## *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.

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***Reliable test results in minutes***

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# Fast and reliable way to test cervix maturity

***Preterm delivery is a serious pregnancy complication that can have devastating effects. It can result in developmental disorders, and it is a major cause of infant deaths during the first month. In approximately 50% of preterm deliveries, the mother has experienced preterm contractions. Although half of pregnant women complain about preterm contractions, only 20% of them actually deliver preterm. There is a need for a reliable test, which can identify the women at an increased risk and differentiate them from those who are not in danger of delivering preterm.***

Actim Partus helps you determine the risk of preterm delivery. It is a fast and simple bedside test that can be used to estimate the ripeness of the cervix during pregnancy. A negative test result effectively rules out the risk of imminent or preterm delivery. Actim Partus does not require any additional equipment, and concrete results are immediately available. Patients with a positive result can be easily motivated to stay in the hospital, where they can be treated appropriately. A negative result, on the other hand, is a concrete and reassuring piece of evidence that hospitalization is not necessary.

## Cervical phIGFBP-1 increases as the cervix matures

The level of phosphorylated IGFBP-1 (phIGFBP-1) in the cervix increases considerably as the cervix matures. In a study by Nuutila et al. it was demonstrated that the phIGFBP-1 level in a ripe cervix was higher than in an unripe cervix. The application of prostaglandin gel leads to a clear elevation of the phIGFBP-1 level in the cervix.

***Cervical level of phIGFBP-1 vs. maturity of cervix***
Nuutila et al. 1999

| *Cervical status* | *Median phIGFBP-1 (µg/l)* |
|---|---|
| Unripe cervix | 6.6 |
| Ripe cervix | 27 |
| 6h after PGE2 application | 51 |

The phIGFBP-1 level in the cervix increases as the cervix matures

## Efficiently rules out risk of imminent delivery

It has previously been shown that 94% of women with a cervical phIGFBP-1 concentration less than 10 µg/l did not deliver preterm or within two weeks of the sampling. None of these women delivered before week 35. Among the women admitted to the hospital with preterm contractions and who delivered preterm, 88% had phIGFBP-1 higher than 10 µg/l. Recent studies have confirmed these findings. Actim Partus helps you identify the patients with an elevated risk of delivering preterm. And more specifically, a negative test result is a safe indication that imminent delivery or delivery within two weeks is highly unlikely.

***Actim Partus test in prediction of preterm delivery***

| *Study* | *Patients* | *n* | *Gestational age (weeks)* | *End-point* | *Sensitivity* | *Specificity* | *PPV* | *NPV* |
|---|---|---|---|---|---|---|---|---|
| Lembet et al. | Symptomatic and Controls | 54 | 20–36 | Delivery <37 weeks | 89.5% | 94.1% | 94.4% | 88.9% |
| | | | | Delivery <7 days | 93.8% | 85% | 83.3% | 94.1% |
| | | | | Delivery <48 hours | 93.3% | 81% | 77.8% | 94.4% |
| Kwek et al. | Symptomatic | 47 | 23–33 | Delivery <36 weeks | 73.7% | 82.6% | 77.8% | 79.2% |
| Elizur et al. | Symptomatic | 64 | 24–35 | Delivery <37 weeks | 69.6% | 70.7% | 57.1% | 80.5% |
| | | | | Delivery <35 weeks | 81.8% | 64.1% | 32.1% | 94.4% |

A negative result rules out the risk of imminent or preterm delivery. Patients with a positive result have an elevated risk to deliver preterm.

## Semen and urine have no effect on test results

Most bodily fluids potentially contaminating a cervical sample, such as semen and urine, contain only trace quantities of phosphorylated IGFBP-1. Therefore a recent intercourse has no effect on the results of the Actim Partus test. Since preterm contractions may be induced by the prostaglandins in seminal fluid, several symptomatic women may recently have had intercourse. These patients do not need to be excluded when using the Actim Partus test.

***Gestational age at delivery according to Actim Partus test results***

| *Study* | *Patients* | *n* | *Actim Partus result* | *n* | *Mean gestational age at sample collection* | *Mean gestational age at delivery* |
|---|---|---|---|---|---|---|
| Lembet et al. | Symptomatic | 36 | Negative | 18 | 29.8 | 37.9 |
| | | | Positive | 18 | 32.4 | 34.4 |
| | Controls | 18 | Negative | 18 | 29.4 | 39.4 |
| | | | Positive | 0 | 29.4 | 39.4 |
| Kwek et al. | Symptomatic | 47 | Negative | 29 | 31.0 | 37 |
| | | | Positive | 18 | 31.5 | 33 |
| Elizur et al. | Symptomatic | 64 | Negative | 36 | 31.2 | 38 |
| | | | Positive | 28 | 29.6 | 36.2 |

Most patients with a negative result didn't deliver prematurely. They gave birth much later than those with a positive result, who in general delivered preterm. The interval between a positive result and delivery was shorter than for patients with a negative result.

## References


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Rutanen EM. Insulin-like growth factors in obstetrics. Curr Opin Obstet Gynecol (2000) 12: 163-168.

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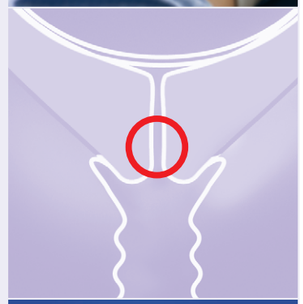
## Patents

EP648335, EP0677170, US5712170, US5965458

## Ordering information

| Product Description | REF number |
|---|---|
| Actim Partus 10 test kit | 31931ETAC |
| Actim Partus 3 test sample kit | 31933ETAC |
| Actim Partus Controls | 31900ETAC |

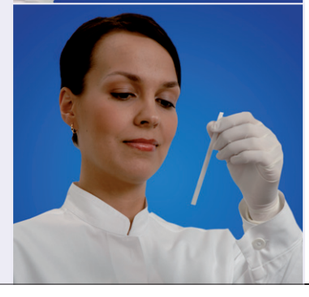
*Actim Partus is a quick bedside test that gives highly reliable results in minutes.*



*Take a cervical secretion sample from the cervix with a sterile polyester swab by leaving the swab in the cervix for 10–15 seconds. This allows the swab to absorb the cervical secretion 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.*