

## AMNIOQUICK® CARD



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

### INTENDED USE

AMNIOQUICK® CARD is a simple and rapid immunochromatographic test that allows *in vitro* detection of IGFBP-1 (Insulin-like Growth Factor-Binding Protein 1). AMNIOQUICK® CARD 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 qualitative result.

The AMNIOQUICK® CARD 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 Premature Rupture of Membranes 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 alkalisation 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-fetoprotein, 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 T 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 T 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.

### MATERIALS PROVIDED

- Cassettes packed in individual pouch containing desiccant bag
- Vaginal swabs flocked with Sterile Nylon CE 0123.
- Dropper bottles with extraction buffer.
- Instructions for use
- Patient cards

### MATERIAL REQUIRED BUT NOT PROVIDED

Stop watch with alarm

### STORAGE AND STABILITY

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

Under these conditions the test is stable until the indicated expiry date. The cassettes 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 eat, smoke, or drink while handling specimens and test.
- Use white coat, disposable gloves and ocular protection 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 suitable procedure for potentially infectious waste.
- Avoid splashes and aerosol formation. Clean up spills thoroughly using an appropriate disinfectant.
- Cassettes and tubes provided in the kit are intended for single use. Do not reuse the tests, swabs, or dilution tubes
- Do not interchange or mix reagents from different kits and lots.
- Do not use a cassette if the foil pouch is opened or damaged.

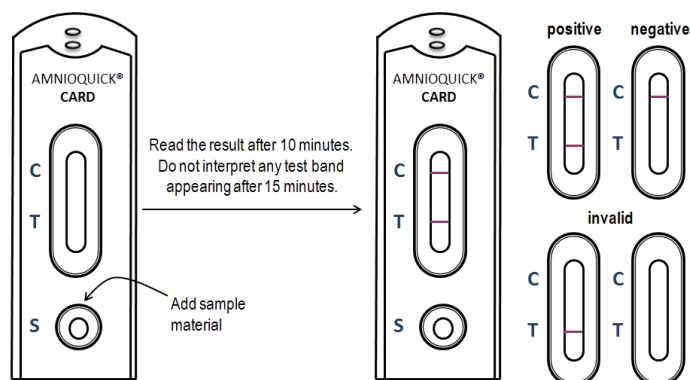
### SPECIMEN COLLECTION AND HANDLING

Use the sterile Nylon 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 contact with the vaginal wall at the level of the posterior fornix for 15 seconds.

### 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. Press the tube walls in order to expel efficiently as much liquid as possible from the swab, and then discard it or break off the swab tip into the vial.
4. Close the tube with the cap and shake the collection tube. Using a piece of tissue, break the upper part of the collection tube with a twisting motion. Hold the collection tube vertically and dispense 3 drops of solution into the round sample well of the test device by applying a gentle pressure to the walls of the tube. Avoid air bubbles in the sample well or splashes of liquid into the result window.
5. Start the timer. As the test begins to work, you will see a reddish coloured liquid front moving across the membrane.
6. The result should be read after 10 minutes. Strong positive results may be observed sooner.  
**Do not interpret any test band appearing 15 minutes after the sample is dropped in the cassette.**
7. Then, eliminate the components of the test and the sample according to the suitable procedure for potentially infectious waste.




### RESULTS

The test result can be read visually or with the help of the **BIO SYNEX Reader**.




## ➤ Visual reading

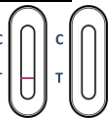
### POSITIVE:

 **Presence of 2 distinct purple lines:** A control line appears at the level of the C zone and one purple line (**even of weak intensity**) appears at the level of the test T zone.

### NEGATIVE:

 **Only one purple line appears at the level of the control line (C).**  
No line appears at the level of the test T zone.

### INVALID:

 **No visible purple band at the level of control line C (whatever test line T apparition).** Results from a test with no control line must be discarded. Review the procedure and repeat it with a new test device. If the problem persists, contact your local distributor.

If the liquid front did not reach the control line level, repeat the procedure by adding one drop of diluted sample and 3 drops of diluent in the sample well of a new device.

## ➤ Reading with the reader

- The AMNIOQUICK CARD test is compatible with the BIOSYNEX Reader, in combination with the SD card 'AMNIOQUICK CARD'.  
To read results with the reader, please refer to the reader Instructions for use.
- The barcode printed on the patient card should be scanned to identify the test lot and to check the compatibility of the SD card.

### 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 by the operator.
- Good laboratory practices recommend the use of control materials to ensure proper kit performance. 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.
- In case of significant quantities of blood in the sample of vaginal secretions, the result has to be interpreted cautiously.
- 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® CARD test determined using a native IGFBP-1 control prepared in the test dilution buffer is **5 ng/ml**.

#### Clinical studies :

The test performances have been determined based on 4 clinical studies.  
The sensibility and specificity are 90 and 97% respectively.

### Literature

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### SYMBOLS



Attention, see instructions for use



Lot number



For *in vitro* diagnostic use only



Manufacturer



Store between 2-30°C



Do not reuse



Tests per kit



Catalog number



Expiry



Extraction buffer

Version **03 BR 03/2015**



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