Eurofins LifeCodexx
Europe's first NIPT

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.

www.lifecodexx.com

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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:

The PrenaTest®

What can the PrenaTest® detect?
The PrenaTest® is Europe's first non-invasive prenatal test (NIPT). In principle, the PrenaTest® can examine your child's entire genetic material for possible changes. These changes, also called chromosomal disorders, can be:

- **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)
- **Rare maldistributions of all fetal chromosomes**
- **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.

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.

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.

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.

More information at **www.lifecodexx.com**

How safe is the PrenaTest®?
The high accuracy of the PrenaTest® has been proven in clinical studies. Test accuracies of more than 99% were achieved, depending on the chromosomal disorder tested. This number means that out of 100 pregnant women whose unborn child is affected by a chromosomal disorder, 99 will be determined correctly. In addition, the probability that an abnormal (that is, positive) test result is not correct is very low. This is indicated by the so-called false-positive rate of 0.1%. This value implies that in a group of 1000 unaffected pregnant women, one pregnant woman will receive an abnormal (that is, positive) test result, although her unborn child is in fact not affected by a chromosome disorder. It is important for you to know that 100% test accuracy should not be expected when non-invasive prenatal tests are used. In rare cases, there may be no or an unclear test result. However, this does not reveal anything about the health of your child. You may then repeat the PrenaTest® at no additional cost. The waiting time for the test result will be accordingly prolonged. Please have your doctor explain to you which level of accuracy the PrenaTest® can offer you and how.

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.

Get Clarity. Reliable. Rapid. Safe.

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.

PrenaTest® options
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 2 *Plus*	Option 3	Option 3 *Plus*
	1	1 2	1 2	1	1
Trisomy 21	•	•	•	•	•
Trisomies 18 and 13		•	•	•	•
Maldistributions of chromosomes X/Y				•	•
Monosomies 21/18/13 and trisomies/monosomies of all other chromosomes 1 – 22			•		•
Optional: 22q11.2 microdeletion*		•	•	•	•
Optional: Fetal gender	•	•	•	•	•

1 for singleton pregnancy 2 for twin pregnancy

* **Additional option only for singleton pregnancy; additional charge**. This examination is particularly useful in cases of abnormalities on ultrasound, for example during organ screening, which may correlate with a DiGeorge or velo-cardio-facial syndrome.