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Pioneering Cell-Free Fetal DNA Testing

In Germany, since 2010, we have developed prenatal genetic tests of the highest quality which allow women to be informed at an early point in their pregnancy and make independent decisions. For this reason, we work closely with gynecologists, prenatal medicine specialists, human geneticists and scientific experts in Germany to provide women concerned with the best possible support.

Our approach is shaped by exceptional compassion, respect, and esteem, especially for expectant mothers and their families, as well as for their treating physicians and the interested public. This is why we strive to provide you with competent and compassionate care at all times.

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PrenaTest®

Get Clarity.
Reliable.Rapid.Safe.

Information for expectant mothers

Non-invasive examination for chromosomal disorders in an unborn child

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Dear expectant mother,

In the next few months, you will be experiencing some touching and exciting moments. Your doctor will support you during this time and provide you with information about possible prenatal tests. These tests are intended to track your health and the development of your child in order to detect any risks early on.

This brochure contains initial information for you about the PrenaTest®. It is a safe test that is harmless to your unborn child.

The PrenaTest® may help relieve your concerns and worries about possible health problems in your child. Before you continue reading, here are two important facts that are good to know:

- Nearly all children are born healthy.
- Over 98% of all PrenaTest® results are normal, even when previous examinations pointed to an initial suspicion.

Find out more about the PrenaTest® by reading the following pages and request a complete explanation and counseling from your doctor. Take this brochure with you when you speak to your doctor and use this space to write down any questions you would like to ask:

My notes:

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The PrenaTest®

What can the PrenaTest® detect?

The PrenaTest® is known as a non-invasive prenatal test (NIPT). From maternal blood, it can detect the following changes in the genetic material of your unborn child, known as chromosomal disorders:

- **Trisomy 21** (Down syndrome)
- **Trisomy 18** (Edwards syndrome)
- **Trisomy 13** (Patau syndrome)
- **Maldistributions of the sex chromosomes X and Y** (Turner, triple X, Klinefelter and XYY syndrome)
- **22q11.2 microdeletion** (DiGeorge syndrome)

If desired, you can also learn whether you are expecting a girl or a boy. In Germany, in accordance with statutory provisions, your doctor will tell you the sex of your child starting from the twelfth week of pregnancy post-conception. National regulations in other countries may vary.

For more information visit www.lifecodexx.com/en

When can I have the PrenaTest® performed?

You can undergo the PrenaTest® after the ninth week of pregnancy has been completed (week 9+0 since LMP). Discuss with your doctor when the test would be most advisable for you personally.

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Should I have the PrenaTest® performed?

In principle, the PrenaTest® is suitable for all pregnant women. You and your doctor can discuss together whether the test is also appropriate for you. Many women choose to undergo the PrenaTest® because of their age or because they are concerned about prior abnormal test results. Talk to your doctor about which of the following test option is advisable for you in your personal situation:

PrenaTest®	Option 1	Option 2	Option 3
Test			
Trisomy 21	■	■	■
Trisomy 13, 18		■	■
Maldistribution of sex chromosomes			■
22q11.2 microdeletion			■
Gender determination	■	■	■
Can be used in the case of/following			
Single pregnancy	■	■	■
Twin pregnancy		■	
Fertility treatment (IVF, ICSI, etc.)	■	■	■

The PrenaTest® can also be performed in the case of a twin pregnancy, following fertility treatment (for example, following IVF or ICSI) as well as after egg donation.

How accurate is the PrenaTest®?

The high degree of accuracy of the PrenaTest® has been proven in many clinical studies. In addition, the test was approved by an independent inspection body which acts on behalf of public authorities. The studies show that in 99.8% of all blood samples from single pregnancies, the test results of the PrenaTest® for the determination of trisomies 13,18 and 21 were correct. This means that out of 1000 blood samples tested, 998 results were correctly determined. The test quality was also verified in the case of twin pregnancies. Here as well, the result was correct for all blood samples tested. The accuracy of the PrenaTest® to detect maldistributions of sex chromosomes (X/Y) is somewhat lower than for the detection of trisomies 13, 18 and 21. In another clinical study, the 22q11.2 microdeletion was also correctly detected in all blood samples.

Clinical studies to detect trisomies 13, 18 and 21 demonstrate:
99.8 % of all results were correct.

It is important for you to know that 100% accuracy in the use of non-invasive prenatal tests should not be expected. In rare cases, there may be no or an unclear test result. However, this does not indicate anything about the health of your child. You may then repeat the test at no additional charge. Please contact your doctor for comprehensive information and advice.

Limits of the test method

Certain special forms of chromosomal disorders, for example, structural changes to chromosomes or mosaics, cannot be detected. In the case of structural chromosomal disorders, a piece of a chromosome is missing, there is an extra piece or a piece was incorporated incorrectly in the chromosome. In a mosaic, cells of a tissue or of the entire organism of the embryo have different genetic information.

I would like to have the PrenaTest® performed. What's the next step?

1 **Information, counseling, blood sampling**
First your doctor will provide you with comprehensive and unbiased counseling and information in accordance with national regulations. After you provide your written consent for the genetic testing, blood will be drawn from a vein in your arm.

2 **Laboratory analysis**
The analysis begins once the blood sample is received by the laboratory and after it has successfully undergone a quality control inspection.

3 **Test result**
Your doctor will be informed of the test result immediately after the analysis is completed. He or she will then explain the result to you and discuss the next step with you.

When do I receive the test result and how should I interpret it?

The test result will be sent to your doctor within a few business days. If the measured analysis values of the chromosome examined in each case are within normal limits, this means that it is highly likely that the corresponding chromosomal disorder is not present in your unborn child (negative test result). Nonetheless, your doctor will track the rest of your pregnancy closely. If the measured analysis values of the chromosome examined in each case are outside of normal limits, this means that it is highly likely that your unborn child has the chromosomal disorder in question (positive test result). Based on your doctor's recommendation, the test result should then be diagnostically clarified further.