REF:

0524 K25

ON TEST AN

AMNIOQUICK®

AMNIOQUICK® is a rapid test that detects IGFBP-1 (Insulin Growth Factor Binding Protein 1) in vaginal secretions. The test is intended to detect rupture of fetal membranes in pregnant woman from a vaginal swab sample.



RELIABLE

- Highly sensitive monoclonal antibodies.
- Specificity: 91%.
- Sensitivity: 100%.

EFFICIENT

- Do not require any instrumentation.
- Visual reading : presence or absence of color bands.

PRACTICAL

- Simple : one step test.
- Fast : results between 10 to 15 minutes.
- Can be used with or without speculum.
- Shelf life: 18 months at room temperature.

PACKAGING

- Ref 0524_K25 : kit of 25 tests containing:
 - 25 strips individually pouched,
 - 25 sterile Dacron swabs,
 - 25 unit dose vials with extraction buffer.
- Also available in :
 - 10 test kit : Ref 0524_K10,
 - 50 test kit : Ref 0524 K50.



PROCEDURE

SAMPLE COLLECTION

1 → Use the sterile Dacron swab to collect secretions on the vaginal surface. Open the swab bag and place the swab into the vagina (5 cm depth) for 1 minute.

2 → Alternatively, speculum may be used and vaginal secretion may be collected by leaving the swab into the vagina (5 cm depth) for 15 seconds.

TEST PROCEDURE



1 -> Bring the complete kit and samples to be tested to room temperature prior to testing. Open the unit dose vial and lay it vertically on a flat and horizontal surface. Dip the swab into the unit dose vial and rotate for 10 seconds.



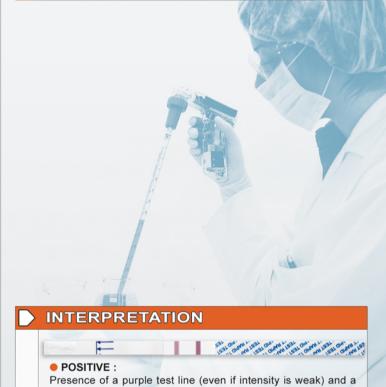
- 2 Dip the strip into the vial with arrows pointing downwards. Gently hit the dipstick on the bottom of the tube to enhance migration. Keep the strip in the tube in vertical position for 10 minutes.
- 3 → Read the result after 10 minutes from the time the strip is dipped in the tube. Do not interpret any Test band appearing 15 minutes after the strip is dipped into the vial.

PRINCIPLE

 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 confirmatory biological test is sometimes useful. Biological tests are based on vaginal detection of alkalinization (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)

AMNIOQUICK® is based on detection of IGFBP-1 which is found in very high concentration in amniotic fluid. AMNIOQUICK® can detect less than 1 µl of amniotic fluid from the collection swab. The test can be used for detection of microrupture or frank rupture of the fetal membranes.

Note: In near term women, positive results may appear even in absence of rupture of membranes as the decidual cells of the cervix may release phosphorylated IGFBP-1 that cross react with



purple control line. Presence of amniotic fluid in sample.

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NEGATIVE :

Absence of purple test line and presence of a purple control line. Amniotic fluid is not present in sample.



A wrong procedure and high viscosity of sample are the two most frequent causes of invalid results. The test has to be run again with a new strip.

