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)
- 99% sensitive and 98% specific
- Not affected by urine, semen, vaginal infections and trace amounts of blood on the swab
- No speculum exam required to run the AmniSure test
- 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 30 minutes of collection or 6 hours if refrigerated
- 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
   - Insert test strip into vial to initiate PAMG-1 detection process. Positive as soon as two lines are visible on strip. 10 minutes to call negative result.

4. Read results
   - Remove test strip from vial, observe and record results. Do not read strip after 15 mins have passed since dripping strip into vial. Note: Faint or broken lines should always be read as positive.
Positive result: Two red lines
PROM may be diagnosed with clinical judgement

Negative result: One red line
PROM may be diagnosed with clinical judgement

Invalid result: No red line

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

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

References:

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