



Non-Invasive Prenatal Testing for trisomies 13, 18 and 21 (NIPT)

The new prenatal trisomy screening test based on a simple maternal blood sample



What is Ninalia by Eurofins Biomnis?

Ninalia is an **innovative genetic screening test** for detecting the main fetal aneuploidies like **trisomy 13, 18 or 21** in pregnant women at risk from these pathologies.

This non-invasive screening test uses **cell-free DNA** thanks to a sampling of maternal blood. **It is without risk to foetus.**

In many cases, NIPT means that invasive sampling can be dispensed with, thus reducing the associated risk of losing the foetus.*

** Non-invasive prenatal testing of trisomies 13, 18 and 21 could make redundant 95% of invasive tests, with an associated risk of miscarriage of around 0.5 to 1%. (source: French National College of Gynaecologists and Obstetricians (CNGOF))*

How does it work?

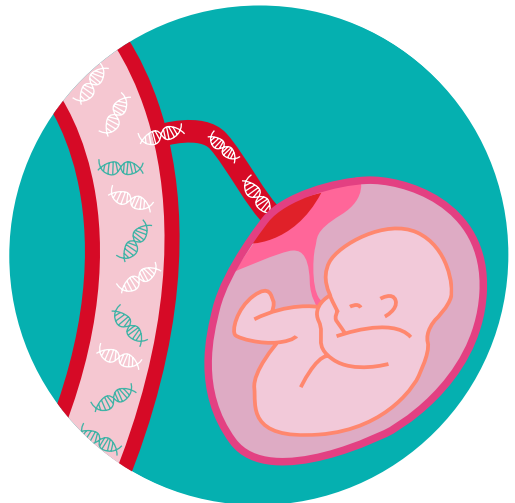
During pregnancy, the placenta releases cell-free DNA which circulates in the maternal blood stream. As a result, the maternal blood contains a mix of foetal and maternal DNA.

The non-invasive screening test uses cell-free DNA thanks to a sampling of maternal blood.

What is the technology used?

Euromis Biomnis has chosen to collaborate with the company Illumina, a world leader in DNA sequencing, for technology transfer of their methodology for NIPT. **This massive DNA sequencing test has been clinically validated for NIPT in more than 85,000 patients.**

It currently offers the best performance for non-invasive screening for the main chromosomal abnormalities.



 **Maternal DNA**

 **Foetus DNA**

What are the performance data for Ninalia?

- Detection rate is **greater than 99%**

	Down Syndrome	Edwards' Syndrome	Patau Syndrome
Sensitivity	99.14%*	98.31%	98.15%
Specificity	99.94%*	99.9%	99.95%
Positive predictive value (PPV)	0.9681*	0.863	0.7977
Negative predictive value (NPV)	0.9999*	0.9999	0.9999

*Bhatt et al. Poster presented at the ISPD, 2014 (34,000 patients).

- The **lowest failure rate** among NIPTs: 0.1%*
- **Deeper sequencing:** 19 million reads
- Interpretation software  **marked**

Who should avail of the Ninalia screening test?

Eurofins Biomnis follows the International recommendations of the American Congress of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) in relation to the indications for non-invasive prenatal screening for patients at risk.



MAIN RECOMMENDATIONS
(absence of ultrasound abnormalities)

- Risk greater than 1/1000 according to maternal serum markers
- Mothers aged ≥ 38 years for patients that did not benefit of the maternal serum markers assay
- History of pregnancy with foetal aneuploidies
- Relative is carrier of a Robertsonian translocation involving chromosome 13 or 21
- Pregnancy with twins
- 1st line screening

What does Ninalia screen for?

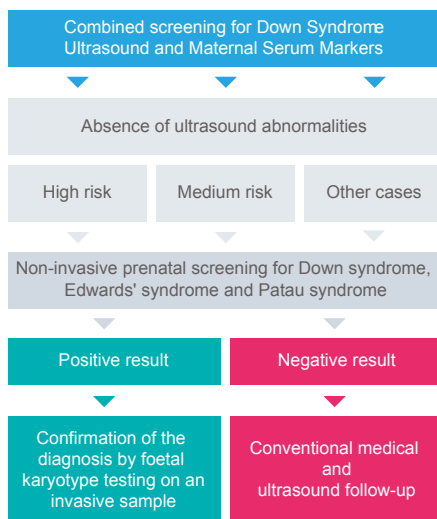
It screens for the main fetal aneuploidies like trisomy 13, 18 and 21.

The test also provides optional fetal gender and sex chromosomes aneuploidies.

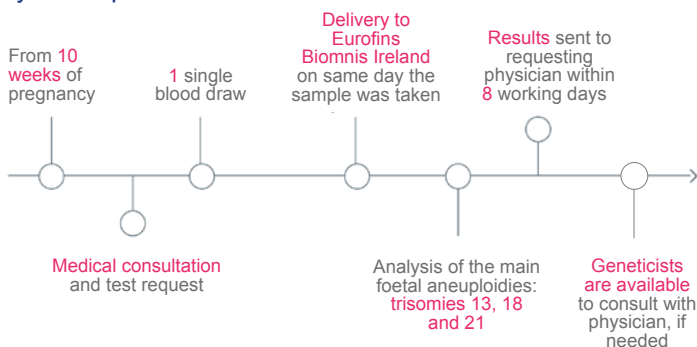
For other chromosome abnormalities such as microdeletion please contact Eurofins

Biomnis at: sales@eurofins-biomnis.ie

Diagnostic strategy for T21



Summary of the process





Eurofins Biomnis in Ireland

Eurofins Biomnis, European leader in specialised medical pathology, has its origins in the laboratory established by Marcel Mérieux in 1897. Its primary focus is the performance of highly specialised analyses requiring the use of high expertise test procedures.

Established in 1991, Eurofins Biomnis Ireland is the leading independent provider of medical laboratory testing services to healthcare organisations throughout Ireland.

Accredited to the ISO 15189 medical testing standard, we provide one of the world's most comprehensive test menus offering over 2,500 different laboratory tests to support health professionals in the diagnosis, monitoring and prevention of disease.

Ninalia at a glance:

- Ninalia by Eurofins Biomnis is a **Non-Invasive Prenatal Test (NIPT)**
- NIPT is a screening test for pregnant women at risk of **trisomy 13, 18 and 21**
- It is **without risk to foetus** since this test requires a simple blood draw
- This test can be performed from **10 weeks** of pregnancy
- **Results** are sent to requesting physician within **8 working days**
- A highly accurate test with a detection rate >99% and the lowest failure rate amongst NIPTs (0.1%)
- The assurance of **Eurofins Biomnis** expertise. The laboratory is the European leader in specialised medical pathology.

To find out more about Ninalia by Eurofins Biomnis and to order the test kit, please visit:

www.eurofins-biomnis.ie





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