PATERNITY For Life

NON-INVASIVE PRENATAL GENETIC SCREENING REQUEST FORM

Genomics for Life NIFTY™ Non-Invasive Fetal TrisomY test

PATIENT DETAILS

Patient Surname:

Patient Given Names:

DOB: ____ / ____ / _____

Patient Address:

Contact Number:

Weight (Kg): _____ Height (cm): _____ BMI: _____

Email:

☐ Please notify me via email when the results have been sent to my referring doctor.

Patient Informed Consent Statement

I have read, understood, and agree to the attached Informed Consent Statement, and fully understand the indication, intended purpose, limitations, and potential risks of this test, as explained by my physician. I confirm the personal information I have provided is true and correct. Please note that some terms in the attached Informed Consent require a 'Yes' or 'No' response.

Patient Signature: **Date:**

ORDERING MEDICAL PRACTITIONER DETAILS

Doctor Name:

Provider Number:

Practice Name:

Practice Address:

Contact Number:

Email (for results):

Copy Doctor(s):

Medical Practitioner Statement

By signing this request form, I confirm that I have patient consent for the testing to be performed and confirm that the patient understands the purpose, scope and performance of the screen explained by either myself, available patient literature or the Genomics For Life website.

Doctor Signature: **Date:**

REQUESTED SCREENING

☐ NIFTY™ Plus

T21, T18, T13, T9, T16, T22, selected Sex Chromosome abnormalities* & 60 Microdeletion/Microduplication Syndromes*. Please see our website for a full list.

***Please note, these tests are not available for twin pregnancies**

☐ Please tick if you WOULD like to know fetal gender

CLINICAL INFORMATION

Gestational Age: ____ weeks ____ days As At date: ____ / ____ / ____

Estimated Due Date: ____ / ____ / ____

No of Fetus: ☐ Singleton ☐ Twin*

*Please note screening for T21, T18 and T13 only is available for Twin pregnancies.

If Twin: ☐ DCDA ☐ MCDA ☐ MCMA ☐ Unsure

IVF: ☐ No ☐ Yes - Implantation Date: ____ / ____ / _____

Prior Down Syndrome Screening Test:

☐ No ☐ Yes – estimated risk of T21: 1/ ___, T18: 1/___, T13: 1/___

First Sampling: ☐ Yes ☐ No - Date of first collection ____ / ____ / _____

Collection Staff Only		Laboratory Use Only	
Date Collect:	Collectors Signature:	Date Rec:	Signature:
Time Collect:		Time Rec:	Comments:

PATIENT MEDICAL HISTORY

Received allogenic blood transfusion within the past 12 months	☐ No ☐ Yes
Transplant surgery	☐ No ☐ Yes
Received immunotherapy in the past 4 weeks	☐ No ☐ Yes
Stem cell therapy	☐ No ☐ Yes
Heparin therapy	☐ No ☐ Yes
Vanishing twin syndrome	☐ No ☐ Yes
The patient has a single-gene disease	☐ No ☐ Yes - Please specify:
Family history of single gene disease or other genetic disease/s	☐ No ☐ Yes - Please specify:
History of tumours (except maligant tumours during pregnancy)	☐ No ☐ Yes - Please specify:
Taking Medicine During Pregnancy	☐ No ☐ Yes - Please specify:
Abnormal Reproductive History	☐ No ☐ Yes - Please specify:
Abnormal Maternal Karyotype	☐ No ☐ Yes - Please specify:

Please attach any further relevant medical history

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NON-INVASIVE PRENATAL GENETIC SCREENING REQUEST FORM

Genomics for Life NIFTY™ Non-Invasive Fetal TrisomY test

INFORMED CONSENT

1. This test is intended to detect fetal Trisomy 21, 18 and 13 for both singleton and twin pregnancies. This test is highly accurate, with a detection rate over 99% and a false positive rate of less than 1% for fetal Trisomy 21, 18, and 13. Due to the limitation of the current technology, a negative result cannot totally exclude the possibility of fetal trisomy. It is also possible to use this test to discover specific sex chromosome aneuploidies and other chromosomal numeric abnormalities, specific locus relevant to 84 kinds of microdeletion/duplication syndromes (please see our website for a full list).

2. It is strongly advised that the NIFTY® test is performed from 10 to 24 gestational weeks of pregnancy. If the test is performed at very early pregnancy stage (<10 gestational weeks), there is a higher risk of a recollection being required due to a low fetal fraction and false-negative results. Therefore, s**amples with gestational week <10 will not be accepted, and a recollection will be required.** Testing may be carried out after 24 gestational weeks only in accordance with local law.

3. NIFTY is NOT a diagnostic test and the result cannot be used as the sole evidence for a diagnostic conclusion. A high-risk result should be followed by confirmatory diagnostic testing, and test report should be interpreted by physician.

4. Although highly accurate, this test cannot be considered a diagnostic test. 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. The high sensitivity and specificity of NIFTY test are based on studies in singleton pregnancies. Based on reported studies so far, and on theoretical grounds, the performance of NIFTY in twin pregnancies is similar to that in singleton pregnancies. **Screening for T21, T18 and T13 only is available for twin pregnancies.**

6. Patients who have received a blood transfusion within one year prior to testing date, transplant surgery or stem cell therapy as well as heparin therapy, are not eligible for the NIFTY® test. We are 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

7. Potential sources of false positive or false negative results and patients who are not suitable for the test 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, malignant tumor during pregnancy, >2 fetus and low fetal fraction, patient's BMI>40 or if the patient has taken specific medications, such as Heparin, during pregnancy. Gender identification can be false if the detected value is within the gray zone.

8. Reports will be available within 10 - 12 working days from the time the laboratory receives the sample. I understand that my sample will be sent to Genomics For Life and/or their partnered laboratory for testing and there is a possibility that the sample may have expired before arriving at the lab. In a small number of cases, samples may fail Quality Control checkpoints. Resampling in these cases are needed; there is no additional cost for resampling and the turnaround time will be prolonged.

9. Unused test material is important for researching biological mechanisms and quality assurance on genetic tests in the lab. I agree to the anonymous storage and use of remaining test material. Patients can withdraw the test at any time through a written statement, and the sample/s submitted as well as data will then be destructed (data that has been anonymous cannot be withdrawn or deleted).

☐ **Yes** ☐ **No**

10. The laboratory may contact the patient and/or their referring healthcare provider for further information regarding the pregnancy and all previous tests such as ultrasound/other screening/diagnostic tests performed during the pregnancy, in particular if my baby is subsequently found with a chromosomal or genetic disease. Clinical information may be used by the laboratory for the purpose of auditing, quality assurance and research. All data will remain anonymous and unidentifiable during data analysis and any personal information will be removed from any reports or publications.

11. There is a possibility for the recognition of incidental findings that are not necessarily related to the reason for ordering the test. These findings can provide information that was not anticipated and that are unrelated to the individual's reported clinical features but can be of medical value for patient care. I consent for information regarding genetic results that are not necessarily related to the specific reason for which the healthcare provider has ordered the test, to be reported to the referring healthcare provider.

☐ **Yes** ☐ **No**

12. Results are sent to the undersigned healthcare provider. Due to the complexity and implications of the test results, results will only be reported to the referring healthcare provider. Patients should contact their healthcare provider to obtain the results of the test.

For full list of remarks and disclaimers, validation publications and test sensitivities please visit genomicsforlife.com.au

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