Sometimes the symptoms are real but the risk isn’t.

A clinically proven, powerful indicator for planning and peace of mind.
Symptomatic patients

Asymptomatic patients

140,000 women exhibit signs and symptoms of preterm labour in the UK per year.

More than 95% don’t go on to deliver within 14 days.

Less than 5% go on to deliver within 14 days.
Avoidable intervention
Bed blocking
Unnecessary in-utero transfers
Unmanageable caseload
Increased maternal anxiety
Financial burden to NHS
What is fFN?

- The adhesive glycoprotein “glue” at the maternal-fetal interface
- Presence in cervicovaginal secretions is highly associated with risk of preterm delivery
- It is measured quantitatively
Mechanisms of Preterm Birth

Clinical validation

The clinically validated timeframe for fFN testing is between:

- **22 – 36 weeks** for *symptomatic* women
- **22 – 28 weeks** for *asymptomatic* women

when elevated levels should not be detected in the vagina.
Specimens should be collected prior to:

- Digital cervical exam
- Collection of culture specimens
- Vaginal probe ultrasound exams

Do not contaminate swab or specimen with:

- Lubricants
- Soaps
- Disinfectants
- Creams

Do not test if patients have:

**Symptomatic**

- Advanced cervical dilation (3 centimetres or greater)
- Rupture of amniotic membranes
- Cervical cerclage
- Moderate or gross vaginal bleeding*
- Placenta Previa
- Sexual intercourse in the last 24 hours*

*If the test is <10ng/ml it can be interpreted as a valid result
Specimen collection
fFN testing: 5 steps, 10 minutes

1. Enter info
2. Insert cassette
3. Add sample
4. Start test
5. Results

Sample ID: 16976565
Test Patient: D2011
User: 0821653N
CASSETTE LOT: D2011
CALCODE: 9XGPM/LDW6
ANALYSER ID: G826P17F0

Rapid fFN 10Q Test Result
fFN CONC: 7 ng/ml
TIME: 09:04 DATE: 22/6/17
SAMPLE: 0821653N
USER: 0821653N
CASSETTE LOT: D2011
CALCODE: 9XGPM/LDW6
ANALYSER ID: G826P17F0
Results

Quantitative result

Traceability

Quality control

HOLOGIC®

Rapid fFN 10Q Test Result

fFN CONC: 7 ng/ml

TIME: 09:04  DATE: 22/6/17

SAMPLE: 0821653N
USER: 0821653N
CASSETTE LOT: D2011
CALCODE: 9XGPM-LRZW6
ANALYSER ID: G826P17F0

INTERNAL CONTROLS
ANALYSER QC: PASS
CASSETTE QC: PASS
Risk assessment

Generally, the risk of preterm birth is low in women with an fFN level **below 200 ng/ml**

<table>
<thead>
<tr>
<th>fFN Level (ng/ml)</th>
<th>% of patients</th>
<th>≤7 days</th>
<th>≤14 days</th>
<th>≤34 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10</td>
<td>57%</td>
<td>1%</td>
<td>1.8%</td>
<td>1.5%</td>
</tr>
<tr>
<td>11 – 49</td>
<td>21%</td>
<td>0%</td>
<td>1.6%</td>
<td>8.2%</td>
</tr>
<tr>
<td>50 – 199</td>
<td>14%</td>
<td>0%</td>
<td>7.7%</td>
<td>11.5%</td>
</tr>
<tr>
<td>200 – 499</td>
<td>5%</td>
<td>14%</td>
<td>29%</td>
<td>33%</td>
</tr>
<tr>
<td>≥ 500</td>
<td>4%</td>
<td>38%</td>
<td>46%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Lower risk 🔴 Higher risk 🔵
Landscape

Symptomatic patients  Asymptomatic patients

Many asymptomatic women have a significant risk for preterm birth

More than 90% don’t go on to deliver before 34 weeks¹

Less than 10% go on to deliver before 34 weeks¹
Risk assessment

Generally, the risk of preterm birth is low in women with an fFN level below 200 ng/ml

<table>
<thead>
<tr>
<th>fFN Level (ng/ml)</th>
<th>&lt;30 weeks</th>
<th>≤34 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 10</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>11 – 49</td>
<td>3%</td>
<td>11%</td>
</tr>
<tr>
<td>50 – 199</td>
<td>5%</td>
<td>15%</td>
</tr>
<tr>
<td>200 – 499</td>
<td>23%</td>
<td>34%</td>
</tr>
<tr>
<td>≥ 500</td>
<td>38%</td>
<td>48%</td>
</tr>
</tbody>
</table>

Lower risk: 🟢  Higher risk: 🟦
The only biomarker test recommended by NICE to help diagnose preterm labour*

*in women with intact membranes
Sometimes the symptoms are real but the risk isn’t.