A complete test kit containing one test cassette (with test strip, timer and patient ID field), one vial with buffer solution, and one sterile vaginal swab.

A quality control test kit containing one positive sample vial and one negative sample vial (sample test cassettes not provided).

1. Collect sample with vaginal swab
2. Mix swab in buffer vial
3. Add sample and activate timer
4. Read test result

Your Local Distributor:
ROM Plus is a rapid, qualitative test for the in vitro detection of amniotic fluid in vaginal secretions of pregnant women. It utilizes a combination of monoclonal and polyclonal antibodies to detect alpha-fetoprotein (AFP) and placental protein 12 (PP12, or insulin growth factor binding protein-1) found in amniotic fluid.

Housed in a convenient test cassette, ROM Plus quickly and accurately provides test results essential to optimizing perinatal outcomes.

### Premature Rupture of Membranes

Premature rupture of membranes (PROM) is a significant complicating factor in contemporary obstetric practice. It occurs in up to 10% of deliveries, and is the cause of 10% of all perinatal deaths. Thirty to 50% of PROM occurs in preterm PROM (PPROM), when the diagnosis is critical because of the lack of development in the fetus.

Timely and accurate diagnosis of PROM allows for gestational age-specific interventions designed to optimize perinatal outcomes and minimize the potential risk of complications, such as preterm delivery, infectious morbidity, cord prolapse and fetal distress.

Proper diagnosis of PROM remains a frequent clinical challenge. Most tests currently available are inaccurate and require an intrusive examination. Current diagnostic methods lack specificity, become progressively less accurate with passage of time after membrane rupture, and are associated with high false-positive rates related to infection, the presence of urine, blood, or semen.

### Reliable Clinical Assessment

The protein markers PP12 and AFP were selected for ROM Plus because of their history of being recognized in high concentrations in amniotic fluid, while being found in extremely low levels of maternal blood and cervicovaginal secretions of women with intact membranes.

Testing for two protein markers using the monoclonal and polyclonal antibody combination increases ROM Plus' sensitivity and improves diagnosis, particularly of PPROM.

A multi-center prospective observational study was performed in patients presenting with signs or symptoms or rupture of amniotic membranes. ROM Plus was compared to current conventional standards of clinical care for diagnosis of ROM.

ROM Plus was found to have higher sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) than conventional clinical assessments.

### Superior Clinical Value

ROM Plus employs a wide range of features and benefits to provide superior clinical value:

- **Two Protein Markers**: Testing for both AFP and PP12 improves diagnostic accuracy.
- **Lateral Flow Technology**: Latest in lateral flow test strip technology makes performing the test and reading results easy.
- **On-Demand, Rapid Test**: No need for a speculum, and using at prescription point-of-care sites produces immediate results.
- **Convenient Cassette**: Cassette contains test strip, built-in timer and patient ID tracker for convenience, portability and quality control.
- **Built-In Timer**: Timer with every cassette provides convenient indication of time for each test.
- **Spill-Resistant Vial / Scored Swab**: Preventing spills enables a clean test procedure and reduces potential for re-sampling, while keeping the swab tip in the vial reduces mess.

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**Clinical Study Results**

- **Sensitivity**: 100%
- **Specificity**: 94%
- **PPV**: 83%
- **NPV**: 100%

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* Unadjusted data provided to the FDA for 510(k) clearance.