PraenaTest®

Get Clarity.
Reliable. Rapid. Safe.

Non-invasive prenatal testing for chromosomal disorders

Information and explanations for expectant mothers

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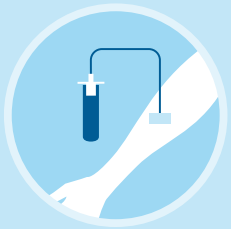
Quality from Germany

Prenatal examination methods in comparison

	PraenaTest®	
		
Ultrasound, analysis of certain pregnancy hormones in the mother´s blood	**Analysis of fragments of the child´s genetic material in the mothers blood**	**Amniocentesis, analysis of placenta**
No medical procedure required (non-invasive)	No medical procedure required (non-invasive)	**Medical procedure required (invasive)**
+ no risk of miscarriage	++ no risk of miscarriage high degree of accuracy	+ highest degree of accuracy
– Limited accuracy		– risk of miscarriage 0,2 – 1%

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Dear Expectant Patient,

This brochure is intended to provide you with initial information about the PraenaTest®, a safe test that does not present any risks to your unborn child. The PraenaTest® may help relieve your concerns and worries about possible health problems in your child if these are unsubstantiated. It is important for you to know that most tests during pregnancy return negative findings.

The PraenaTest® examines certain changes in the chromosomes – known as chromosomal disorders – in the genetic material of your unborn child. Previous tests determine these chromosomal disorders using ultrasound, such as in the case of nuchal fold thickness measurement, for example, as well as by measuring certain pregnancy hormones in the blood. They are non-invasive and thus they also are safe for the child, but they have limited accuracy. In addition, there are also invasive test methods in which amniotic fluid or placental tissue is sampled during a medical procedure and examined. The invasive methods have a very high degree of accuracy, however, they run the risk of a miscarriage.

With the PraenaTest®, a new testing method with the advantages and without the drawbacks of the two conventional methods is now available to you. On the one hand, it is safe for your unborn child and on the other hand, it determines very accurately whether or not any of the chromosome disorders tested are present.

Read more about the PraenaTest® on the following pages and get complete information and advice from your doctor.

Sincerely Yours,

Dr. rer. medic. Wera Hofmann
Medical-Scientific Director

The PraenaTest®

What can the PraenaTest® detect in my child?

The PraenaTest® can detect certain changes to chromosomes, so-called chromosomal disorders, in your unborn child. These are the trisomies 21, 18 and 13, Klinefelter and Turner syndrome as well as triple X and XYY syndrome. More information about these chromosomal disorders, their causes and effects can be found at www.lifecodexx.com. With the PraenaTest®, you can individually decide which chromosome disorders you would like to test for. For example, you can test your child only for trisomy 21 or for the three trisomies 21, 18 and 13. Talk to your doctor about which tests are advisable for you in your personal situation. Incidentally: If desired, you can also learn whether you are expecting a girl or a boy.

How safe is the PraenaTest®?

In studies to assess the accuracy of the PraenaTest® in single pregnancies, a correct result was determined in 99.8% of all blood samples. This means that out of 1000 blood samples tested, only two results were not correct. The accuracy of the PraenaTest® was also verified in twin pregnancies. The result was correct in all blood samples tested. Since there were no cases with trisomy 13 or 18 in these studies, there are still no scientific data on this (Feb. 2014). The accuracy of the PraenaTest® to determine numerical maldistributions of the sex chromosomes (X and Y) was also investigated in clinical studies. It is currently less accurate than the PraenaTest® in the case of trisomies 21, 18 and 13 and may vary, depending on the chromosomal disorder tested.

TÜVRheinland® ZERTIFIZIERT
Management System EN ISO 13485:2012
www.tuv.com ID 0000038150

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Limits of the test

The PraenaTest® cannot be used to determine structural changes to chromosomes. In these cases, for example, a piece of a chromosome is missing, there is an extra piece or a piece was incorporated incorrectly in the chromosome. So-called „mosaics" can also not be definitively determined. In a mosaic, cells of a tissue or of the entire organism of the embryo have different genetic information. In addition, despite performing the PraenaTest® with utmost care, there may be no or an unclear test result. It may then be necessary to repeat the test. We may then need a new blood sample from you. It is important for you to know that this does not reveal anything about the health of your child.

What happens to my genetic data and my child's data?

Your personal data and your child's data are in safe hands with us. Your blood samples and all of the associated information are used exclusively for the genetic testing which you ordered. The test result is sent exclusively to your doctor or his/her representative, if one was named in the test order.

Your pregnancy

Should I have the PraenaTest® performed?

You and your doctor will decide together whether the PraenaTest® is appropriate for you. Well over ten thousand women have already undergone the PraenaTest®. They decide to undergo the blood test due to their age or because they had concerns following other positive test results. Many women also have the PraenaTest® performed because they simply have concerns that their child could be affected by a chromosome disorder.

I am pregnant following infertility treatment. Can I have the PraenaTest® performed?

Yes. The PraenaTest® can be used without any limitations following infertility treatment, including after egg donation.

Approx. 55%

... of pregnant women, who have the PraenaTest® performed are over 35 years of age.

Approx. 29%

... of the women displayed anomalies in the ultrasound or at a blood test within the scope of the first trimester screening.

Approx. 13%

... of the women who took the PraenaTest® were inspired by a psychological need for security.

„In our case, our health insurance plan covered the costs of the PraenaTest® in full, which really made things easy for us."

(found on eltern.de/foren)

From which week of pregnancy can I undergo the PraenaTest®?

You can generally undergo the PraenaTest® after the ninth week of pregnancy has been completed (week 9+0 since LMP). However, our experience shows that it is generally performed in connection with an ultrasound, that is, generally starting in the 12th week of pregnancy. Discuss with your doctor when the PraenaTest® would be most advisable for you personally.

I'm expecting twins. Can I have the PraenaTest® performed anyway?

Yes. The PraenaTest® can be performed in the case of twin pregnancies. The price of the PraenaTest® is still the same.

The price

What does the PraenaTest® cost and how do I pay?

The price depends on the scope of the selected test. Discuss with your doctor which chromosomal disorders may be of significance for you. Payment is made via direct debit. The amount will not be debited until the test result has been forwarded to your doctor.

	PraenaTest® Option 1	PraenaTest® Option 2	PraenaTest® Option 3
Can be used in the case of/following	Trisomy 21, Gender determination	Trisomy 21, 18, 13, Gender determination	Trisomy 21, 18, 13, Maldistribution of the sex chromosomes, gender determination
Single pregnancy	■	■	■
Twin pregnancy	■	■	–
All fertility treatments (IVF, ICSI, etc.)	■	■	■
Price including VAT & shipping	**EUR 595 CHF 800***	**EUR 745 CHF 950***	**EUR 895 CHF 1,100***
Test result in 2 weeks. Guaranteed in 1 week with express service (for an additional EUR 100/CHF 100*).			
*suggested price			

Will my health insurance plan cover the costs of the PraenaTest®?

The PraenaTest® is known as a self-pay service. This means that you must pay the costs yourself. However, private as well as statutory health insurance plans have already paid for the costs in many individual cases. Therefore you must clarify whether your health insurance plan will also cover the costs, if applicable.
At www.lifecodexx.com you will find step-by-step instructions and many useful templates to help you.

The test procedure

Where can I have the PraenaTest® performed?

If you are interested in having the PraenaTest® performed, first speak with your doctor. If he/she does not perform the test him-/herself, he/she may refer you to a specialized prenatal diagnostic center or to a doctor specializing in human genetics. You can also find additional locations in your area using our medical practice finder at www.lifecodexx.com.

I have decided to undergo the PraenaTest®. What happens next?

After your doctor has provided you with comprehensive information and genetic counseling and after you have signed the order and the informed consent form for the PraenaTest®, the doctor will take blood from a vein in your arm using a special PraenaTest® blood sampling set. Your blood will be sent via overnight courier to our diagnostic laboratory in Konstanz (Baden-Wuerttemberg, Germany), where we will analyze it. Incidentally – only in the case of the PraenaTest® does the analysis take place in Germany according to German and European quality and data privacy standards.

The test result

How quickly will I receive the test result?

Your doctor will receive the test result in an average of eight to ten working days after your blood sample is received in our diagnostic laboratory and following successful quality control. He/she will inform you of the result. If the express service is selected, your waiting time will only be four to six working days.

If the test result is negative – does that mean that my child is healthy?

An unremarkable, negative test result means that the presence of the chromosomal disorders tested in your child can be ruled out with a high degree of accuracy. Nonetheless, your doctor will track the rest of your pregnancy particularly closely. If your child is affected by another illness, the PraenaTest® cannot provide any information about this. The PraenaTest® is also unable to determine certain special forms of chromosomal disorders. For more information, see the section entitled "Limits of the test" and talk to your doctor.

If the test result is positive – what's the next step?

An abnormal, positive test result means that your unborn child is highly likely to have the chromosomal disorder in question. According to medical recommendations, the test result should then be further clarified diagnostically by an invasive examination, generally amniotic fluid testing. This is also necessary because in very rare cases, the chromosomal disorder demonstrated may be present in the placenta, however the unborn child itself is not affected by it.

More information about the PraenaTest®

Visit **www.lifecodexx.com** for more information, many useful links and practical templates to clarify whether your health insurance plan will also cover the costs.

Or simply give us a call. We´re here to help you!

Telephone +49 (0) 7531 9769460

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PraenaTest®

Get Clarity.
Reliable. Rapid. Safe.

Non-invasive prenatal testing for chromosomal disorders

- Can be used in single and twin pregnancies
- Can be used after infertility treatments
- Test result in 4 – 6 working days (express service)
- Covered by health insurance plans in many individual cases
- Performed in Germany in accordance with European quality and data privacy standards

If you have any questions, please call us
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Clinic / practice stamp