NEW
PraenaTest® express
Your results in just 1 week

PraenaTest®

Quality made in Europe

Non-invasive prenatal testing for fetal trisomies

Information and explanations for expectant mothers

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Dear expectant mother,

probably all parents-to-be wonder if their child will be born into this world healthy. Your doctor will inform you about the possibilities available for checking the health of your unborn child in the womb. The majority of prenatal examinations report no anomalies, which also contributes to reducing anxiety and to a problem-free pregnancy. Of course, it is up to you to decide which diagnostic options you wish to employ personally or whether you maybe prefer to do without special prenatal examinations altogether.

One important element of prenatal diagnostics are checks for possible chromosome mutations in the child, for example trisomy 21, in which the child has three copies of chromosome 21 instead of the usual two. Trisomy 21 is typical of Down syndrome and is one of the most common chromosomal disorders. Trisomy 18 and trisomy 13 are much less common. Have your doctor explain the significance of these chromosomal disorders to you and discuss with him whether your child is at a relevant risk of developing one of these fetal trisomies.

If you and your doctor decide to have your unborn child tested for these chromosome mutations (trisomy 21, 18 and 13), the non-invasive PraenaTest® is a risk-free alternative to invasive examinations such as amniocentesis (amniotic fluid test). In general, invasive examinations are associated with a miscarriage rate of approx. 0.2% to 1%.

The PraenaTest® can establish with a great degree of certainty whether your unborn child has one of the trisomies listed above or not.

Possibilities in prenatal diagnostics for identifying infantile chromosomal disorders

Prior to the birth, there is the possibility of performing non-invasive and invasive examinations. Standard non-invasive examinations calculate the probability that the unborn child will be the carrier of a trisomy. A high risk of trisomy is calculated in up to 5% of examinations although there is actually none present. In the past, the only way to verify these results was with invasive methods. Today, the non-invasive PraenaTest® provides pregnant women with valuable information to help them decide on or against invasive prenatal diagnostics.

The examination methods in comparison

Prenatal diagnostics for infantile chromosomal disorders, in particular trisomy 21, 18, 13

Non-invasive, e.g., first trimester screening

Ultrasound, analysis of certain pregnancy hormones in the mother's blood

- \+ No risk of miscarriage
- − Calculation of probability

Non-invasive, molecular genetic: PraenaTest®

Analysis of fragments of the child's genetic material in the mother's blood

- \+ No risk of miscarriage
- \+ Clear result

Invasive

Amniocentesis, analysis of placenta

- − Risk of miscarriage 0.2 – 1%
- \+ Clear diagnostic result

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What happens in the PraenaTest®?

Once your doctor has informed you comprehensively and you have received genetic counselling and signed a declaration of consent for the PraenaTest®, your doctor will take a blood sample. This blood will then be sent to the LifeCodexx diagnostics laboratory in Baden-Württemberg, Germany. The analysis takes one week (express) or two weeks (standard). The results are sent to your attending doctor, who will inform you of the results of the analysis.

When is the performance of the PraenaTest® recommended?

The PraenaTest® was developed for women in high-risk pregnancies in terms of the listed trisomies. Risk factors include the following:

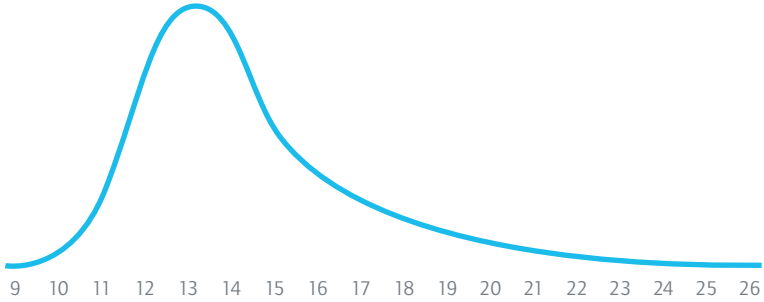
- Age 35 years or older
- Anomalies in the ultrasound or blood tests within the scope of the first semester screening
- Previous pregnancy with a fetal trisomy
- Genetic risk of fetal trisomy in family

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 blood tests within the scope of the first semester screening

Approx. 13% of the women who took the PraenaTest® were inspired by a psychological need for security

Thousands of women have already had the PraenaTest® performed in specialised prenatal medical clinics and practices. An inconspicuous result brought immense relief about the health of their unborn child to the majority of these women (approx. 98%).



In which week of pregnancy is the PraenaTest® performed?

The PraenaTest® can be performed as of week 9+0. As experts only recommend performance after a differentiated ultrasound, the PraenaTest® is usually performed in combination with the first trimester ultrasound. You can plan a suitable time window together with your doctor.

What is the next step if the result of the test is negative?

A negative test result means that you can rule out the presence of trisomy 13, 18 or 21 in your child with a great degree of certainty. Nevertheless, depending on the medical reason for which the PraenaTest® was performed, your responsible doctor will continue to monitor you especially carefully throughout your pregnancy and may advise the performance of additional tests, usually by ultrasound.

What is the next step if the result of the test is positive?

A positive test result indicates that there is a great degree of certainty that your unborn child has the trisomy in question. It is then expressly recommended to undergo human genetic counselling and then to clarify the result of the PraenaTest® diagnostically in an invasive examination, usually amniocentesis. This additional examination is also necessary as in extremely isolated cases, the chromosomal defect detected may be present in the placenta, but the unborn child itself may not be affected.

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PraenaTest® – Quality made in Europe

If you and your doctor decide on the performance of a non-invasive, molecular genetic blood test, ensure that the quality is controlled and certified in Europe. PraenaTest® is the only test where the analysis is performed in Germany in accordance with the European quality and data privacy standards.

Where can I take the PraenaTest®?

If you are interested in the PraenaTest®, please ask your attending gynaecologist and visit www.lifecodexx.com

PraenaTest® – Knowledge with a high degree of certainty

The PraenaTest® determines the free trisomies 13, 18 and 21 with a great degree of certainty. In studies conducted to assess the PraenaTest®, 99.8% of all blood samples were determined correctly. In just one case, a trisomy 21 was not detected (false negative), and in another case trisomy 18 was wrongly determined, which was not present in the unborn child in reality (false positive). The PraenaTest® does not detect other chromosomal disorders or rare forms of the listed trisomies (so-called "mosaic trisomies" and "structural aberrations"), so it is not possible to make any valid statements in this respect. In isolated cases, despite the test having been performed carefully, it might still prove impossible to achieve any or a definitive result. In this case it may be necessary to repeat the test and consequently to request a new blood sample.

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- Certified Management System
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