

**เอกสารยืนยันการขอตรวจ  
CONFIRMATION STATEMENT**

**NIFTY is used to represent NIFTY Focus, NIFTY Core, NIFTY Pro and NIFTY Twin in the below text body**

Bangkok Genomics Medical Technology Clinic and/or Bangkok Genomics Innovation Public Company Limited and/or BGI Health (HK) Co., Ltd. (henceforth referred to as "BGI") requires the patient/testee and the physician, nurse, medical technologist and/or any other relevant healthcare professional (collectively referred to as "Medical Personnel") to read through these confirmation statement carefully, and then provide their signature. If the patient/testee is a minor, incompetent person, or quasi-incompetent person, the legal representative, legal guardian, or legal custodian (as the case may be) of the patient/testee must also consent to the patient/testee doing so by signing this confirmation statement together with the patient/testee.

**I fully understand of the following information:**

- 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 laws. BGI accepts no legal responsibility for testing that is provided by local healthcare partners and/or Medical Personnel that contravenes local law governing the provision of prenatal testing.
- Besides T21, T18, T13, NIFTY Pro can also detect other chromosomal numeric abnormalities, specific locus relevant to 92 kinds of deletion/duplication syndromes; 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.
- NIFTY is NOT a diagnostic test; a high-risk result should be followed by confirmatory diagnostic testing and the test report should be interpreted by Medical Personnel.
- Abnormalities caused by chromosomal polyploid (triploid, tetraploid, etc.), chromosomal translocation, inversion, ring, UPD, monogenic/polygenic disease, etc., cannot be detected by this test; this test cannot exclude the fetal mosaic chromosomal diseases.
- The NIFTY test specificity and sensitivity for common trisomies are detailed in the table below.

Clinical Data(*)	Sensitivity	Specificity
Trisomy 21	99.17%	99.95%
Trisomy 18	98.24%	99.95%
Trisomy 13	100%	99.96%

\* Zhang H, Gao Y, Jiang F, Fu M, Yuan Y, Guo Y, Zhu Z, Lin M, Liu Q, Tian Z, Zhang H, Chen F, Lau TK, Zhao L, Yi X, Yin Y, Wang W.

Non-invasive prenatal testing for trisomies 21, 18 and 13: clinical experience from 146,958 pregnancies. *Ultrasound Obstet Gynecol.* 2015 May;45(5):530-8. doi: 10.1002/uog.14792.

Epub 2015 Apr 8. Erratum in: *Ultrasound Obstet Gynecol.* 2015 Jul;46(1):130. PMID: 25598039

- Potential sources of false positive or false negative results include but are not limited to maternal, fetal and/or placental mosaicism (patient has two or more genetically different sets of cells in the body), as well as where there is chromosomal abnormality in either parent. NIFTY is therefore unable to accept some specimens as detailed in the NIFTY sample collection manual as the foregoing conditions affect NIFTY results. Gender identification can be false if the detected value is within the gray zone.
- In a small number of cases (around 2.8% of all samples received), samples are lost by irresistible factors and in other circumstances (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.
- BGI will not be responsible for samples that expire before arrival. The samples have a validity period of 7 days from the date of blood collection.

**I, as the personal data subject, hereby acknowledge that BGI will collect, use, and/or disclose my personal data including my genetic information for the purposes of the NIFTY test in accordance with the Personal Data Protection Act B.E. 2562 and the company's privacy policy. I fully understand and agree to the following conditions:**

- BGI will collect, use, and/or disclose my personal data for the purpose of providing the NIFTY test as I have provided on the test request form.
- My specimens and my genetic data will be sent for analysis at Bangkok Genomics Medical Technology Clinic in Bangkok (Thailand) and/or Hong Kong (China) and/or referral laboratories. In which case, BGI will ensure an adequate degree of protection is afforded to the transferred personal data, or that the transfer is otherwise permitted in accordance with the applicable data protection law.
- BGI will render my remaining specimens and my result as anonymous data and/or pseudonymous data for the purposes of improving clinical analysis and laboratory quality assurance.
- BGI will render my result as anonymous data and/or pseudonymous data prior to transfer to other BGI-affiliated laboratories in Bangkok (Thailand) and/or Hong Kong (China) and/or referral laboratories.
- Any remaining specimen, and a hard copy of the test request form will be stored for 2 years after receipt, while electronic files of the test request form will be stored for 5 years after receipt in accordance with the company's privacy policy.
- BGI will store my genetic information and analysis results for 5 years after receipt as required by the Ministry of Public Health announcement on "The standards of Medical Service for Genomic Medicine" (ประกาศกระทรวงสาธารณสุข เรื่อง มาตรฐานการบริหารเวชศาสตร์จีโนมของสถานพยาบาล)
- Under the insurance scheme underwritten by the People's Insurance Company of China (PICC), in the case of a high-risk or false negative result during or after pregnancy for up to 1 year, BGI will be required to disclose my personal data such as name, surname, ID card number, date of birth, my test results, and any other information as requested to PICC. I fully understand the insurance consent form and hereby confirm my consent with the following signature.
- The signature on the insurance consent form is crucial. If the Insurance consent form document is not signed, I will not be eligible for coverage as per the insurance terms and won't be able to claim rights later.
- The NIFTY service period starts when the sample is received with completed request form, confirmation statement, and PICC insurance consent form and ends upon the NIFTY report is delivered.
- I understand that the commercial terms and conditions of the test I am taking are as provided by the local test provider. I acknowledge and understand all disclaimers, sample collection procedures, and potential risks during sample collection and analysis in full.

**Informed Consent**

In receiving the NIFTY test, I hereby consent to BGI to collect, use and/or disclose information relating to my sample and health condition in order to enable BGI to provide such service to me

Consent  Do not consent - If checkbox is not selected or "Do not consent" is selected, you will not be able to obtain the NIFTY test

I hereby consent BGI and BGI-affiliated companies to collect, use and/or disclose my personal data for the purpose of sending information such as customer satisfaction forms, press releases, advertisements, promotional content, marketing of products, services, and other special offers to me.

Consent  Do not consent - If 'Do not consent' is selected, you will not receive information from BGI which may be useful to you.

I understand that the consent or withdrawal of consent may affect my ability to obtain the service. I can read the privacy policy which explains on how my personal data is collected, used and/or disclosed in detail at [www.bangkokgenomics.com](http://www.bangkokgenomics.com). I can exercise any of my rights in relation to my personal data through a written request submitted to a staff member or by e-mail to [privacy@bangkokgenomics.com](mailto:privacy@bangkokgenomics.com). In this regard, my rights will be exercised per the conditions and exceptions as prescribed under the Personal Data Protection Act B.E. 2562.

In addition, I have read this confirmation statement carefully and understand the nature of the test, who is suitable for the test, the purpose, the necessity of the test. Furthermore, my Medical Personnel has been on duty to provide information, explain, answer questions, and promise to keep my personal data confidential. I confirm that all information stated above is correct and is true in all respects.

**MEDICAL PERSONNEL STATEMENT**

- We/I confirm that the patient/testee has been duly informed about the specific purpose of this genetic screening test, its risks, and its limitations.
- We/I have clearly explained that this test is a screening test and results are not diagnostic test and that therefore 'false positive' and 'false negative' results can occur.
- We/I confirm that the patient/testee has been informed that the test will provide results and covered for the conditions indicated on this form (pre-counseling) and we/I will ensure that the test results will be interpreted to the patient in an appropriate setting with accompanying genetic counseling (post-counseling).
- We/I have answered all the patient/testee's questions regarding this test.
- We/I have reviewed the confirmation statement with the patient/testee and obtained the patient/testee's signed consent on the confirmation statement form and the insurance consent form for Conducting Genetic Analysis.
- We/I confirm that the patient/testee currently does not have any blood-borne infectious disease.
- We/I confirm that we/I carry out our duties in accordance with any and all applicable laws, rules, and professional standards. The location that is used in the performance of our duties also complies with any and all applicable laws.
- I understand the Test Description and I have read and accepted the Test Disclaimer as outlined in the overleaf.



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For the benefit of the Patient/Testee, the contents of this confirmation statement has been verified as in compliance with the Personal Data Protection Act by an external legal firm.

**This document has no legal effect as it is only a translation.**