

ROM plus[®]

Rupture of Membranes Test

ROM Plus[®] Rupture of Membranes Test provides best in class sensitivity¹, delivered conveniently and cost effectively.



ACCURACY IN PRESENCE OF WHOLE BLOOD

Since its introduction, ROM Plus remains the only immunoassay test with FDA approved labeling quantifying whole blood concentrations.

ROM Plus is cleared by the FDA to be used with up to a 10% concentration of whole blood with no effect on test performance.

This is what 10% whole blood concentration looks like.

INCREASED SENSITIVITY IN ALL GESTATIONAL AGES²



	PATIENTS	SENSITIVITY	SPECIFICITY
THOMASINO, 2013 ¹	285	99.5%	91.1%
IGBINOSA, 2017 ²	111	96.4%	98.8%
SENANAYAKE, 2013 ³	95	98.9%	N/A
ROGERS, 2016 ⁴	75	100%	94.8%



NITRAZINE¹⁰

FERNING¹⁰

POOLING

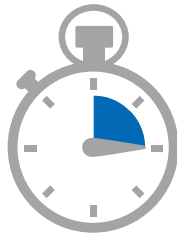
	SENSITIVITY	SPECIFICITY
	89.3-98.6%	87.5-98.1%
	95-100%*	83-97%
	90-97%	16-70%
	51-98%	70-88%
	Subjective	Subjective

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

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, 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.
 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 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. Metern 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

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

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*

\$88.36

*The National Limitation Amount (NLA) for CPT 84112 for 2017 is \$88.36. 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 saves you time and money.

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 ROM-5025 & 1 box ROM-6000	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 ROM-5025 & 1 each ROM-QC	ROM-7055	1 box
Lab Correlation Kit- 1 box ROM-5025 & 1 box 1 each ROM-QC	ROM-7065	1 box
Correlation Kit- 20 known, blinded, frozen samples	ROM-CS	1 box

Local Distributor:

clinicalinnovations.com

| 747 West 4170 South | Murray, Utah USA 84123
Phone 801.268.8200 | Fax 801.266.7373 |
Toll Free 888.268.6222



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