

Use of the AMNIOQUICK test kits

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First entry

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1 Purpose and Principle

The Amnioquick test kits are used to provide a rapid test for the detection of ruptured foetal membranes in pregnant women. Premature rupture of membrane (PROM) is suspected in 5-10% of all pregnancies and may result in the preterm delivery and foetal infection. The leakage of amniotic fluid is not always detectable by clinical examination and may require a biological test. AMINOQUICK is one test that relies on the presence of the IGFBP-1 molecule.

A pair of IGFBP-1 monoclonal antibodies is used for IGFBP-1 detection. One is immobilized on the membrane of the test kit on the test line the other is attached to colloidal gold particles. During the sample migration IGFBP-1 in the sample forms an antigen-antibody complex with the colloidal gold antibody. This complex is captured by the antibody on the test line and produces a purple line.

2 Patient Preparation & Sample Requirements

Use the dacron swab to collect secretions from the vaginal wall. Open the swab bag and place the swab into the vagina to a depth of 5cm and leave for 1 minute. If a speculum is used the secretions may be collected by leaving the swab in contact with the vaginal wall at the level of the posterior fornix for 15 seconds.

The swab must be placed in the dilution tube immediately after collection. Once the swab is in the extraction tube it may be stored for 6 hours at room temperature.

3 Tasks, Responsibilities and Authorisations

- Sampling – must only be undertaken by a suitable person who has received documented training in the sampling procedure.
- Use of test kits – must only be undertaken by a suitably designated member of staff with documented training/competency in the test procedure.
- Reports – the person performing the test is responsible for ensuring the results are placed in the patient's notes and a copy in the results book.

Tasks	Responsible	Authorised
Sampling	Healthcare professionals who have received documented training	
Use of test kits	Healthcare professionals with documented training/competency in the test procedure.	
Reporting	The person performing the test is responsible for ensuring the results are placed in the patient's notes and a copy in the results book.	

4 Equipment

Test kit –product code 1090003

Kits should be stored at 2-30°C and used at 15-30 °C. They are stable until the expiry date shown on the packaging. Once the test pouch is opened the test should be performed within an hour.

Material provided in the test kit.

- Individual wrapped test strip with desiccant
- Sterile Dacron vaginal swab
- Unit dose vial containing diluent.
- Dose vial rack.

Also required.

- Timer

Control solutions –product code 6090001

Kits and control solutions are ordered from BioSynex.

5 Chemicals and Reagents

N/A

6 Risk Assessment (Environmental and Safety Controls)

For full Risk Assessment see PC/RA/YS-19



Staff carrying out this procedure should have read and understood the Local Rules or Health and Safety Manual applicable to their site which should be followed at all times during the procedure.

- All human samples must be treated as potentially BIO-HAZARDOUS.
- Approved Personal Protective Equipment (PPE) including laboratory coats, disposable gloves must be worn. Eye protection should also be considered and must be worn when directed within the procedure.

This SOP and the associated risk assessment(s) have considered all hazards and necessary precautions required to control any risks identified. Where appropriate this is detailed in the COSHH assessment and Risk Assessment. Any risk; where possible is mitigated and or monitored with health surveillance to ensure health and safety for all those affected by this procedure

7 Calibration

N/A

8 Quality Control

Internal controls are included in the test. A colour line appearing in the control zone (C) ensures that sufficient specimen volume has been loaded and that the correct procedure has been followed.

Positive and negative controls are also available for assessing operator technique.

9 External Quality Assurance (EQA)

N/A

10 Procedural Steps

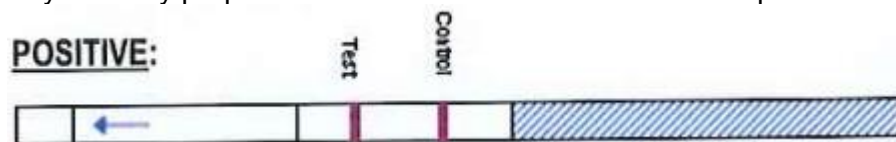
- Bring the complete kit to room temperature prior to testing.
- Open the vial containing the diluent and place it in the rack tube to keep it vertical.
- Dip the swab into the diluent and rotate for 10 seconds. The swab may then be discarded.
- Place the test strip arrows pointing downwards into the vial making sure it rests in the bottom of the tube. The strip must be left in the tube for 10 minutes.
- After 10 minutes read the test results from the strip. Results should not be read after 15 minutes, and the vial and strip should be discarded in compliance with local policies.

11 Reporting of Results

The test strips should be read in good light.

Positive tests for amniotic fluid require

- A purple line in the control line area of the test strip
- Any intensity purple line in the test line area of the test strip.



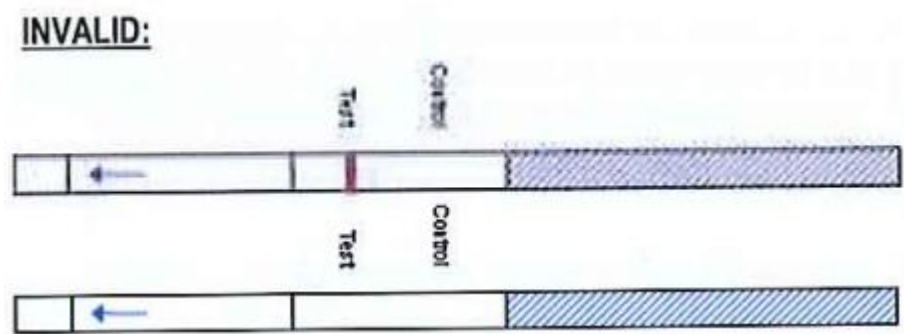
Negative Test for amniotic fluid

- A purple line in the control line area of the test strip.
- No line should be visible in the test area of the test strip



Invalid test

- Absence of a purple line in the control line area of the test strip i.e no lines visible on the test strip or a line visible only in the test area of the test strip.



12 Reference Intervals

N/A

13 Performance Characteristics

Detection limit

The detection limit for the AmnioQuick test kit is 5ng/ml

False positive results

May be caused by

- IGFBP-1 in bleeding
- Decidual cells on the when the cervix is mature enough.

False negative results

- Test carried out >12 hours post amniotic leak.

14 Known Limitations

Interference studies

The following do not interfere with the AmnioQuick test.

- Capillary blood
- Urine
- Semen

15 Related Forms/Templates and Documents

Risk Assessment PC/RA/YS-19

AmnioQuick test kit User Guide PC/IFU/YS-1

16 References

AmnioQuick test kit User Guide PC/IFU/YS-1