



AmniSure[®] ROM Test

Quick Reference Guide

Reading AmniSure ROM Test Results

AmniSure ROM Test Quick Facts

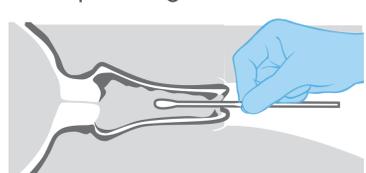
- AmniSure is a rapid, non-instrumented, qualitative immunoassay to aid in the detection of ROM (Rupture Of [fetal] Membranes)
- 98.9% sensitive and 98.1% specific
- Not affected by urine, semen, vaginal infections and trace amounts of blood on the swab
- No speculum exam required
- No gestational age limit
- Billable with CPT[®] 84112

Proper Sample Collection Tips

- Collect specimen from patients presenting with signs, symptoms or complaints suggestive of ROM
- Specimen should be tested within 4 hours of collection*
- Collect specimen prior to digital examination or lubricants
- Collect specimen prior to use of any disinfectant solutions or medicines or 6 hours after their removal

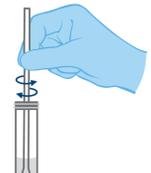
AmniSure 4-Step Testing Procedure*

1



Collect sample
1 minute - collection.
Collect sample of vaginal discharge with sterile collection swab (no speculum required).

2



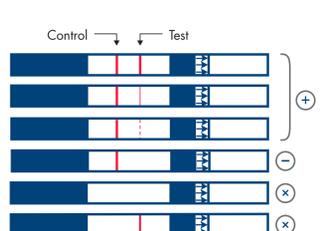
Transfer to solvent
1 minute - dilution.
Rinse specimen swab in solvent vial. **Discard swab.**

3



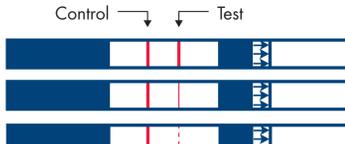
Insert test strip
10 minutes - removal of test strip.
Insert test strip into vial to initiate PAMG-1 detection. Remove the test strip after 10 minutes and then read the test results within 5 minutes.

4

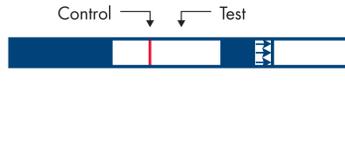


Read results
Remove test strip from vial, observe and record results. Do not read after 15 minutes have passed since inserting the strip into the vial. **Note: Faint or broken lines should always be read as positive.**

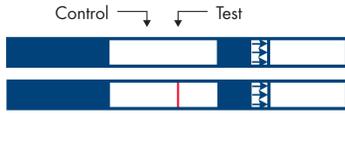
Positive result: Two Lines



Negative result: One Control Line



Invalid result: No Lines or Test Line only



Additional notes for reading the test results:

- Faint or broken lines should always be read as positive.
- The presence of no lines or only a test line indicates an invalid test result. DO NOT interpret this as a negative test result. Invalid results require a retest.

Important limitations of use:

- Failure to detect membrane rupture does not assure the absence of membrane rupture.
- Results should be used in conjunction with other clinical information.

Learn more at www.herQIAGEN.com/AmniSure

References:

(1) AmniSure ROM (Rupture of [fetal] Membranes) Test Instructions for Use. QIAGEN, 2019.

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*If the patient sample is not tested within 4 hours and sample storage is necessary, tightly close the sample vial and place in a refrigerator. Do not test the sample after more than 6 hours have passed since sample collection.

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