Abbott

ACTIM® PARTUS

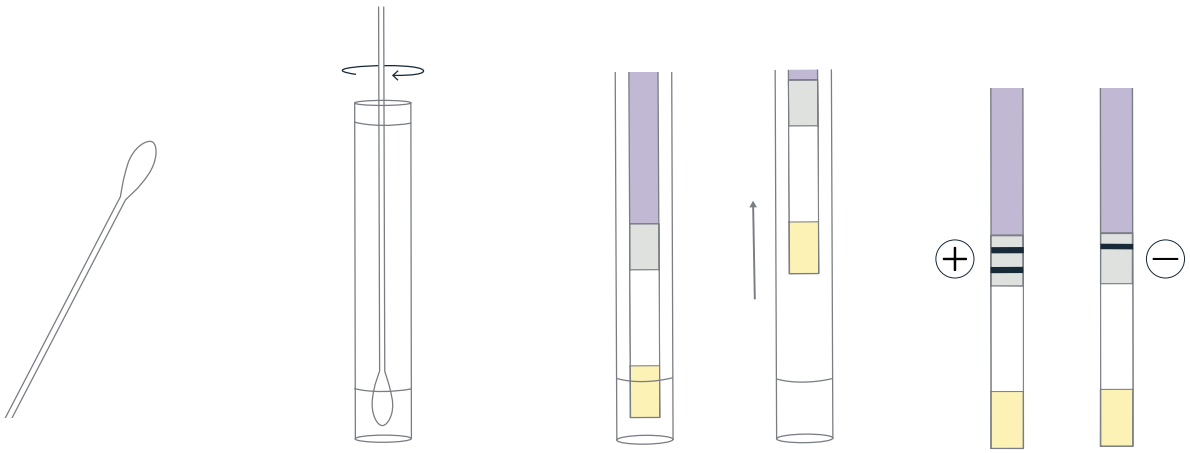
The Reliable Way to Identify and Rule out the Risk of Preterm Delivery

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 childbirth. 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.

HOW TO USE ACTIM® PARTUS



STEP 1
Collect sample

STEP 2
Extract specimen

STEPS 3–4
Activate the test

STEP 5
Interpret results

The test kit contains all the necessary materials and can be stored at room temperature. Consult the Instructions for Use supplied with the kit for complete information.

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.

NEW: Quantitative Actim® Partus results in combination with the Actim® 1ngeni.

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.

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.

Actim® Partus can be used on all patients, as test results are not affected by vaginal medications, infections or various other interfering factors.

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.

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

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[1]	468	28–36	95	92	86	97
Azlin et al., 2010[2]	51	24–36	80	94	57	98
Brik et al., 2010[3]	276	24–34	73	66	22	95
Tanir et al., 2009[4]	68	24–37	93	79	56	98
Eroglu et al., 2007[5]	51	24–35	83	84	42	97
Ting et al., 2007[6]	94	24–34	69	78	39	92
Lembet et al., 2002[7]	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, which means hospitals won't need to treat all patients who have preterm contractions.** This saves cost and time for both the patient and hospital.

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.

+ 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 two out of three 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[1]	468	28–36	< 37 weeks	81	97	95	88
Tripathi et al., 2016[1]	468	28–36	< 34 weeks	94	89	78	97
Brik et al., 2010[3]	276	24–34	< 32 weeks	76	66	18	96
Tanir et al., 2009[4]	68	24–37	< 34 weeks	70	75	48	89
Eroglu et al., 2007[5]	51	24–35	< 35 weeks	70	88	58	92
Akercan et al., 2004[9]	45	24–36	< 37 weeks	78	87	73	90
Lembet et al., 2002[7]	36	20–36	< 37 weeks	90	94	94	89

ACTIM® PARTUS IS ALREADY IN USE

all over the world,

AND IT HAS BEEN INCLUDED IN SEVERAL NATIONAL TREATMENT GUIDELINES.

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

BRIK ET AL., 2009[3]

"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[4]

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

KEKKI ET AL., 2001[8]

"The combined use of phIGFBP-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[2]

"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[7]

ORDERING INFORMATION	
Product Name	Product No.
ACTIM® PARTUS 10T (VISUAL READ)	31931ETAL
ACTIM® PARTUS 1NGENI 10T	31931RETAL
ACTIM® 1NGENI INSTRUMENT	19100AC

COMBINE ACTIM® PARTUS WITH ACTIM® PROM,

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

FOR MORE INFORMATION, CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE OR VISIT GLOBALPOINTOFCARE.ABBOTT

T: 1800 622 642 (free call AU) | T: 0800 466 951 (free call NZ) | T: +61 7 3363 7100 | rapiddx.ANZ.enquiries@abbott.com

1. Tripathi, R. *et al..*, 2016. Comparison of rapid bedside tests for phosphorylated insulin-like growth factor-binding protein 1 and fetal fibronectin to predict preterm birth. *International Journal of Gynecology & Obstetrics*, 135(1), pp.47-50.
2. Azlin, M. *et al..*, 2010. Role of phIGFBP-1 and ultrasound cervical length in predicting pre-term labour. *Journal of Obstetrics and Gynaecology*, 30(5), pp.456-459.
3. Brik, M. *et al..*, 2010. Phosphorylated insulin-like growth factor binding protein-1 and cervical measurement in women with threatening preterm birth. *Acta Obstetricia et Gynecologica Scandinavica*, 89(2), pp.268-274.
4. Tanir, H. *et al..*, 2009. Cervical phosphorylated insulin-like growth factor binding protein-1 for the prediction of preterm delivery in symptomatic cases with intact membranes. *Journal of Obstetrics and Gynaecology Research*, 35(1), pp.66-72.
5. Eroglu, D. *et al..*, 2007. Prediction of Preterm Delivery among Women with Threatened Preterm Labor. *Gynecologic and Obstetric Investigation*, 64(2), pp.109-116.
6. Ting, H. *et al..*, 2007. Comparison of bedside test kits for prediction of preterm delivery: Phosphorylated insulin-like growth factor binding protein-1 (pIGFBP-1) test and fetal fibronectin test. *Annals of the Academy of Medicine*, Singapore, 36(6), pp.399-402.
7. Lembet, A. *et al..*, 2002. New rapid bed-side test to predict preterm delivery: phosphorylated insulin-like growth factor binding protein-1 in cervical secretions. *Acta Obstetricia et Gynecologica Scandinavica*, 81(8), pp.706-712.
8. Kekki, M. *et al..*, 2001. Insulin-like growth factor-binding protein-1 in cervical secretion as a predictor of preterm delivery. *Acta Obstetricia et Gynecologica Scandinavica*, 80(6), pp.546-551.
9. Akercan, F. *et al..*, 2004. Value of cervical phosphorylated insulin-like growth factor binding protein-1 in the prediction of preterm labor. *The Journal of Reproductive Medicine*, 49(5), pp.368-372.

© 2020 Abbott. All rights reserved. All trademarks referenced are trademarks of either the Abbott group of companies or their respective owners. Actim® is a registered trademark of Actim Oy. Any photos displayed are for illustrative purposes only. Any person depicted in such photos is a model. A2779.3 11/20

Abbott