quantus FLM

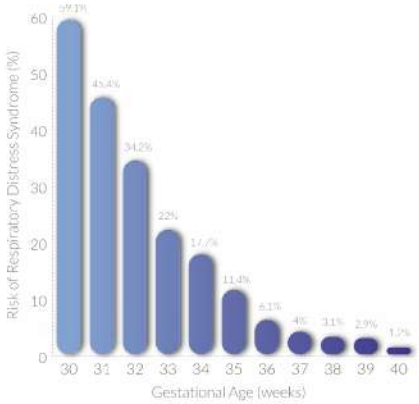
A Revolution in Ultrasound-Based Diagnosis

The First 100% Non-Invasive test to predict

Neonatal Respiratory Morbidity Risk

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 assesment of Fetal Lung Maturity** (FLM) require an amniocentesis, wich limits their practice due to the associated risks and discomfort.



Data extracted and adapted from differents publications: J AMA 2010, J AMA Pediatr. 2013 and Paediatr Perinat E.p. 2013

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.

Comparision of quantusFLM and other commercial FLM test:

	Sensitivity	Specificity	PPV	NPV
L/S Ratio [A]	74,6%	82,5%	34,1%	96,4%
PG [A]	82,7%	54,4%	18,0%	96,3%
Lamellar body [A]	84,2%	74,4%	27,9%	97,6%
quantusFLM [B]	71.0%	94.7%	67.9%	95.4%

L/S: Lecithin / Sphingo myelin
PG: Phosphatidol Gl ycerol

[A] Average reported values (references 4-9) in clinical studies
[B] Data extracted and apadted from Scientific Reports 2019 (ref. 23)

*Defined as either Respira tory Dist ress Synd rome or Transient Tachypnea of the n ewborn that requi re his admission to a special unit and the use of medical respira tory suppo rt.
**The term "Fetal Lung Matu rity" is uni versally used by the scientific and medical communi ty to define the capaci ty of fetal lungs to achi eve normal respira tory fun ction if the fetus is bo rn.

HOW TO USE quantusFLM?

Using quantusFLM is easy only with 3 simple steps:

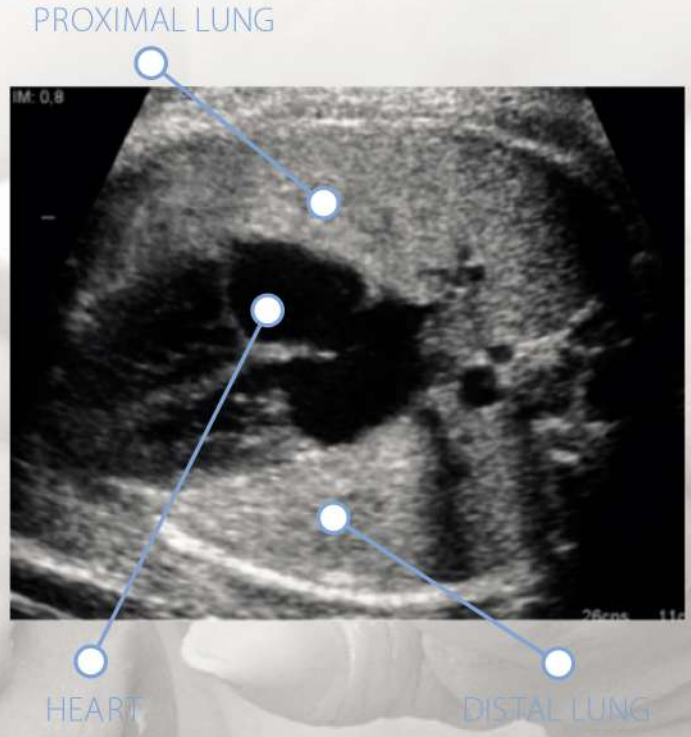
1. Acquire an ultrasound image

2. Upload it to quantusFLM web App

3. Get the results in few minuts

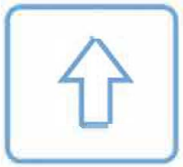
Step 1: Acquire an ultrasound image

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.



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:



Upload

The DICOM image More than one image can be upload for your conven ence.

Label

Introduce clinical data to be analysed.

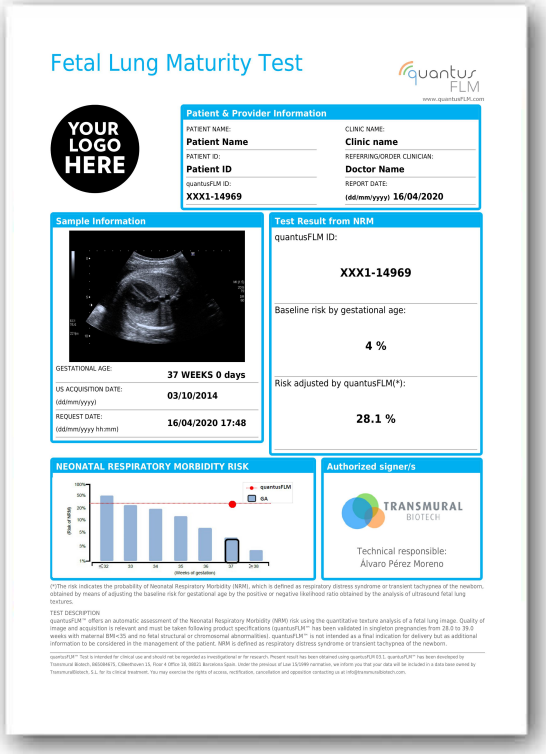
Select

The desired image to be analysed.

Send

The sample to be analysed

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



Fetal Lung Maturity Test

quantusFLM

www.quantusFLM.com

YOUR LOGO HERE

Patient & Provider Information

PATIENT NAME: Patient Name	CLINIC NAME: Clinic name
PATIENT ID: Patient ID	REFERRING/ORDER CLINICIAN: Doctor Name
quantusFLM ID: XXX1-14969	REPORT DATE: (dd/mm/yyyy) 16/04/2020

Sample Information

GESTATIONAL AGE:	37 WEEKS 0 days
US ACQUISITION DATE: (dd/mm/yyyy)	03/10/2014
REQUEST DATE: (dd/mm/yyyy hh:mm)	16/04/2020 17:48

Test Result from NRM

quantusFLM ID: XXX1-14969

Baseline risk by gestational age: 4 %

Risk adjusted by quantusFLM(*): 28.1 %

NEONATAL RESPIRATORY MORBIDITY RISK

Authorized signer/s

TRANSMURAL BIOTECH

Technical responsible: Álvaro Pérez Moreno

(*)The risk indicates the probability of Neonatal Respiratory Morbidity (NRM), which is defined as respiratory distress syndrome or transient tachypnea of the newborn, obtained by means of adjusting the baseline risk for gestational age by the positive or negative likelihood ratio obtained by the analysis of ultrasound fetal lung textures.

TEST DESCRIPTION

quantusFLM™ offers an automatic assessment of the Neonatal Respiratory Morbidity (NRM) risk using the quantitative texture analysis of a fetal lung image. Quality of image and acquisition is relevant and must be taken following product specifications (quantusFLM™ has been validated in singleton pregnancies from 28.0 to 39.0 weeks with maternal BMI<35 and no fetal structural or chromosomal abnormalities). quantusFLM™ is not intended as a final indication for delivery but as additional information to be considered in the management of the patient. NRM is defined as respiratory distress syndrome or transient tachypnea of the newborn.

quantusFLM™ Test is intended for clinical use and should not be regarded as investigational or for research. Present result has been obtained using quantusFLM 03.1. quantusFLM™ has been developed by Transmural Biotech. B65584675. Cillenhoven 15. Floor 4 Office 18. 08021 Barcelona Spain. Under the previous of Law 15/1999 normative, we inform you that your data will be included in a data base owned by TransmuralBiotech. S.L. for its clinical treatment. You may exercise the rights of access, rectification, cancellation and opposition contacting us at info@transmuralbiotech.com.

WHEN TO USE quantusFLM

quantus FLM 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 6.1%. However, a risk adjusted by quantusFLM below the baseline risk might reduce the chances of morbidity to 5.2%, while if the risk adjusted by quantusFLM is above the baseline risk, the probability of respiratory morbidity might be 33.7%. Thus, knowing FLM (without the need of an invasive technique) may have a clear impact in the clinical management of this case.

quantusFLM OFFERS TIMELESS AND BORDERLESS USER EXPERIENCE:

- **Unrestricted and 24/7 access:** As long as there is Internet, you can use quantusFLM and review the results ANYTIME, ANYWHERE.
- **No installation required:** quantusFLM is designed to give new users an easy start because neither downloading nor installation of any software is required.
- **Great compatibility:** quantusFLM is compatible with the main web browsers as well as the most commonly-used Obstetrics and Gynecology Ultrasound Machines.

quantusFLM OFFERS GREAT ECONOMIC VALUE:

- **NO initial infrastructure investment is required!**
- **Pay per Use: You pay for each analysis you order!**
- **30-day FREE trial available, no conditions!**

To sign up for a 30-day FREE trial, contact us at sales@transmuralbiotech.com

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.

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quantus FLM

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NON INVASIVE

RELIABLE

FAST

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Transmural Biotech S.L., CIF: B65084675.

C/ Beethoven 15 Planta 4 Desp. 18 08021 Barcelona, Spain

Revision 3 21/04/2020