

Surname, <i>Firstname</i>	DOB
Address:	

Information sheet and declaration of consent for first-trimester screening for chromosomal abnormalities and screening for preeclampsia

in the first third of pregnancy (CRL 45,0 mm – CRL 84,0 mm)
according to the German Genetic Diagnostics Act (GenDG)

Dear patient

First-trimester screening can give **early information about the risk of having a baby with an abnormal number of chromosomes**. Screening by a combination of maternal characteristics, ultrasound markers and biochemical maternal serum markers offers best detection rates. A positive screening test result does not establish the presence of a chromosomal abnormality in your child. The purpose of the screening test is to detect an individual risk for disease. If the screening test results in a high risk this may give rise to further diagnostic approaches. On the other hand, if the screening test results in a low risk this does not exclude a chromosomal abnormality with absolute certainty. Your physician will provide you with detailed information about the first-trimester screening test.

In addition, an **individual risk for the severe pregnancy-specific hypertensive disease preeclampsia** can be determined within the first-trimester screening. For this purpose, it is necessary to detect another maternal serum marker, the placental growth factor PIGF. Screening for high risk of progression to preeclampsia at initial presentation could greatly aid in the management of patients with gestational hypertension. A positive screening test result enables a preventive therapy with low-dose acetylsalicylic acid (ASA). Treatment with low-dose ASA in women at high risk for preterm preeclampsia reduces substantially the incidence of this disease.

The first-trimester screening for chromosomal abnormalities as well as the screening for preeclampsia are medical contracts that are not chargeable to health insurance companies. If you decide to do a first-trimester test, you will have to bear the costs for detection of the biochemical serum markers yourself:

- GOÄ € 33,52** – screening for chromosomal anomalies
- GOÄ € 60,48** – screening for preeclampsia
- GOÄ € 77,24** – screening for chromosomal anomalies & for preeclampsia

Declaration of consent for prenatal risk assessment

I had the opportunity to speak to my physician about the meaning and the possible consequences of the intended prenatal risk assessment. My queries were answered satisfactorily. I have no further questions. With my signature, I hereby confirm that I have been sufficiently informed and that I do agree to implementation of a prenatal risk assessment. I will pay the above-mentioned costs by myself.

Declaration of consent for maintaining of investigational material

- I agree that my specimens may be archived for result verification purposes or further diagnostic testing.
- Test results may be archived after the final medical report for a longer time than the statutory period of 10 years. This allows the verifiability of test results. However, claims for storage of specimens and extended archiving of test results cannot be asserted.
- I agree that my specimens may be stored for quality control purposes in pseudonymous form.
- I agree that, if required, my specimens may be forwarded to collaborating medical laboratories.

— strike out if not applicable —

All personal data and test results are subject to medical confidentiality and the general data protection regulation (GDPR). All medical findings are reported to the submitting physician and will only be disclosed with prior consent. I may withdraw my consent without giving any reason entirely or in part at any time.

place, date signature of patient/ signature of parent or legal guardian

place, date **responsible physician** (print name, signature, seal)

I agree that the invoice for the above-mentioned testing will be generated by the Privatärztliche Verrechnungsstelle Sachsen (PVS). For that purpose, I agree that all relevant data regarding the invoice will be transferred to the Privatärztliche Verrechnungsstelle Sachsen GmbH.

place, date signature of patient/ signature of parent or legal guardian