VERAgene®
comprehensive NIPT

Single test for aneuploidies, microdeletions and monogenic diseases

MEDICOVER GENETICS

VERAgene NEW GENERATION NIPT

VERAgene is a **comprehensive non-invasive prenatal test (NIPT)** that can accurately identify pregnancies at high risk of certain fetal genetic disorders such as **fetal aneuploidies**, **microdeletions**, and **monogenic diseases**, as early as the 10th week of pregnancy.

- Validated for **singleton** and **twin** pregnancies
- Applicable for women of **all ages**
- Preferred for its **accuracy**, and **robustness**
- Applicable for **IVF** pregnancies

WHAT IS A PRENATAL TEST?

It is a test that you can take during the course of your pregnancy to check if your fetus has certain genetic conditions. Prenatal tests are divided into **screening tests** and **diagnostic tests**, which **work synergistically**.

Screening tests (ultrasound, biochemical testing, and NIPT), which are applicable for **all pregnancies**, are safe tests which can identify whether your fetus has an **increased risk** of having a certain condition. High risk pregnancies are **referred** for confirmatory, diagnostic testing. Diagnostic tests (chorionic villus sampling and amniocentesis) have approximately a 1 in 200 risk of causing a miscarriage. Therefore, the more accurate a screening test is, the fewer women are referred for diagnostic testing.

WHY SHOULD I CONSIDER NIPT?

According to medical gynecological societies, NIPTs are the **most accurate screening test for the detection of common fetal aneuploidies** (change to the chromosome number)[1,2]. As such, they can reduce the number of women being unnecessarily referred for invasive, diagnostic testing. Furthermore, they can detect sex chromosome aneuploidies and microdeletions, which:

- are not associated with maternal age, and therefore can happen in any pregnancy
- may not be detected by other screening tests (ultrasound and biochemical testing)
- can occur more frequently than autosomal aneuploidies[1,2]

WHY SHOULD I CONSIDER **VERAgene** NIPT?

VERAgene combines the detection of aneuploidies and microdeletions with the screening of monogenic diseases. Monogenic diseases arise from mutations (changes in DNA) in a single gene. These mutations are inherited so if both parents are carriers of a mutation on the same gene, they could have a child who is affected. By screening for aneuploidies, microdeletions and monogenic diseases, VERAgene provides a **comprehensive picture of the pregnancy using a single test**.

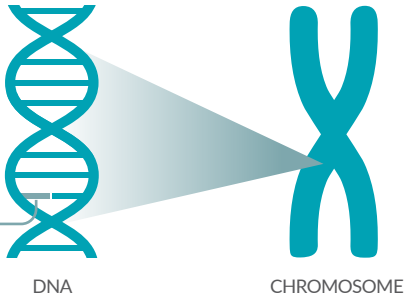
The cumulative risk for a fetus to be affected by one of the genetic conditions screened by VERAgene is **1 in 50** in moderate to high risk pregnancies and could be higher in some ethnic populations where some of the conditions are more prevalent.

WHAT DOES **VERAgene** NIPT TEST FOR?

The conditions tested by VERAgene are commonly found in the population and have a serious effect on life or life quality of the affected individual.

Prenatal detection of these conditions can improve prenatal care and facilitate taking informed decisions early on.

GENE MUTATION
A change in the DNA



AUTOSOMAL ANEUPLOIDIES

A change in one of the chromosomal pairs 1-22

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

Conventional prenatal screening tests, such as ultrasounds and biochemical testing, also test for autosomal aneuploidies, but NIPTs are recognized by professional medical societies as the most accurate screening method for these conditions[1,2].

SEX CHROMOSOME ANEUPLOIDIES

A change in the 23rd chromosomal pair, which defines gender

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

In some cases, sex chromosome aneuploidies can be detected through conventional screening tests. However, as conventional screening tests were not designed to specifically detect these aneuploidies, they cannot detect sex chromosome aneuploidies as consistently or as accurately as NIPTs can.

MICRODELETIONS

A small part of a chromosome is missing

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

In some cases, microdeletions can be detected through conventional screening tests. However, as conventional screening tests were not designed to specifically detect microdeletions, they cannot detect them as consistently or as accurately as NIPTs can.

MONOGENIC DISEASES

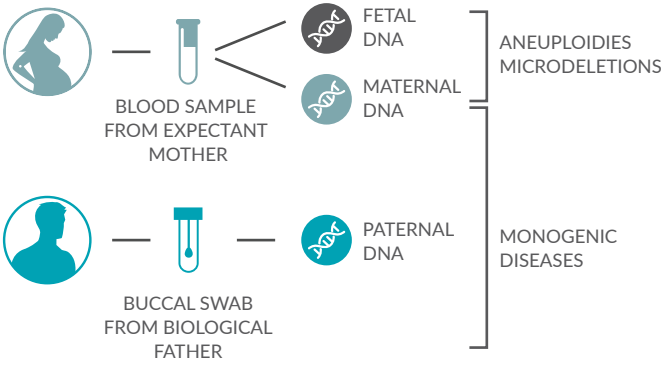
A DNA change in a specific gene

100 Monogenic diseases
Disorders tested are of hematological, renal, cardiac, and metabolic nature, among others. For a complete list of the diseases, please visit www.medicover-genetics.com

Monogenic diseases may not have ultrasound or biomarker findings. Identifying the risk for a monogenic disease early on during pregnancy, can help to improve clinical management.

HOW DOES **VERAgene** WORK?

During pregnancy, fetal DNA travels from the placenta to your bloodstream and circulates along with your own DNA. The healthcare provider will collect a blood sample from you, and a buccal swab from the biological father and send them to our laboratory for analysis. The blood sample, containing your DNA and the fetal DNA, will be analyzed for aneuploidies and microdeletions. The biological father's DNA will be analyzed along with your DNA for potential genetic mutations. Our proprietary technology and bioinformatics will accurately calculate the risk of the fetus having an aneuploidy, microdeletion or monogenic disease.



HOW SAFE IS **VERAgene**?

VERAgene is safe and does not pose any risk for you or your baby.

ARE THE CONDITIONS TESTED BY **VERAgene** ASSOCIATED WITH MATERNAL AGE?

The incidence of autosomal aneuploidies increases with maternal age. However, sex chromosome aneuploidies, microdeletions and monogenic diseases are not associated with maternal age so they can manifest at any maternal age group. In fact, medical gynecological societies recommend testing for:

- Trisomies 21, 18, 13
- Sex Chromosome Aneuploidies
- 22q11.2 deletion

The VERAgene test can be done by all pregnant women regardless of age or risk category.

WHAT ARE THE BENEFITS OF **VERAgene** NIPT OVER OTHER NIPTs?

In addition to screening for common fetal aneuploidies and microdeletions with high accuracy, VERAgene also determines the risk of your fetus having any of the 100 monogenic diseases tested. Our validated, novel technology ensures the reliability of the results.

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. *Gregg, Anthony R., et al. "Noninvasive Prenatal Screening for Fetal Aneuploidy, 2016 Update: A Position Statement of the American College of Medical Genetics and Genomics." Genetics in Medicine, vol. 18, no. 10, 2016, pp. 1056–1065.*

BENEFITS OF **VERAgene**

SAFE
Non-invasive sample collection

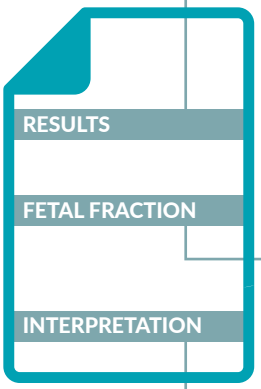
EASY
Blood sample from the pregnant woman and buccal swab from the biological father

ACCURATE
>99% detection rate*

FAST
Results in 4-7 working days from sample receipt

WHAT WILL THE **REPORT** SAY?

The VERAgene report will be sent to your healthcare provider. It will include a detailed explanation which will guide your healthcare provider on the best clinical management for you.



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

- In cases of very low risk results, your healthcare provider will continue with routine pregnancy clinical management

VERY HIGH RISK
Increased possibility of the fetus having one of the tested conditions

- In cases of very high risk results, your healthcare provider will advise you on recommended next steps, such as genetic counseling and performing an invasive procedure to confirm whether the fetus has the genetic condition

The percentage of the fetal DNA in the maternal circulation

Correct measurement of the fetal fraction is vital for accurate test results. If the fetal fraction is not accurately measured, or if it's not above the specified percentage defined by medical gynecological societies[3], there is a risk for false negative results. VERAgene accurately measures fetal fraction using novel software, and reports the fetal fraction percentage on the report as per recommendations from medical gynecological societies[3].

A summary of the results and recommendations

**The percentage refers to the detection of aberrations (changes in the chromosomes or the DNA) covered by VERAgene*

HOW CAN I TAKE THE **VERAgene** TEST?

Be at least 10 weeks pregnant

Ask your healthcare provider about **VERAgene**

Your healthcare provider will collect a blood sample from you and a buccal swab from the biological father

The samples will be sent to **Medicover Genetics**

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

Results will be sent to your healthcare provider within 4-7 working days from sample receipt

MORE **QUESTIONS**?

If you have additional questions or concerns, please ask your healthcare provider.
You can also contact us at **info.genetics@medicover.com**

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