

surname, forename	DOB
address:	

## Information Sheet and Consent Form 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 samples are stored after completion of the biochemical assay and the final report for checking purposes as well as for possible other diagnostic tests. Test results can be kept beyond the legal period of 10 years. No claim to storage can be made.

I agree that my samples are stored in pseudonymous form for quality control purposes.

I agree that the investigation could be transferred to another specialised laboratory if the test cannot be performed in the above-mentioned laboratory.

— strike out if not applicable —

Of course, your personal data and the results of any examinations are subject to medical confidentiality requirements and to the legal requirements for data protection (DSGVO). Transmission of your test results occurs only with your prior approval. The declaration of consent or parts of the declaration can be revoked in writing without giving any reasons at any time.

location, date

signature of the patient respectively legal guardian

location, date

**liable physician** (print name, signature and stamp)

I agree that the invoice for the above-mentioned test is generated by the "Privatärztliche Verrechnungsstelle Sachsen (PVS)". Therefore, I agree that all data, which are necessary for registration of the invoice, can be transmitted to the PVS GmbH.

location, date

signature of the patient respectively legal guardian