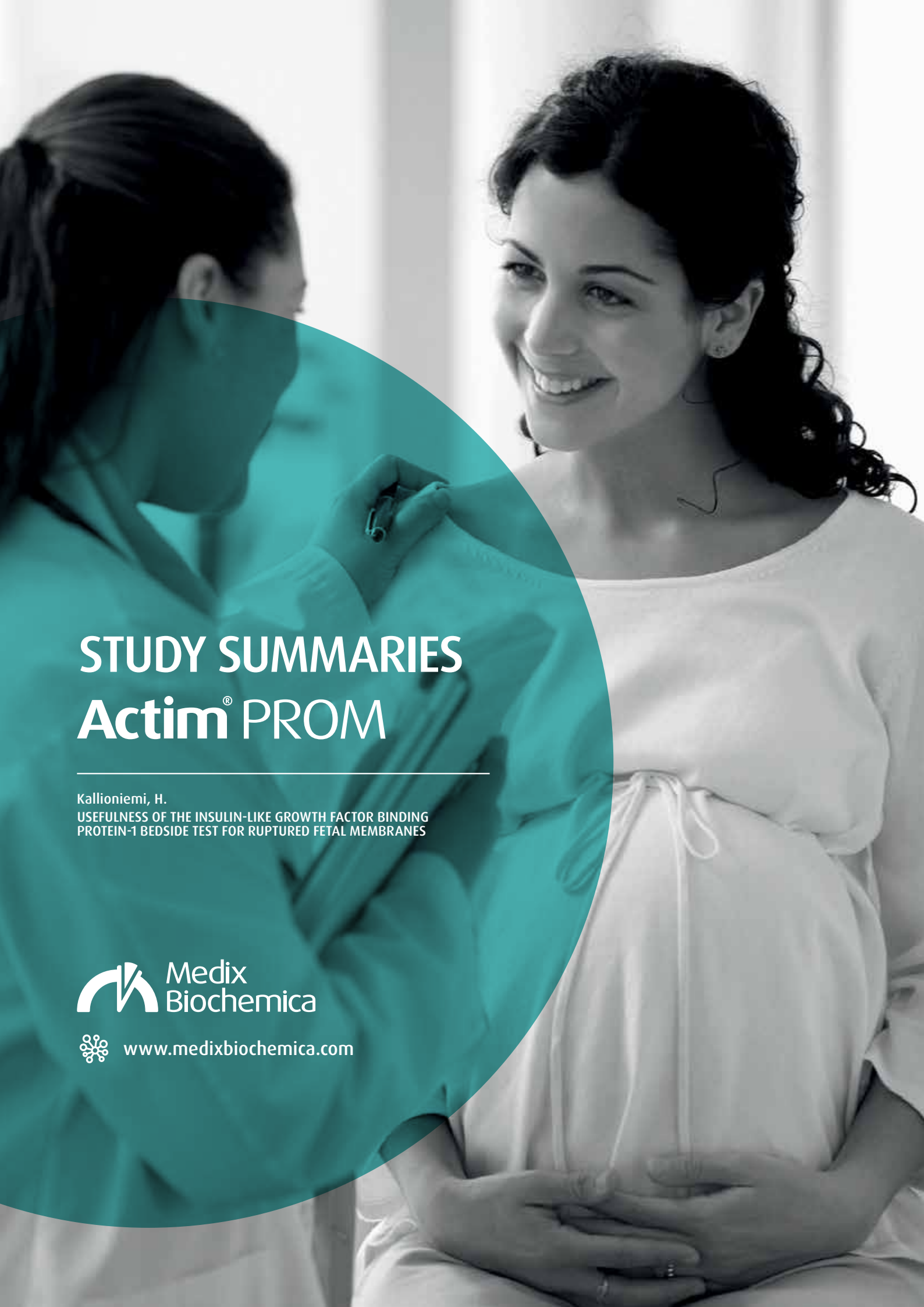

STUDY SUMMARIES
Actim® PROM

Kallioniemi, H.
USEFULNESS OF THE INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1 BEDSIDE TEST FOR RUPTURED FETAL MEMBRANES

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Kallioniemi, H., Rahkonen, L., Heikinheimo, O., Stefanovic, V. and Paavonen, J.

USEFULNESS OF THE INSULIN-LIKE GROWTH FACTOR BINDING PROTEIN-1 BEDSIDE TEST FOR RUPTURED FETAL MEMBRANES

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"The insulin-like growth factor binding protein-1 bedside test (Actim PROM) can be used for detection of rupture of membranes in patients with vaginal bleeding."

Method

A total of 247 pregnant women between 24 and 42 weeks of gestation, consulting the obstetric emergency unit with self-reported amniotic fluid leakage were enrolled in the study. Vaginal secretion was collected from 247 women. Of the women, 50 were preterm (< 37 weeks of gestation) and 197 women were at term (≥ 37 weeks of gestation). A routine medical history was taken, specifically focusing on the presence of any vaginal bleeding. Bleeding was considered to be present when blood was visible in the vaginal fluid.

The Actim PROM swab sample was obtained from the posterior vaginal fornix. The swab was then transferred into the extraction solution. The Actim PROM dipstick test was conducted and also concentration of IGFBP-1 isoforms were measured using immunoenzymomatic assays (IEMA) using monoclonal antibodies. Women with profuse bleeding and women subject to immediate obstetric care were excluded from the study.

Clinical examination was considered positive for ROM when the presence of fluid in the vagina or fluid leakage from the cervix was observed at presentation or in subsequent examinations.

Results

The dipstick test for IGFBP-1 (Actim PROM) was positive in 92 (37.2%) of the 247 women. Of those with a positive test result 12 (13.0%) were preterm. Vaginal bleeding was present in 48 (19.4) women, of whom 32 (66.7%) were dipstick test positive. Overall, 53 (21.5%) women had clinically obvious ROM, and all expect one were dipstick test positive regardless of the presence or absence of vaginal bleeding.

In the dipstick-test-positive women the median concentration of IGFBP-1 was higher in the absence of vaginal bleeding. However, the difference in phIGFBP-1 concentration was not significant. In women with clinical evidence of ROM both IGFBP-1 and phIGFBP-1 concentrations were lower in women with vaginal bleeding than in woman without vaginal bleeding. Of those women without clinically observed ROM, 23 (57.7%) had a spontaneous delivery and all but one delivered within 48h. This proves that the positive dipstick-result was likely to be a true positive.

In the dipstick-test-negative women, vaginal bleeding was present in 16 (10.3%) of the 155 women. Concentrations of IGFBP-1 and phIGFBP-1 were higher in women with vaginal bleeding than in women without vaginal bleeding

Conclusion

In women who were dipstick test positive without clinically observed ROM, IGFBP-1 and phIGFBP-1 concentrations did not differ by the presence of vaginal bleeding, supporting our hypothesis that blood does not interfere. This indicates that the dipstick test is reliable also in cases where amniotic fluid is not visible, but where vaginal bleeding is present. In dipstick-test-negative women both IGFBP-1 and phIGFBP-1 concentrations were higher in women with vaginal bleeding. The amount of blood in the test swab may explain this. However, concentrations did not exceed the dipstick test cut-off. In conclusion, the IGFBP-1 bedside test (Actim PROM) can be used for the diagnosis of ROM in women with or without bleeding both at term and preterm.

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