A Revolution in Fetal Lung Maturity Tests

100% Non-Invasive

Reliable Results Within 10 Minutes

Excellent Negative Predictive Value
AN UNSOLVED CLINICAL NEED

- Preterm Birth Rate is increasing year by year in developed countries.
- Neonatal Respiratory Morbidity* remains as the leading problem in preterm babies despite prenatal and postnatal treatments.
- Current tests for the assessment of Fetal Lung Maturity** (FLM) require an amniocentesis, which limits their practice due to the associated risks and discomfort.

quantusFLM – the First 100% non-invasive Fetal Lung Maturity test

- Non-invasive: quantusFLM is the first Fetal Lung Maturity test in the market based on analysis of an ultrasound image of the fetal lungs. It gives the opportunity to avoid the need for an invasive technique to predict neonatal respiratory morbidity in the clinical practice.
- Fast: quantusFLM can provide accurate results in just a few minutes.
- Reliable: The results of quantusFLM are as reliable as any other commercial test.

Comparison of quantusFLM and other commercial FLM test:

<table>
<thead>
<tr>
<th></th>
<th>Sensibility</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>L/S Ratio *</td>
<td>72%</td>
<td>84%</td>
<td>37%</td>
<td>95%</td>
</tr>
<tr>
<td>PG *</td>
<td>88%</td>
<td>65%</td>
<td>24%</td>
<td>97%</td>
</tr>
<tr>
<td>Lamellar body</td>
<td>88%</td>
<td>66%</td>
<td>19%</td>
<td>98%</td>
</tr>
<tr>
<td>quantusFLM *</td>
<td>86%</td>
<td>86%</td>
<td>62%</td>
<td>96%</td>
</tr>
</tbody>
</table>

*Defined as either respiratory distress syndrome or transient tachynea of the newborn that require his admission to a special unit and the use of medical respiratory support.
**The term “fetal lung maturity” is universally used by the scientific and medical community to define the capacity of fetal lungs to achieve normal respiratory function if the fetus is born.

HOW TO USE quantusFLM?

Using quantusFLM is easy only with 3 simple steps:

1. Acquire an ultrasound image
2. Upload it to quantusFLM web App
3. Get the results in few minutes

Step 1: Acquire an ultrasound image

Obtain ultrasound images of the fetal thorax at the level of the cardiac 4-chamber view in DICOM format. A clear guideline on how to acquire optimal images is available inside quantusFLM web application.
Difficult-to-control hypertension or diabetes, maternal fluid retention with edema, very symptomatic cholestasis, previous history of unexplained fetal death or abruption, and any situation where an elective cesarean section <39+0 weeks is considered.

quantusFLM web application is a simple tool that allows you to send to the system the image you want to analyze. You just need to follow 4 simple steps to complete the analysis:

1. Upload
   The DICOM image.
   More than one image can be uploaded for your convenience.

2. Select
   The desired image to be analysed.

3. Label
   Introduce clinical data and draw the lung region to be analysed.

4. Send
   The sample to be analysed.

Step 2: Use quantusFLM web application to analyze the image

quantusFLM web application is a simple tool that allows you to send to the system the image you want to analyze. You just need to follow 4 simple steps to complete the analysis:

Step 3: Get the results from the web application in just a few minutes.

quantusFLM can be particularly useful where elective delivery could be an acceptable option but the risk of neonatal respiratory morbidity should be known. In many clinical situations the decision of whether to deliver or wait is in a "grey zone", particularly in late preterm to early-term (34+0 to 38+6 weeks) pregnancies. Typical examples can be:

- Difficult-to-control hypertension or diabetes,
- maternal fluid retention with edema,
- very symptomatic cholestasis,
- previous history of unexplained fetal death or abruption,
- and any situation where an elective cesarean section <39+0 weeks is considered.

In these and other circumstances delivery may be a reasonable, but not an absolute, option to avoid danger to mother or fetus. Knowing the risk of neonatal respiratory morbidity can be a critical information in the decision-making process, either to confirm or otherwise delay delivery.

For instance, in a 36+0 week pregnancy, the baseline risk of morbidity and NICU admission for respiratory support is 6%. However, a "low risk" result in quantusFLM reduces the chances of morbidity to 2%, while if the result is "high risk" the probability of respiratory morbidity will be 30%. Thus, knowing FLM (without the need of an invasive technique) may have a clear impact in the clinical management of this case.
WHY DOES quantusFLM WORK?

Changes occurring at the histological level of a tissue, including the proportion of collagen, fat or water, among others, affect ultrasound backscattering signals. This constitutes the basis for ultrasound image reconstruction. Computerized quantitative ultrasound analysis detects extremely subtle changes, unpercievable by the human eye, in order to accurately infer relevant information of tissue microstructure.

Fetal lung maturity constitutes an obvious candidate for the use of quantitative ultrasound solutions as it results from the combination of the evolving changes in lung airways and alveoli during gestation, and the concentration of surfactant. Over the last 30 years research has focused on the extraction of quantitative information about tissue characteristics from ultrasound images.

Transmural Biotech’s quantusFLM software uses a combination of cutting-edge image analysis technologies that make individualized predictiveness of the risk of neonatal respiratory morbidity. quantusFLM  reaches unprecedented levels of accuracy and reproducibility for a completely non-invasive ultrasound-based test.

References
We offer a 30-DAY FREE Trial without any conditions. Contact us now to try it for free!