

**Actim[®]
PROM**

Detect
membrane
ruptures
reliably

**FAST
SIMPLE**

ACCURATE

ACCURATE PROM DETECTION, EVEN IN THE
PRESENCE OF MORE THAN TRACE BLOOD
AND OTHER CONTAMINANTS¹

CooperSurgical
Medical Devices



ACCURATE IN THE PRESENCE OF
**MORE THAN
TRACE BLOOD
AND OTHER
CONTAMINANTS¹**

5 MIN
THE FASTEST² PROM TEST
TO COMPREHENSIVE
RESULTS

7M³+
PROM TESTS DISTRIBUTED
WORLDWIDE

Premature rupture of membranes (PROM) is a complication in approximately one third of preterm births, and can lead to significant perinatal morbidity and mortality.⁴ Existing methods of diagnosing PROM have inherent limitations that can be challenging to clinicians and lab personnel.

Actim PROM is the fastest² point-of-care dipstick PROM test available for easy, accurate results within 5 minutes. With more than 7 million³ tests distributed in over 70 countries, Actim PROM provides highly reliable testing sensitivity and specificity, even in the presence of more than trace blood and a host of common contaminants that can compromise other PROM tests.



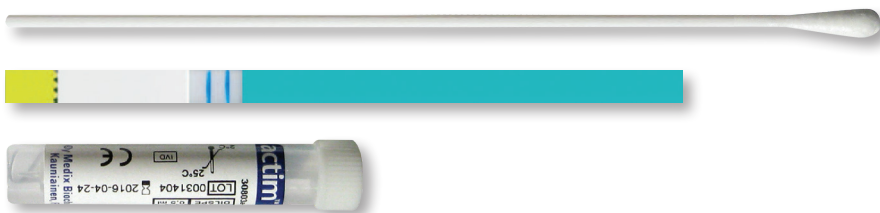
THE FASTEST² TO COMPREHENSIVE RESULTS; HIGHLY SPECIFIC AND EXCEPTIONALLY ACCURATE PROM TEST.



ACTIM PROM'S DIAGNOSTIC ACCURACY COMBINED WITH CLINICAL FINDINGS, CONFIRMS THE NEED FOR PATIENT TREATMENT

In a pregnancy event like PROM where rapid, effective decision-making is a must, Actim PROM provides accurate results that assists in the diagnosis and treatment plan of the patient. Trust that more than 7 million³ Actim PROM tests have been distributed worldwide to:

- Test for PROM even when a patient has more than trace blood, an infection or is compromised by other contaminants¹
- Diagnose PROM and begin necessary intervention including hospitalization, medication, induction or other care
- Avoid treating a patient for false positive results that could ultimately compromise mom and baby



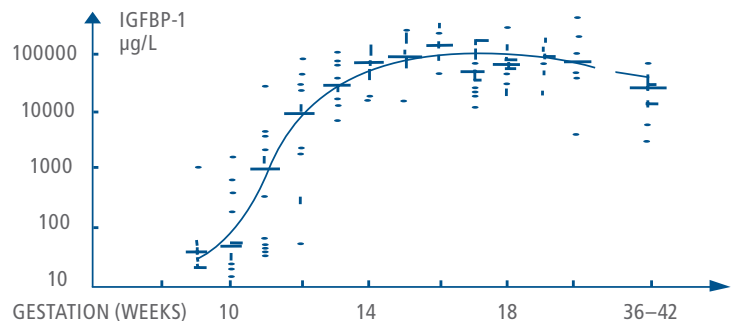
THE PROVEN SCIENCE BEHIND ACTIM PROM

The underlying science behind Actim PROM is detection of the protein biomarker, Insulin-like Growth Factor Binding Protein-1 (IGFBP-1).

IGFBP-1 is produced in the decidual cells, (a layer in fetal membranes found between the chorion and myometrium) and the fetal liver during pregnancy.

The protein accumulates in very high concentrations in amniotic fluid—rising quickly in early pregnancy and remaining high until delivery,⁵ with levels much higher than are found in other body fluids.⁶

A study in the Journal of Obstetrics and Gynaecology Research concludes that IGFBP-1 was more sensitive and specific in diagnosing rupture of fetal membranes than ferning or nitrazine tests.⁷



The IGFBP-1 level in amniotic fluid rises in early pregnancy and remains elevated throughout.

HIGH SENSITIVITY AND SPECIFICITY PROMOTES ACCURATE PROM DIAGNOSIS⁸

Actim PROM is optimized to be so sensitive it detects even microruptures of membranes that are clinically invisible (less than 1 µl of amniotic fluid), yet clinically relevant as they can induce delivery, cause infections, and threaten the health of both mother and child. Actim PROM's high specificity and sensitivity help to promote diagnostic accuracy, minimizing false negative and false positive results.

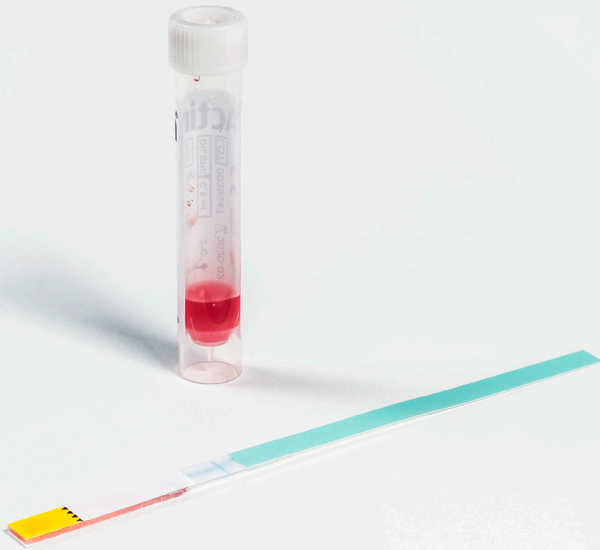
TABLE 1. Actim PROM has the highest sensitivity, specificity, and accuracy in PROM diagnosis⁸ versus standard of care PROM tests.

	Sensitivity %	Specificity %	Accuracy %
Actim PROM test	97	97	97
Nitrazine test	97	16	56
AFI < 80 mm	94	91	92
Ferning ⁷	84	78.7	81.3



For labs, Actim PROM controls can be frozen for up to one year⁹ for additional cost savings and convenience.

BLEEDING MAY OCCUR IN UP TO 20% OF ALL SUSPECTED PROM CASES



ACTIM PROM IS EFFECTIVE IN THE PRESENCE OF MORE THAN TRACE BLOOD¹

Importantly, Actim PROM remains effective in the presence of vaginal bleeding, a condition present in up to 20% of PROM patients.¹⁰ Actim PROM works in the presence of more than trace blood because:

- The concentration of IGFBP-1 in amniotic fluid is 100-1000 times higher than in maternal blood
- The detection limit of Actim PROM has been set above the known concentrations in maternal blood (25 µg/L in the extracted sample) which corresponds to a concentration of >400 µg/L in the sample taken from the woman and is well above the level found in maternal blood (29–300 µg/L)
- Whole blood with concentrations corresponding to typical pregnancy levels of IGFBP-1 were tested and did not affect Actim PROM's performance¹¹

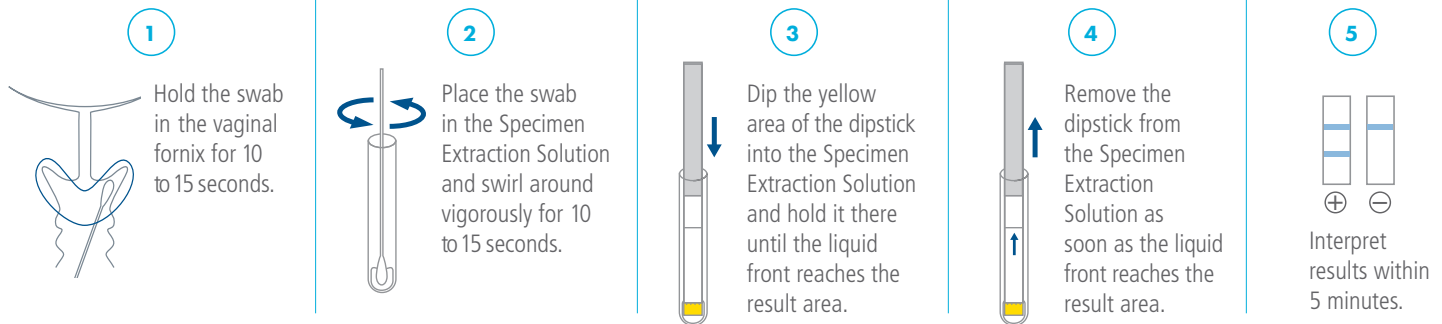
TESTED TO WORK IN THE PRESENCE OF INTERFERING SUBSTANCES¹²:

Semen
Whole Blood
RepHresh Vaginal Gel
Urine
Personal Lubricant
Baby Oil
Baby Powder
Feminine Deodorant Suppositories
Feminine Deodorant Film
Pevaryl (Econazole Nitrate)
Gyno-Trosyd (Tioconazole)
Flagyl (Metronidazole)
Canesten (Clotrimazole)
Candida Albicans
Gardnerella Vaginalis
Neisseria Gonorrhoeae
Chlamydia Trachomatis
HSV-1
HSV-2

Actim[®] PROM

Detect membrane ruptures reliably

SIMPLE STEPS. 5 MINUTES TO RESULTS. THE FASTEST² PROM TEST AVAILABLE.



ORDERING INFORMATION

ITEM NUMBER	DESCRIPTION
30831ETUS	Actim PROM 10 Test Kit
30800ETUS	Actim PROM Control Test Kit

References

1. The test has been designed to minimize interference from bleeding, but in cases of heavy bleeding the blood locally may have a higher concentration of IGFBP-1 protein. In these cases, a positive result should be interpreted with caution. Actim PROM IFU.
2. AmniSure Product Insert/Instructions for Use. ROM Plus Product Insert/Instructions for Use.
3. Internal Document from Medix Biochemica
4. Medina, T. M. & Hill, D. A. (2006). Preterm premature rupture of membranes: diagnosis and management. *Am Fam Physician*, 73(4), 659-64.
5. Wathen, et al (1993). Levels of insulin-like growth factor-binding protein-1 increase rapidly in amniotic fluid from 11 to 16 weeks of pregnancy. *J Endocrinol*. 137:R1-R4.
6. Rutanen E-M., et al (1993). Measurement of insulin-like growth factor binding protein-1 in cervical/vaginal secretions: comparison with the ROM-check Membrane immunoassay in the diagnosis of ruptured fetal membranes. *Clinica Chimica Acta*. 214: 73-81.
7. Abdelazim, I. A. (2013). Insulin-like growth factor binding protein-1 (Actim[®] PROM test) for detection of premature rupture of fetal membranes. *Journal of Obstetrics and Gynaecology Research*, 40(4), 961-967.
8. Erdemoglu E and Mungan T. Significance of detecting insulin-like growth factor binding protein-1 in cervicovaginal secretions: Comparison with nitrazine test and amniotic fluid volume assessment. *Acta Obstet Gynecol Scand* (2004) 83: 622-626.
9. Internal documentation from Medix Biochemica
10. Palacio et al.: Meta-analysis of studies on biochemical marker tests for the diagnosis of premature rupture of membranes: comparison of performance indexes. *BMC Pregnancy and Childbirth* 2014 14:183
11. Actim PROM 510(k) K123986
12. Actim PROM IFU Page 9

800.243.2974 | 203.601.5200
www.coopersurgical.com
95 Corporate Drive, Trumbull, CT 06611

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