, see the Directions for use	Σ	Tests per kit	REF	Product reference
IVD	For *in vitro* diagnostic use only	2°C 30°C	Store between 2°C and 30°C		Single use only
	Manufacturer	LOT	Batch no.		Expiry
DIL	Diluent		Do not use if the packaging is damaged		

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