

## World-class Pioneers

Medix Biochemica specializes in monoclonal antibodies and diagnostic tests for numerous medical conditions. We have succeeded in combining the scientific community and high-tech diagnostics. More than twenty years ago, we were one of the first companies in the world to produce monoclonal antibodies. We immediately understood their enormous potential in healthcare. Today we are a dynamic high-tech corporation with a global customer base.



As a result of our respected global reputation, more than 150 companies in over 30 countries use MedixMAB monoclonal antibodies and numerous laboratories and physicians rely on our Actim diagnostic healthcare tests. High quality has always been the cornerstone of all our operations. Our entire company is certified as being in conformity with ISO 9001:2000. In addition, operations related to diagnostic test kits including controls and reagents are ISO 13485:2003 certified. We also value research and development. A substantial part of our turnover is still devoted to R&D. Our expertise covers the whole production chain from raw materials (monoclonal antibodies) to finished products, such as the Actim diagnostic tests.



**actim™**  
**Reliable test results in minutes**



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**actim™**  
**PROM**



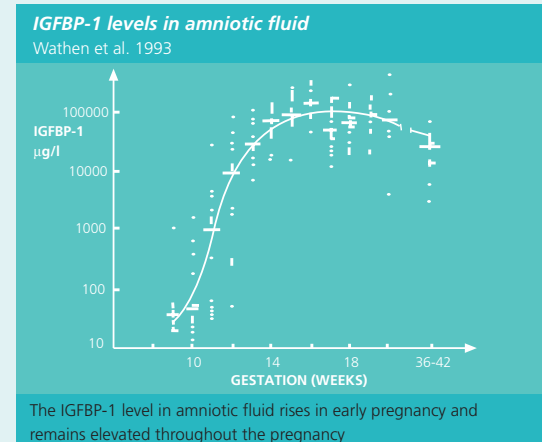
## The original rapid test to detect premature rupture of fetal membranes

**Premature rupture of fetal membranes (PROM) is a serious pregnancy complication that causes approximately one third of premature deliveries. Prematurity increases the risk of perinatal morbidity and mortality. Additionally, PROM increases the risk of maternal and fetal infections. Although an accurate diagnosis is vital, traditional methods are highly insufficient. They frequently give wrong results, and they are sensitive to contaminating substances, such as blood, semen, and cervical mucus.**

A decade ago, Medix Biochemica was the first in the world to create a reliable method to detect PROM. Since then, hundreds of thousands of women have benefited from the test's superior performance. Actim PROM is a fast immunochromatographic dipstick test that reacts to the presence of amniotic fluid in vaginal secretions. Based on monoclonal antibodies, it detects IGFBP-1 (insulin-like growth factor binding protein-1) in a vaginal sample. Since the concentration of IGFBP-1 is substantially high in amniotic fluid, finding IGFBP-1 in the vaginal sample indicates a membrane rupture (PROM).

### Well established and widely used

Research findings show that the level of IGFBP-1 in amniotic fluid increases significantly in early pregnancy and remains high throughout. The Actim PROM test can, therefore, be used since the early stages of pregnancy.



The test has been evaluated in several independent studies around the world. All of them have constantly proven that it is an extremely specific and sensitive method to detect premature rupture of fetal membranes. Therefore Actim PROM provides results you can always rely on.

### Evaluation studies on the Actim PROM test as a method to detect premature rupture of fetal membranes

Publication	Number of patients	Gestational age (wk)	End-point	Sensitivity	Specificity	NPV	PPV
Rutanan et al. 1996	130	15-37	Clinical confirmation	100%	94.7%	100%	93.2%
Ragosch et al. 1996	75	22-41	Clinical confirmation, Dye injection	100%	83%	100%	83%
Jain et al. 1998	100	24-42	Clinical confirmation	100%	89%	100%	75%
Erdemoglu et al. 2004	71	31.9±5.3	Clinical confirmation	97%	97%	97%	97%
Kubota et al. 1998	48	15-41	Clinical confirmation	94.7%	93.1%	N/A	N/A

Actim PROM is a highly specific and sensitive method to detect a membrane rupture.

### Superior performance

Compared to other methods commonly used for detecting PROM, Actim PROM clearly surpasses them in performance. Neither the specificity nor sensitivity of other methods comes even close to the reliability of Actim PROM.

### Comparison of methods to detect PROM

Kubota & Takeuchi 1998

	Actim PROM	pH	Ferning
Sensitivity	94.7	73.3	42.1
Specificity	93.1	72.4	75.9

Actim PROM is the most reliable test for detecting premature rupture of fetal membranes.

### References

- 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.
- Rutanan E-M. Insulin-like growth factors in obstetrics. Curr Opin Obstet Gynecol (2000) 12: 163-168.
- Guibourdenche J et al. Rapid detection of insulin-like growth factor-binding protein-1 and foetal fibronectin in cervico-vaginal secretions to diagnose premature membrane rupture. Ann Clin Biochem (1999) 36: 388-390.
- Jain K and Morris P G. A clinical study to evaluate the usefulness of the MAST test in diagnosing pre-labour rupture of membranes. J Obstet Gynaecol (1998) 18: 33-36.
- Kubota T and Takeuchi H. Evaluation of insulin-like growth factor binding protein-1 as a diagnostic tool for rupture of the membranes. J Obstet Gynecol Res (1998) 24: 411-417.
- Ragosch V et al. Insulin like growth factor binding protein 1 (IGFBP-1) and fetales Fibronectin in der Diagnostik eines vorzeitigen Blasensprunges. GebFra (1996) 56: 1-6.
- Rutanan E-M et al. Evaluation of a rapid strip test for insulin-like growth factor binding protein-1 in the diagnosis of ruptured fetal membranes. Clinica Chimica Acta (1996) 253: 91-101.

### Reliable results regardless of contaminating substances

The concentration of IGFBP-1 in amniotic fluid is 100-1000 times higher than in maternal serum, so its presence in a sample is a very clear indication of ruptured fetal membranes. The detection limit of the test is so low that it even detects micro ruptures.

Semen and urine contain insignificant quantities of IGFBP-1. Since amniotic fluid can only be present in the vagina if fetal membranes are no longer intact, the presence of IGFBP-1 in the sample is a reliable indication of a membrane rupture. Blood contamination is extremely unlikely to affect the test results, since the 95th percentile of normal IGFBP-1 levels in maternal serum falls below the test's detection limit.

### IGFBP-1 concentration in various body fluids

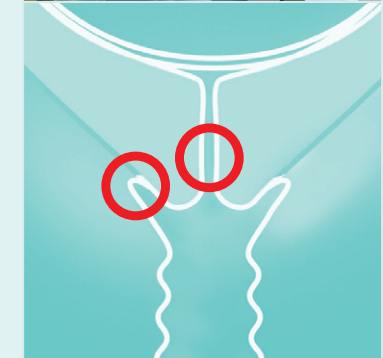
Rutanan et al. 1993

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 concentration is extremely high in amniotic fluid only.



Actim PROM is a quick bedside test that gives highly reliable results in minutes.



Take a vaginal fluid sample with a polyester swab from the posterior fornix of the vagina – or from the cervix if no fluid is visible – by leaving the swab in the vagina for 10-15 seconds. This allows the swab to absorb sufficient amount of specimen.



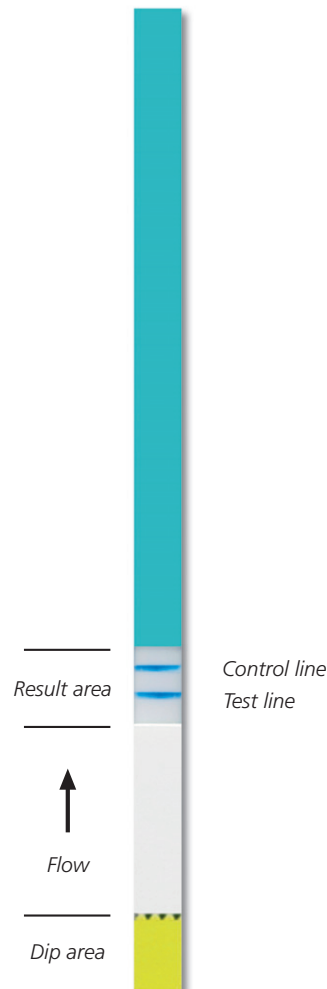
Place the polyester swab in the Specimen Extraction Solution provided and swirl it around vigorously for 10 seconds.



After extraction, dip the yellow area of the dipstick into the solution and hold it there until the liquid front reaches the result area. Then remove the dipstick from the solution and place it in a horizontal position.



You can see the positive test result as soon as two blue lines – a control line and a test line – appear in the result area. If, after five minutes, only the control line has appeared, the test result is negative.



### Patents

EP0677170, EP0565541, US5554504, US5712170, US5965458

### Ordering information

Product Description	REF number
Actim PROM 20 test kit	30832ETAC
Actim PROM 10 test kit	30831ETAC
Actim PROM 3 test sample kit	30833ETAC
Actim PROM Controls	30800ETAC