AmniSure® ROM Test

AmniSure ROM Test Quick Reference Guide

AmniSure ROM Test quick facts (1)

- 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 (1)

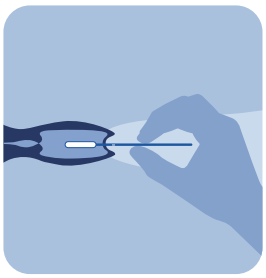
- Collect specimen from patients presenting with signs, symptoms or complaints suggestive of ROM
- Specimen should be tested within 4 hours of collection*
- Collect specimen prior to digital examination or lubricants
- Collect specimen prior to use of any disinfectant solutions or medicines or 6 hours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

The AmniSure 4-step test procedure*

1

Collect sample

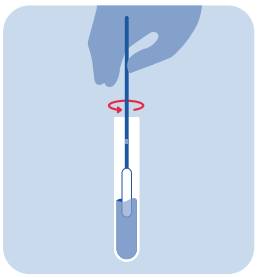
1 minute collection.
Collect sample of vaginal discharge with sterile collection swab (no speculum required).



2

Transfer to solvent

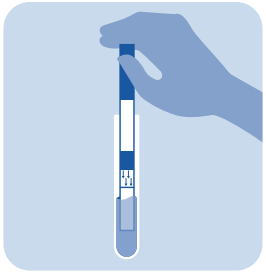
1 minute dilution.
Rinse specimen swab in solvent vial.
Discard swab.



3

Insert test strip

Insert test strip into vial to initiate PAMG-1 detection process.
After 10 minutes, remove the test strip, and read the results within 5 minutes.

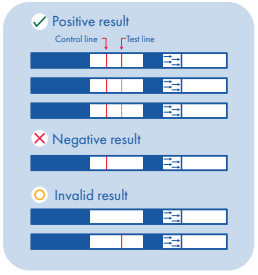


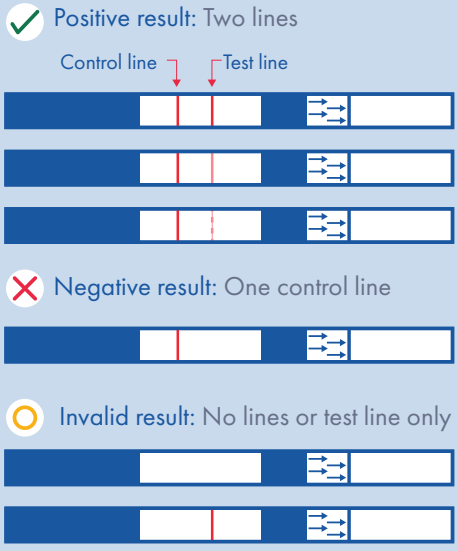
4

Read results

Remove test strip from vial, observe and record results. Do not read strip after 15 minutes have passed since dipping strip into vial.

Note: Faint or broken lines should always be read as positive.





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 (1):

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

References:

1. AmniSure ROM Test Instructions for Use, QIAGEN, 1090607, Rev. 06, 02/2022. Available at **www.qiagen.com**.

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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.

Learn more at www.qiagen.com or contact an AmniSure specialist at AmniSureNA@qiagen.com.