

Actim[®] PROM

The most accurate test for
detecting the premature
rupture of fetal membranes

Actim[®] PROM is the fastest and the most specific test available on the market for detecting the premature rupture of fetal membranes. It gives reliable results in minutes, even in the presence of blood, making the test suitable for all patients with suspected PROM. The superior performance of the easy-to-use bedside test has revolutionized pregnancy monitoring and helped millions of pregnant people all around the world.

As Actim PROM has been carefully designed to detect even non-visible ruptures in fetal membranes, proper treatment can be started early. Correct PROM diagnosis targets treatment to those who need it – improving patient safety and reducing costs.

No interference
with blood
or semen, urine,
vaginal medications,
lubricants, bathing
products or
infections.



IGFBP-1 testing to diagnose the premature rupture of fetal membranes

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) present in amniotic fluid in high amounts.

The IGFBP-1 level in amniotic fluid rises early in pregnancy and remains elevated until delivery. Amniotic fluid is normally not found in the vagina, but when fetal membranes rupture, amniotic fluid leaks into the vagina and the IGFBP-1 concentration quickly rises. Actim PROM detects IGFBP-1 in vaginal swab samples and helps to identify membrane ruptures.

With its optimal detection limit, Actim PROM can identify very small amounts of amniotic fluid with a minimal risk of false positives due to the very low levels of IGFBP-1 normally found in the vagina.

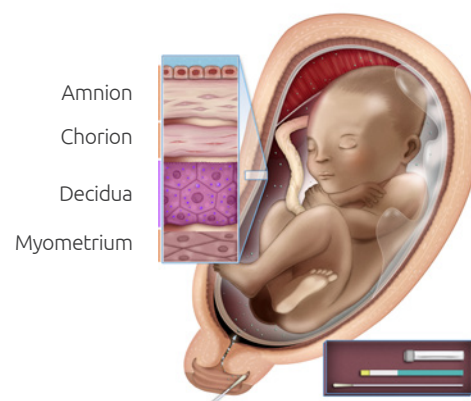


Figure 1. Actim PROM identifies membrane rupture through a simple vaginal swab sample.

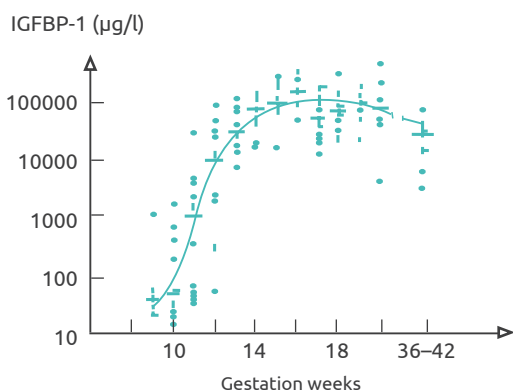


Figure 2. IGFBP-1 concentration in amniotic fluid rises quickly in early pregnancy and remains high until delivery. (Wathen et al. 1993).

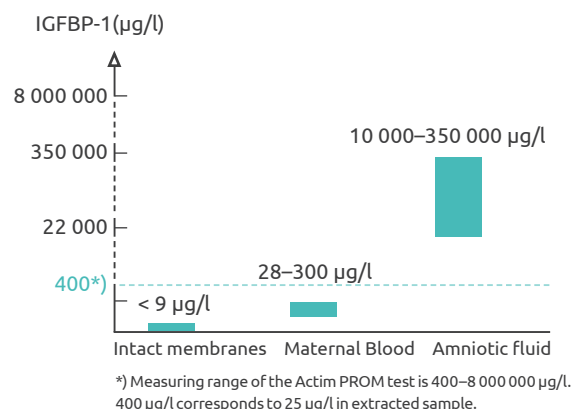
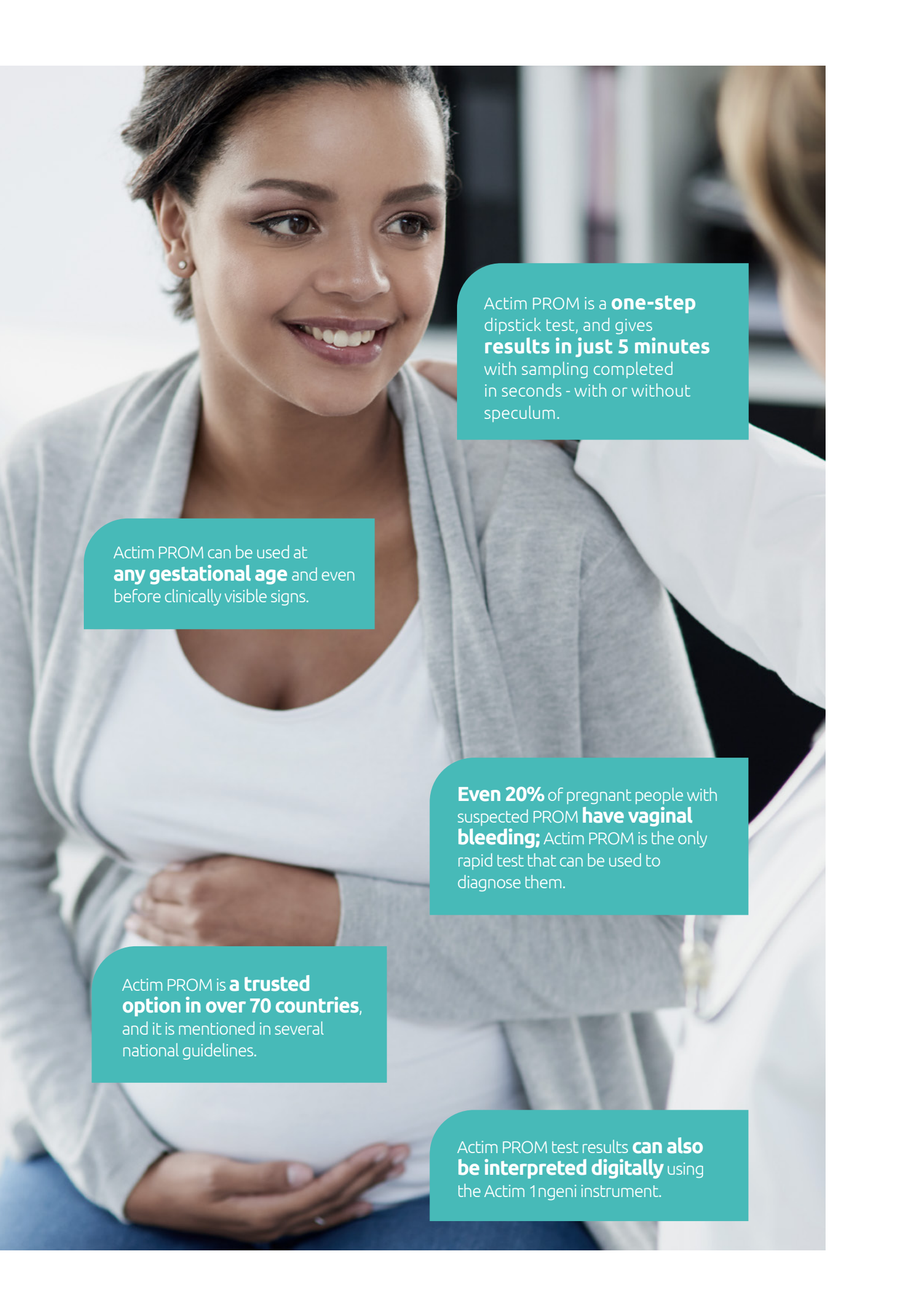


Figure 3. Actim PROM's detection range covers all clinically relevant concentrations from the smallest ruptures to the highest levels.

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 birth-giver 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.



Actim PROM is a **one-step** dipstick test, and gives **results in just 5 minutes** with sampling completed in seconds - with or without speculum.

Actim PROM can be used at **any gestational age** and even before clinically visible signs.

Even 20% of pregnant people with suspected PROM **have vaginal bleeding**; Actim PROM is the only rapid test that can be used to diagnose them.

Actim PROM is a **trusted option in over 70 countries**, and it is mentioned in several national guidelines.

Actim PROM test results **can also be interpreted digitally** using the Actim 1ngeni instrument.

Actim PROM detects all PROM cases

IGFBP-1-testing is mentioned in several national guidelines as a recommendation to detect PROM when the rupture of membranes remains uncertain after a full evaluation*

Actim PROM is specially optimized to be **so sensitive that it detects even the smallest ruptures** 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 the birth-giver and the fetus.

Thanks to Actim PROM's **specificity** to the amniotic fluid forms of IGFBP-1, **the test can be performed 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.

Table 1. Actim PROM has the highest sensitivity, specificity, and accuracy in PROM diagnosis. (Erdemoglu & Mungan, 2004). When also patients with bleeding are included, Actim PROM surpasses PAMG-1 tests. (Marcellin et al. 2011)

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

| | Sensitivity | Specificity | PPV** | NPV*** |
|-------------|--------------------|--------------------|--------------|---------------|
| Actim PROM | 98 % | 97 % | 98 % | 97 % |
| PAMG-1 test | 95 % | 95 % | 95 % | 95 % |

Table 2. Clinical evidence of accurate PROM diagnosis with Actim PROM.

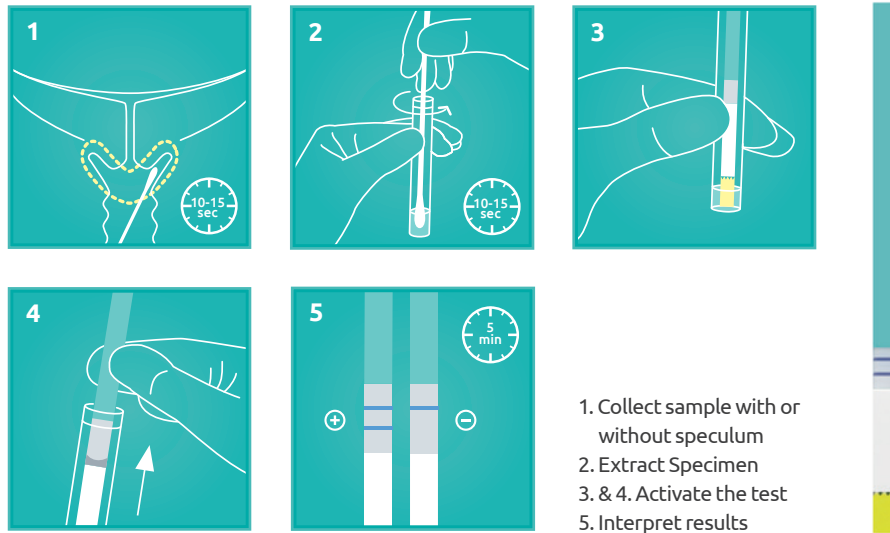
| | Sensitivity | Specificity | PPV | NPV |
|----------------------------|--------------------|--------------------|------------|------------|
| Akercan et al., 2005 | 100 % | 92 % | 84 % | 100 % |
| Erdemoglu and Mungan, 2004 | 97 % | 97 % | ND | ND |
| Jain and Morris, 1998 | 100 % | 89 % | 76 % | 100 % |
| Rutanen et al., 1996 | 100 % | 95 % | 93 % | 100 % |

*Examples include "Preterm labour and birth", NICE (National Institute for Health and Care Excellence), 2015: www.nice.org.uk/guidance/ng25 (cited on 17.11.2022) and "Permatute Birth". Working group established by the Finnish Medical Society Duodecim and the Finnish Gynecological Association. Finnish Medical Society Duodecim, 2018: www.kaypahoito.fi/hoi50089 (cited on 20.09.2022).

**PPV (Positive Predictive Value) = Positive predictive value

***NPV (Negative Predictive Value) = Negative predictive value

Fast results at the bedside in minutes



Actim PROM saves lives, time, and money

Traditionally, diagnosis of PROM is based on a variety of clinical symptoms and methods. As the symptoms can be very different between patients, PROM diagnosis is often difficult and time-consuming. Rapid and reliable PROM diagnosis with Actim PROM makes patient care safer and easier, and saves valuable resources.

- Medical attention can be directed to the right patients.
- Enables proper care - even for bleeding patients.
- Unnecessary use of medication and their side-effects can be avoided.
- Unnecessary labor inductions are minimized.
- Reduces avoidable hospital visits and patient transfers.
- Gives birth-givers peace of mind.

Contact us

Ordering information

| | |
|-----------------------------|------------|
| Actim PROM, 20 tests | 30832ETAC |
| Actim PROM, 10 tests | 30831ETAC |
| Actim PROM, 1 test | 30830ETAC |
| Actim PROM Controls | 30800ETAC |
| <hr/> | |
| Actim 1ngeni Instrument | 19101AC |
| Actim PROM 1ngeni, 10 tests | 30831RETAC |

Combine Actim PROM with Actim Partus


The simple bedside test for ruling out the risk of preterm or imminent delivery.

Actim Oy

– part of Medix Biochemica Group
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 Test kit contains all necessary materials and can be stored at room temperature.

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The full reference list can be found on our website.