

Workplace address:

Genetika Plzeň, s.r.o., Parková 1254/11a, 326 00 Plzeň

Phone: +420 377 241 529, 603 174 793

INFORMED CONSENT WITH GENETIC TEST: NON-INVASIVE PRENATAL TESTING (NIPT) USING PANORAMA KIT**1. PURPOSE OF NON-INVASIVE PRENATAL TESTING**

The purpose of NIPT is to non-invasively screen for trisomies of chromosomes 21 (Down syndrome), 18 (Edwards syndrome), 13 (Patau syndrome) and aneuploidies of the X and Y chromosomes. Chromosomal aberrations are manifested by a specific appearance, intellectual disability, and multiple organ defects. Treatment of chromosomal disorders is currently unavailable. The sex of the fetus is determined by detecting the Y-chromosome DNA. The patient will not be informed of the fetus sex until after 12 weeks of pregnancy.

2. SAMPLING AND NIPT PROCEDURE

Approximately 20 ml of blood is needed for the test. The blood is collected into „EDTA/Cell-Free DNA Streck“ tubes by needle puncture after disinfection of the puncture site. The tubes with collected blood must be gently inverted eight to ten times. Plasma is separated by centrifugation within 48 hours after blood collection and then used for DNA isolation and testing with the Panorama TM kit (Natera, USA) in cooperation with Biopstická laboratoř s.r.o. The result of the examination will be made available within three weeks after sample receipt. The fee for NIPT will be refunded a) if the test is not concluded even after repeated (the second) sampling; b) if the result of the second sample is likely to be known after 24 weeks of gestation; or c) in case of a false-positive result.

3. RISKS OF THE PROCEDURE AND OF UNEXPECTED FINDINGS FOR THE PATIENT AND RELATIVES

Prenatal non-invasive testing is free from the risk of spontaneous abortion or infection and is highly accurate. During blood collection, bruising or inflammation may very rarely occur at the puncture site. Although recently published data have confirmed accuracy of this test for the trisomies of chromosomes 21 (99%), 18 (96.4%), and 13 (99%) and for the monosomy of chromosome X (92.9%), it should only be considered a highly effective screening but not a diagnostic test. Therefore, in the case of a positive finding of fetal impairment, the result must be verified by the invasive examination of chorionic villus sampling (CVS) or of the amniotic fluid (AMC). Due to the limitations of current technology, a negative (normal) NIPT result cannot completely exclude fetal impairment.

4. LIMITATIONS AND RESTRICTIONS OF PANORAMA TEST

Pregnant women who have undergone bone marrow transplantation, blood transfusion within the last six months, or have suffered vanishing twin syndrome cannot be subject to the Panorama NIPT test. The test cannot be evaluated if the fetal fraction is less than 2.8%.

5. NIPT EXAMINATION HAS THE FOLLOWING ALTERNATIVES

Invasive examination, i.e., chorionic villus sampling (CVS) and amniocentesis (AMC), or non-invasive tests offered by other companies. You are entitled to choose from the above alternative tests.

6. INFORMATION ON POSSIBLE LIMITATIONS IN THE USUAL WAY OF LIFE AND ABILITY TO WORK

Blood collection poses no limitations. The examination itself is non-invasive and therefore does not restrict you in the normal way of life.

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7. INFORMATION ON THE PATIENT'S RIGHT TO DECIDE FREELY ON THE PROCEDURE FOR THE PROVISION OF HEALTH SERVICES

In accordance with Section 28(1) of Act No 372/2011 Coll., on Health Services, the patient has the freedom of decision on the proceeding with the provided healthcare unless other legislation states otherwise.

8. CONSENT TO THE EXAMINATION

I agree to the above described collection of blood samples, their centrifugation, plasma extraction, DNA isolation and testing in the molecular genetic laboratories of Genetika Plzeň, s.r.o., Parková 1254/11A, Plzeň and Bioptická laboratoř s.r.o., Mikulášské nám. 4, Plzeň. I also grant permission to Genetika Plzeň s.r.o. to interpret the test results. I declare that I have been fully and sufficiently informed by the attending physician about the reasons leading to the planned examination. The doctor has informed me in detail and in a comprehensible manner about the procedure and nature of the proposed examination, its advantages and success rate. I further declare that I have been informed by the physician of the consequences and possible risks of this method, of its alternatives and of other relevant circumstances relating to the examination. The physician has also informed me of the possible restrictions on my way of life and ability to work after the test has been carried out and of my right to decide freely whether to undergo this examination. I had the opportunity to ask the physician about anything I did not understand. The doctor answered all my additional questions clearly and comprehensibly. I fully understood all the points in the instructions and the answers to the additional questions. I further declare that I have disclosed to the physician all the facts relevant to the assessment of my condition. I accept the warning that if this statement is false, neither the above companies nor the attending physician shall be liable for the consequences arising therefrom. I will inform the doctor immediately in writing in the event of any substantial change. I agree to the processing of my personal data by Genetika Plzeň s.r.o. and to use of my clinical data by the attending physician or the laboratory for audits, quality control of examinations, and scientific purposes while keeping my personal data anonymous.

Name of the examined woman:

Insurance No./Date of birth of the examined woman:

I wish to know the sex of the fetus:

 YES NO

Signature of the examined woman

(or of her legal representative): Date:

I, the undersigned, hereby certify that I have duly informed the patient (legal representative) as stated above.

I further certify that the patient has received genetic counselling in accordance with the active legislation.

Clinician's signature: Date:

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