

AmniSure[®]

Rapid, reliable ROM testing

Literature review



Literature Review Summary

Accuracy of PAMG-1 immunoassay (AmniSure ROM Test) to aid in the diagnosis of ROM

Study authors	Year	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Sosa, C.G. et al.	2014	100%	99.1	96.3	100
Ng, B.K. et al.	2013	95.7	100	100	75
Abdelazim, I.A. and Makhlof, H.H. et al.	2013	97.3	98.7	98.6	97.4
Abdelazim, I.A. and Makhlof, H.H. et al.	2012	97.3	98.7	98.6	97.4
Birkenmaier, A. et al.	2012	94.4	98.6	96.2	98.0
Albayrak, M. et al.	2011	94.3	97.5	97.6	93.9
Tagore, S. and Kwek, K.	2010	92.7	100	100	95.2
Lee, S.E. et al.	2007	98.7	87.5	98.1	91.3
Cousins, L.M. et al.	2005	98.9	100	100	99.1

The table above includes performance metrics from published independent research involving the AmniSure ROM Test used on patients presenting with suspicion of ROM in accordance with the package insert. Study details follow.



Comparison of placental alpha microglobulin-1 in vaginal fluid with intra-amniotic injection of indigo carmine for the diagnosis of rupture of membranes

Sosa, C.G. et al. (2014) J. Perinat. Med. 42, 611-616.

Objective Compare the diagnostic performance of an immunoassay for placental alpha microglobulin-1 (PAMG-1) in vaginal fluid with the intra-amniotic instillation of indigo carmine for diagnosing membrane rupture

Study design Multi-site, prospective observational
Study population: Patients presenting with signs/symptoms of membrane rupture between 21 and 42 weeks of gestation without obvious leakage from the cervical os during speculum examination and without confirmation of ROM by traditional methods (n=140)
Reference method: Intra-amniotic injection of indigo carmine dye

Results SN: 100% | SP: 99.1% | PPV: 96.3% | NPV: 100%

Findings The PAMG-1 test highly correlates with a "Gold Standard" for ROM diagnosis, invasive injection of indigo carmine (100% sensitivity, 99.1% specificity).

Dye injection test

PAMG-1	No ROM	ROM	Total
Negative	112	0	112
Positive	1	27	28
Total	113	27	140

Comparison between AmniSure placental alpha microglobulin-1 rapid immunoassay and standard diagnostic methods for detection of rupture of membranes

Ng, B.K. et al. (2013) Biomed. Res. Int. 587438.

Objective: Determine accuracy of placental alpha microglobulin-1 assay and standard diagnostic methods for detecting rupture of membranes (ROM)

Study design: Prospective observational

Study population: Patients presenting with signs/symptoms of membrane rupture between 21 and 42 weeks of ROM, either in labor or not in labor, 24+ weeks gestational age (n=211)

Reference method: At least 2 coinciding results from the nitrazine, fern, and pooling tests, plus post-delivery review of data

Results: SN: 95.7% | SP: 100% | PPV: 100% | NPV: 75.0%

Findings: Study results indicate that the PAMG-1 test is a rapid and accurate method to aid in the diagnosis of rupture of membranes as part of the overall clinical assessment. In all 41 cases where the PAMG-1 test result was positive but negative with standard diagnostic methods, the PAMG-1 test provided the accurate result.

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1	95.7%	100%	100%	75.0%
Standard methods	78.1%	100%	100%	36.9%
Nitrazine test	77.5%	100%	100%	36.3%
Fern test	62.6%	100%	100%	25.5%
Pooling	86.6%	100%	100%	49.0%

Placental alpha microglobulin-1 (AmniSure test) versus insulin-like growth factor binding protein-1 (Actim PROM test) for detection of premature rupture of fetal membranes

Abdelazim, I.A. and Makhlof, H.H. (2013) J. Obstet. Gynaecol. Res. 39, 1129-1136.

Objective Compare accuracy of placental alpha microglobulin-1 (PAMG-1) assay versus insulin-like growth factor binding protein-1 (IGFBP-1) to diagnose premature rupture of fetal membranes (PROM)

Study design Prospective observational

Study population Pregnant women after 37 weeks gestation presenting for induction of labor and divided into 2 groups according to presence or absence of PROM (n=150)

Reference method Patient history, pooling, ferning, nitrazine, confirmed by visualization of fluid passing from the cervical canal during sterile spec exam and transvaginal ultrasound to measure AFI (AFI \leq 5cm)

Results SN: 97.3% | SP: 98.7% | PPV: 98.6% | NPV: 97.4%

Findings The PAMG-1 test most accurately detected rupture of membranes

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (Amnisure)	97.3%	98.7%	98.6%	97.4%
IGFBP-1 (Actim PROM)	89.3%	82.7%	83.8%	88.6%
Ferning test	84%	78.7%	79.7%	83.1%
Nitrazine test	86.7%	81.3%	82.2%	85.9%

Placental alpha microglobulin-1 (AmniSure test) for detection of premature rupture of fetal membranes

Abdelazim, I.A. and Makhlof, H.H. (2012) Arch. Gynecol. Obstet. 285, 985-989.

Objective: Determine the accuracy of placental alpha microglobulin-1 (PAMG-1) to diagnose premature rupture of fetal membranes (PROM)

Study design: Prospective observational

Study population: Pregnant women after 37 weeks gestation presenting for induction of labor and divided into 2 groups according to presence or absence of PROM (n=150)

Reference method: Patient history, pooling, ferning, nitrazine, confirmed by visualization of fluid passing from the cervical canal during sterile spec exam and transvaginal ultrasound to measure AFI (AFI \leq 5cm)

Results: SN: 97.3% | SP: 98.7% | PPV: 98.6% | NPV: 97.4%

Findings: "Detection of the PAMG-1 in the vaginal fluid using AmniSure test is an accurate method to diagnose rupture of fetal membranes with high sensitivity, specificity, negative and positive predictive values.

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (Amnisure)	97.3%	98.7%	98.6%	97.4%
Ferning test	84%	78.7%	79.7%	83.1%
Nitrazine test	86.7%	81.3%	82.2%	85.9%

Placental - microglobulin-1 to detect uncertain rupture of membranes in a European cohort of pregnancies

Birkenmaier, A. et al. (2012) Arch. Gynecol. Obstet. 285, 21-25.

Objective To evaluate the performance of the placental alpha-microglobulin-1 immunoassay (AmniSure) in cervicovaginal secretions in patients with uncertain rupture of membranes (ROM) and the influence of examiner experience

Study design Prospective observational

Study population Pregnant women presenting with uncertain signs and/or symptoms of ROM between 17 and 42 weeks of gestation (n=199)

Reference method Two of the following three signs: (1) visual leaking or pooling of fluid from the cervix on speculum examination, (2) positive Nitrazine test, or (3) AFI <5 cm in ultrasound exam. Final ROM diagnosis occurred on review of medical records.

Results SN: 94.4% | SP: 98.6% | PPV: 96.2% | NPV: 98.0%

Findings AmniSure is a simple, reliable, highly sensitive and cost-effective test with strong performance to aid in the diagnosis of ROM as part of the overall clinical assessment.

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (Amnisure)	94.4%	98.6%	96.2%	98%
Clinical assessment	72.2%	97.9%	92.9%	90.5%

Comparison of the diagnostic efficacy of the two rapid bedside immunoassays and combined clinical conventional diagnosis in prelabour rupture of membranes

Albayrak, M. et al. (2011) Eur. J. Obstet. Gynecol. Reprod. Biol. 158, 179-182.

Objective To compare the diagnostic efficacy of PAMG-1 and IGFBP-1 immunoassay tests and combined conventional clinical diagnostic methods in PROM

Study design Prospective observational

Study population Pregnant women presenting with signs and/or symptoms of PROM between 16 and 41 weeks of gestation (n=167)

Reference method Visualization of clear fluid leakage from the cervix upon speculum examination or two of the following three signs: ferning, vaginal pooling and nitrazine. Final diagnosis made through review of medical records after delivery

Results: SN: 94.3% | SP: 97.5% | PPV: 97.6% | NPV: 93.9%

Findings:

- PAMG-1 assay was found to be most accurate
- "...even a small statistically insignificant difference in diagnostic performance may impact clinical practice. When this is considered, the PAMG-1 test seems preferable."

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (Amnisure)	94.3%	97.5%	97.6%	93.9%
Ferning test	89.8%	97.5%	97.5%	89.5%
Nitrazine test	88.6%	94.5%	95.1%	88.2%

Comparative analysis of insulin-like growth factor binding protein-1 (IGFBP-1), placental alpha-microglobulin-1 (PAMG-1) and nitrazine test to diagnose premature rupture of membranes in pregnancy

Tagore, S. and Kwek, K. (2010) J. Perinat. Med. 38, 609-612.

Objective: To compare IGFBP-1, PAMG-1 and Nitrazine test to diagnose premature rupture of membranes (PROM)

Study design: Prospective observational

Study population: Pregnant women presenting with signs and/or symptoms of PROM between 17 and 37 weeks of gestation (n=100)

Reference method: Three or more of the following conditions: pooling of clear fluid during speculum examination, oligohydramnios on ultrasound, signs and symptoms of chorioamnionitis, and preterm delivery w/ in a week of presentation with convincing history of leakage. Final ROM diagnosis occurred on review of medical records after delivery.

Results: SN: 92.7% | SP: 100% | PPV: 100% | NPV: 95.2%

Findings

- Among the three tests, PAMG-1 demonstrated the highest sensitivity, specificity, PPV and NPV
- "PAMG-1 is also easy to use, does not require a speculum, and gives rapid results."

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (Amnisure)	94.3%	97.5%	97.6%	93.9%
Ferning test	89.8%	97.5%	97.5%	89.5%
Nitrazine test	88.6%	94.5%	95.1%	88.2%

AmniSure placental alpha microglobulin-1 rapid immunoassay versus standard diagnostic methods for detection of rupture of membranes

Cousins, L. M. et al. (2005) Am. J. Perinatol. 22. 317-320.

Objective Compare the AmniSure rapid immunoassay with standard methods for diagnosing rupture of fetal membranes (ROM)

Study design Prospective observational

Study population Pregnant women presenting with signs and/or symptoms of membrane rupture between 15 and 42 weeks of gestation (n=203)

Reference method At least two coinciding results from the nitrazine, fern, and pooling tests. Final ROM diagnosis occurred on review of medical records after delivery.

Results SN: 98.9% | SP: 100% | PPV: 100% | NPV: 99.1%

Findings "The AmniSure PAMG-1 immunoassay provides qualitative results that exceed in timeliness, accuracy, sensitivity, specificity, and reliability the currently available methods."

Control test results			
Amnisure	No ROM	ROM	Total
Negative	112	1	113
Positive	0	90	90
Total	112	91	203

Measurement of placental alpha-microglobulin-1 in cervicovaginal discharge to diagnose rupture of membranes

Lee, S.E. et al. (2007) *Obstet Gynecol.* 109, 634-640.

Objective: Compare the accuracy of an immunoassay to measure levels of placental alpha-microglobulin-1 in cervicovaginal discharge with that of conventional clinical assessment for the diagnosis of rupture of membranes
Study design: Prospective observational

Study population: Pregnant women presenting with signs and/or symptoms of PROM between 11 and 42 weeks of gestation (n=184)

Reference method: Visualization of fluid leaking from the cervical os OR at least two coinciding results from the nitrazine, fern, and pooling tests. Final ROM diagnosis occurred on review of medical records after delivery.

Results: SN: 98.7% | SP: 87.5% | PPV: 98.1% | NPV: 91.3%

Findings

- “We have shown that the placental alpha-microglobulin-1 immunoassay is superior to both the combined conventional clinical tests and the nitrazine test alone, which is commonly used to identify women with ROM.”
- 20 patients with a positive PAMG-1 test and negative clinical assessment were subsequently determined to have PROM

Test	Sensitivity	Specificity	PPV	NPV
PAMG-1 (AmniSure)	94.3%	97.5%	97.6%	93.9%
Ferning test	89.8%	97.5%	97.5%	89.5%
Nitrazine test	88.6%	94.5%	95.1%	88.2%



Evaluate PROM confidently by including AmniSure as part of your clinical assessment.

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