How long does GOLDnatal® take and how much does it cost?

GOLDnatal® costs CHF 534.- incl. a test repetition if the first evaluation does not lead to a conclusive result (incl. gonosomal aneuploidies CHF 634.-). Tests that give no conclusive results are free of charge. If the first trimester test shows an anomaly, GOLDnatal®(without gonosomal aneuploidies) can be reimbursed by the national health scheme. It takes 4 working days for the test to be carried out.

How and where is GOLDnatal® performed?

GOLDnatal® is based on an analytical procedure by Illumina® and is carried out in our laboratory facilities in Goldach SG, Switzerland.

M14783

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GOLDnatal®

High-sensitivity, non-invasive prenatal test

labor team w ag

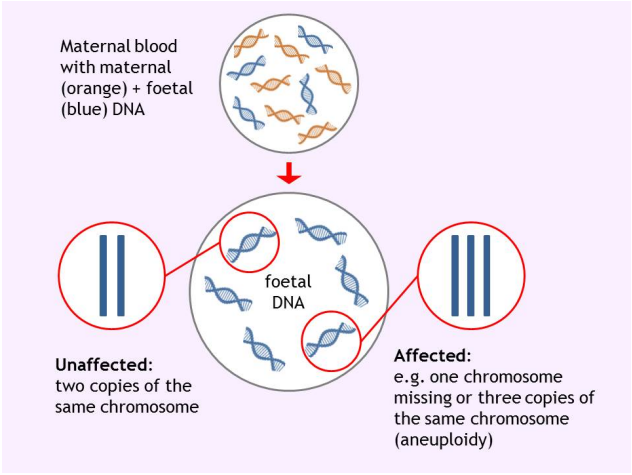
Dear mother-to-be

There are many reasons for being concerned about the health of your unborn child. Whether it be related to age, an abnormal first trimester test, or a child in the family who is suffering from an congenital illness. GOLDnatal® is a high-sensitivity, non-invasive prenatal test in the early stages of pregnancy.

This test detects certain future or existing potentially harmful condition in the child. Based on the results, action can be taken and early preparations can be made for post-natal treatment.

How GOLDnatal® works

The human body's cells contain 23 pairs of chromosomes that carry genetic information (DNA). For each of these pairs, one chromosome stems from the mother and one from the father. A pair of chromosomes determines the gender: girls have two X chromosomes and boys have one X and one Y chromosome. During pregnancy, small parts of foetal and placental DNA enter the mother's bloodstream. This can be isolated from the mother's venous blood and sequenced by means of state-of-the-art technologies (MPS = Massive Parallel Sequencing). The DNA from the chromosomes can be classified and quantified to find any chromosome abnormalities.



Chromosome abnormalities detected by GOLDnatal®

Irregularities arise if a pair of chromosomes has an extra chromosome or if one is missing. In the case of trisomy, a chromosome of the body cells occurs three times instead of twice. The likelihood of this genetic defect increases with the mother's age. GOLDnatal® offers the possibility of testing for the most frequently occurring forms of trisomy.

Trisomies

Trisomy 21 (Down syndrome): Trisomy 21 is the most well-known and the most frequent chromosome defect (occurrence: 0.2% (Switzerland)). Typical symptoms include mental retardation, developmental delays and anomalies of some organs (e.g. hearing and sight problems, heart defects).

Trisomy 18 (Edwards syndrome): Trisomy 18 (occurrence: approx. 0.04% (Switzerland)) causes very serious developmental defects. The majority of foetuses do not survive birth. The symptoms and the severity vary greatly; a total of over 100 different malformations are associated with the Edwards syndrome.

Trisomy 13 (Patau syndrome): The Patau syndrome (occurrence: 0.01< - 0.02% (Switzerland)) causes serious malformations of various organs. Most foetuses die before birth and only few babies survive the first year.

Sex chromosome aneuploidies

Sex chromosome aneuploidies are described as defects of the sex chromosomes. GOLDnatal® tests for the following anomalies:

Monosomy X (Turner syndrome): In monosomy X, an X chromosome is partly or entirely missing. There is no mental disability and the life expectancy is within the average range for the whole population. Hormone treatment can help ensure normal development for affected girls.

Triple-X syndrome: With trisomy X, the woman has an additional X chromosome. Affected women often have an above-average body size. Most women are only slightly affected or don't suffer from any symptoms at all.

Klinefelter syndrome (XXY): Healthy men have an X and a Y chromosome, while those with Klinefelter syndrome have an additional X chromosome. There is no mental disability, the body size is above average and there is often a testosterone deficit.

Jacobs syndrome (XYY): Men with Jacobs syndrome have an additional Y chromosome. Affected men often have an above-average body size. Their intelligence, life expectancy and fertility are largely unaffected.

Reliability of GOLDnatal®

GOLDnatal® is, unlike the invasive amniocentesis procedures or chorionic villus sampling, a non-invasive prenatal test that simply requires a venous blood sample for the analysis. This means there is no risk for you nor for your child. Compared with other non-invasive tests (e.g. first trimester test) GOLDnatal® is much more reliable:

GOLDnatal® sensitivity >99%; i.e. more than 99% of the tested chromosome abnormalities are correctly detected by the test. Specificity >99.9%; i.e. the frequency of an incorrectly diagnosed chromosome defect is less than 0.1%.

First trimester test sensitivity 85%; i.e. 85% of the tested chromosome abnormalities are correctly detected by the test. Specificity >95%; i.e. the frequency of an incorrectly diagnosed chromosome defect is approx. 5%.

Limitations of GOLDnatal®

With GOLDnatal®, a risk assessment (high/low risk) is provided for each syndrome previously described. If there is a high risk of one of these, a conclusive test by means of amniocentesis/chorionic villus sampling is strongly recommended. A low risk means that it is highly likely that your child does not carry the chromosome abnormalities being tested for. As with all non-invasive prenatal tests, it is not possible to guarantee 100% certainty.

In rare cases, it is possible that an insufficient quantity of foetal DNA in the mother's blood poses a limitation to the reliability of the test result. A twin that dies during early pregnancy (vanishing twin) or a variation in the chromosome pool of the placenta cells (placenta mosaic) can also lead to results with limited reliability. For twin pregnancies, the test is suitable to detect trisomies 21, 18 and 13, but not sex chromosome aneuploidies.

GOLDnatal® can be carried out from the 10th week of pregnancy (9+0 WOP).