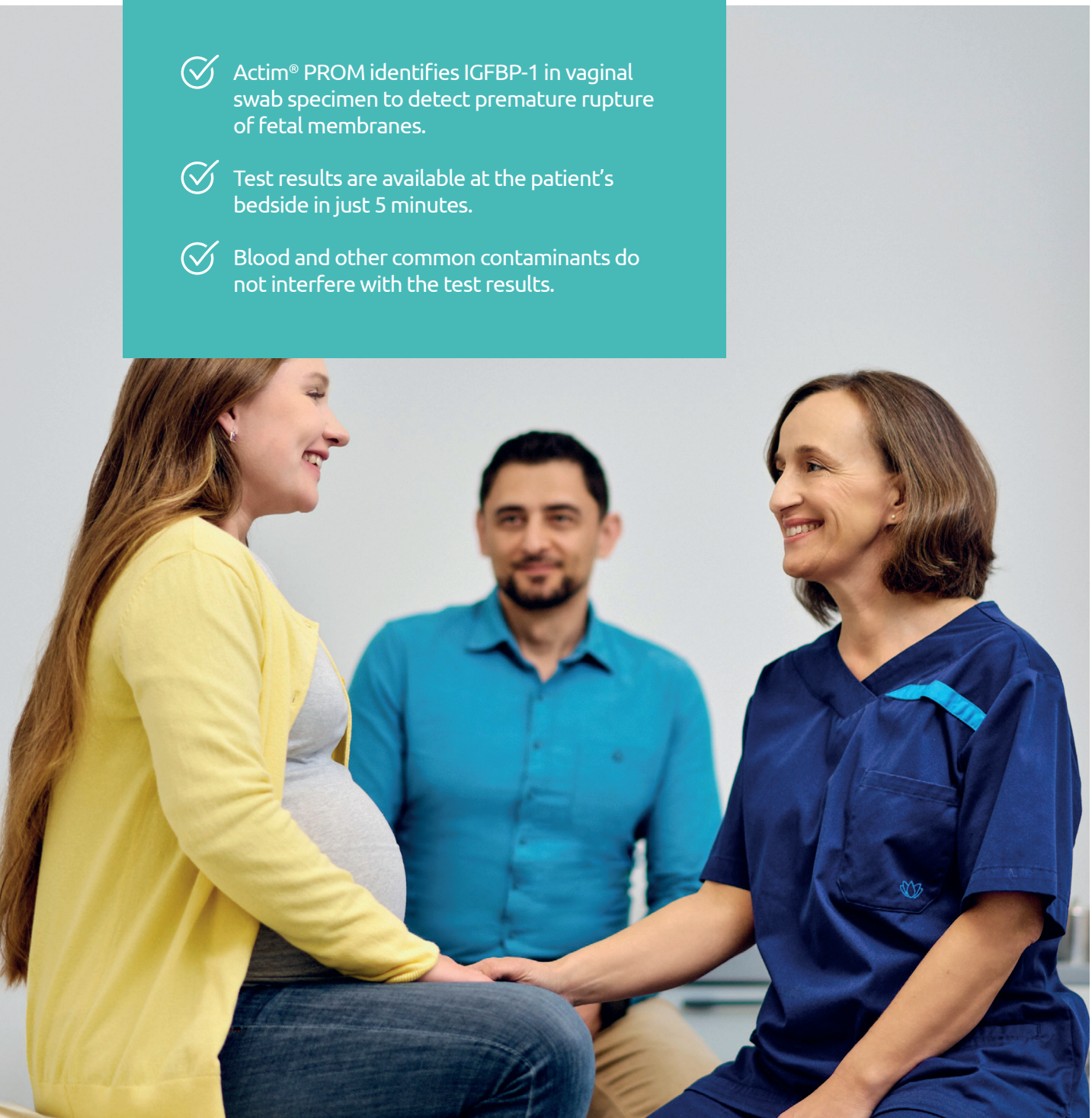
Actim® PROM

A rapid diagnostic test for the detection of premature rupture of fetal membranes.

No interference with blood, semen, urine, or infections.

- Actim® PROM identifies IGFBP-1 in vaginal swab specimen to detect premature rupture of fetal membranes.
- Test results are available at the patient's bedside in just 5 minutes.
- Blood and other common contaminants do not interfere with the test results.



actimtest.com

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

Actim PROM can be used at **any gestational age.** Furthermore, blood, semen, urine, shower and bath products or infections do not interfere with the test results.

About 20% of pregnant people with suspected PROM **have vaginal bleeding.** All these patients can be diagnosed with the help of Actim PROM.

Actim PROM is helping **millions of pregnant people** with suspected PROM around the globe.

Actim PROM test results **can be digitally interpreted** with Actim® 1ngeni, taking data connectivity one step further in pregnancy monitoring.

A unique rapid test that detects IGFBP-1 in vaginal fluids

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

Thanks to its optimal cut-off, Actim PROM can identify even small amounts of amniotic fluid with a minimal risk of false positive results due to the very low levels of IGFBP-1 normally found in the vagina during pregnancy.

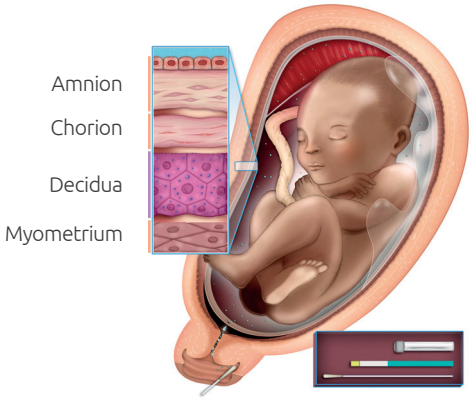


Figure 1. Actim PROM identifies premature rupture of fetal membranes from a vaginal swab sample

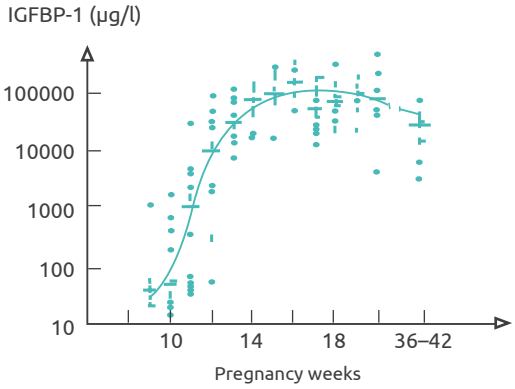
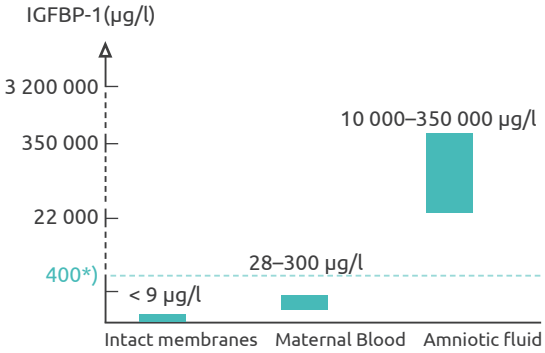


Figure 2. IGFBP-1 concentration in amniotic fluid rises quickly in early pregnancy and remains high until birth (Wathen et al. 1993).



*) Measuring range of the Actim PROM test is 400–3 200 000 µg/l. 400 µg/l corresponds to 25 µg/l in extracted sample.

Figure 3. The measuring range of Actim PROM covers all clinically relevant concentrations of IGFBP-1.

Complications of PROM

Premature rupture of membranes (PROM) occurs when the fetal membranes break before the onset of labor. If rupture of membranes occurs before 37 weeks of gestation, it is referred to as preterm PROM (PPROM). Once the membranes break, both the birth-giver and the child are at high risk of infection and other complications.

Premature rupture of membranes causes complications in 2% to 20% of pregnancies. It can occur at any gestational age, and it eventually leads to the start of labor and delivery. PROM is a leading cause of approximately one third of all preterm births, and it is associated with one fifth of perinatal deaths.

A reliable test for all patients suspected with PROM

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

Actim PROM is opimized to be **so sensitive that it detects even the smallest ruptures** that are clinically invisible (even less than 2 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, other bodily fluids or infectious agents in the extracted specimen.** The high specificity and sensitivity minimize false negative and false positive results, making Actim PROM an optimal solution for diagnosing premature rupture of membranes.

Table 1. Actim PROM has the highest sensitivity, specificity and accuracy in PROM diagnosis (Erdemoglu & Mungan, 2004). When patients with bleeding are also included in the study, the performance of 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 PROM diagnosis with Actim PROM.

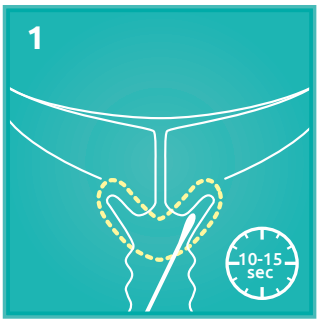
	Sensitivity	Specificity	PPV	NPV
Akercan et al., 2005	100 %	92 %	84 %	100 %
Erdemoglu and Mungan, 2004	97 %	97 %	ND	ND
Jain and Morris, 1998	100 %	89 %	76 %	100 %
Rutanen et al., 1996	100 %	95 %	93 %	100 %

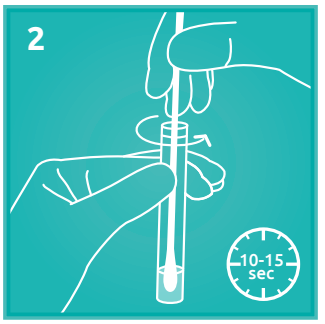
*Examples include "Preterm labour and birth", NICE (National Institute for Health and Care Excellence), 2015: www.nice.org.uk/guidance/ng25 (cited on 17.11.2022) and "Permature Birth". Working group established by the Finnish Medical Society Duodecim and the Finnish Gynecological Association. Finnish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

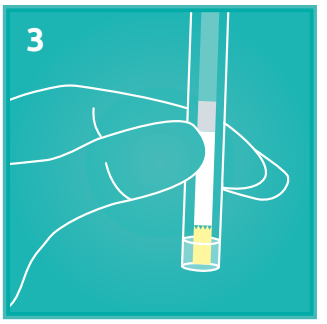
**PPV (Positive Predictive Value) = Positive predictive value

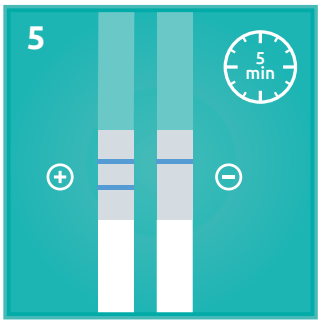
***NPV (Negative Predictive Value) = Negative predictive value

Results available at the bedside in just 5 minutes









1. Collect the specimen with or without a speculum.
2. Extract the specimen.
3. & 4. Activate the test.
5. Interpret the test result.

Actim PROM saves time and valuable resources

The diagnosis of PROM is traditionally based on a variety of clinical symptoms and methods. Because symptoms differ among patients, diagnosing this condition can often be challenging and time-consuming.

With Actim PROM, the diagnosis can be made in a timely manner, so treatment can be decided early on to avoid any complications for both the pregnant patient and the fetus.

- Medical attention can be directed to the right patients.
- Unnecessary use of medication and their side effects can be avoided.
- Avoidable hospital visits and patient transfers can be reduced.
- Birth-givers' peace of mind is improved, limiting unnecessary anxiety and worries.

Ordering information

Product	Product code
Actim PROM, 20 tests	30832ETAC
Actim PROM, 10 tests	30831ETAC
Actim PROM, 1 test	30830ETAC
Actim PROM Controls	30800ETAC

Actim 1ngeni Instrument	19101AC
Actim PROM 1ngeni, 10 tests	30831RETAC

The test kit contains all the materials needed - no extra laboratory equipment is required to perform the test.

The test kit can be conveniently stored at room temperature.

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Selected references

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The full reference list can be found on our website.