Non-Invasive Prenatal Test

▪ Requisition and Consent Form ▪

Sample ID

Barcord

*All required fields MUST be filled in.

Patient Info.	Name*				Registration no.	
	Date of Birth*	YYYY / MM / DD	City/State		Country	
	Ethnicity	□ East Asian □ Southeast Asian □ African □ Caucasian □ Hispanic □ Other _____				
Obstetrical History	□ Pregnancy with genetic disorder : □ Blood transfusion/Stem cell treatment : □ Other specifications :				Abortion history	□ Yes(times) □ No
Clinical Info.	No. of fetus*	□ Singleton □ Twin	Gestational age* (by ultrasound)	weeks days	IVF application	□ Yes □ No
	Patient* height/weight	cm kg	BMI:		Prenatal biochemical screening test	□ Yes (high risk) □ Yes (low risk) □ No
	Significant features	(ex. Ultrasonography, vanishing twin, etc)			NT	mm
Specimen	Date of collection*	YYYY / MM / DD	Hr : Min	□ AM □ PM		

Test Selections

Test Request	□ **G-NIPT Lite (T21, T18, T13)** □ **G-NIPT Basic (T21, T18, T13 + SCA)** □ **G-NIPT Premium (T21, T18, T13 + SCA* + Other Chromosomes + Microdeletions)**	□ **Fetal Sex** (Optional)

*SCA : Sex chromosomal aneuploidies

G-NIPT Test Features

1. G-NIPT is a noninvasive prenatal screening test for detecting numerical chromosome abnormalities such as T21/T18/T13(Down/Edward/Patau syndrome).
2. G-NIPT Basic screens T21/T18/T13 and sex chromosomal aneuploidies [XO/XXY/XXX/XYY(Turner/Klinefelter/Triple-X syndrome/Jacob's syndrome)].
3. G-NIPT Premium screens T21/T18/T13, sex chromosomal aneuploidies [XO/XXY/XXX/XYY(Turner/Klinefelter/Triple-X syndrome/Jacob's syndrome)], deletion syndromes [1p36, 2q33.1, 5p15 (Cri-du-chat), 11qter (Jacobsen)] and other chromosomes.
4. G-NIPT does not report fetal sex, sex chromosome abnormalities and microdeletion syndromes in the case of a twin fetus.

G-NIPT Test Limitations

1. G-NIPT is highly sensitive but not a confirmatory test. It is recommended that a high risk result and/or other clinical indications of a chromosomal abnormal ity be confirmed through fetal karyotype analysis such as amniocentesis. A low risk result does not guarantee an unaffected pregnancy due to the screening limitations of the test.
2. In cases of the patient holding chromosomal aneuploidy, mosaicism, chromosomal microdeletion/duplication, or multiple fetuses, the test result may not be accurate.
3. Patient with blood transfusion, stem cell treatment, or transplantation history may receive inaccurate results due to exogenous DNA.
4. For a variety of reasons, including biological, the test has a failure rate (insufficient quantity of fetal DNA in maternal blood, or low quality test data due to premature testing, a twin fetus, high BMI, specimen hemolysis, transportation issues, or other unknown factors).
5. G-NIPT is not eligible for patients with an excess number of fetuses (more than two fetuses, vanishing triplets) or overweighing patients (over 100kg).
6. G-NIPT test is performed between 10 weeks and 22 weeks of pregnancy, and in the case of vanishing twins, the test can be performed at least 6 weeks after the disappearance, but it is recommended to test after 9 weeks. Test result done earlier than the recommended time may not be accurate.

Informed Consent for Patient

1. I agree to provide accurate personal information.
2. I understand the test is not for diagnostic purposes.
3. I understand the limitations of the test. Test sensitivity and specificity is high, but 'false negative' or 'false positive' test results still may occur.
4. All chromosomal abnormalities of the fetus are analyzed regardless of the test type, but only test options that I have agreed will be reported. However, I understand that maternal chromosomal abnormalities or other conditions that affect the determination of fetal chromosomal aneuploidy may be reported when discovered.
5. I understand that the G-NIPT is not validated for use in the following cases, and therefore the test result may not be accurate.
   - singleton: numerical chromosome abnormalities other than T21, T18, T13, sex chromosomes, and chromosomal microdeletion/duplication syndromes.
   - twins: numerical chromosome abnormalities, chromosomal microdeletion/duplication syndromes
6. I agree that information regarding the sex of the fetus will only be provided under the consent by the patient.
7. I agree to provide clinical information after childbirth, particularly when the infant is later affected by chromosomal genetic diseases.
8. I agree to my clinical information being used anonymously with all my personal information deleted, for test warranty and research purposes.
9. I understand that the test result can be received within 7 days after the specimen arrives at the laboratory. I also understand that the result can be delayed due to natural disasters, emergencies, or any other unavoidable situations.
10. I understand redraw may be requested in the cases of low fetal DNA concentration, damage of specimen, or any other unexpected causes. (Test failure rate: 0%~12.2%[1])

※ When a single fetus has reported a low risk of T21, T18, and T13, while the born baby having the disease is determined by a specialist doctor within 1 year after childbirth, **compensation of KRW 50 million will be covered** by the insurance company that the provider is enrolled in. (Excluded from payment of consolation: Other chromosomal abnormalities including sex chromosomes, microdeletion syndrome, twins, and false positives)

Ref. 1) Ultrasound Obstet Gynecol. 2017 Sep;50(3):302-314.

Test Subject (Name : _____ Signature : _____)

has understood and agreed to all of the □ Test Features, □ Test Limitations, and □ Informed Consent for Patient.

My Counseling Doctor (Hospital : _____ , Name : _____ Signature : _____)

has explained and answered to all of my questions.

Consent Date (YYYY/MM/DD)

GC Genome

Tel. +82) 31-280-9900 Fax. +82) 31-260-9087
107, Ihyeon-ro 30beon-gil, Giheung-gu, Yongin-si, South Korea www.gc-genome.com

G-NIPT-TRF(EN)-v3.1-EX-OBD-21.07.28