



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

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



## What is Ninalia by Eurofins Biomnis?

Ninalia is an **innovative genetic screening test** that detects 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** from a maternal blood sample, ensuring no risk to the foetus.

In many cases, NIPT eliminates the need for invasive sampling, thus reducing the associated risk to 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))*

## What is cell-free DNA?

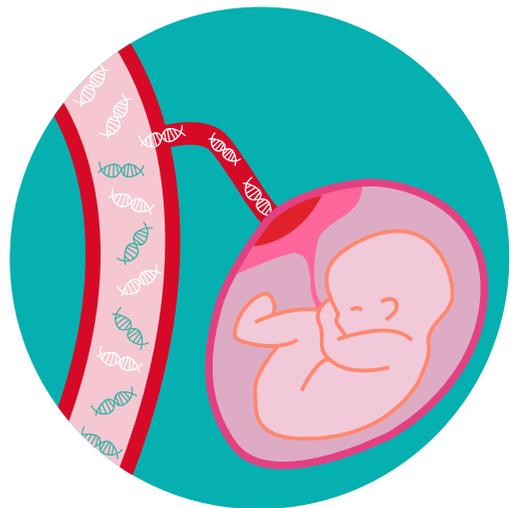
During pregnancy, the placenta releases cell-free DNA which circulates in the maternal blood stream. As a result, the maternal blood contains a mix of foetal and maternal DNA in varying proportion. This is the foetal fraction.

**Our laboratory isolates this circulating DNA in order to detect the presence of genetic material relating to chromosomes 21, 18 or 13. If the fetal fraction is too low, a new sample may be required for analysis.**

## What is the technology used?

Eurofins Biomnis has chosen to collaborate with the company Illumina, a world leader in DNA sequencing, for non-invasive screening for the main chromosomal abnormalities.

The new VeriSeq NIPT method offers improved performances in order to enhance patient care.



 **Maternal DNA**

 **Foetus DNA**

## What are the performance data for Ninalia?

- An excellent detection rate of Ninalia: **99%**

	Down Syndrome
Sensitivity	99%*
Specificity	99.9%*

\* Data from the supplier Illumina, February 2017

- Extremely low failure rate: 0.68%\*
- Short turnaround time: 8 business days
- A complete **CE [IVD]** marked solution

## 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  $\geq 38$  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

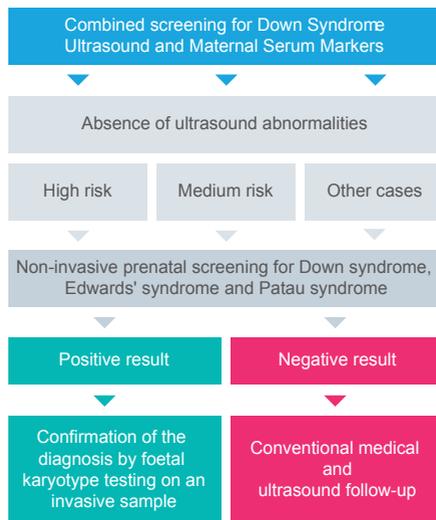
## What does Ninalia screen for?

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

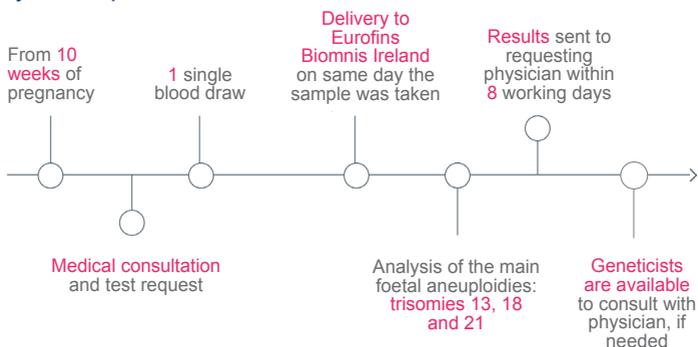
The test also provides optional fetal gender and sex chromosomes aneuploidies.

For any further information please contact Eurofins Biomnis at: [sales@eurofins-biomnis.ie](mailto: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 3,000 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 maternal blood sample.
- 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 an extremely low failure rate.
- 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](http://www.eurofins-biomnis.ie)





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