PrenaTest®

Information for physicians

Non-invasive prenatal testing (NIPT) for chromosomal aneuploidies in the unborn child

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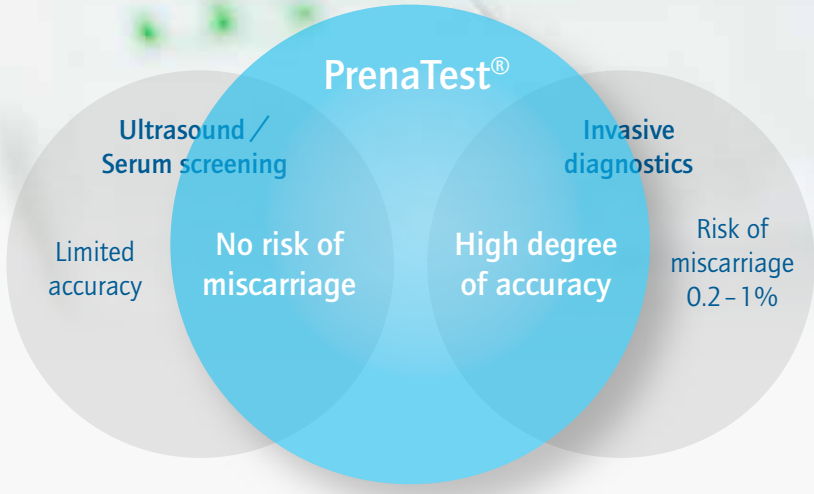
Pioneering Cell-Free Fetal DNA Testing

PrenaTest® gives clarity.

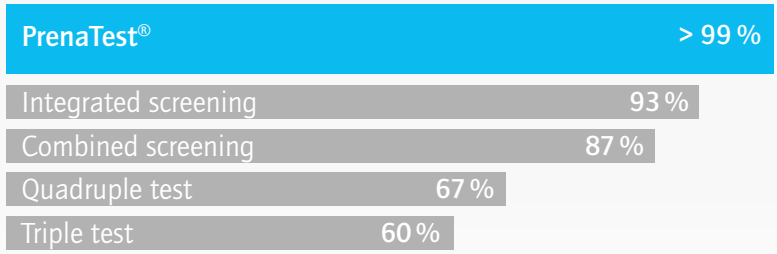
Reasons for PrenaTest®

Further clarification of common screening methods, thus reduction of the number of unnecessary invasive examinations.



Comparison of screening methods

Detection rates of screening methods for the determination of fetal trisomy 21 compared to PrenaTest®[1,4]



NIPT can be used as a primary screening method for fetal trisomy 21 in pregnant women of every age and risk group

Austrian-German-Swiss Recommendations for NIPT 2016[5]

[...] any patient may choose cell-free DNA analysis as a screening strategy for common aneuploidies regardless of her risk status [...] ACOG 2015[5]

[...] NIPT offers improved accuracy when testing for common autosomal aneuploidies compared with existing tests such as cFTS [...] ESHG/ASHG 2015[5]

[...] informing all pregnant women that NIPS is the most sensitive screening option for traditionally screened aneuploidies [...] ACMG 2016[5]

[...] NIPT as a primary test can be offered to all pregnant women [...] ISPD 2015[5]

PrenaTest®

1 Test

Safe. Rapid. Reliable. And Affordable.

Starting from the ninth week of pregnancy (9+0 weeks since LMP) the PrenaTest® determines *trisomies 21, 18 and 13, gonosomal aneuploidies* ***(Turner, triple X, Klinefelter, and XYY syndromes)*** as well as *the 22q11.2 microdeletion* ***(associated with the DiGeorge syndrome***) from maternal blood. If desired, the gender of the fetus may also be determined.

Safe	> 99 % Detection rate[1,2]	0.1 % False positive rate[1,2]	< 0.6 % No-call rate[1]	Applicable under LMWH therapy
Rapid	4 – 6 DAYS[3]			
Reliable	+ In accordance with the **In-Vitro Diagnostic Directive 98/79/EC** since 2012 + **Worldwide first NIPT with CE-marked data analysis software** + Patent Licensee of Illumina & LabCorp (USA) for NIPT development			
Affordable	The new PrenaTest® offers **unbeatable value** for money. Contact us to learn more: **tel. +49 (0) 7531 9769460, info@lifecodexx.com**			

+ Also applicable in the case of a ***twin pregnancy*** – including gender determination
+ Can be used ***following assisted reproduction*** – even if donor eggs are used

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2 Methods

The only NIPT which employs two leading medical diagnostic methods

While the *qPCR-based NIPT (qNIPT)* assures a cost-efficient and rapid analysis, the *NIPT based on random massively parallel sequencing (rMPS)* ***offers a broad test spectrum*** and is the most routinely employed NIPT method worldwide with ***more than one million tests performed*** to date.

NEW! Smart qNIPT

Developed by LifeCodexx AG, the smart qNIPT assay is based on a quantitative real-time polymerase chain reaction (qPCR). Due to different methylation patterns of specific gene regions of the maternal and fetal DNA, positive and negative samples will be distinguished. The fetal fraction will also be measured and reported.

Well-established rMPS-based NIPT

With the method of random massively parallel sequencing (rMPS) the cell-free DNA is decoded with the most modern analytical equipment. The objective is to determine whether the quantity of sequences for the respectively investigated chromosome exceeds the normal range found in the case of a euploid, i.e. normal, chromosome set. It is the most widely used NIPT technology worldwide to date and has been validated in numerous studies.

The first NIPT prospective clinical follow-up study in Germany

According to the European guidelines for medical devices, the PrenaTest® was evaluated in the context of a *prospective clinical follow-up study in Germany, which included over 2,200 patients* with singleton pregnancy. ***Final results demonstrate a sensitivity and specificity of 100% for the fetal trisomy 21.***

3 Options

The only NIPT which measures the fetal fraction right after sample receipt

The doctor will be notified the next day following receipt of the blood sample if the level of cell-free fetal DNA (cffDNA) in the maternal blood is too low for successful analysis. For singleton pregnancies, a successful analysis using qNIPT requires a cffDNA level in the maternal DNA mixture of ***at least 2.4%, and at least 4%*** using rMPS. For twin pregancies, a minimum of 8% is required.

Option 1

Determination of fetal trisomy 21

for singleton pregnancy
incl. gender determination on request

Option 2

Determination of fetal trisomies 21, 18 and 13

for singleton or twin pregnancy
incl. gender determination on request

Option 3

Determination of fetal trisomies 21, 18, 13, Turner, triple X, Klinefelter, XXY syndrome and the 22q11.2 microdeletion (DiGeorge syndrome)

for singleton pregnancy
incl. gender determination on request

1 Internal data from lab routine (August 2012 to September 2016) based on rMPS. Reported test accuracies for all determined chromosomal aneuploidies.
2 Blinded validation study on the qNIPT assay approved and certified by Notified Body.
3 Turnaround times after sample receipt. Monday to Friday, except Saturday, Sunday and public holidays in Germany. Delivery time starts upon sample receipt in the laboratory and depends on the chosen service.
4 Cuckle H, Benn P, Wright D (2005). Down syndrome screening in the first and/or second trimester: model predicted performance using meta-analysis parameters. Seminars in Perinatology 29, 252-257.
5 Recommendations of medical associations available at www.lifecodexx.com/en/for-physicians/download-center

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Pioneering Cell-Free Fetal DNA Testing

First NIPT provider in Europe

Headquartered in Konstanz (Germany), LifeCodexx AG has been developing innovative and clinically validated non-invasive prenatal tests since 2010. With the launch of the PrenaTest® in 2012, Europe's first non-invasive prenatal test (NIPT) for the determination of the most common chromosomal disorders in unborn children, LifeCodexx AG has been changing prenatal diagnostics considerably. Today the PrenaTest® is firmly established in many prenatal practices in Europe, the Middle East and Asia as a reliable, rapid and safe examination method. Every 30 minutes a pregnant woman opts for the PrenaTest®, and this figure is increasing.

Worldwide first NIPT with CE-marked data analysis software

The proprietary bioinformatic PrenaTest® DAP.plus analysis software for the determination of all examined chromosomal disorders has been CE marked since 2012. Rely on certified and independently monitored quality in accordance with German and European law combined with the highest levels of scientific expertise.

Short turnaround times of less than a week

LifeCodexx AG's non-invasive examination methods offer short turnaround times of less than a week after receipt of the blood samples in the laboratory, while providing a very high degree of accuracy, and without risk to the mother or the pregnancy.

Continuous development of safe and reliable NIPT

LifeCodexx AG closely cooperates with many doctors and laboratory partners worldwide to further develop safe and reliable non-invasive prenatal tests for the sake of the mother and the unborn child. Contact us to discuss with us the opportunity to examine a special medical case from your own practice within the framework of a research project.

Contact us to learn more:
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