NICE®
Non Invasive
Chromosome Examination

Test Requisition Form

ACCOUNT / ORDERING CLINICIAN / PROVIDER

Physician Name

Account name (Provider / Hospital)

Address

Phone

PATIENT INFORMATION

PATIENT Name

DOB (dd/mm/yy)

Medical Record / Chart #

Weight lb/kg Height cm

CLINICAL INFORMATION

Gestational age Wks Days

Dating method ☐CRL ☐LMP ☐Date of implantation ☐Other

Date of draw

Specimen type Blood 8-10mL (with NICE® tube)

Comments

TEST INFORMATION

* Include fetal gender in the report

☐ NICE LITE –T21, 18, 13 ☐ without fetal gender

☐ NICE Basic–T21, 18, 13, 9, 16, 22

☐ NICE Premium - All Chromosomes (Trisomies)

Option

☐ Sex Chromosomes (Singleton Only)

☐ 8 Microdeletions

or

☐ 116 Microdeletions/duplications

☐ **Singleton (available for GA 10 weeks or more)**

☐ **Twin (available for GA 12 weeks or more)**

TEST INDICATIONS

☐ Advanced maternal age

☐ Positive serum screen

☐ Abnormal ultrasound

☐ Personal or family history of aneuploidy

☐ IVF (in vitro fertilization)

PATIENT CONSENT

By signing this form, I voluntarily request that EDGC perform the NICE® prenatal test. I have read and have received a copy of the patient consent included below from my provider. The risks, benefits, and limitations of this test have been adequately explained to me.

Date (dd/mm/yy):

Patient Name: (signature)

PHYSICIAN CONSENT

I verify that the patient and prescriber information in this form is complete and accurate to the best of my knowledge and that I have ordered the NICE® prenatal test based on my professional judgment of medical necessity. I have addressed the limitations of this test, and have answered any question to the best of my ability.

Date (dd/mm/yy):

Physician Name: (signature)

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.

About 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 (X and Y)—present in your fetus. The test can also look at microdeletions (1p36, 2q33.1, 4p16.3, 5p-, 7q11.23, 11q23, 15q11.2-q13, and 22q11.2 deletion). 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.

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 all chromosomes in 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, fetal 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

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