Actim PROM test provides the first reliable method for detecting premature rupture of fetal membranes. Based on extensive, high quality research, Actim PROM is easy to use and gives results you can rely on.

Premature rupture of fetal membranes (PROM) is a serious pregnancy complication that increases the risk of maternal and fetal infections.

PROM causes approximately 1/3 of premature deliveries, which are linked to the risk of perinatal morbidity and mortality.
The Insulin-like growth factor binding protein 1 (IGFBP-1) is a protein produced by human decidua during pregnancy, and not normally present in the vagina. However, after the rupture of fetal membranes, amniotic fluid with a high concentration of IGFBP-1 mixes with vaginal secretions. Actim PROM can identify this simply through the use of a vaginal swab sample (Figure 1).

The amniotic fluid contains less and non-phosphorylated forms of IGFBP-1 protein, and these forms are specifically detected by monoclonal antibodies within Actim PROM test. The decidual forms of IGFBP-1, as well as those in blood, are highly phosphorylated. This is why they have minimal interference with the Actim PROM test.1

### Why Actim PROM is the best way to test

- **Actim PROM is highly specific to amniotic fluid**
- **It’s sensitive enough to detect even micro ruptures**
- **It provides fast results at the bedside in just 5 minutes**
- **It measures the optimal biomarker IGFBP-1**
- **Blood, semen, urine, vaginal medications, lubricants or bathing products don’t interfere with its results**
- **Scientific evidence from multiple studies have proven its effectiveness**

### Why IGFBP-1 is the reliable way to identify ruptured membranes

Amniotic fluid contains huge amounts of IGFBP-1 protein. However, the concentration of IGFBP-1 in biological fluids potentially contaminating vaginal secretions is minimal (Table 1). This makes IGFBP-1 a reliable marker for identifying ruptured membranes.

What’s more, the IGFBP-1 concentration rises early and remains high until term (Figure 2). This means that premature rupture of fetal membranes (PROM) can be identified whenever it is clinically relevant. The role of IGFBP-1 during pregnancy has been thoroughly investigated, with studies published in numerous peer reviewed scientific journals.

### Comparison of methods to detect PROM

<table>
<thead>
<tr>
<th>Method</th>
<th>Sensitivity %</th>
<th>Specificity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actim PROM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH Ferning</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actim PROM</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH Ferning</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **Ragosch et al. 1996** 100 94 NA 83 63 NA
- **Kubota and Takeuchi 1998** 94.7 73.3 42.1 93.1 72.4 75.9
- **Erdemoglu and Mungan 2004** 97 97 NA 97 16 NA

NA = not available

Actim PROM is a superior method for detecting premature rupture of fetal membranes compared to pH or ferning.

### IGFBP-1 concentration on various body fluids

<table>
<thead>
<tr>
<th>Sample</th>
<th>Concentration of IGFBP-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum (pregnancy)</td>
<td>58–600 µg/l</td>
</tr>
<tr>
<td>Urine</td>
<td>Undetectable</td>
</tr>
<tr>
<td>Semen</td>
<td>Undetectable</td>
</tr>
<tr>
<td>Amniotic fluid</td>
<td>10 500–350 000 µg/l</td>
</tr>
</tbody>
</table>

**IGFBP-1 concentration is extremely high in amniotic fluid only.**

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**Figure 1**

- Amnion
- Chorion
- Decidua
- Myometrium

**Table 1**

**Table 2**
HOW ACTIM PROM HELPS YOU DIAGNOSE BETTER

1. IT DETECTS EVEN THE SMALLEST AMOUNTS OF AMNIOTIC FLUID

Actim PROM has been specially optimized to be so sensitive that it will detect even the microruptures that are clinically invisible (even less than 1 µl of amniotic fluid) yet have the same consequences as regular PROM. Actim PROM’s detection range covers all clinically relevant concentrations from the smallest traces to the highest levels (Figure 3).

2. IT WORKS EVEN ON BLEEDING PATIENTS

Infections or fluids in the vagina can complicate clinical diagnosis. Blood, for example, can be present in the vagina of up to 20% of women with suspected PROM. To combat this, Actim PROM has been designed to be specific to amniotic fluid only, enabling you to gain correct results from patients otherwise almost impossible to diagnose (Figure 3). With thanks to its unique test design, Actim PROM is not affected by other fluids either, such as semen, urine, infections, topical agents (medications, lubricants) or bathing products.

3. IT’S BEEN SCIENTIFICALLY PROVEN TO WORK BRILLIANTLY

Time after time, published clinical studies have proven that Actim PROM’s performance and reliability clearly surpass other commonly used methods for detecting PROM (Table 2). What’s more, Actim PROM is the only test that has repeatedly been clinically validated for all patients with suspected PROM, even those women with vaginal bleeding.

Actim PROM has helped millions of pregnant women worldwide and is currently the trusted option for professionals in over 70 countries.

**IGFBP-1 levels in amniotic fluid**

Wathen et al. 1993

The IGFBP-1 level in amniotic fluid rises in early pregnancy and remains elevated throughout the pregnancy.

**Detection limit of Actim PROM**

400 µg/l = 25 µg/l in the extracted sample.

**Measuring range of the Actim PROM test**
10 WAYS ACTIM PROM SAVES MONEY, LIVES AND TIME

- It helps to stop delays in correct diagnosis and patient care
- It helps to stop unnecessary patient transfers
- It helps to stop unnecessary medications
- It helps to stop unnecessary labor inductions
- It ensures proper and fast care for the right patients
- It prevents unnecessary hospital stays
- It prevents unnecessary medications
- It prevents unnecessary labor inductions
- It enables proper care of bleeding patients, too
- Its reliable results give patients peace of mind

COST SAVINGS

IMPROVED PATIENT CARE
HOW TO USE ACTIM PROM

- One-step dipstick test – very easy to use
- Sampling in seconds – with or without speculum
- Fast results at the bedside in just 5 minutes
- Test kit contains all the necessary materials

Technical information

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biochemical marker</td>
<td>IGFBP-1 (Less and non-phosphorylated forms)</td>
</tr>
<tr>
<td>Sample type</td>
<td>Swab from posterior fornix (no speculum needed)</td>
</tr>
<tr>
<td>Sampling time</td>
<td>10–15 seconds</td>
</tr>
<tr>
<td>Processing time</td>
<td>10–15 seconds</td>
</tr>
<tr>
<td>Reading time</td>
<td>5 minutes or less</td>
</tr>
<tr>
<td>Detection limit</td>
<td>25 µg/l in the extracted sample, optimal for detection of amniotic fluid</td>
</tr>
<tr>
<td>Measuring range</td>
<td>25–4 000 000 µg/l</td>
</tr>
<tr>
<td>Potential interference</td>
<td>None</td>
</tr>
<tr>
<td>Storage</td>
<td>+2...+25 °C</td>
</tr>
</tbody>
</table>

Figure 4

1. Collect sample
2. Extract Specimen
3.–4. Activate the test
5. Result interpretation
Selected references


The full reference list can be found on our website.