DX-PD-S151 V1.0

REQUEST FORM

NIFTY™ BGI technology inside

Sample Barcode

* ☐ NIFTY-Focus (T21, T18, T13, SCA and Gender)
☐ NIFTY-Pro (T21, T18, T13, SCA, Gender and other Additional findings)
☐ NIFTY-Twin (T21, T18, T13, Y Chromosome)

Non-invasive Prenatal Genetic Testing for Fetal Chromosomal Aneuploidies

PATIENT INFORMATION

* First Name(Given Name) **IN CAPITAL**

* Last Name(Surname) **IN CAPITAL**

* ID/Passport No.

Nationality

* DATE OF BIRTH
D D - M M - Y Y Y Y

Phone

Weight(kg) Height(cm)

HOSPITAL/CLINIC INFORMATION

* HOSPITAL/CLINIC

Doctor Name

Tel/Email

HISTORY

Gravida(n) Parity(n)	Date of Last Delivery/Abortion	Spontaneous Abortions	Terminations of Pregnancies	Molar pregnancies	Ectopic pregnancies
	D D - M M - Y Y Y Y				

☐my 1st pregnancy ☐not my 1st pregnancy ☐history of tumor ☐abnormal reproductive history ☐abnormal ultrasound result

I have received ☐transplant surgery ☐stem cell therapy ☐allogenic blood transfusion ☐cellular immunotherapy ☐heparin therapy ☐human serum albumin therapy ☐immunotherapy on(dd/mm/yyyy): _____

☐my BMI>40 ☐took medication during pregnancy, the name of the drug is:_____

I have abnormal karyotype with ☐qh+/, ps+/, pstk+/, pss ☐with dup, del, t, rob, inv, p-, q-, p+, q+, +mar
(additional consent may be needed if boxes above are checked)

CURRENT PREGNANCY

LMP
D D - M M - Y Y Y Y

* **Working EDC (by LMP/USG)**
D D - M M - Y Y Y Y

* **Gestational Week (w+d)**

IVF
☐YES
☐NO

* **USG**
Date: D D - M M - Y Y Y Y
☐Singleton
☐Twin pregnancy
☐DCDA ☐MCDA ☐MCMA
☐ Vanishing Twin
☐Occurred before 8 GW
☐Blood sampling after 8 weeks from vanishing occurence

Structure
☐Normal
☐Abnormal
Please specify_____

Prior Down Syndrome Screening Test
☐No,first time for down syndrome screening
☐Yes, the estimated risk of T21: 1/____, T18: 1/___, T13:_____

Type of test:
☐1st Trimester NT+Bch
☐1st Trimester NT only
☐1st Trimester Bch only
☐2nd Bch only
☐1st and 2nd Trimester integrated
☐2nd Trimester USG only
☐Other, please specify_____

SAMPLE INFORMATION

Sample type
☐Whole blood
☐Plasma

Sampling tube
☐Streck tube
☐Geneseek Tube
☐Others

Shipment condition
☐Room Temp
☐Dry Ice
☐Blue Ice

* **Blood collection**
Date: D D - M M - Y Y Y Y
Time

* **GENDER REQUESTED (Singleton only)**
Include the Fetal gender on the report
☐YES ☐NO
(If box is not choosen, gender will be reported.)

PHYSICIAN STATEMENT

We/I confirm that the patient has been duly informed about the specific purpose of this genetic screening test, its risks, and its limitations.
We/I confirm that the patient has been informed that the test will cover the disorder(s) indicated on this form, and we/I will ensure that the test results will be interpreted to the patient in an appropriate manner, and that the patient will not receive the results without accompanying genetic counseling.
We/I have answered all the patient's questions with regard to this test.

Physician Name:

* **Signature:**

INFORMED CONSENT

NIFTY BGI technology inside

- ☐ NIFTY-Focus (T21, T18, T13, SCA and Gender)
- ☐ NIFTY-Pro (T21, T18, T13, SCA, Gender and other Additional Findings)
- ☐ NIFTY-Twin (T21, T18, T13, and Y Chromosome)

Sample Barcode

Informed consent of the pregnant woman：

(NIFTY is used to represent both NIFTY Focus, NIFTY pro and NIFTY Twin in the below text body)

1. NIFTY test is performed from 10 to 24 gestational weeks of pregnancy. Testing may be carried out after 24 gestational weeks only in accordance with local law. BGI accepts no legal responsibility for testing that is provided by local healthcare partners that contravenes local law governing the provision of prenatal.

2. Besides T21, T18, T13, this test can also detect other chromosomal numeric abnormalities, specific locus relevant to 84 kinds of microdeletion/duplication syndromes according to OMIM and Decipher database (ask physician for detailed condition list); due to the limited database and reference, the risk of false positive/negative result can be increased compared to T21 T18 T13;For twin pregnancy, only T21, T18, T13 and detection of Y chromosome will be available; the result for gender information "Detected" returns as that there is at least one male fetus of the twin pregnancy; the result "NOT Detected" returns as that both fetuses of the twin are female.

3. NIFTY is NOT a diagnostic test, a high risk result should be followed by confirmatory diagnostic testing, and test report should be interpreted by physician.

4. Abnormalities caused by chromosomal polyploid (triploid, tetraploid, etc), chromosomal balanced translocation, inversion, ring, UPD, monogenic/polygenic disease, etc, cannot be detected by this test; this test cannot exclude the fetal mosaic chromosomal diseases.

5. Potential sources of false positive or false negative results include but are not limited to maternal, fetal and/or placental mosaicism (mixtures of chromosomally normal and abnormal cells in the pregnancy), chromosomal abnormality in either parent, transplant surgery, stem cell therapy, blood transfusion within one year, cellular immunotherapy where exogenous DNA is introduced within 4 weeks, abnormal ultrasound indication, malignant tumor during pregnancy, >2 fetus and low fetal fraction. Gender identification can be false if the detected value is within the gray zone. NIFTY is also unable to accept samples in cases of 'vanishing twin syndrome' where developmental arrest has been identified as occurring after week 8 of pregnancy, or within 8 weeks prior to NIFTY testing date.

6. In a small number of cases (around 2.8% of all samples received), samples are loss by irresistible factors and in other circumstance, for example the fetal DNA is individually too low, resampling in these cases are needed; there is no additional cost for resampling and the turnaround time will be prolonged.

7. I have read and understand the insurance consent form; I agree that BGI insures my test with PICC.

8. Unused test material is important for researching biological mechanisms and quality assurance on genetic tests in the lab. I consent to the anonymous storage and use of my remaining test material for improving the genetic diagnosis and treatment.

9. I understand that my sample will be sent for analysis at a BGI owned and operated laboratory located in Hong Kong, China or tested in a local laboratory in Bangkok, Thailand. and I know BGI is not responsible for sample expiration before arriving.

10. I choose to receive also information regarding genetic results that are not necessarily related to the specific reason for which my healthcare provider ordered the test.

11. With my signature I give my consent for BGI to conduct genetic analysis of my blood sample. It has been pointed out to me that I can withdraw my consent in full or in part at any time without stating reasons and that I have the right to not know the test results.

12. I understand that not donating my sample and data will not influence my right to get the test and to get further treatment. I can withdraw my test at any time through a written statement, and my sample as well as data will then be destructed (data that has been anonymous cannot be withdrew or deleted). If test cost occurs, I have to pay for the test, not paying is not acceptable.

13. I understand that the commercial terms and conditions of sale of the test I am taking are provided by the local test provider. I have also been noticed all the disclaimers, sample requirements and potential risk stated in the sample collection manual.

14. I have read this Patient Consent carefully and fully understood the characteristic, suitable users, purpose and necessity of this test. My physician has fulfilled the obligations of informing, explained my doubts and questions and promised confidentiality of my personal information. I promise all the information provided above are true and accurate. I understand that the commercial terms and conditions of sale of the test that I am taking are provided by the local test provider.

* Name (In capital) _____ Signature: _____ Date(DD/MM/YYYY): _____

Physician/Counsellor

* Name(In capital): DR. _____ Signature: _____ Date(DD/MM/YYYY):_____

Supplemental terms for women at late pregnancy (>24 weeks):

I understand there exist certain risk at late pregnancy (>24 weeks) because I miss the ideal time for prenatal diagnosis. I agree to take NIFTY test and I will take responsibility to all the risks due to I cannot take a clinical diagnostic test to confirm the results.

Name(In capital) :_____ Signature:_____Date(DD/MM/YYYY):_____

BGI
Bangkok Genomics Innovation Co., Ltd.
Website:www.bangkokgenomics.com
Address:3689 Rama4 Phra Khanong, Khlong Toei, Bangkok 10110

PICC Insurance Consent form for NIFTY-Pro

Dear Customers:

Thank you for choosing BGI Non-invasive prenatal testing (NIFTY-Pro, test includes Trisomy 21, Trisomy 18, Trisomy 13, other chromosomal numeric abnormalities and 84 kinds of microdeletion/duplication syndromes, NIFTY-Pro report takes the standard, and for microdeletion/duplication syndromes, PICC covers only when variant fragments are > 5M and fall in the range of what NIFTY-Pro bioinformatic system analyzes). The insurance cover is underwritten by PICC Health Insurance Company Ltd. Shenzhen Branch. To ensure you understand the insurance cover provided, please read the below details carefully. The insurance duties are as follows:

1. "Positive"

- If the test result is "high risk"/ "positive"/ "detected" or other description indicates the aneuploidy of other chromosomes, you are eligible for financial reimbursement towards the cost of prenatal diagnostic testing including but not limited to amniocentesis, chorionic villus sampling (CVS), umbilical cord, karyotyping analysis, auxiliary molecular genetics testing (such as FISH), chromosomal microarray analysis including array CGH, SNP array, QF-PCR, NGS, etc. The reimbursement will be up to maximum RMB 5000 per person for singleton. PICC will end all the insurance responsibilities for the testee and the fetus once the compensation goes into effect. Testee will not be able to ask BGI, PICC, clinic/hospital for any more compensation.

2. "False Negative"

- If the test result is "low risk"/ "negative"/ "not detected", but that later your baby is born and diagnosed with any disease included in NIFTY-Pro (except for mosaic chromosomal abnormality) by a qualified healthcare professional within one year after delivery, you are eligible for compensation of RMB 400,000 for singleton. PICC will end all the insurance responsibilities for the testee and the fetus once the compensation goes into effect. Testee will not be able to ask BGI, PICC, clinic/hospital for any more compensation.

- If the test result is "low risk"/ "negative"/ "not detected", but that later your fetus is diagnosed with any disease included in NIFTY-Pro (except for mosaic chromosomal abnormality) by a qualified healthcare professional before delivery, and you have terminated the pregnancy, you are eligible for compensation of RMB 20,000 for singleton. PICC will end all the insurance responsibilities for the testee and the fetus once the compensation goes into effect. Testee will not be able to ask BGI, PICC, clinic/hospital for any more compensation.

Documents for compensation application	
Positive	Application form (medical costs), NIFTY-Pro report provided by clinic/hospital, invoice/bill, diagnostic/confirmation report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by PICC and BGI for paying and verifying.
False Negative (before childbirth)	Application form (specific diseases), NIFTY-Pro report provided by clinic/hospital, pregnancy termination report, diagnostic/confirmation report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by PICC and BGI for paying and verifying.
False Negative (after childbirth)	Application form (specific diseases), NIFTY-Pro report provided by clinic/hospital, diagnostic/confirmation report, certificate of diagnosis, certificate of childbirth, paternity test report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by BGI and PICC for paying and verifying reasons, degree and other aspects of the accident.

I have received and read the insurance consent form of NIFTY-Pro. I understand that the information of pregnant woman needs to be true and be same as that of testee. I will take responsibilities when PICC refuses to provide compensation because of the inconsistent information between the real identify and what was provided when purchasing the insurance. I will provide all the documents needed by PICC when applying for the compensation.

***Signature of Testee:**_____ **Date**_____**Month**_____**Year**_____

NIFTY pro™
NON-INVASIVE FETAL TRISOMY TEST

PICC Insurance Consent form for NIFTY-FOCUS and NIFTY-Twin

Dear Customers:
Thank you for choosing BGI Non-invasive prenatal testing NIFTY-Focus (test includes Trisomy 21, Trisomy 18, Trisomy 13 and Sex Chromosome Abnormalities (XO, XXY, XXX, XYY)) or NIFTY Twin (test includes Trisomy 21, Trisomy 18 and Trisomy 13). BGI offers an insurance scheme with provision of the NIFTY-Focus and NIFTY-Twin test. The insurance cover is underwritten by PICC Health Insurance Company Ltd. Shenzhen Branch. To ensure you understand the insurance cover provided, please read the below details carefully. The insurance duties are as follows:

1. "Positive"
If the test result is "high risk" or "positive" for "Trisomy21","Trisomy18" or "Trisomy13" "Sex Chromosome Abnormalities (XO, XXY, XXX, XYY)", you are eligible for financial reimbursement towards the cost of invasive, confirmatory prenatal diagnostic testing including but not limited to amniocentesis, chorionic villus sampling (CVS), umbilical cord puncture sampling, karyotyping analysis, chromosome fluorescence in situ hybridization and FISH. The reimbursement will be up to maximum RMB 2500 per person in the case of a singleton pregnancy. In the case of a twin pregnancy the maximum reimbursement amount is set as RMB 4000.
Please Note that: PICC will not provide any compensation for any baby born with any of the conditions outlined in this section to any clients who did not undertake any follow up confirmatory invasive prenatal diagnosis after receiving a high risk result for any of the conditions listed within this section.

2. "False Negative"
If the test result is "low risk" or "negative", but that later your baby is born and diagnosed with any disease included in NIFTY-Focus/NIFTY-Twin (except for mosaic chromosomal abnormality), either Trisomy 21, Trisomy18, Trisomy 13 or "Sex Chromosome Abnormalities (XO, XXY, XXX, XYY)" by a qualified healthcare professional within one year of baby's birth date, you are eligible for compensation up to a maximum amount of RMB 400,000.

3. "False Negative in the Event of Diagnosis and Termination Before Live Birth"
In the event that your NIFTY-Focus/NIFTY-Twin test result is reported as "low risk" or "negative" but that later your baby is diagnosed before birth with any disease NIFTY-Focus/NIFTY-Twin (except for mosaic chromosomal abnormality) either Trisomy 21, Trisomy 18, Trisomy 13 or "Sex Chromosome Abnormalities (XO, XXY, XXX, XYY)" by a qualified healthcare professional and you have terminated pregnancy, you are eligible for compensation. The compensation amount is set at a maximum amount of RMB 20,000. All above insurance liability is subject to the terms outlined within this section, and shall be terminated after compensation.

Documents for compensation application	
Positive	Application form (medical costs), NIFTY-Focus/NIFTY-Twin report provided by clinic/hospital, invoice/bill, diagnostic/confirmation report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by PICC and BGI for paying and verifying.
False Negative (before childbirth)	Application form (specific diseases), NIFTY-Focus/NIFTY-Twin report provided by clinic/hospital, pregnancy termination report, diagnostic/confirmation report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by PICC and BGI for paying and verifying.
False Negative (after childbirth)	Application form (specific diseases), NIFTY-Focus/NIFTY-Twin report provided by clinic/hospital, diagnostic/confirmation report, certificate of diagnosis, certificate of childbirth, paternity test report, copy of ID card and bank account information (includes but not limited to Name of policy holder (need to be testee), Account Number, Bank Name, Bank Address, Swift Code (testee should sign on the copy files and write down the account information), other documents needed by BGI and PICC for paying and verifying reasons, degree and other aspects of the accident.

I have received and read the insurance consent form of NIFTY-Focus/NIFTY-Twin. I understand that the information of pregnant woman needs to be true and be same as that of testee. I will take responsibilities when PICC refuses to provide compensation because of the inconsistent information between the real identify and what was provided when purchasing the insurance. I will provide all the documents needed by PICC when applying for the compensation.

***Signature of Testee:_____ Date_____Month_____Year_____**