Consent-Requisition Form

BGI Barcode

Patient Information

Patient Name (Last Name, First Name):

Patient Identification No:

Date of Birth (dd/mm/yyyy):

Weight: __ kg **Height: __ cm**

Gestational Age at sampling: ___weeks ___ days

Due Day (dd/mm/yyyy):

Number of fetus: □1 □2 (NIFTY-Pro tests for all chromosomal abnormalities and is only available for singleton)

Clinic Information

Clinical Name:

Ordering Clinician:

Street Address:

City: **State/Province:**

Country: **Zip/Postal/ Code**

Email:

Contact Number:

Required Test Information

☐**NIFTY pro** ☐with ☐without gender information

☐**NIFTY** with ☐SCA ☐T9, 16, 22 ☐T9, 16, 22+SCA ☐T9, 16, 22+SCA+Del/Dup ☐T9, 16, 22+SCA+Del/Dup +Incidental findings* ☐Gender information (2 checks at most)

Date of Blood Sampling(dd/mm/yyyy):

Sampling Tube: ☐Geneseek tube ☐Streck tube □Other:

Shipping Condition: ☐Room temperature ☐Dry ice □Blue ice

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

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

☐had vanishing twin syndrome, developmental arrest finished 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

Notes*: SCA stands for Sex Chromosome Aneuploidy; T9, 16, 22 stands for Trisomy 9, 16, 22; Del/Dup stands for microdeletion or microduplication syndromes; Incidental findings is defined as other chromosome abnormalities found during the test but out of the condition list

Patient Consent Form

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, NIFTY pro can also detect other chromosome numeric abnormalities, specific locus relevant to 84 kinds of microdeletion/duplication syndromes according to OMIM and Decipher database; NIFTY can also detect other chromosome numeric abnormalities and 60 kinds of microdeletion/duplication syndromes. Please 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 18 T13;
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 hereby confirm that I have carefully read BGI PRIVACY POLICY, considered as part of this Consent-Requisition Form, and that I am fully aware of my rights under this policy. ☐YES ☐NO (If both are left blank, test will not be conducted).
8. I hereby give my consent for BGI to conduct genetic analysis of my blood sample for the execution of the NYFTY Test described here above. ☐YES ☐NO (If both are left blank, test will not be conducted).
9. I understand that my sample will be sent abroad for analysis at a BGI owned and operated laboratory located in Hong Kong, China. I know that there is a possibility that my sample would have been expired before arriving at BGI lab. I hereby confirm that BGI is not responsible for sample expiration before arriving; I will still want to take this test and be willing to take responsibilities for the relevant risk. I confirm that in case of sample expiration before arriving, resampling will be necessary. ☐YES ☐NO (I will take resampling) (If both are left blank, test will not be conducted).
10. I understand that in the course of the execution of the test, some information concerning genetic results that are not necessarily related to the specific reason for which my healthcare provider ordered the test might be found. I hereby choose to receive these additional informations. ☐YES ☐NO (If both are left blank, test will not be conducted).
11. I understand that unused test material is important for researching biological mechanisms and quality assurance on genetic tests in the lab. I hereby consent to the anonymous storage and use of my remaining test material for the purpose of research in order to improve the genetic diagnosis and treatment. ☐YES ☐NO (If both are left blank, test will not be conducted).
12. I understand that my refusal to let BGI use my remaining sample and data in an anonymous way for research purposes will not influence my right to get the test and to get further treatment. ☐YES ☐NO (If both are left blank, test will not be conducted).
13. It has been pointed out to me that I can withdraw my consent in full or in part at any time, without stating reasons, through a written statement. My samples as well as my data will then be destructed, except if I agreed on point 11 and my data has already been made anonymous. In this case, I understand that my data cannot be deleted. I also have the right to ask not to know the test results. ☐YES ☐NO (If both are left blank, test will not be conducted).
14. I understand that the commercial terms and conditions of sale of the test I am taking are provided by the local test provider and not BGI. I have also been informed that all the disclaimers, sample requirements and potential risk are stated in the sample collection manual. ☐YES ☐NO (If both are left blank, test will not be conducted).
15. I have read and understand the insurance consent form; I agree on the fact that BGI insures my test with PICC. In this regard, I hereby authorize BGI to share my personal data with PICC limited to what appears to be strictly necessary for insurance purpose. ☐YES ☐NO (If both are left blank, test will not be conducted).
16. 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 and not BGI. ☐YES ☐NO (If both are left blank, test will not be conducted).

Both testee and physician confirm that the above contents are truly expressed; physician has fulfilled the obligation of informing the test coverage, limitation and requirements; the testee has got the right of fully understanding and choosing.

Signature of Testee: **Signature of Physician:**

Date: dd mm yyyy **Date: dd mm yyyy**