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# ROM Plus® ES

Rupture of Membranes Test

OBSTETRICS, GYNECOLOGY & NEONATAL

Accurately testing for proteins found in cervicovaginal secretions to diagnose ruptured fetal membranes.

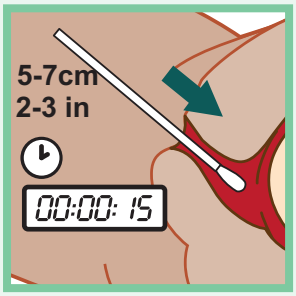
## ROM Plus® Rupture of Membranes Test

- Reliable sensitivity[1]
- Conveniently delivered
- Cost effective
- Quick and easy

ROM plus® Rupture of Membranes Test

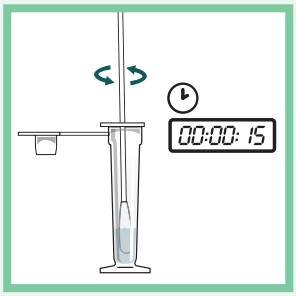
### 1. Collect Sample

Insert swab 5-7 cm and collect sample for 15 sec.



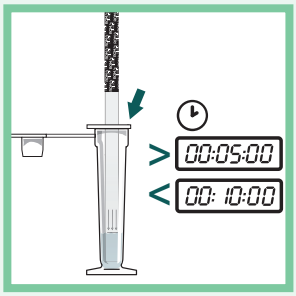

### 2. Place Swab & Mix

Place swab into vial and mix in buffer solution for 15 sec.



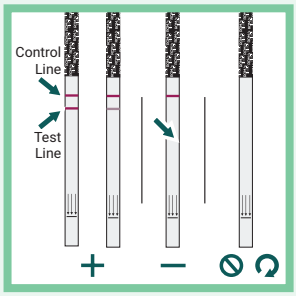

### 3. Insert Test Strip

Place ROM Plus ES strip into the vial with the arrows down.




### 4. Remove & Interpret

Remove strip if two lines are visible or after 10 minutes.




**See Package Insert for Full Instructions, Warnings, Precautions & Contraindications**

## High sensitivity in all gestational ages

| ROM Plus® Test | Patients | Sensitivity | Specificity |
|---|---|---|---|
| Thomasino, 2013[2] | 285 | 99.5% | 90.7% |
| Igbinosa, 2017[3] | 111 | 96.4% | 98.8% |
| Senanayake, 2013[1] | 95 | 98.9% | N/A |
| Rogers, 2016[4] | 75 | 100% | 94.8% |
| Esplin, 2019[9] | 324 | 91.7% | 97% |
| ROM Plus® IFU | 285 | 99.5% | 90.7% |

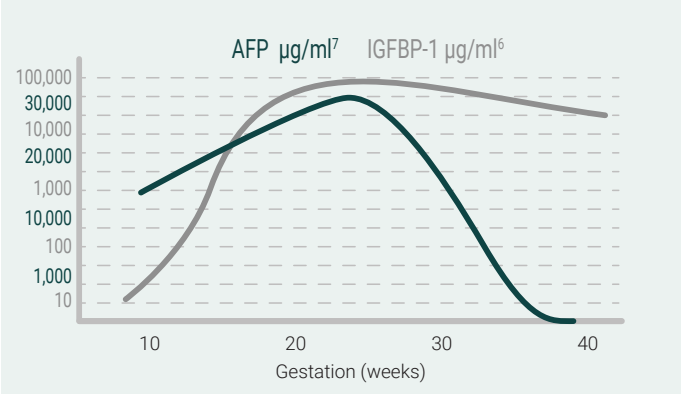
**Traditional methods**

| Test | Sensitivity | Specificity |
|---|---|---|
| Nitrazine[5] | 90-97% | 16-70% |
| Ferning[5] | 51-98% | 70-88% |
| Pooling | Subjective | Subjective |

# The science behind the ROM Plus® Rupture of Membranes Test

## Two Proteins

▼ Protein Levels in Amniotic Fluid

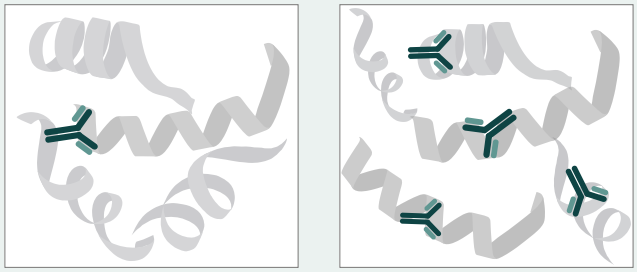



Increased sensitivity in all gestational ages by detecting AFP as well as IGFBP-1.[2]

## Two Antibodies

▼ Monoclonal Antibody (One receptor site)

▼ Polyclonal Antibodies (Multiple receptor sites)



Increase the likelihood of detecting proteins and help avoid false negatives by using both monoclonal and polyclonal antibodies.[8]

## Potential Savings

Potential savings compared to similar immunoassay tests. Ask for additional details.

## Ordering information

| Product Description | Product Code | Box Quantity |
|---|---|---|
| Test Kits- Kit w/test strip, swab, vial with solution | ROM-1025 | 25/box |


1. 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.
2. 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): 187–194.
3. Igbinosa, Irogue & A. Moore, Ferney & Johnson, Cheri & Block, Jon. (2017). Comparison of rapid immunoassays for rupture of fetal membranes. BMC Pregnancy and Childbirth. 17. . 10.1186/s12884-017-1311-y.
4. Rogers LC, Scott L, Block JE. Accurate point-of-care detection of ruptured fetal membranes: improved diagnostic performance characteristics with a monoclonal/polyclonal immunoassay. Clin Med Insights Reprod Health. 2016;10:15–8.
5. Caughey, et al. Rev Obstet Gynecol 2008; 1:11-22. de Haan et al., Am J Perinatol 1994; 11:46-50
6. Wathen et. al 1993
7. Rose, N. C., MD, & Mennuti, M. T., MD. Gynecology & Obstetrics (Vol. 3).
8. McQuivey RW, Block JE. ROM Plus: accurate point-of-care detection of ruptured fetal membranes. Med Devices (Auckl) 2016;9:69–74.
9. Esplin, et. al. Prospective evaluation of the efficacy of immunoassays in the diagnosis of rupture of themembranes. J Matern Fetal Neonatal Med. 2019 Jan 13:1-7. doi: 10.1080/14767058.2018.1555809. [Epub ahead of print]


**This product is not currently for sale in the U.S.**

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