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