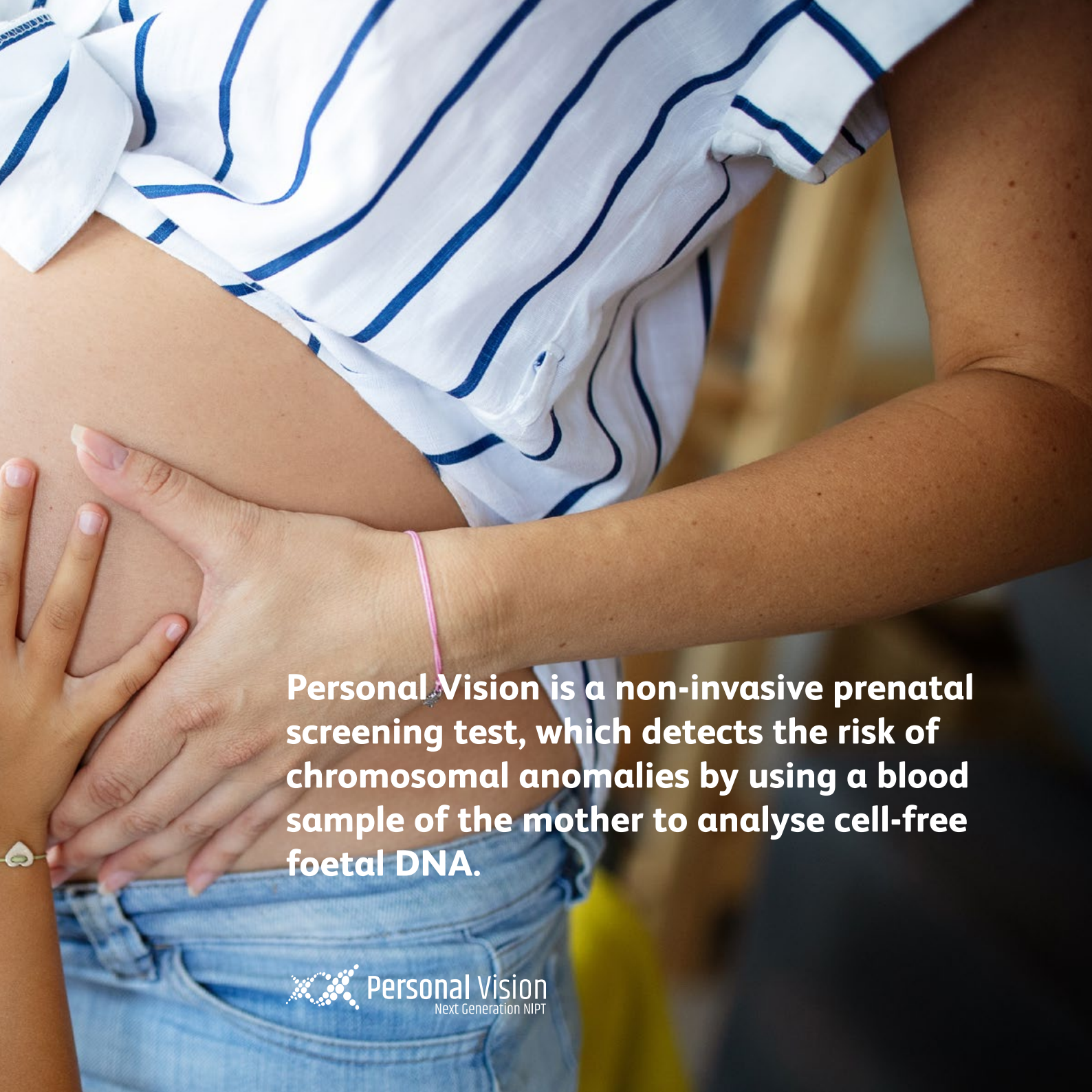
Your solution provider
in the world of genomics

Personal Genomics

PERSONAL VISION
INNOVATIVE GENETICS IN PRENATAL DIAGNOSIS

CE IVD

Personal Vision
Next Generation NIPT



Personal Vision is a non-invasive prenatal screening test, which detects the risk of chromosomal anomalies by using a blood sample of the mother to analyse cell-free foetal DNA.

Personal Vision
Next Generation NIPT

PERSONAL VISION
NON-INVASIVE PRENATAL TEST

The NIPT test is a non-invasive prenatal screening test that performs significantly better than screening tests based on biochemical analysis and nuchal translucency, which may or may not precede invasive diagnostic tests. The NIPT test drastically reduces the use of invasive diagnostic investigations, lowering the number of miscarriages related to invasive foetal material collection techniques.

Personal Vision uses technology to analyse foetal DNA present in the mother's blood for chromosomal anomalies.

Personal Vision
Next Generation NIPT

CE IVD

Usable forms and exhaustive information

The forms required to perform the service are user-friendly and designed to be filled in quickly, together with the professional collecting the consent.
The test determines the foetal fraction percentage and reports it as a guarantee of the accuracy and depth of the investigation, as required by the national SIEOG guidelines, (www.sieog.it).

Availability of nursing services at home

Our nationwide organisation enables us to provide a sample collection service at the patient's home*. Simply by contacting Personal Genomics' Customer Care Service, you can schedule a date that best suits your needs.

Pre-test and post-test genetic consulting services

Our geneticists are always at the patient's side to provide free genetic consulting services both before collecting the sample and after the report is issued to discuss it together. It is essential for the woman/couple to receive pre-test consulting services to receive the explanations they need to make an informed decision about whether to have a screening test.

Tests performed for twin pregnancies and egg donation

All Personal Vision tests can be performed for twin pregnancies, egg donation and twin pregnancies using donor eggs. Personal Vision also uses a method to identify vanishing twins.

The importance of NIPT is acknowledged by professional bodies.

ispd

Consider the NIPT test the primary screening tool for all women.

ACOG
The American College of Obstetricians and Gynecologists

Advise operators to inform patients about the benefits and limitations of the NIPT test.

* The home sample collection service is available in leading city centres.

WHY CHOOSE **PERSONAL VISION**

The test is recommended for all pregnant women, especially in the following conditions:

At-risk pregnancies where invasive diagnostic procedures are contraindicated.

Women with a history of miscarriages.

Familiarity with chromosomal diseases and aneuploidies.

Pregnancies at risk of miscarriage.

Twin pregnancies

Egg donation pregnancies.

1 PERSONAL VISION BASIC (CE - IVD)

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Turner syndrome
- Trisomy X
- Klinefelter syndrome
- Jacobs syndrome
- Determination of foetal sex

2 PERSONAL VISION MEDIUM (CE - IVD)

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Turner syndrome
- Trisomy X
- Klinefelter syndrome
- Jacobs syndrome
- Determination of foetal sex
- Non-sex chromosome aneuploidies

3 PERSONAL VISION FULL (CE - IVD)

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Turner syndrome
- Trisomy X
- Klinefelter syndrome
- Jacobs syndrome
- Determination of foetal sex
- Cri du Chat syndrome
- Prader Willi/Angelman syndrome
- Wolf-Hirschhorn syndrome
- 1p36 deletion syndrome
- Non-sex chromosome aneuploidies

4 PERSONAL VISION PLATINUM

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)
- Turner syndrome
- Trisomy X
- Klinefelter syndrome
- Jacobs syndrome
- Determination of foetal sex
- Di George syndrome
- Cri du Chat syndrome
- Prader Willi/Angelman syndrome
- Wolf-Hirschhorn syndrome
- 1p36 deletion syndrome
- Non-sex chromosome aneuploidies
- Jacobsen syndrome
- Langer-Giedion syndrome
- Smith-Magenis syndrome
- Brachydactyly syndrome - cognitive deficiency
- Alagille syndrome - JAG1
- CHARGE syndrome - CHD7
- Cornelia de Lange syndrome type 1 - NIPBL
- Nevo syndrome - Sotos syndrome type 1 - NSD1
- Bohring-Opitz syndrome - ASXL1
- Schinzel-Giedion syndrome - SETBP1
- Imperfect osteogenesis type I, II, III, IV - COL1A1
- Achondrogenesis type 2 - COL2A1
- Imperfect osteogenesis type II, III, IV - COL1A2
- Achondroplasia - FGFR3
- Crouzon syndrome with acanthosis nigricans - FGFR3
- Hypochondroplasia - FGFR3
- Muenke syndrome - FGFR3
- Thanatophoric dysplasia type I and II - FGFR3
- CATSHL syndrome - FGFR3
- 1p32-p31 deletion syndrome
- 1p31 duplication syndrome
- 1q41-q42 deletion syndrome
- 2p16.1-p15 deletion syndrome
- 2q31.1 duplication syndrome
- Cleft hand and foot malformation (SHFM5) 2q31
- 2q33.1 deletion syndrome
- 2q35 duplication syndrome
- 3pter-p25 deletion syndrome
- 3q13.31 deletion syndrome
- Dandy-Walker syndrome 3q22-q24
- 3q29 deletion syndrome
- 3q29 duplication syndrome
- 4q21 deletion syndrome
- 4q32.1-q32.2 triplication syndrome
- 5q12 deletion syndrome
- 5q14.3 deletion syndrome
- 6pter-p24 deletion syndrome
- 6q24-q25 deletion syndrome
- 8q22.1 deletion syndrome
- 8q22.1 duplication syndrome
- 8p23.1 deletion syndrome
- 8p23.1 duplication syndrome
- 10q22.3-q23.2 10q23 deletion syndrome
- 10q26 deletion syndrome
- WAGR syndrome 11p13-p12
- Potocki-Shaffer syndrome 11p11.2
- 12q14 microdeletion syndrome
- 13q14 deletion syndrome
- 14q22.1-q22.3 microdeletion syndrome
- 15q14 deletion syndrome
- 15q25 deletion syndrome
- 16p13.3 deletion syndrome
- 16q22 deletion syndrome
- Yuan-Harel-Lupski syndrome 17p12-p11.2
- Potocki-Lupski syndrome 17p11.2
- 17q12 deletion syndrome
- 17q12 duplication syndrome
- 17q23.1-q23.2 deletion syndrome
- De Grouchy syndrome - Monosomy 18p
- 19q13.11 deletion syndrome

PERSONAL VISION
SENSITIVE, COMFORTABLE, SAFE AND RELIABLE

Sensitivity is the ability to correctly identify a truly high risk case as such.
For example, in a group of 21 trisomy cases, Personal Vision will identify more than 99.9% of the cases.

Specificity is the ability to correctly identify an unaffected case as low risk.

Condition	Sensitivity	IC	Specificity	IC
Trisomy 21	>99.9% (130/130)	97.1% - 100%	99.90% (1.982/1.984)	99.63%, 99.97%
Trisomy 18	>99.9% (41/41)	91.4%, 100%	99.90% (1.995/1.997)	99.64%, 99.97%
Trisomy 13	>99.9% (26/26)	87.1% 100%	99.90% (2.000/2.002)	99.64%, 99.97%
RAA	96.4% (27/28)	82.3%, 99.4%	99.80% (2.001/2.005)	99.49%, 99.92%
CNV ≥ 7 Mb	74.1% (20/27)	55.3%, 86.8%	99.80% (2.000/2.004)	99.49%, 99.92%
Any anomaly	95.5% (318/333)	92.7%, 97.3%	99.34% (1.954/1.967)	98.87%, 99.61%

IC = 95% confidence interval.
Information in the table concerns the general performance of the test.

Technique used

Personal Vision uses MPS Illumina technology and the VeriSeq NIPT algorithm of Illumina.
The MPS method allows to «count» the DNA sequences produced after sequencing.

Sensitive, precise and validated

Personal Vision gives an accurate result with FF (Foetal Fraction) > 4%, and it has a low failure rate.
Personal Vision uses a technique validated by leading scientific studies.

Comfortable and rapid

All it takes is a simple venous blood sample, from the 10th week of pregnancy onwards, taken in a laboratory or clinic that has an agreement with us, but it can also be taken at home through our always available nursing service.

Safe and reliable

Personal Vision is an abortion and infection risk-free examination performed in Italy at the Personal Genomics laboratories in Verona, with back up at the Illumina laboratory in the USA. Sensitivity and specificity of the Personal Vision Test are close to 99.9%, ensuring high reliability.

HOW TO PERFORM **THE TEST**

1

Request and complete the service activation form
.
Following a thorough consultation with your gynaecologist, you will need to request and complete the Personal Vision service activation form by contacting either your doctor or our geneticists.

2

Submit to blood sample collection.
After activation, as agreed with your gynaecologist, you will be able to submit to a simple blood sample collection from the tenth week of gestation onwards, either at the same practice, at a contracted laboratory or directly at home.

3

The sample is analysed in the laboratory, and data are evaluated and compared.
The sample will then be sent to our laboratory where it will be carefully processed and analysed using the most accurate and sophisticated techniques.

4

Wait for the report from your doctor.
Personal Genomics will send you and, with your consent, your gynaecologist, the results of the analysis by e-mail as soon as possible.

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Prenatal test performed in Italy

CUSTOMER CARE
800 589 057

customercare@personalgenomics.it

Personal Genomics

Personal Genomics Srl
Via Roveggia, 43b
37136 Verona (VR) Italy
t +39 045 8202351
info@personalgenomics.it
www.personalgenomics.it

Biotechnology Division

DIATHEVA
Bringing Research to application

Personal Genomics

CRYOLAB

SOLGROUP
a breath of life