

Actim[®] Partus

THE RELIABLE WAY TO IDENTIFY AND RULE OUT THE RISK OF PRETERM DELIVERY

Actim Partus is a quick and reliable bedside test to identify patients with a real risk of imminent or preterm delivery, even before symptoms are clinically visible.

Every year 15 million infants are born before the pregnancy has gone full term. Preterm delivery (PTD), delivery before 37 weeks of gestation, is the leading global cause of morbidity and mortality associated with child birth. Early detection of high-risk patients is challenging, as half of pregnant women experience symptoms, yet only one fifth of these are at real risk of immediate or preterm delivery.

Identification of patients in need of urgent care helps to avoid unnecessary and potentially hazardous treatment in low-risk patients, thus improving patient care and inducing cost savings.

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HOW ACTIM PARTUS WORKS

The **Actim Partus** rapid test is based on unique and highly specific monoclonal antibodies that bind to the phosphorylated form of **insulin-like growth factor binding protein-1 (phIGFBP-1)**. phIGFBP-1 is produced in the fetal decidua, but leaks into the cervix when the decidua and chorion detach (Figure 1).

A phIGFBP-1 concentration of 10 µg/l or more in the cervical fluid extract causes a **positive Actim Partus test result**. This indicates significant tissue damage, potentially leading to PTD. A **negative test result**, in turn, means

that there are no significant changes in the choriodecidual layer; delivery is therefore very unlikely within the next 1-2 weeks, even if the patient has contractions.

EFFECTIVE IN PREDICTING PRETERM DELIVERY

Clinical evidence from multiple studies shows that Actim Partus has a very **high (98 %) negative predictive value (NPV)**, and is therefore a reliable tool to rule out the risk of imminent (Table 1) or preterm (Table 2) delivery.

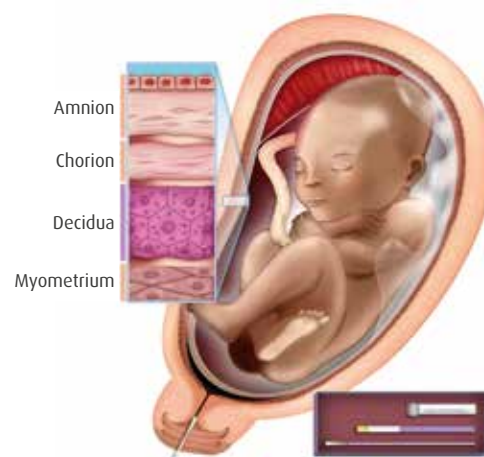


FIGURE 1. Actim Partus identifies the risk of PTD through a simple cervical swab sample.

ACTIM PARTUS: KEY FACTS

- Reliably rules out the risk of imminent or preterm delivery when fetal membranes are unbroken
- Can be used from week 22 onwards
- Easy-to-use one-step dipstick test
- Gives test results at the bedside in just 5 minutes, with sampling completed in seconds
- Test results are not affected by intercourse, semen, urine, vaginal medications, lubricants, bathing products, or infections

ACTIM PARTUS CAN BE USED ON ALL PATIENTS,

as test results are not affected by vaginal medications, infections, or various other interfering factors.

TABLE 1. Clinical evidence of Actim Partus as a predictor of delivery within 7 days.

Reference	Number of patients	GA (wk)	Sensitivity %	Specificity %	PPV %	NPV %
Tripathi et al., 2016	468	28-36	95	92	86	97
Azlin et al., 2010	51	24-36	80	94	57	98
Brik Spinelli et al., 2010	276	24-34	73	66	22	95
Tanir et al., 2009	68	24-37	93	79	56	98
Eroglu et al., 2007	51	24-35	83	84	42	97
Ting et al., 2007	94	24-34	69	78	39	92
Lembet et al., 2002	36	20-36	94	85	83	94

HOW ACTIM PARTUS HELPS

Identifying patients who have harmless contractions from those at real risk of preterm delivery can be difficult. In practice, this means that over-diagnosis and over-treatment are often the only option.

Actim Partus supports clinical decision making by helping correct PTD diagnosis. **Patients who don't require immediate medical attention can be sent home, instead of treating all patients who have preterm contractions.** This saves cost and time for both the patient and hospital.

A POSITIVE ACTIM PARTUS TEST RESULT

- The patient has a higher risk of PTD and should be evaluated for treatment aiming at delaying the delivery or preparing the baby for delivery.
- Early identification of patients at real risk of PTD allows timely interventions.

A NEGATIVE ACTIM PARTUS TEST RESULT

- The patient can be sent home unless otherwise clinically indicated, as delivery is highly unlikely within the next 1-2 weeks.
- Unnecessary treatments with potential side effects can be avoided, the mother is given peace of mind, and hospital resources are saved.
- More than 2/3 of the symptomatic women get a negative result.

TABLE 2. Clinical evidence of Actim Partus as a predictor of delivery before week 32-37.

Reference	Number of patients	GA (wk)	End-point	Sensitivity %	Specificity %	PPV %	NPV %
Tripathi et al., 2016	468	28-36	< 37 weeks	81	97	95	88
Tripathi et al., 2016	468	28-36	< 34 weeks	94	89	78	97
Brik Spinelli et al., 2010	276	24-34	< 32 weeks	76	66	18	96
Tanir et al., 2009	68	24-37	< 34 weeks	70	75	48	89
Eroglu et al., 2007	51	24-35	< 35 weeks	70	88	58	92
Akercan et al. 2004	45	24-36	< 37 weeks	78	87	73	90
Lembet et al., 2002	36	20-36	< 37 weeks	90	94	94	89

MOST WOMEN REMAIN SEXUALLY ACTIVE DURING PREGNANCY,

and because intercourse and semen do not interfere with the Actim Partus results, there is no need to rule out these patients.

“ Cervical pIGFBP-1 provided additional information for assessing symptomatic women at high risk of preterm delivery. ”

Brik Spinelli et al., 2009

“ The high negative predictive value of this test, especially for delivery within seven days, may aid the clinician to avoid unnecessary and potentially hazardous medications. ”

Tanir et al., 2009

“ Pregnant women who are in preterm labor with intact fetal membranes, and who have a positive pIGFBP-1 test result in cervical secretion, have an increased risk of preterm delivery. ”

Kekki et al., 2001

“ As the test also has a high negative predictive value, this may enable physicians to prevent overtreatment of patients with uterine contractions. Therefore, many unwanted side-effects and complications of potentially hazardous tocolytic therapy can be prevented. ”

Lembet et al., 2002

“ The combined use of pIGFBP-1 and transvaginal ultrasound cervical length showed a higher efficacy in predicting PTL [pre-term delivery] as compared with either indicator alone. Thus, implementation of the combined methods in women with suspicion of pre-term labour has potential to improve the prediction of pre-term labour, and thus, treatment can be more directed. ”

Azlin et al., 2010

Actim Partus is already in use
**ALL OVER THE
WORLD,**

and it has been included in
several national treatment
guidelines.

HOW TO USE ACTIM PARTUS

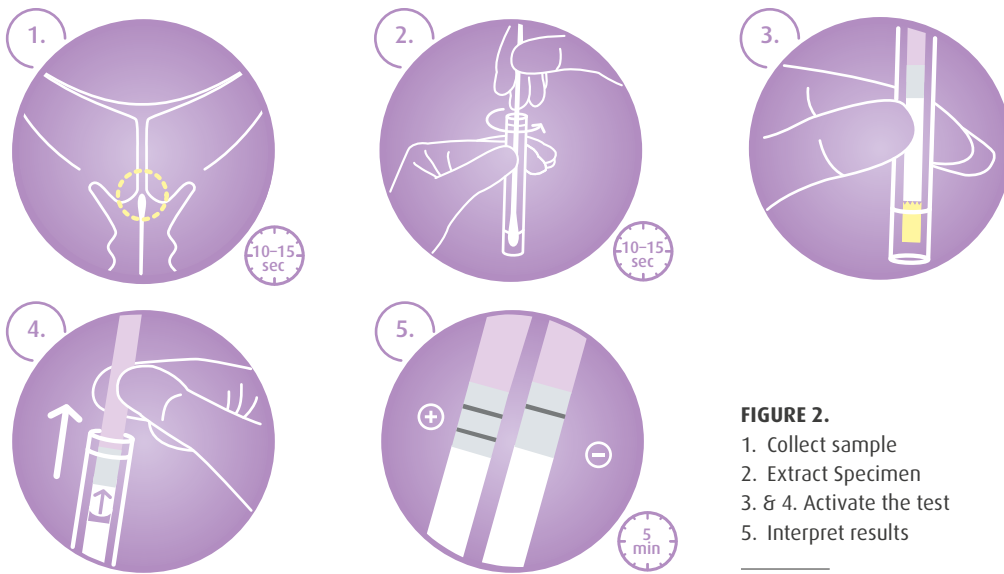


FIGURE 2.
1. Collect sample
2. Extract Specimen
3. & 4. Activate the test
5. Interpret results



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 PARTUS WITH ACTIM PROM

The original rapid test for detecting premature fetal membrane rupture (PROM), for more confident clinical decision-making.

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Ordering information

Actim Partus 10 test kit	31931ETAC
Actim Partus 1 test	31930ETAC
Actim Partus Controls	31900ETAC
Actim Partus Sample Collection kit	31935ETAC
Actim 1ngeni Instrument	19100AC
Actim Partus 1ngeni 10 test kit	31931RETAC