

ROM Plus[®]

Rupture of Membranes Test

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

Unique for detecting both Alpha-fetoprotein (AFP) & Insulin-like growth factor-binding protein 1 (IGFBP-1)

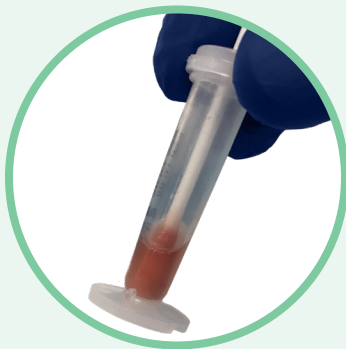
- Reliable sensitivity¹
- Conveniently delivered
- Cost effective



Accuracy in presence of whole blood

As described in the ROM Plus Instructions for Use, whole blood at a 10% concentration level did not interfere with the effectiveness of the test.

However, significant amounts of bloody discharge may cause the test to malfunction. ROM Plus is not recommended for use in these situations, and the cause of the bleeding should be determined.



▲ This is what 10% whole blood concentration looks like.

Reliable sensitivity in all gestational ages

ROM Plus[®] Rupture of Membranes Test provides reliable sensitivity, delivered conveniently and cost effectively.

ROM Plus[®] performance

ROM Plus [®]	Patients	Sensitivity	Specificity
Thomasino, 2013 ¹	285	99.5%	90.7%
Igbinosa, 2017 ²	111	96.4%	98.8%
Senanayake, 2013 ³	95	98.9%	N/A
Rogers, 2016 ⁴	75	100%	94.8%
Esplin, 2019 ¹¹	324	91.7%	97%

ROM Plus[®] compared to other tests

Test	Sensitivity	Specificity
ROM Plus [®] IFU	99%	75%
Amnisure ^{3,5-8}	89.3-98.6%	87.5-98.1%
Actiprom ⁹	95-100%	83-97%
Nitrazine ¹⁰	90-97%	16-70%
Ferning ¹⁰	51-98%	70-88%
Pooling	Subjective	Subjective

*Currently only FDA cleared for use on patients >29 weeks GA

ROM Plus® Rupture of Membranes Test

Convenient for all involved

- 15 second vaginal swab, 15 second sample mix
- Lay-flat design helps prevent sample spills
- Positive results can be achieved in minutes
- Less invasive than SSE, no speculum needed

Confidence delivered cost effectively

- Potential savings of 25% or more compared to similar immunoassay tests*

*Ask for additional details

ROM-CS saves time and money for correlations and annual competencies

- ▶ ROM-CS: Correlation Samples, 20 known, blinded, frozen samples



Reimbursement information

CPT Code	Reimbursement Limit **
84112	\$98.11

**The National Limitation Amount (NLA) for CPT 84112 for 2018 is \$98.11. Reimbursement amount may vary by state.

***Laborie is in no way advertising or guaranteeing reimbursement. Work with your coding & billing department to determine what works for your facility.

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):187-194.
2. Igbinoza, 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.
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.
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. Albayrak, M, Ozedemir I, Koc O, et al. Comparison of the diagnostic efficacy of two rapid bedside immunoassays combined clinical conventional diagnosis in prelabor rupture of membranes. *European J Obstet. Gynecol. Reprod. Bio* 2011, 158: 179-182

The collection process is easier on the patient and the ease of testing is great for the techs.¹²

Ordering information

Product Description	Product Code	Box Quantity
P.O.C Kits - box of 25 complete test kits	ROM-5025	25/box
Collection Kits - box of 25 collection kits only	ROM-6000	25/box
Lab Kits - 1 box of 25 cassettes & 1 box of 25 collection kits	ROM-6025	25/box
Quality Control - 1 Positive Control & 1 Negative Control	ROM-QC	5/box
Validation Kit - 1 box of 25 cassettes & 3 boxes of ROM-QC	ROM-7025	1 box
POC Correlation Kit - 1 box of ROM-5025 & 1 each ROM-QC	ROM-7055	1 box
Lab Correlation Kit - 1 box of ROM-6025 & 1 each ROM-QC	ROM-7065	1 box
Correlation Samples - 20 known, blinded, frozen samples	ROM-CS	1 box

6. AmniSure website www.amnisure.com
7. Lee SI, Park JS, Norwitz ER et al. Measurement of placental alpha-microglobulin-1 in cervicovaginal discharge to diagnose rupture of membranes. *Obstet Gynecol* 2007; 109:634-40
8. Lee SM, Lee J, Seong HS, Lee SE, et al. The clinical significance of a positive AmniSure test in women with term labor with intact membranes. *J. Matern Fetal Neonatal Med* 2009 Apr; 22(4): 305-310
9. Ragosch et al., *Geburtshilfe Frauenheilkd* 1996 Jun; 56(6):291-6
10. Caughey, et al. *Rev Obstet Gynecol* 2008; 1:11-22. de Haan et al., *Am J Perinatol* 1994; 11:46-50
11. Esplin, et. al. Prospective evaluation of the efficacy of immunoassays in the diagnosis of rupture of the membranes. *J Matern Fetal Neonatal Med.* 2019 Jan 13:1-7. doi: 10.1080 / 14767058.2018.1555809. [Epub ahead of print]
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