THE QUANTITATIVE ACTIM® PARTUS 1NGENI RAPID TEST RELIABLY PREDICTS PRETERM OR IMMINENT DELIVERY IN SYMPTOMATIC PREGNANT WOMEN

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Elevated cervical phIGFBP-1 indicates preterm and imminent birth

Spontaneous preterm birth (sPTB) continues to be responsible for the majority of neonatal morbidity and mortality. Only about 20% of women presenting with suspected preterm labour will actually deliver preterm.[1] In order to be able to focus treatment, it is important to have a test to help predict who is most likely to deliver preterm.

An elevated concentration of the highly phosphorylated isoform of insulin-like growth factor binding protein 1 (phIGFBP-1), produced in decidua[2,3,4,] in cervical secretions is a predictor of preterm or imminent birth.[5,6]

Actim® Partus 1ngeni is an immunochromatographic, quantitative rapid test that employs monoclonal antibodies specific for decidual phIGFBP-1 to identify women with intact membranes who are at increased risk for preterm birth.[5,7,8,9,10] We retrospectively evaluated the clinical performance of the quantitative Actim Partus 1ngeni to predict sPTB within 7 and 14 days of sample collection at different gestational ages.

Materials & Methods

Cervical phIGFBP-1 concentration from 691 samples obtained at hospitals or maternal clinics was quantified using the fully automated Actim® 1ngeni System (Figure 1) with quantitative Actim Partus 1ngeni test according to manufacturer's instructions. The key inclusion criteria were: singleton pregnancy with signs and/or symptoms of labor, gestational age ≥22 and <36 weeks, and intact amniotic membranes. Women with heavy vaginal bleeding were excluded from the study. The primary clinical outcome of the study was the occurrence of sPTB after sample collection. The relative risk (RR) of sPTB within 7 and 14 days was calculated for elevated phIGFBP-1 concentration categories defined in the Actim Partus 1ngeni test, as compared to phIGFBP-1 concentrations of ≤2 µg/mL.

Figure 1. phIGFBP-1 concentration was quantified from cervical swab samples using an automated and digital Actim 1ngeni System with Actim Partus 1ngeni test.

Elevated Actim Partus 1ngeni test result reliably predicts delivery within 7 and 14 days

Of the women included in this study, 360 (52%) experienced a spontaneous labor. Nine of these women (3%) delivered within 7 days and 21 (6%) within 14 days of sample collection. Among women with cervical phIGFBP-1 concentrations of 50.0–249.9 µg/mL and ≥250 µg/mL the RR of sPTB within 7 days of sample collection was 15.8 ($p<0.05$) and 22.8 ($p<0.01$), respectively. Additionally, the RR of sPTB within 14 days of sample collection was increased for women with cervical phIGFBP-1 concentrations of 50.0–249.9 µg/mL (4.5; $p<0.05$) and ≥250 µg/mL (8.1; $p<0.001$).

Table 1. The increasing concentration of cervical phIGFBP-1 correlates with increased relative risk (RR) of delivery within 7 and 14 days from sample collection.

phIGFPB-1 (ng/mL)	Delivery ≤ 7 days	Delivery ≤ 14 days
≤ 2	-	-
2.1-9.9	5.9	0.8
10.0 -49.9	10.0	2.1
50.0-249.9	15.8*	4.5*
≥ 250	22.8**	8.1***

Relative risk compared to phIGFBP1 ≤ 2 ng/mL
z-statistics significance: *P<0.05, **P<0.01, ***P < 0.001

Conclusions

In this quantitative retrospective analysis, quantitative Actim Partus 1ngeni results with increasing cervical phIGFBP-1 concentrations are associated with increasing risk of sPTB within 7 and 14 days of sample collection. The Actim Partus 1ngeni holds promise as a rapid point-of-care test for identifying women at increased risk of sPTB. This detection of different risk groups allows for more directed interventions for high-risk patients and reduces the cost and unnecessary treatment for patients in low risk of sPTB.

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