VERAgene®
comprehensive NIPT

Single test for aneuploidies, microdeletions and monogenic diseases

MEDICOVER GENETICS

VERAgene NEW GENERATION NIPT

VERAgene is the first comprehensive **non-invasive prenatal test** (NIPT) that can simultaneously screen for fetal **aneuploidies**, **microdeletions**, and **100 monogenic diseases**.

- Validated for **singleton** and **twin** pregnancies
- Can be done from the **10th week** of pregnancy
- Applicable for **IVF** pregnancies
- Applicable for women of **all ages**

CLINICAL UTILITY

According to professional societies such as ACMG and ACOG, NIPT is the most accurate screening test for the detection of common fetal aneuploidies[1,2]. The use of NIPT in combination with conventional prenatal screening tests, such as ultrasounds and biochemical markers, provides thorough evaluation of the pregnancy and improves prenatal care.

NIPT can reduce the number of invasive diagnostic procedures for common fetal autosomal aneuploidies and can also increase the prenatal detection rate for sex chromosome aneuploidies and microdeletions which:

- are not associated with maternal age
- often do not have ultrasound or biomarker findings
- can occur more frequently than autosomal aneuploidies[2]

By combining detection of aneuploidies and microdeletions with the screening of monogenic diseases, VERAgene provides a **comprehensive picture of the pregnancy using a single test**. The disorders screened by VERAgene are often severe with significant impact on the quality of life. The cumulative risk for the fetus to be affected by one of the genetic conditions screened by VERAgene is approximately **1 in 50** based on high and moderate risk pregnancies[3].

WHAT DOES **VERAgene** NIPT TEST FOR?

AUTOSOMAL ANEUPLOIDIES

Down syndrome *(Trisomy 21)*
Edwards syndrome *(Trisomy 18)*
Patau syndrome *(Trisomy 13)*

SEX CHROMOSOME ANEUPLOIDIES

Turner syndrome *(Monosomy X)*
Triple X syndrome *(Trisomy X)*
Klinefelter syndrome *(XXY)*
Jacobs syndrome *(XYY)*
XXYY syndrome

Gender determination can optionally be performed

MICRODELETIONS

DiGeorge syndrome *(22q11.2)*
1p36 deletion syndrome *(1p36)*
Smith-Magenis syndrome *(17p11.2)*
Wolf-Hirschhorn syndrome *(4p16.3)*

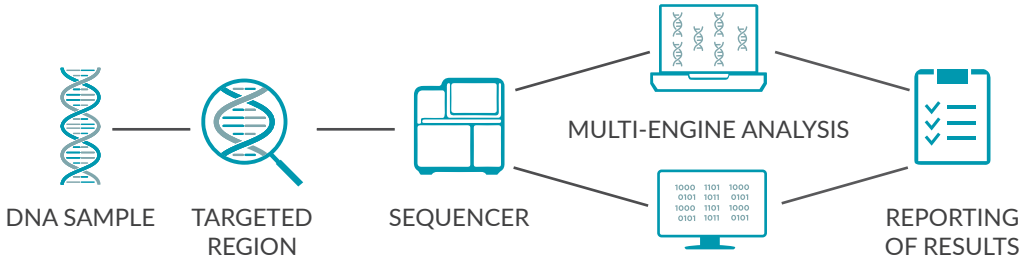
100 MONOGENIC DISEASES

VERAgene targets over 2000 point mutations related with 100 autosomal recessive and X-linked monogenic diseases of hematological, renal, ophthalmological, cardiac, endocrine, neurological, muscular and metabolic nature.

For a complete list of the monogenic diseases screened by VERAgene, please visit www.medicover-genetics.com

PROPRIETARY TARGETED METHODOLOGY

VERAgene captures, calculates and analyzes cell-free DNA (cfDNA) fragments from selected genomic regions using **Target Capture Enrichment** and **Next Generation Sequencing** (NGS) Technology with proprietary genetic and analytical tools.



TARGETED GENOMIC ANALYSIS

VERAgene uses proprietary technology, specifically designed to avoid genomic regions with complex architecture that affect test performance. This overcomes problems associated with other NIPTs and increases the precision and accuracy of VERAgene.

HIGH READ-DEPTH

Read-depth is the number of times a nucleotide in the genome is read during analysis. VERAgene captures and enriches DNA fragments from targeted regions on chromosomes of interest. VERAgene is able to analyze these selected regions at an extremely high read-depth which improves the statistical accuracy of the analysis and increases the sensitivity and specificity of VERAgene.

FETAL FRACTION MEASUREMENT

A proprietary bioinformatics software accurately calculates fetal fraction which increases the robustness and reliability of VERAgene.

MULTI-ENGINE ANALYSIS PIPELINES

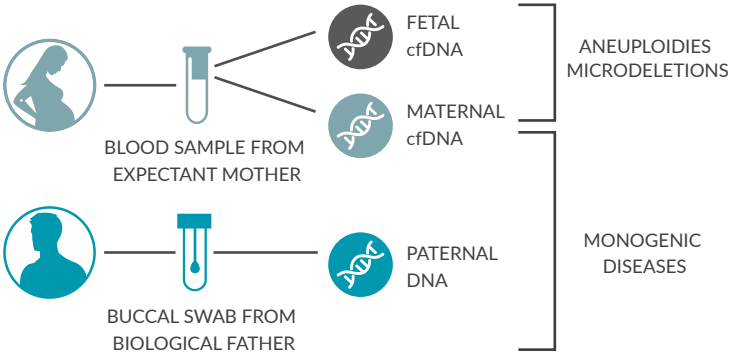
Proprietary bioinformatic pipelines analyze the sequencing data produced from each test. This multi-engine analysis increases the sensitivity and specificity of aneuploidy, microdeletion, monogenic disease, and fetal gender detection.

HOW DOES **VERAgene** WORK?

Maternal blood contains cfDNA from both the mother and the fetus.

The fetal cfDNA is analyzed for the detection of aneuploidies and microdeletions. Concurrently, maternal cfDNA is analyzed along with the paternal DNA for the determination of the risk for monogenic diseases.

Sophisticated algorithms are then used to compute the risk of the fetus having an aneuploidy, microdeletion or monogenic disease.



WHO IS **VERAgene** APPLICABLE FOR?

	AUTOSOMAL ANEUPLOIDIES	SEX CHROMOSOME ANEUPLOIDIES	MICRODELETIONS	MONOGENIC DISEASES
Singleton	●	●	●	●
Twin/Vanishing Twin	●		●	●
IVF (self-egg used) Singleton	●	●	●	●
IVF (self-egg used) Twin/Vanishing Twin	●		●	●

Patients with malignancies or history of malignancies, with bone marrow or organ transplant, who have recently had a transfusion, or who achieved pregnancy through the use of donor egg or through surrogate, are not eligible for the test.

The ACMG recommends[1]:

- NIPT screening for all pregnant patients with singleton and twin gestations for fetal trisomies 21, 18 and 13
- NIPT screening for patients with singleton gestation for sex chromosome aneuploidies
- NIPT screening for all patients for 22q11.2 deletion

1. *Dungan, Jeffrey S., et al. "Noninvasive Prenatal Screening (NIPS) for Fetal Chromosome Abnormalities in a General-Risk Population: An Evidence-Based Clinical Guideline of the American College of Medical Genetics and Genomics (ACMG)." Genetics in Medicine, vol. 25, no. 2, 2023, p. 100336*
2. *ACOG Committee Practice on Bulletins. "Screening for Fetal Chromosomal Abnormalities." Obstetrics & Gynecology, vol. 136, no. 4, 2020, pp. 859–867*
3. *Internal data*

BENEFITS OF **VERAgene**

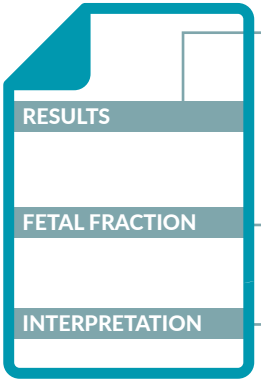
SAFE
Non-invasive procedure

EASY
Blood sample from pregnant woman and buccal swab from the biological father

ACCURATE
>99% detection rate*

FAST
Results in 4-7 working days from sample receipt

WHAT WILL THE **REPORT** TELL ME?



VERY LOW RISK
Reduced risk of the fetus having one of the tested conditions

VERY HIGH RISK
Increased risk of the fetus having one of the tested conditions
As VERAgene NIPT is a screening test, high risk results should always be confirmed with a diagnostic test

As per ACMG 2016 Position Statement, fetal fraction is accurately measured and clearly stated (*Gregg et al. 2016*)

Summary of the results and recommendations

The result of the test does not eliminate the possibility that other genetic conditions might be present, nor does it guarantee a healthy baby.

WHAT CAN I DO AFTER **VERAgene**?

- Inform your patient about the result
- Recommend genetic counseling, if applicable
- Confirm very high risk results with a prenatal diagnostic procedure *e.g. CVS or amniocentesis*
- Discuss about next steps and management

**The percentage refers to the detection of aberrations covered by VERAgene.*

HOW TO ADMINISTER THE **VERAgene** TEST?

Recommend **VERAgene** to the expectant parents

Collect a blood sample from the pregnant woman and a buccal swab from the biological father

Send the samples to **Medicover Genetics**

The samples will be analyzed at **Medicover Genetics** laboratories

Results will be available within 4-7 working days from sample receipt, through a secure digital portal

MORE **QUESTIONS**?

If you have additional questions or concerns, please contact us at **info.genetics@medicover.com**

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www.medicover-genetics.com

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