

ROM Plus[®] ES

Rupture of Membranes Test

OBSTETRICS, GYNECOLOGY & NEONATAL
Accurately testing for proteins found in cervicovaginal secretions to help diagnose ruptured fetal membranes.

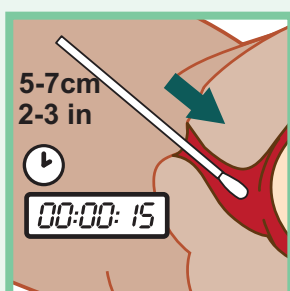
ROM Plus[®] Rupture of Membranes Test

- Reliable sensitivity¹
- Conveniently delivered
- Cost effective
- Quick and easy



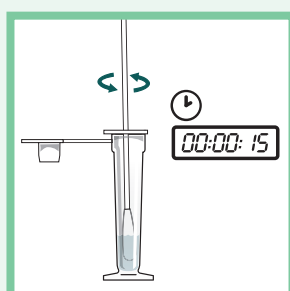
1. Collect Sample

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



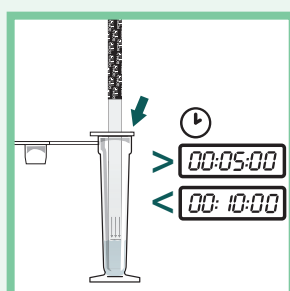
2. Place Swab & Mix

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



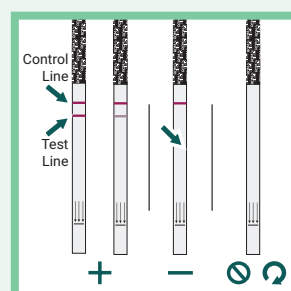
3. Insert Test Strip

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%
Igbinoza, 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%

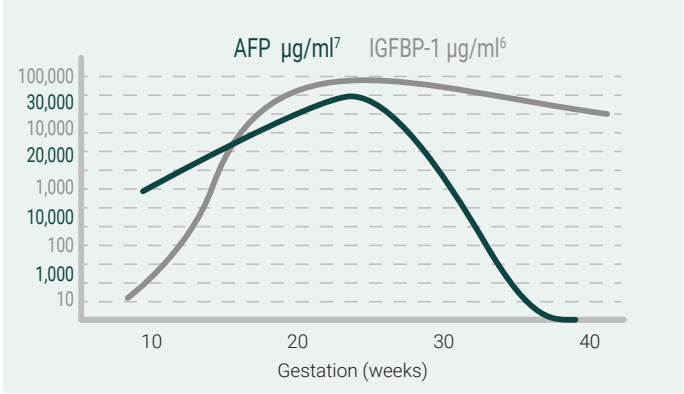
Traditional methods

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

Potential Savings

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

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, Iroque & 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.

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

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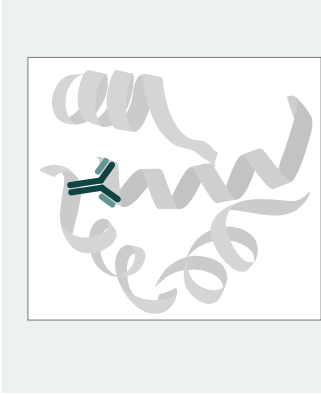
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AUSTRALIA

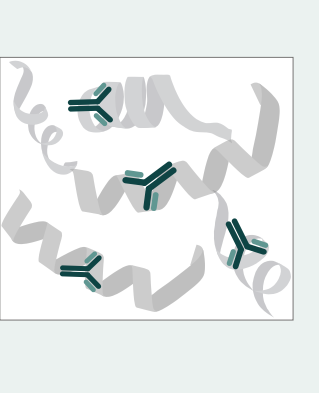
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Two Antibodies

▼ 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

Ordering information

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

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]



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