NICE® Non Invasive Chromosome Examination

Test Requisition Form

PATIENT INFORMED CONSENT FOR NICE® PRENATAL TEST

This blood test is designed to measure the combined maternal and fetal DNA present in maternal blood, and is considered a genetic test. Your written consent is required to perform a genetic test. This consent form provides information about the Eone-Diagnomics Genome Center (Hereinafter "EDGC") NICE® prenatal test, including what the test is for, the testing process, and what results may mean. Before signing this document, you should ask your healthcare provider to answer any questions you may have about this test.

NICE® prenatal test: The NICE® prenatal test looks at the DNA (genetic material) in your blood. The test can tell if there are too many or too few copies (also called an "aneuploidy") of certain chromosomes 21, 18, 13, 9, 16, 22 and sex chromosomes —present in your fetus. The test can also look at sex chromosomes (X and Y). The NICE® prenatal test has been studied in patients who have an increased risk for having a baby with an incorrect change in the number of certain chromosomes. Your healthcare provider has determined that you are an appropriate candidate for this test.

Common Aneuploidies: Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome), Trisomy 13 (Patau syndrome). Trisomies occur when three, instead of the usual two, copies of a chromosome are present. Trisomy 21, trisomy 18, and trisomy 13 are three of the most commonly occurring trisomies seen in babies at birth. Although the outcomes are variable, these conditions can cause mild to severe intellectual disabilities, and can cause multiple physical problems including congenital heart defects, defects in other organs, and a shortened life span. The chance of having a baby with one of these conditions gets higher as a woman gets older.1 For more information on these conditions, please visit our website at http://www.edgc.com. Your healthcare provider or genetic counselor can also give you more information about these conditions. If your healthcare provider chooses the sex chromosome option, and no sex chromosome aneuploidies are found, then the test report will state whether your baby is expected to be a girl or boy. If you do not wish to know the gender of your baby, please let your healthcare provider know in advance to not disclose this information to you.

The Testing Process: To analyze the DNA from your blood, your healthcare provider will take a blood sample from you (between 8 and 10mL, in a standard blood draw). The physical risk to you of obtaining the blood sample is usually minimal.

Some important points about the testing and reporting process:

- Your test results are confidential to the extent required by law. The EDGC Notices of Privacy Practices set forth the companies' privacy policies and are available on the company websites at http://www.edgc.com.
- Only EDGC personnel will have access to your blood sample and testing information and results. All results will be kept confidential as per applicable laws and guidelines. Results will only be disclosed to your ordering healthcare provider(s).
- Only authorized tests will be performed on your identified blood sample.
- Your sample will be destroyed at the end of the testing process, in accordance with our company's requirements. Collecting information on your pregnancy after prenatal diagnosis is part of a laboratory's standard practice for quality purposes, and is required in several states. As such, EDGC may contact your healthcare provider to obtain this information.

The test is performed after 10 weeks, 0 days of pregnancy. Adequate DNA in the blood sample is required to complete the test. Additional samples may be needed if the sample is damaged in shipment or incorrectly submitted. After analysis in EDGC genetic laboratory, the test results will be returned to your healthcare provider, who will discuss them with you.

Obtaining and Interpreting Test Results:

Your test results will be returned to your healthcare provider after analysis by EDGC. The results will be reported by EDGC only to the qualified healthcare provider(s) indicated on the front of this form. Your results will tell your healthcare provider whether too few or too many copies of the chromosomes being tested for are present. It is the responsibility of the healthcare provider ordering this test to understand the specific uses and limitations of this test, and to make sure you understand them as well. If a genetic disorder is detected, follow up testing (such as amniocentesis or chorionic villus sampling) may be recommended to confirm the result.

Limitations of the NICE® Test:

1. NICE® test is designed to screen for fetal chromosome aneuploidies from cell free DNA analysis, and is validated for detecting chromosome 21, 18, 13, 9, 16, 22, X and Y clinical sample testing. This test is also designed to screen for subchromosomal deletions in chromosomal regions- 1p36, 2q33.1, 4p16.3, 5p-, 7q11.23, 11q23, 15q11.2-q13, 22q11.2. The test is validated for singleton pregnancies with gestational age of at least 10 weeks, as estimated by last menstrual period.
2. This test is possible even in the case of twin pregnancies, but only on chromosomes 21, 18, and 13, and available for gestational age of 12 weeks or more.
3. These results do not eliminate the possibility that this pregnancy may be associated with other chromosomal or subchromosomal abnormalities, birth defects, and other conditions. This test is not intended to identify pregnancies at risk for open neural tube defects.
4. A negative test result does not eliminate the possibility of chromosomal abnormalities such as trisomy 21, trisomy 18, trisomy 13, trisomy 9, trisomy 16, trisomy 22. There is a small possibility that the test results might not reflect the chromosomes of the fetus, but may reflect chromosomal changes of the placenta(confined placental mosaicism) or of the mother(chromosomal mosaicism).
5. Potential sources of an inaccurate test result may include but are not limited to: maternal, fetal and/or placental mosaicism, low fetal fraction, blood transfusion, transplant surgery and stem cell therapy. Especially, fetak deduction including vanishing fetus, fetal demise can result in false negative result or false positive result. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis would be necessary.

1. Genetic Disorders and the Fetus: Diagnosis, Prevention, and Treatment. Sixth Edition, ©2010; Milunsky and Milunsky; p 9, Table 1.3, p 197, Table 6.2, p 858, p 4, p 199, p 278

Website: www.edgc.com | E-mail: info@edgc.com

REIMBURSEMENT POLICY FOR NIPT SERVICE

1. **High risk (positive and false positive case)**

   In the case of a "High Risk or False Positive" result, we provide up to maximum THB 25,000 (KRW 821,500) per person about amniotic fluid test for confirmation of high risk in the case of a pregnancy. Please, refer to limitation of NICE® test in TRF.

2. **False negative of delivery baby**

   In the event, compensation is only available for T21/ T18 and T13.

   - NICE®/NICE® LITE/NICE® TWIN: 2,000,000 THB (USD 64,536.96 / KRW 78,096,891)

3. **False negative of terminate pregnancy**

   - NICE®/NICE®TWIN: 100,000 THB (USD 3,228 / KRW 3,904,844)
   - NICE® LITE: 50,000 THB (USD 1,614 / KRW 1,952,422)

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