Actim® PROM

RAPID TEST FOR DETECTING PREMATURE RUPTURE OF FETAL MEMBRANES

Actim PROM is a reliable test for quickly and easily detecting premature rupture of fetal membranes (PROM) in all patients.

PROM is the most common identifiable cause of preterm births and a major cause of maternal and fetal morbidity. Correct PROM diagnosis is important to guide treatment and to minimize complications. However, PROM symptoms differ between patients, which makes diagnosis challenging.

With Actim PROM, even clinically invisible ruptures in the fetal membranes are rapidly and accurately detected. Unlike any other rapid PROM test, Actim PROM gives reliable results even in the presence of blood or other interfering substances, making the test suitable for all women with suspected PROM. Correct PROM diagnosis allows proper patient care, helps to avoid unnecessary treatment, and reduces costs.

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HOW **ACTIM PROM** WORKS

The **Actim PROM** rapid test is based on highly specific and unique monoclonal antibodies that bind to the **insulin-like growth factor binding protein-1 (IGFBP-1)** which is present in the amniotic fluid throughout pregnancy (Figure 2). IGFBP-1 is produced by decidual cells and is the major protein in amniotic fluid. When fetal membranes rupture amniotic fluid leaks into the vagina, where it is not normally found (Figure 1). The presence of amniotic fluid can be detected with the Actim PROM test.

Actim PROM is specially opimized to be **so sensitive that it detects even the microruptures** that are clinically invisible (even less than 1 µl of amniotic fluid). These tiny ruptures cannot be detected with traditional methods, but are clinically relevant as they can induce delivery, cause infections, and threaten the health of both mother and child.

Thanks to Actim PROM's **specificity** to the amniotic fluid forms of IGFBP-1, **test can be completed even in the presence of blood and other bodily fluids, infections, and medical products.** The high specificity and sensitivity minimize false negative and false positive results, making Actim PROM superior in diagnostic accuracy.

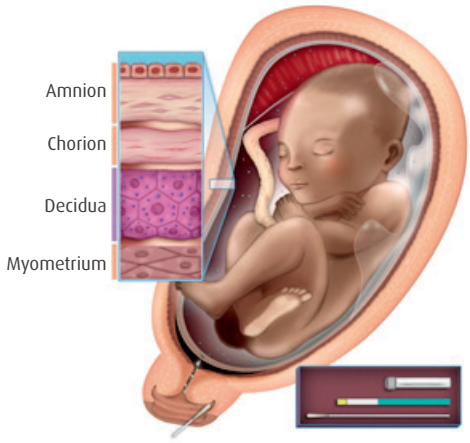


FIGURE 1. Actim PROM identifies membrane rupture through a simple vaginal swab sample.

ACTIM PROM: KEY FACTS

- Reliably detects PROM even before any clinically visible signs
- Can be used at any gestational age
- Easy-to-use one-step dipstick test
- Gives test results at the bedside in just 5 minutes, with sampling completed in seconds – with or without speculum
- Test results are not affected by blood, intercourse, semen, urine, vaginal medications, lubricants, bathing products, or infections

TABLE 1. Actim PROM has the highest sensitivity, specificity, and accuracy in PROM diagnosis. (Erdemoglu & Mungan, 2004)

	Sensitivity %	Specificity %	Accuracy %
Actim PROM test	97	97	97
Nitrazine test	97	16	56
AFI < 80 mm	94	91	92

TABLE 2. When also patients with bleeding are included, Actim PROM surpasses AmniSure-test. (Marcellin et al. 2011)

	Sensitivity %	Specificity %	PPV %	NPV %
Actim PROM	97.5	97.4	97.5	97.4
AmniSure	95.0	94.8	95.0	94.8

TABLE 3. Clinical evidence of accurate PROM diagnosis with Actim PROM.

Reference	Number of patients	Sensitivity %	Specificity %	PPV %	NPV %
Rutanen et al., 1996	130	100	95	93	100
Jain and Morris, 1998	100	100	89	76	100
Akercan et al., 2005	87	100	92	84	100

HOW **ACTIM PROM** HELPS

Traditionally, diagnosis of PROM is based on a variety of clinical symptoms. As the symptoms can be very different between patients, PROM diagnosis is often difficult, inaccurate, and time-consuming.

Rapid and reliable PROM diagnosis with Actim PROM enables **safer and easier patient care while saving valuable resources.**

ACTIM PROM SAVES MONEY, LIVES, AND TIME

- It ensures proper and fast care for the right patients.
- It helps avoid unnecessary use of medications and their side-effects.
- It prevents unnecessary labor inductions.
- It reduces unnecessary hospital stays and patient transfers.
- Reliable results gives expecting mothers peace of mind.

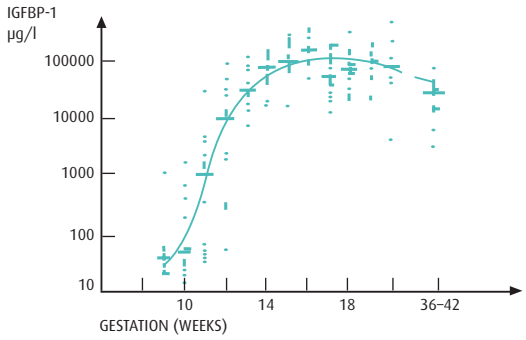
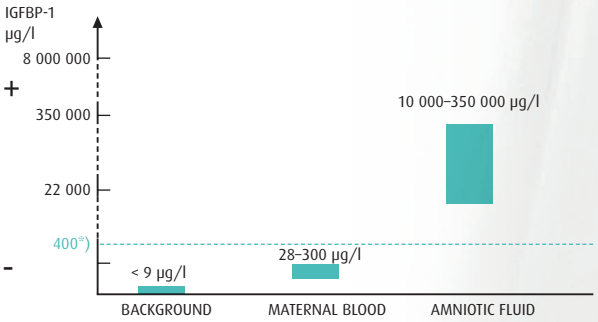


FIGURE 2. IGFBP-1 concentration in amniotic fluid rises quickly in early pregnancy and remains high until delivery. (Wathen et al. 1993)



*) Measuring range of the Actim PROM test is 400–8 000 000 µg/l. 400 µg/l corresponds to 25 µg/l in extracted sample.

FIGURE 3. Actim PROM's detection range (400–8 000 000 µg/l.) covers all clinically relevant concentrations from the smallest microruptures to the highest levels. The test has been designed to be specific to amniotic fluid only, enabling to gain correct results from patients otherwise almost impossible to diagnose.

Actim PROM is a trusted option in over

70 COUNTRIES,

and it is mentioned in several national treatment guidelines.

PREMATURE RUPTURE OF MEMBRANES

Premature rupture of membranes (PROM) is a serious pregnancy complication, in which fetal membranes break before the onset of labor. Once the membranes break, both the mother and the child are at high risk of infection and other complications.

PROM can occur at any gestational age, and it eventually leads to delivery, causing approximately one third of preterm labor events. PROM causes complications in 2–20% of deliveries and is associated with one fifth of perinatal deaths.

"The dipstick method of detecting IGFBP-1 in the vaginal fluid is a rapid, reliable and noninvasive method. Unlike other tests, the PROM test is not affected by semen, blood or discharge."

Erdemoglu and Mungan, 2004

"The test detects amniotic fluid in the vagina with high sensitivity."

Rutanen et al., 1996

"Detection of IGFBP-1 in the cervical–vaginal secretions by a rapid test is to be of value and clinically useful in the identification of women with suspected rupture of membranes in whom the clinical diagnosis was not established with certainty."

Akercan et al., 2005

"Unlike other diagnostic tests, gestational age will not affect the accuracy in detecting the presence of IGFBP-1 since the high amniotic fluid-serum ratio of IGFBP-1 is retained from the second trimester up to and past term."

Jain and Morris, 1998

"In conclusion, the IGFBP-1 bedside test can be used for the diagnosis of PROM in women with or without bleeding both at term and preterm."

Kallioniemi et al, 2014

EVEN 20%

of women with suspected PROM suffer from vaginal bleeding; Actim PROM is the only rapid test that can be used to diagnose them.

HOW TO USE **ACTIM PROM**

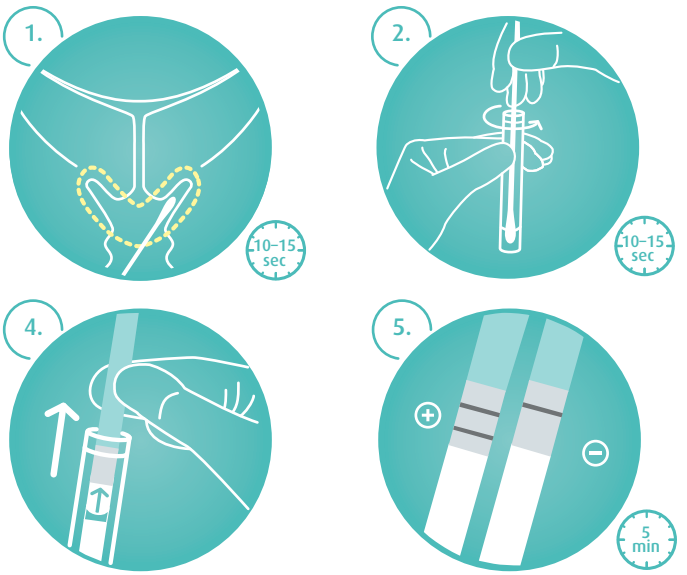


FIGURE 2.
1. Collect sample with or without speculum
2. Extract Specimen
3. & 4. Activate the test
5. Interpret results

The test kit contains all necessary materials and can be stored at room temperature.

THE ACTIM 1NGENI

instrument can be used to digitally interpret test results. As Actim 1ngeni automatically saves and interprets test results, data traceability is improved and more time can be devoted to patient care.

Selected references
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The full reference list can be found on our website.

COMBINE ACTIM PROM WITH ACTIM PARTUS

The rapid and reliable test for detecting the patients at elevated risk of preterm labour, for more confident clinical decision-making.

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Ordering information	
Actim PROM 20 test kit	30832ETAC
Actim PROM 10 test kit	30831ETAC
Actim PROM 1 test kit	30830ETAC
Actim PROM Controls	30800ETAC
Actim 1ngeni Instrument	19100AC
Actim PROM 1ngeni 10 test kit	30831RETAC

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