Dear expectant mother,

alongside other methods, the non-invasive PrenaTest® offers the possibility of testing your child for various chromosomal disorders after the 9th week of pregnancy has been completed.

Before the test is performed and you provide a blood sample, it is important that you understand the possibilities, restrictions and risks of this testing method so that you can make an informed decision.

What can the PrenaTest® detect in my child?
The PrenaTest® can detect certain changes to chromosomes, so-called chromosomal disorders, in your unborn child:

**Trisomy 21, 18 and 13**
If a certain chromosome is present in the cells of the child three times instead of two times as usual, this is referred to as “trisomy”. The most frequent is trisomy 21, in which chromosome 21 is present three times in the child instead of twice. It causes Down syndrome and occurs approximately once in every 500 to 800 births. The risk of maldistribution of chromosome 21 increases with increasing age of the woman and also of the man. Trisomy 18, also known as Edwards syndrome, occurs much more rarely. It occurs in approximately one out of 5000 newborns. Trisomy 13, known as Patau syndrome, is even rarer. Estimates indicate that it occurs once in every 16,000 births.

**Monosomy X (XO) / Ullrich Turner syndrome**
If one chromosome is missing from a pair of chromosomes and is thus present only once instead of twice as usual, this is known as “monosomy”. In monosomy X (also known as Turner syndrome or Ullrich Turner syndrome), the second sex chromosome is missing. It is the only viable monosomy in humans, affects only girls, and occurs approximately once in every 2500 female infants.

**Triple X syndrome (XXX)**
In so-called triple X syndrome, three copies of the X chromosome are present. This disorder also affects only girls and occurs approximately once in 1000 female newborns.

**Klinefelter syndrome (XXY)**
In Klinefelter syndrome, which affects only boys, an additional X chromosome is present in the cells of the body. This occurs in approximately one out of 500 male newborns.

**Diplo Y-Syndrom/Jacobs syndrome (XYY)**
In XYY syndrome, which also affects only boys, there is an additional Y chromosome in the cells. This occurs in approximately one out of 1000 male newborns.

**22q11.2 Microdeletion syndrome**
In this syndrome there is a chromosome alteration on the chromosome 22, which can influence the development of the unborn child. It occurs in about one out of 6000 newborns. Your physician will request the determination of this chromosomal
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disorder, also known as "DiGeorge syndrome", only in the case of a concrete medical indication.

The PrenaTest® can be performed in case of twin pregnancies and after infertility treatment (including egg donation).

What happens in the PrenaTest®?
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 PrenaTest®, the doctor will take about 20 ml of blood. Your blood will be sent via overnight courier to the diagnostic laboratory. Your doctor will receive the test result in a few working days after your blood sample is received in the laboratory and following successful quality control. He/she will inform you of the result.

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 PrenaTest® cannot provide any information about this. The PrenaTest® is also unable to determine certain special forms of chromosomal disorders. For more information, see the section entitled “Limits of the examination” 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.

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 correctly detected in all blood samples.

It is important for you to know that 100% accuracy in the use on 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 examination
The PrenaTest® 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 PrenaTest® 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.

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Alternatives to the PrenaTest®

The main non-invasive, prenatal examination available as an alternative to the PrenaTest® in the first and second trimester is an ultrasound examination, possibly in combination with an analysis of some of the mother’s blood values.

Definitive diagnosis of the presence or ruling out of a chromosomal disorders, and other chromosomal defects or certain other conditions is only possible by means of an invasive method such as testing the amniotic fluid (amniocentesis) or the placental tissue (chorionic villus sampling). The risk of losing the child as a result of this type of invasive procedure is estimated at approx. 0.2-1%.

Please note

The majority of prenatal examinations report no anomalies, which also contributes to reducing anxiety and to a problem-free pregnancy. However, if anomalies are found during an examination, that often leads to a sometimes considerable uncertainty and conflict. Your doctor will inform you comprehensively and offer you support. In this situation in particular, psychosocial counselling is also recommended. Your doctor will be able to provide you with further information.

Genetic counselling

In addition to the patient briefing, the German Genetic Diagnostics Act (GenDG) stipulates that pregnant women must be offered genetic counselling prior to the performance of an additional examination and once the results of the examination are available.

In accordance with the GenDG, genetic counselling prior to a genetic examination includes:

- the clarification of your personal situation
- the analysis of available medical findings or test reports
- the investigation of your personal and family medical histories for anomalies relating to the examination (anamnesis)
- information about the necessity for a genetic examination taken from your personal situation or medical history

Genetic counseling must be offered prior to the performance of an additional examination and once the results of the examination are available.
Consent to perform the PrenaTest® in accordance with the German Genetic Diagnosis Act (GenDG) §9

I have received, read and understood the general written information (and the additional special written information, as the case may be) on genetic analyses pursuant to GenDG. With my signature I provide consent to the PrenaTest® analysis as well as to the blood withdrawals that shall be required for this purpose.

I am aware that I am not informed about results that are not directly related to the actual question (so-called incidental findings). I had sufficient opportunities to discuss any questions I had.

I have been advised that I may fully or partially recall my consent at any time, without having to provide any reasons, without such decision resulting in disadvantages to my person, and that I have the right to not be informed of the test results (right to ignorance).

I am aware that I may halt already initiated testing procedures, up to notification of the results, at any time. I may also request the destruction of the test materials, including any components obtained as a result, as well as all results and findings compiled up to that point. The revocation must be in written form. If I do not wish to be notified of the results of the examination, I am still obligated to pay LifeCodexx AG for the services rendered according to the company’s Terms and Conditions.

Additional notes (to be completed by the doctor)

Place / Date

Name and first name of the patient (in capital letters)

Signature of the patient