Assess the Risk of Preterm Birth

“PartoSure is the single most accurate test when compared to fFN and CL for prediction of imminent spontaneous delivery”

– Nikolova et al. 2015

CONFIDENTLY IDENTIFY WOMEN AT RISK FOR PRETERM BIRTH
28% of patients presenting with signs and symptoms of threatened preterm labour may be admitted to the hospital\(^1\)

**A MAJOR DIAGNOSTIC CHALLENGE ... UNTIL NOW**

Clinical evaluation alone, including the measurement of cervical length and dilatation, is not sufficiently predictive of imminent delivery among patients with signs of threatened preterm labour. Similarly, currently available biomarker tests, such as that based on the detection of fetal fibronectin (fFN), have extremely poor positive predictive values for imminent delivery.\(^2\)

**A SUPERIOR TEST FOR ASSESSING PRETERM BIRTH RISK**

The PartoSure Test is a rapid, non-invasive strip test for the detection of placental alpha microglobulin-1 (PAMG-1) in patients presenting with signs and symptoms of preterm labour. PartoSure’s unique features include:

- High Positive (PPV) and Negative Predictive Value (NPV)
- Speculum examination optional
- Results in 5 minutes or less
- No special equipment or training needed
- Wide gestational age range

Although the PPV and the sensitivity of PAMG-1 are the highest, the main utility of this test, as is the measurement of cervical length, is its high negative predictive value; its prognostic capacity increases in populations with high prevalence of prematurity.

- Spanish Preterm Guidelines, SEGO 2014\(^4\)
85% of patients admitted to the hospital for threatened preterm labour (PTL) do not deliver within the next 7 days.\(^5\)

**IMPROVED CONFIDENCE WHEN CERVICAL LENGTH IS EQUIVOCAL**

Cervical length measurement (CL) is least accurate as a predictor of imminent spontaneous delivery in threatened preterm labour (PTL) patients when it is between 15 & 30 mm.\(^3\)

If CL is used as an initial screen, PartoSure can be used to improve the diagnostic value of CL when it falls in the equivocal range of 15 & 30 mm.

**CONSISTENT PERFORMANCE ACROSS STUDIES AND GEOGRAPHIES**

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>N</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
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<tbody>
<tr>
<td>Nikolova et al. (^4)</td>
<td>2014</td>
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<td>Nikolova et al. (^3)</td>
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<td>El Masry et al. (^5)</td>
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<td>Heverhagen et al. (^6)</td>
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<td>64</td>
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<td>Bolotskih et al. (^7)</td>
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<td>Van Holsbeke et al. (^8)</td>
<td>2015</td>
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<td>75</td>
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PartoSure performance for prediction of spontaneous preterm delivery ≤ 7 days in patients with threatened preterm labour

**TESTING WITH THE POTENTIAL TO DECREASE UNNECESSARY COSTS**

An average unnecessary admission during which the patient is treated can cost up to 8000 €.\(^9\)

The high accuracy of the PartoSure test may therefore contribute to reducing costs by:

- Decreasing unnecessary admissions and acute interventions
- Reducing the length of stay of high risk patients
- Minimizing unnecessary patient transfers

PartoSure is a tool of tremendous value for assessing threatened preterm labor. It can be performed by the midwife quickly, providing results in 5 minutes. But its most important value is in cases where preterm labor is false, where it has helped our hospital reduce use of [tocolytics] by over 75%.

-Dr. Vlaemynck AZ Sint-Rembert te Torhout Hospital
SIMPLE & EASY TESTING PROCEDURE AT THE POINT OF CARE

1. Collect sample of vaginal discharge with sterile collection swab (speculum optional).
2. Rinse specimen swab in solvent vial. Discard swab.
3. Insert test strip into vial and remove if 2 lines are visible, or at 5 minutes sharp.
4. Test strip is extracted from vial and results observed and recorded.

For complete instructions for use, please refer to the package insert.

The PartoSure Test is intended to be used as an aid to rapidly assess the risk of preterm delivery in ≤7 or ≤14 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of early preterm labour, intact amniotic membranes and minimal cervical dilatation (≤ 3 cm), sampled between 20 weeks, 0 days and 36 weeks, 6 days gestation.

ORDERING INFORMATION

<table>
<thead>
<tr>
<th>PRODUCT DESCRIPTION</th>
<th>PRODUCT CODE</th>
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<tbody>
<tr>
<td>PartoSure Test - Test kit of 5</td>
<td>TTDT-1-5-ML</td>
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<tr>
<td>PartoSure Test - Test kit of 20</td>
<td>TTDT-1-20-ML</td>
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</tbody>
</table>

REFERENCES

For more information please:
-http://www.partosure.com
-Email info@partosure.com
-Visit www.partosure.com

For complete instructions for use, please refer to the package insert.