WHY CHOOSE NATIVA

NATIVA is a non-invasive, fast and risk-free prenatal test to detect Down Syndrome and the most common chromosomal abnormalities.

EARLY

As from the 10th week of single or twin pregnancy, NATIVA is able to offer reliable and safe answers based on the foetal DNA present in maternal blood.

COMPLETE

NATIVA is the CE-IVD certified prenatal test **for trisomies 21, 18 and 13, sexual aneuploidies** and it also detects the **sex of the child**.

FAST

The report is processed **in a few working days** from receipt of the sample at the laboratories.

CERTIFIED

The complete analysis flow for **NATIVA** is **CE/IVD certified**.

NON-INVASIVE

Since based on taking a normal sample of maternal blood.

ACCURATE

NATIVA uses an NGS platform that ensures the **best performance in terms of accuracy and sensitivity**, with the lowest rate of false positives and false negatives.

PERFORMED IN ITALY

NATIVA is entirely carried out at the San Raffaele Science Park in Milan.

GENETIC CONSULTING

Our **Customer Care** and **Genetic Consulting Team** are available to answer questions in a clear and timely manner.

www.biorep.it
www.nativaprenatale.it

BIOREP | SAPIO LIFE

BIOREP S.R.L.
Via Olgettina, 60 - c/o DIBIT2 - Palazzina San Michele 1 - 20132 Milan
Tel. No. +39 02 58014369 - Fax No. +39 02 58018471 - Email nipt@biorep.it

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NATIVA

The new generation test for the analysis of fetal DNA

CE IVD

BIOREP

NATIVA is a new generation, non-invasive, prenatal test (NIPT - Non Invasive Prenatal Test).

It is a screening test that provides answers about the possible presence of foetal chromosomal abnormalities.

By analyzing fetal circulating freely DNA fragments, it is possible to identify which subjects are at risk and are recommended to undergo a further investigation via invasive diagnostic techniques.

NATIVA: PRENATAL SCREENING FOR CHROMOSOMAL ABNORMALITIES

WHAT DOES IT ANALYZE?

Some genetic diseases are hereditary, others, such as Down Syndrome, can occur in any pregnancy. The risk of chromosomal abnormalities is greater as gestational age increases, rising drastically after the age of 35.

NATIVA is the prenatal screening test able to detect **trisomies 21, 18 and 13, sex chromosome aneuploidies (variations in the number of X and Y chromosomes) and the sex of the unborn child.**

NATIVA IS CE-IVD CERTIFIED FOR TRISOMIES 21, 18 AND 13, AND SEX CHROMOSOME ANEUPLOIDIES ACCORDING TO CURRENT MINISTERIAL GUIDELINES.

Trisomies are conditions that occur when a subject has an extra chromosome as compared to the normal pair of chromosomes such as:

- **Down syndrome (or trisomy 21): is the most frequent trisomy at birth** and is caused by the presence of an extra chromosome 21. It is associated with moderate to severe mental retardation; in about 40% of cases malformations of the heart, kidneys, stomach and skeleton are observed.
- **Edwards Syndrome (trisomy 18):** is caused by the presence of an additional chromosome 18 and is associated with severe multiple congenital malformations that are not compatible with life.
- **Patau Syndrome (trisomy 13):** is caused by the presence of an extra chromosome 13 and is often incompatible with the life of the foetus. Children born with Patau Syndrome usually have severe congenital heart defects and other malformations and are unlikely to survive beyond the first year of life.

NATIVA is performed at BioRep's laboratories in its Milan office inside the San Raffaele Scientific Park and the entire analysis flow is **CE-IVD certified (In-Vitro Diagnostics) in accordance with Directive 98/79/EC.**

NATIVA is able to detect abnormalities in the number of sex chromosomes such as Klinefelter Syndrome, Turner Syndrome or X-chromosome monosomy.

Frequency of the main trisomies in relation to maternal age

Maternal age	Down Syndrome Frequency	Edwards Syndrome Frequency	Patau Syndrome Frequency
15 - 19	1:1.400	1:17.000	1:33.000
20 - 24	1:1.250	1:14.000	1:25.000
25 - 29	1:1.100	1:11.000	1:20.000
30 - 34	1:700	1:7.100	1:14.000
35 - 39	1:200	1:2.400	1:4.800
40 - 44	1:60	1:700	1:1.600

Hook EB. (1981) Rates of chromosomal abnormalities at different maternal ages, Obstetrics & Gynecology, 58(3):282-5

NATIVA IS CE-IVD CERTIFIED FOR TRISOMIES 21, 18 AND 13, AND SEXUAL ANEUPLOIDIES ACCORDING TO CURRENT MINISTERIAL GUIDELINES.

WHO IS THIS TEST INTENDED FOR?

NATIVA is ideal for all pregnant women eliminating risk associate with invasive diagnostic tests.
NATIVA analyzes child's DNA fragments released by placenta and circulating freely in maternal blood. It can be performed **between the 10th and the 18th week of pregnancy.**
It is suitable **for single or twin pregnancies after natural conception or assisted fertilisation.**

There are conditions for which a foetal DNA screening test is particularly recommended:

- when the mother is over 35 years old;
- a POSITIVE result for the first or second quarter screening (Bi/Tri Test);
- pregnant women with miscarryng risk;
- aneuploidy ultrasound evidence.

HOW TO TAKE THE TEST

Before undergoing the **NATIVA** prenatal screening test, specialised medical advice and a foetal ultrasound are recommended. The procedure is simple and the result is obtained in only 5/7 working days from the time of receipt of the blood sample at the laboratory.

With **NATIVA** a doctor can obtain, in a few working days, all the information necessary for the correct interpretation of a pregnancy and help the future mother make the most appropriate decision in terms of medical treatment.

BioRep keeps offering you assistance after issuing the report: in case of positive results, our geneticists will be available for consultation and it will be possible to perform amniocentesis or chorionic villus sampling free of charge at affiliated centres.

THE MOST RELIABLE AND ACCURATE ANSWER

NATIVA is a screening test able to appropriately examine a child's fetal DNA thanks to a NGS (Next Generation Sequencing) platform.

NATIVA has been validated on more than 3,000 pregnant women and it provides precise and timely information on trisomies 21, 18 and 13, sexual aneuploidy and sex of the foetus.

NATIVA can reduce the use of invasive diagnostic tests, thus reducing the ensuing risk of miscarrying, thanks to its greater sensitivity as compared to the combined test.

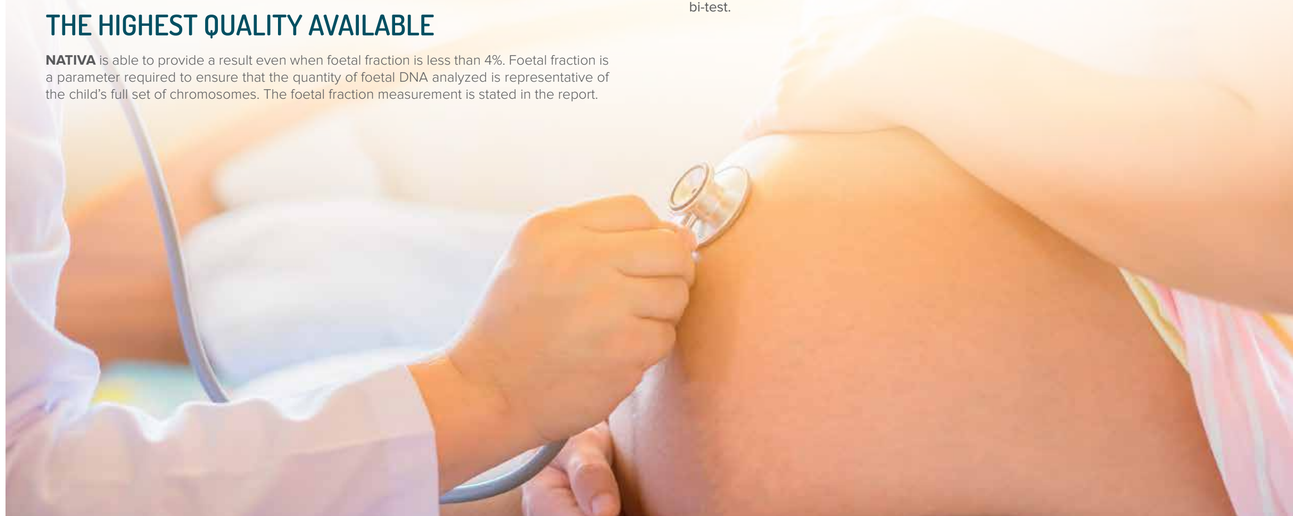
The reliability and accuracy of the results provided by **NATIVA** are very high, with frequencies of false positives or false negatives lower than 0.1%.

SENSITIVITY
> 99.9%
IT IDENTIFIES THE PRESENCE OF ABNORMALITIES
IT HAS REDUCED POSSIBILITIES OF FALSE NEGATIVES

SPECIFICITY
> 99.9%
IT EXCLUDES THE PRESENCE OF ABNORMALITIES
IT HAS REDUCED POSSIBILITIES OF FALSE POSITIVES

THE HIGHEST QUALITY AVAILABLE

NATIVA is able to provide a result even when foetal fraction is less than 4%. Foetal fraction is a parameter required to ensure that the quantity of foetal DNA analyzed is representative of the child's full set of chromosomes. The foetal fraction measurement is stated in the report.



COMPARISON BETWEEN NATIVA AND THE COMBINED TEST *

NATIVA is a screening test based on foetal DNA analysis and is the best alternative to the combined test.

The **combined test** is performed on blood samples, estimating the probability for the fetus to be affected by trisomy 21 and is based on the evaluation of multiple parameters, such as:
• hormonal dosage or BI-Test, via the measurement of biochemical parameters;
• nuchal translucency, namely an ultrasound measurement of the nape of the foetal neck;
• mother's age (over 35).

	Combined Test	NATIVA
Risk of miscarriage	None	None
Sensitivity	85%-95%*	> 99.9%
Specificity	95%	> 99.9%

* Limited to trisomy 21
Driscoll DA, Gross SJ. First trimester diagnosis and screening for foetal aneuploidy. Genet Med. 2008; 10: 73-5
Mayo Clinic Complete Book of Pregnancy & Baby's First Year. Johnson, Robert V., M.D., et al, Ch. 6.

NATIVA is more reliable and accurate than a combined test because it is based on cutting-edge technologies that ensure greater sensitivity and specificity than those of the traditional bi-test.