Unique monoclonal and polyclonal antibody approach unites to create the most sensitive ROM 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 pregnancies<sup>1</sup>
- PPROM is responsible for 20-40% of preterm births<sup>1</sup>
- Conventional methods to detect PROM are frequently inaccurate and inconvenient<sup>1,2</sup>

### 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<sup>1,2</sup>
- Accurate diagnosis also helps avoid false-positive results, which may lead to unnecessary hospitalization, administration of medications and even induced premature delivery<sup>1</sup>

"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."<sup>2</sup>





# Accurate diagnosis when it matters most

• ROM Plus ES demonstrated 100% sensitivity and 100% specificity between 24-34 weeks gestation<sup>1</sup>

"...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.

# Now best in class sensitivity is delivered conveniently and cost effectively<sup>3</sup>

#### Highly accurate, with a unique dual-protein approach

- ROM Plus ES 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% sensitive 90.7% specific<sup>1</sup>

 In a prospective, multi-center study involving 285 patients, ROM Plus ES 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 Collection: only a 15 second swab for sample
- Convenient: Spill resistant vial and pre-scored swab help prevent spills and need to resample
- Noninvasive: no speculum required

## Ordering Information

POC (Point of Care) Test Kits

ROM Plus® ES Complete Test Kit

Test kit includes a lateral flow test strip, swab, vial with buffer solution and convenient shipper cap

ROM Plus® ES Strip Quality Control

1 positive control and 1 negative control. Each box contains 1 activation sleeve

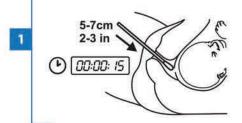
- Thomasino T, Levi C, Draper M, Neubert AG. Diagnosing rupture of membranes using combination monoclonal/polyclonal immunologic protein detection. J Reprod Med. 2013;58(5-6):187-94.
- Mariona FG, Cabero L. Are we ready for a new look at the diagnosis
  of premature rupture of membranes? J Matern Fetal Neonatal Med.
  2012;25(4):403-407.
- 3. Senanayake HM. Actim<sup>™</sup> 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.slcog.lk/sljog/

#### Your Local Distributor:

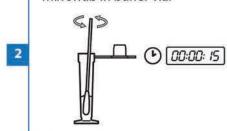
### Test Procedure

Box

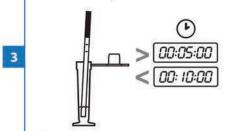
Collect sample with vaginal swab

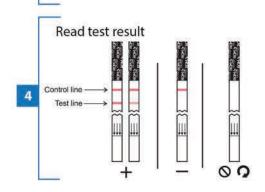


Mix swab in buffer vial



Add test strip to vial and set timer





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