



Non-invasive Prenatal Testing

CentoNIPT

Expertise You Can Trust





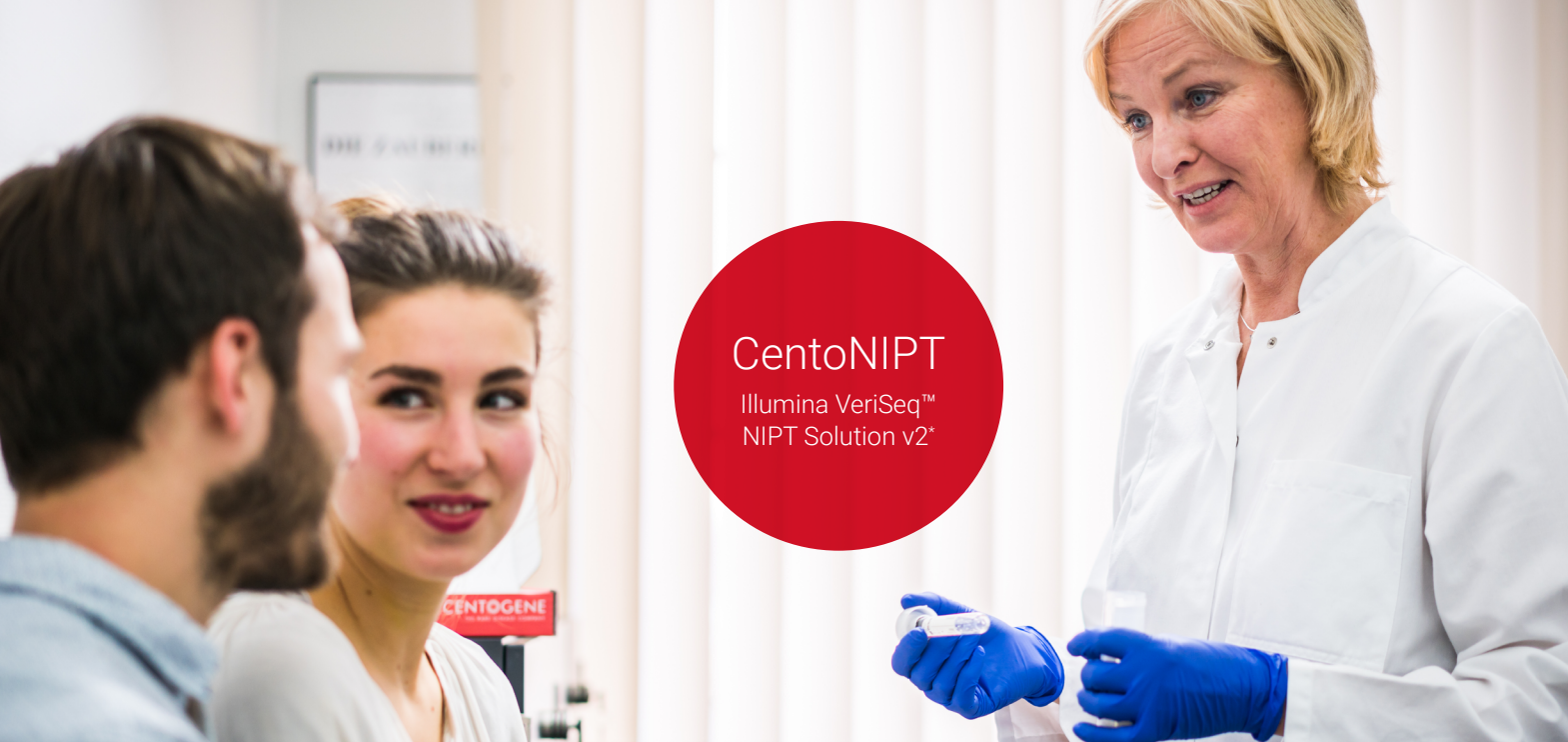
Expertise You Can Trust

Conventional prenatal testing for fetal chromosomal abnormality involves either chorionic villus sampling or amniocentesis. These procedures are highly invasive and carry an elevated risk of miscarriage. Despite this risk they are standard practice in most of the world because of their high levels of accuracy and the range of abnormalities they can detect.

With CentoNIPT, CENTOGENE now offers non-invasive prenatal testing that provides **fast and accurate screening for the most common prenatal chromosomal abnormalities (Trisomies 21, 18, 13, X0, XXY, XXX, XYY).**

CentoNIPT is performed on a single maternal blood sample and combines the latest NGS technology with the highest quality medical reporting. It provides unparalleled accuracy and detection compared to other non-invasive testing methods – ultrasonography or nuchal translucency testing.

Our medical expertise is ideally suited to provide you and your patients with reliable, well supported interpretations of results.



CentoNIPT offers genetic, Non-invasive Prenatal Testing (NIPT) to screen for the most common fetal chromosomal abnormalities (Trisomies 21, 18, or 13 and optionally sex chromosome aneuploidies). CentoNIPT Expanded screens for Trisomies 21, 18, 13, rare autosomal aneuploidies (RAAs), CNVs $\geq 7\text{Mb}$ in autosomes and optionally, for sex chromosome aneuploidies. Optionally, fetal gender reporting can be selected. Our test combines the latest Next Generation Sequencing (NGS) technology with expert medical reporting.

- NIPT is a screening test based on the analysis of a maternal blood sample without the risks of invasive prenatal testing
- Results within 5 business days
- Comprehensive reporting by our expert medical team
- Test from the 10th gestational week**
- 7–10 ml of blood from the mother required
- CAP and CLIA accreditation with fully validated workflows for sample analysis
- Analysis of twins (monozygotic and dizygotic) is also possible***

* Sample preparation and analysis software are CE-IVD marked

** Please note that in Germany, fetal gender may only be disclosed to the pregnant woman after the end of the 12th gestational week post-conception and with her consent (§ 15 para. 1 of the Genetic Diagnostics Act). Please ensure that you comply with your local laws regarding this matter.

*** Gonosomal aneuploidies cannot be detected for twin pregnancies

Fetal Chromosomal Abnormalities

Approximately 1 % of all babies will be born with a chromosomal abnormality which can cause physical disability and/or mental retardation. Roughly 70% of syndromic chromosomal abnormalities are due to Trisomies 21, 18, or 13 and 10% due to Turner syndrome (Monosomy X). The risk of Trisomy increases significantly with maternal age.

Common Autosomal Aneuploidies	Sensitivity	Specificity
Trisomy 21 Down syndrome	> 99.9%	99.9%
Trisomy 18 Edwards syndrome	> 99.9%	99.9%
Trisomy 13 Patau syndrome	> 99.9%	99.9%

Rare Autosomal Aneuploidies	Sensitivity	Specificity
Estimate % (n/N)	96.4% (27/28)	99.80% (2001/2005)
2-sided 95% CI	82.3%, 99.4%	99.49%, 99.92%

Partial Deletions and Duplications (CNVs ≥7Mb) in Autosomes	Sensitivity	Specificity
Estimate % (n/N)	74.1% (20/27)	99.80% (2000/2004)
2-sided 95% CI	55.3%, 86.8%	99.49%, 99.92%

Sex Chromosome Aneuploidies & Fetal Gender	Concordance with Cytogenetic Results
XX	100.0%
XY	100.0%
XO Turner syndrome	90.5%
XXX Triple X syndrome	100.0%
XXY Klinefelter syndrome	100.0%
XYY Jacobs syndrome	91.7%

Results and Limitations

CentoNIPT and CentoNIPT Expanded are screening tests intended to detect fetal chromosomal abnormalities from 10 weeks of gestation onward. CentoNIPT screens for the common autosomal aneuploidies (Trisomies 21, 18, 13). CentoNIPT Expanded screens for increased risk of common prenatal chromosomal abnormalities, rare autosomal aneuploidies (RAAs), and autosomal CNVs ≥ 7 Mb. Sex chromosome aneuploidies can optionally be detected for singleton pregnancies. However, neither test can fully exclude chromosomal abnormalities, clinically significant CNVs (e.g., microdeletions), other genetic conditions (e.g., monogenic disorders), or congenital anomalies (e.g., neural tube defects). CentoNIPT Expanded does not detect all CNVs or structural abnormalities; it does not assess balanced rearrangements, low-level mosaicism, CNVs < 7 Mb, single-gene disorders, or sequence variants, and it only analyzes autosomal CNVs (not sex chromosomes). The clinical utility of screening for RAAs (excluding chromosomes 13, 18, 21) and CNVs ≥ 7 Mb remains limited (ACMG guidelines, PMID: 36524989). Test performance for RAAs and CNVs ≥ 7 Mb is lower than for common trisomies (13, 18, 21), expected to result in higher false-positive and false-negative rates.

Test performance has been primarily validated for singleton pregnancies. In twin gestations, autosomal aneuploidies and genome-wide CNVs may be detected but cannot be assigned to an individual fetus, and sensitivity and specificity are reduced. Fetal gender can be optionally determined for singleton pregnancies, for twin gestations only the presence of of Y chromosome can be determined hence, fetal gender cannot be assigned to a specific twin.

The CENTOGENE Advantage



CENTOGENE offers a comprehensive package starting with NIPT for most common chromosome aneuploidies to prenatal whole exome/whole genome sequencing. After birth, we offer biomarker testing and our whole genetic test portfolio including specialized genetic analysis for critically ill newborns on ICU.



High Sensitivity & Specificity

CentoNIPT combines NGS with integrated measurement of fetal fraction, even for fetal fractions less than 4%. This results in the lowest technical failure rate and eliminates unnecessary invasive testing as follow-up of NIPT.

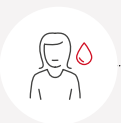


Fast & Accurate Results

Our optimized workflows enable comprehensive, high-quality medical reports with validated results within 5 business days.



Do you already have a starter set for CentoNIPT®?



Prepare the maternal sample using your individual starter set for CentoNIPT®



Order a test on CentoPortal® using the NI code from your CentoNIPT blood collection tube



Package and ship the sample in your starter set for CentoNIPT® – **for free**



Sample processing and results within 5 business days



Download your report



Do you have any questions? **Please contact us.**

Note: CentoNIPT and CentoNIPT Expanded are unavailable in the U.S.

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