VERACITY®

new generation NIPT

Delivering results you can trust

MEDICOVER GENETICS

VERACITY NEW GENERATION NIPT

VERACITY is a **non-invasive prenatal test** (NIPT) for the detection of **fetal autosomal aneuploidies**, **sex chromosome aneuploidies**, and **microdeletions** that can be done as early as the 10th week of pregnancy.

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

CLINICAL UTILITY

According to professional societies such as ACMG, ACOG, and ISPD, NIPT is the most accurate screening test for the detection of common fetal aneuploidies[1,2,3]. 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** (SCAs) 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]

WHAT DOES **VERACITY** NIPT TEST FOR?

Early, safe and accurate detection of autosomal aneuploidies, SCAs and microdeletions facilitates taking informed decisions.

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

MICRODELETIONS

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

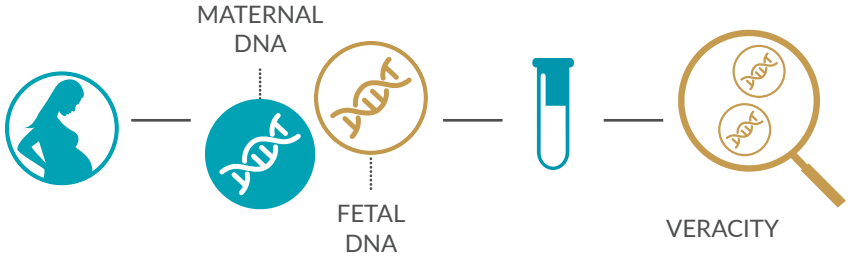
Gender determination can optionally be performed

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 SCAs
- NIPT screening for all patients for 22q11.2 deletion

PROPRIETARY TARGETED METHODOLOGY

VERACITY NIPT was designed to avoid the shortcomings of other NIPTs. VERACITY uses novel **Targeted Capture Enrichment Technology** that enables aneuploidy detection as well as fetal fraction measurement with unparalleled accuracy and reliability.



TARGETED GENOMIC ANALYSIS

VERACITY 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 VERACITY.

HIGH READ-DEPTH

Read-depth is the number of times a nucleotide in the genome is read during analysis. VERACITY captures and enriches DNA fragments from targeted regions on chromosomes of interest. VERACITY 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 VERACITY.

FETAL FRACTION MEASUREMENT

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

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 and fetal gender detection.

WHO IS **VERACITY** APPLICABLE FOR?

	AUTOSOMAL ANEUPLOIDIES	SEX CHROMOSOME ANEUPLOIDIES	MICRODELETIONS
Singleton	•	•	•
Twin/Vanishing Twin	•		•
IVF (self-egg used) Singleton	•	•	•
IVF (self-egg used) Twin/Vanishing Twin	•		•
IVF (Donor egg used or Surrogate) Singleton	•	•	•

Patients with malignancies or history of malignancies, with bone marrow or organ transplant, or who have recently had transfusion are not eligible for the test.

CLINICAL PERFORMANCE OF **VERACITY** NIPT

AUTOSOMAL ANEUPLOIDIES

KARYOTYPE	NO.	FOLLOW-UP	CORRECT CALLS	SPECIFICITY	NPV
NORMAL	10280	10280	10280	99.98% (95% CI, 99.93 - 99.998%)	100% (95% CI, 99.96 - 100%)

KARYOTYPE	NO.	FOLLOW-UP	CORRECT CALLS	SENSITIVITY	PPV
Trisomy 21	126	44	44	100% (95% CI, 92 - 100%)	100% (95% CI, 92 - 100%)
Trisomy 18	24	10	10	100% (95% CI, 69 - 100%)	100% (95% CI, 69 - 100%)
Trisomy 13	16	7	5	100% (95% CI, 48 - 100%)	71% (95% CI, 29 - 96%)

SEX CHROMOSOME ANEUPLOIDIES

KARYOTYPE	NO.	FOLLOW-UP	CORRECT CALLS	SPECIFICITY	NPV
NORMAL	6200	6200	6200	99.95% (95% CI, 99.86 - 99.99%)	100% (95% CI, 99.94 - 100%)

KARYOTYPE	NO.	FOLLOW-UP	CORRECT CALLS	SENSITIVITY	PPV
45, X	16	7	4	100% (95% CI, 40 - 100%)	57% (95% CI, 18 - 90%)
47, XXX	6	2	2	-	-
47, XXY	10	4	4	-	-
47, XYY	3	0	-	-	-
48, XXYY	1	1	1	-	-

Kypri et al. "Non-invasive Prenatal Testing of Fetal Chromosomal Aneuploidies: Validation and Clinical Performance of the Veracity Test." Molecular Cytogenetics vol. 12 34. 15 Jul. 2019

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 Committe on Practice Bulletins. "Screening for Fetal Chromosomal Abnormalities." Obstetrics & Gynecology, vol. 136, no. 4, 2020, pp. 859–867*
3. *Hui, Lisa, et al. "Position Statement from the International Society for Prenatal Diagnosis on the Use of Non-Invasive Prenatal Testing for the Detection of Fetal Chromosomal Conditions in Singleton Pregnancies." Prenatal Diagnosis, vol. 43, no. 7, 16 May 2023, pp. 814–828*

BENEFITS OF **VERACITY**

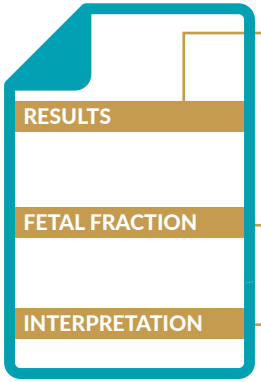
SAFE
Non-invasive procedure

EASY
Blood sample from pregnant woman

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 VERACITY 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

WHAT CAN I DO AFTER **VERACITY**?

- 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

HOW TO ADMINISTER THE **VERACITY** TEST?

Recommend **VERACITY** to the expectant parents

Collect a blood sample from the pregnant woman

Send the sample to **Medicover Genetics**

The sample 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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