

Monoclonal and Polyclonal, Unite!



Unique monoclonal and polyclonal antibody approach unite to create the most sensitive ROM test.



ROM
plus+
Rupture of Membranes Test

It's not a test, it's a life. Don't let PROM compromise your clinical outcomes

- PROM is one of the most common diagnostic dilemmas in obstetrics, affecting 5–10% of all pregnancies¹
- PPRM is responsible for 20-40% of preterm births¹
- Conventional methods to detect PROM are frequently inaccurate and inconvenient^{1,2}

Early and accurate diagnosis is critical

- Allows for interventions necessary to optimize perinatal outcome and minimize serious complications, including preterm delivery, chorioamnionitis, and neonatal sepsis^{1,2}
- Accurate diagnosis also helps avoid false-positive results, which may lead to unnecessary hospitalization, administration of medications and even induced premature delivery¹

"The critical importance of accurate and prompt diagnosis of PROM at any gestational age to decrease or avoid its inherent and potential serious complications for mother and fetus have been repeatedly emphasized by investigators for the last 50 years."²



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Rupture of Membranes Test



1. Thomasino T, Levi C, Draper M, Neubert AG. Diagnosing rupture of membranes using combination monoclonal/polyclonal immunologic protein detection. *J Reprod Med.* 2013;58(5-6):187-94.
2. Mariona FG, Cabero L. Are we ready for a new look at the diagnosis of premature rupture of membranes? *J Matern Fetal Neonatal Med.* 2012;25(4):403-407.
3. Senanayake HM. Actim™ PROM, AmniSure®, and ROM+plus®: Rupture of membrane kits tested on amniotic fluid from women at C-section: a comparative study. *Sri Lanka Journal of Obstetrics and Gynaecology.* 2013; 116-121. Available at: <http://www.slcojg.lk/sljog/>

Now best in class sensitivity is delivered conveniently and cost effectively³

Highly accurate, with a unique dual-protein approach

- ROM Plus uses a monoclonal and polyclonal antibody approach to detect two proteins, placental protein 12 (PP12) and alpha-fetoprotein (AFP), found in significant concentrations in amniotic fluid
 - AFP peaks late in the second trimester when accurate diagnosis matters most

99.5% sensitivity, 90.7% specificity¹

- In a prospective, multi-center study involving 285 patients, ROM Plus resulted in an overall sensitivity of 99.5% and a specificity of 90.7%

100% terrific

- **Rapid**, immediate results at the point of care
- **Easy to read** samples require require 15 second swab
- **Convenient** cassette with built in timer and patient ID tracker
- **Noninvasive**, no speculum required
- **Spill resistant** vial and pre-scored swab help prevent spills and need to resample

"...development of a point-of-care test that is both accurate and easy to use by a wide array of clinicians, (nurses, midwives, physicians, etc.) would be a true asset."

—Mariona F, Cabero L. *J Matern Fetal Neonatal Med.* 2012.

Order Information

Box

<p>POC (Point of Care) Test Kits</p> <p>ROM Plus® Complete Test Kit</p> <p>Test kit includes a cassette with test strip, built-in timer, and patient ID tracker, a swab, vial with solution and convenient dropper cap</p>	ROM-5025	25 ea
<p>Collection Kits</p> <p>ROM Plus® Collection Kit</p> <p>1 box of 25 collection kits includes a swab, vial with solution and convenient dropper cap</p>	ROM-6000	25 ea
<p>Lab Test Kits</p> <p>ROM Plus® Cassette/Collection Kit</p> <p>1 box of 25 collection kits includes a swab, vial with solution and convenient dropper cap, 1 box of 25 cassettes with test strip, built-in timer, and patient ID tracker</p>	ROM-6025	25 ea
<p>ROM Plus® ROM Quality Controls</p> <p>ROM Plus® Quality Control</p> <p>1 Positive control & 1 Negative control) (Each box contains 1 activation sleeve)</p>	ROM-QC	5 ea
<p>ROM Plus® Validation and Correlation Kits (used for initial customer validation/correlation only)</p> <p>ROM Plus® Validation Kit</p> <p>1 box of 25 cassettes with test strip, built-in timer, and patient ID tracker 3 boxes of 5 ROM-QC Quality Control Kits (1 Positive control & 1 Negative control)</p>	ROM-7025	1 bx
<p>ROM Plus® POC Correlation Kit</p> <p>1 box of 25 test kits includes a cassette with test strip, built-in timer, and patient ID tracker, a swab, vial with solution and convenient dropper cap 1 each ROM-QC Quality Control kits (1 Positive control & 1 Negative control)</p>	ROM-7055	1 bx
<p>ROM Plus® Lab Correlation Kit</p> <p>1 box of 25 collection kits includes a swab, vial with solution and convenient dropper cap 1 box of 25 cassettes with test strip, built-in timer, and patient ID tracker 1 each ROM-QC Quality Control kits (1 Positive control & 1 Negative control)</p>	ROM-7065	1 bx

Warning: The test may report positive results in patients with intact membranes and therefore decisions to induce labor should not be based solely on the ROM Plus test results.

Test Procedure

- Collect sample with vaginal swab
- Mix swab in buffer vial
- Add sample and activate timer
- Read test result

Your Local Distributor:



ROM
plus

Rupture of Membranes Test

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