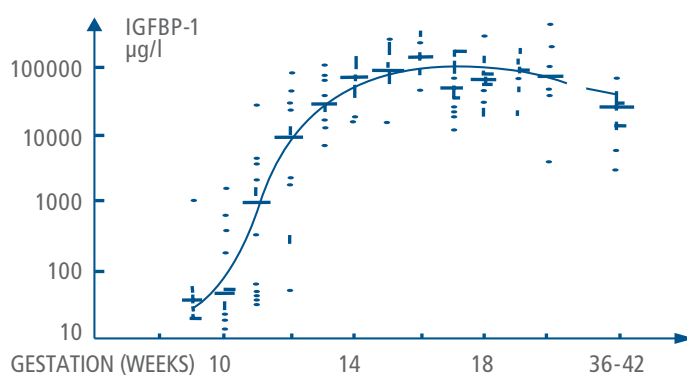


The Science Behind Accurately Diagnosing PROM



The Actim[®] PROM test is a rapid immunoassay that specifically detects Insulin-like Growth Factor Binding Protein-1 (IGFBP-1). IGFBP-1 is a subgroup of proteins of the insulin-like growth system, which has a function in the control mechanism of fetal and placental growth and development¹. IGFBP-1 accumulates at very high concentrations in amniotic fluid². The levels are much higher than found in other body fluids³. When the membranes are ruptured, IGFBP-1 is detectable in a vaginal sample.

IGFBP-1 Levels in Amniotic Fluid²



IGFBP-1 levels in amniotic fluid rise in early pregnancy and remain high until term

IGFBP-1 Concentration in Various Body Fluids³

Sample	Concentration of IGFBP-1
Normal Adult Serum	0.5 - 30 µg/l
Serum (Pregnancy)	58 - 600 µg/l
Urine	Undetectable
Semen	Undetectable
Amniotic Fluid	10,000 - 400,000 µg/l

IGFBP-1 levels in amniotic fluid are 100-1000 times higher than those found in serum, urine or semen

With 20 years of proven results outside the U.S. and more than 5,000,000 PROM tests performed, Actim PROM test allows you to confidently diagnose membrane ruptures, even in the presence of common contaminants such as blood, urine, semen, bath & odor products, common vaginal infections and medications⁴.

Actim[®] PROM

Up To 20% of PROM Patients Exhibit Vaginal Bleeding⁵

Other point-of-care PROM tests are only indicated for use with trace vaginal bleeding while Actim PROM has been proven to perform regardless of the amount of vaginal bleeding.

With up to 20% of women presenting with vaginal bleeding at the time of PROM diagnosis, you need a reliable test for all patients.

Why Blood Doesn't Affect Actim PROM

- The concentration of IGFBP-1 in amniotic fluid is 100-1000 times higher than in maternal blood.
- The detection limit of the Actim PROM test 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 was tested and did not affect Actim PROM test performance.⁶



While other PROM tests have purposely excluded patients with active vaginal bleeding from their study protocols, Actim PROM has numerous points of data to support its use in patients with vaginal bleeding:

- Kallioniemi et. al 2014
- Novikova et al. 2007
- Erdemoglu and Mungau 2004
- Guibourdenche et al. 1999
- Kubota et al. 1998
- Rutanen et al. 1996

*Additional data available on file at Medix Biochemica, Finland.

Sources:

1. Fowler, D.J., et al (2000). Insulin-like growth factor binding protein 1 (IGFBP-1): a multifunctional role in the female reproductive tract. *Human Repro Update* 6: 495-504.
2. 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.
3. 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.
4. Please refer to the Actim PROM 510(k) K123986 for a full list of drugs, shower and bath products, odor control products and vaginal pathogens that were tested with Actim PROM and found not to affect test performance.
5. 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
6. Actim PROM 510(k) K123986

For more information, call 800.243.2974 or 203.601.5200 or visit www.coopersurgical.com. Also, see us on YouTube at YouTube.com/CooperSurgical.

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