

VERACITY NEW GENERATION NIPT

VERACITY is a **non-invasive prenatal test (NIPT)** that can accurately detect the presence of certain fetal genetic disorders as early as the 10th week of pregnancy, through a blood sample from the pregnant woman.

Validated for singletonApplicable forApplicable forPreferred for its accuracy,and twin pregnanciesIVF pregnancieswomen of all agesand robustness

WHAT IS A PRENATAL TEST?

It is a test that a pregnant woman can take to check if her fetus has certain genetic conditions. Prenatal tests are divided into **screening tests** and **diagnostic tests**, which **work synergistically**.

Prenatal screening tests

Include ultrasounds, biochemical testing and NIPT

- Prenatal screening tests are safe for both the pregnant woman and the fetus.
- In most cases, some prenatal screening tests or a combination of them are offered to all pregnant women throughout their pregnancies, as part of routine prenatal care.
- The purpose of a screening test is to identify whether a
 fetus has an increased risk of having a certain condition.
 High risk pregnancies are referred for confirmatory,
 diagnostic testing.
- Different screening tests are better in identifying certain conditions; for example while ultrasounds are best for identifying anatomical abnormalities, NIPTs are the most accurate method for detecting common fetal aneuploidies^{1,2}.

Aneuploidy: A change in the chromosome number

The more accurate a screening test is, the fewer women are referred for diagnostic testing.

Prenatal diagnostic tests

Include chorionic villus sampling (CVS) and amniocentesis

- Performed between the 11th and 14th week (CVS), and 15th and 20th week (amniocentesis) of pregnancy.
- Prenatal diagnostic tests are used to confirm or rule out whether a fetus has the specified condition the screening tests have referred them for.
- Prenatal diagnostic tests have approximately a 1 in 200 risk of causing a miscarriage. As such, they are not performed in all pregnancies, only in the ones which as classified as 'high risk' from the prenatal screening tests.

WHY SHOULD I CONSIDER NIPT?

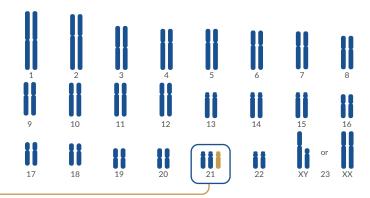
According to esteemed medical gynecological societies, NIPTs are the **most accurate screening test for the detection of common fetal aneuploidies**^{1,2}. As such, they can reduce the number of women being unnecessarily referred for invasive, diagnostic testing. Furthermore, they can detect sex chromosome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

- are not associated with maternal age
- may not be detected by other screening tests (ultrasound and biochemical testing)
- can occur more frequently than autosomal aneuploidies^{1,2}

WHAT DOFS **VERACITY** TEST FOR?

The conditions tested by VERACITY 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 and accurate decisions** early on.



TRISOMY

3 copies of a chromosome instead of 2.

AUTOSOMAL ANEUPLOIDIES

A change in one of the chromosomal pairs 1-22

Down syndrome (Trisomy 21) Edwards syndrome (Trisomy 18) Patau syndrome (Trisomy 13) Down, Edwards and Patau syndromes are the most common autosomal fetal aneuploidies. The incidence of these conditions increases with maternal age.

Conventional prenatal screening tests, such as ultrasounds and biochemical testing, also test for these, but NIPTs are recognized by professional medical societies as the most accurate screening method for these conditions¹.

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

Sex chromosome aneuploidies occur frequently in the population. They are not associated with maternal age, and as such they could potential occur in pregnancies irrespective of maternal age.

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 NIPT can.

MICRODELETIONS

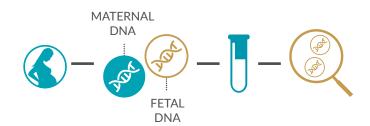
A small part of a chromosome is missing

DiGeorge syndrome (22q11.2) 1p36 deletion syndrome (1p36) Smith-Magenis syndrome (1p11.2) Wolf-Hirschhorn syndrome (4p16.3) Apart from DiGeorge syndrome, which occurs frequently in the population, most microdeletions are rare. Microdeletions are not associated with maternal age, and as such have the same possibility of occurring in women of all ages.

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 NIPT can.

HOW DOES VERACITY WORK?

During pregnancy, fetal DNA travels from the placenta to the maternal bloodstream and circulates along with her own DNA. The healthcare provider will collect a blood sample and send it to our laboratory for analysis. Our proprietary technology analyzes the fetal DNA and identifies the genetic disorders tested with high accuracy and precision. The results are provided to your healthcare provider in a few working days.



HOW SAFE IS VERACITY?

VERACITY is safe and does not pose any risk for the pregnant woman or her baby.

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

The incidence of autosomal aneuploidies increases with maternal age. However, sex chromosome aneuploidies and microdeletions 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 VERACITY test can be performed in all pregnancies, regardless of maternal age or risk category, including pregnancies achieved through donor egg or sperm, or via surrogate.

Certain testing exceptions apply. Your healthcare provider will advise you if VERACITY is the right NIPT for you.

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

VERACITY NIPT was designed by our in-house team of experts to avoid problems associated with other NIPTs. It is based on a technology known as 'Target Capture Enrichment', which analyzes the parts of the DNA containing the tested aneuploidies hundreds of times, resulting in high accuracy and reliability.

Sensitivity >99%, Specificity >99%



- 1. ACOG Committe on Practice Bulletins. "Screening for Fetal Chromosomal Abnormalities." Obstetrics & Disterics & Obstetrics (Spreading Synthesis (1997) (19
- 2. 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.
- 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 **VERACITY**



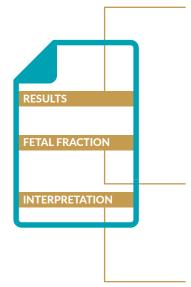






WHAT WILL THE **REPORT** SAY?

The VERACITY 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 societies³, there is a risk for false negative results. Our laboratory accurately measures fetal fraction using novel software, and reports the fetal fraction percentage on the report as per recommendations from medical gynecological societies³.

A summary of the results and recommendations

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



Be at least 10 weeks pregnant



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



Ask your healthcare provider about **VERACITY**



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



Your healthcare provider will collect a blood sample from you



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**













