

ROM plus[®]

Rupture of Membranes Test



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

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



Rupture of Membranes Test

	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 IFU	264	99%	75%



NITRAZINE¹⁰

FERNING¹⁰

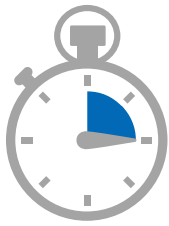
POOLING

	SENSITIVITY	SPECIFICITY
AmniSure ^{3,5-8}	89.3-98.6%	87.5-98.1%
Actim PROM ^{*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.

CONVENIENT FOR ALL INVOLVED

15 second vaginal swab
15 second sample mix



Lay-flat design helps prevent sample spills

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

-Nicole Fisher MT(ASCP), MHA
Lab Clinical Facilitator



Positive results can be achieved in minutes



Less invasive than SSE
No speculum needed

See Instructions for Use for full instructions, precautions, limitations & warnings

CONFIDENCE... DELIVERED COST EFFECTIVELY



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

*Ask for additional details

Reimbursement Information

CPT Code:

84112

Reimbursement Limit*

\$98.11

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

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

PRODUCT SUPPORT



For correlations and annual competencies, ROM-CS can save you time and money.

Ordering Information

Product Description	Product Code	Box Quantity
POC 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

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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, Ozdemir 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
6. AmniSure website www.amnisure.com
7. Lee SJ, Park JS, Norwitz ER et al. Measurement of placental alpha-microglobulin-1 in cervicovaginal discharge to diagnose rupture of membranes. Obstet Gyencol 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. Metern Fetal Neonatal Med 2009 Apr; 22(4): 305-310
9. Ragosch et al., Geburtshilfe Frauenheilkd 1996 Jun; 56(6):291-6
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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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