المختبر المرجعي الوطني
National Reference Laboratory
A Mubadala Health Partner

NON-INVASIVE PRENATAL SCREENING TEST REQUISITION FORM

NIFTY

PATIENT INFORMATION

Surname	First Name
MRN	Patient ID
Date of Birth DD | MM | YY	Weight (kg) ..... Height (cm) .....

FOR LAB USE ONLY

PATIENT INFORMED CONSENT STATEMENT

☐ * I consent to the test of NIFTY, a non-invasive prenatal screening. I confirm that I have acknowledged, understood and agree to the Informed Consent provided on the BACK PAGE of this form. I confirm that I have had the opportunity to discuss the test and ask relevant questions with my physician, and I have fully understood the indication, intended purpose, procedure, eligibility, limitations, and potential risks of this test as explained to me by my physician.

☐ * I confirm that I have read the Privacy Policy on the BACK PAGE of this form.

☐ * I consent to the processing of my personal data by means and for purposes defined in the Privacy Policy.

☐ * I confirm the personal information I have provided is true and correct.

☐ I consent to the preservation and use of my leftover specimens and de-identified test results in the statistics database for the laboratory's quality improvement, research and validation purposes as stated in the Informed Consent.

Patient Signature or
Patient Guardian Signature

Date DD | MM | YY

* In accordance with the applicable regulations, we are not permitted to conduct our test without these consents.

TEST OPTIONS

☐ **NIFTY®** - Trisomy 21, Trisomy 18, Trisomy 13

☐ Sex Chromosome Aneuploidies (optional for singletons only)

☐ **NIFTY® Pro** - Trisomy 21, Trisomy 18, Trisomy 13, Trisomy 9, Trisomy 16, Trisomy 22, Sex Chromosome Aneuploidies (for singletons only), other Aneuploidies, 92 types of Microdeletion and Microduplication syndromes

Fetal sex to be reported ☐ Yes ☐ No

SPECIAL SAMPLE CONCESSIONS

I understand that my sample may not meet the acceptance criteria for the following reasons:

- Samples must arrive in the laboratory within 96 hours from withdrawal
- Gestational weeks more than 24 weeks
- BMI more than 40.

I am fully aware of the associated risks of my situation, including failed and/or inaccurate test results, and am still willing to continue to test and accept the risks.

Patient Signature or
Patient Guardian Signature

Date DD | MM | YY

ACCOUNT INFORMATION

Account Number
Ordering Clinician
Client Name

CLINICAL INFORMATION

Gestational Age	.....weeks .....days
Estimated Due Date	DD | MM | YY
No. of Fetus	☐ Singleton ☐ Twins
First Sampling	☐ Yes ☐ No, code of first sampling .....

PATIENT'S MEDICAL CONDITION

Received allogenic blood transfusion:
☐ No ☐ Yes, date of receiving DD | MM | YY

Received heparin therapy:
☐ No ☐ Yes, date last taken DD | MM | YY

Received immunotherapy and/or human serum albumin therapy:
☐ No ☐ Yes, date of last injection DD | MM | YY

Diagnosed with vanishing twin syndrome:
☐ No ☐ Yes, date of vanishing DD | MM | YY

Received assisted reproductive technology treatment:
☐ No ☐ Yes, please specify .....

Family history of genetic disease(s) or syndromes:
☐ No ☐ Yes, please specify .....

Abnormal reproductive history:
☐ No ☐ Yes, please specify .....

Abnormal results of other prenatal:
☐ No ☐ Yes, please specify .....

HEALTHCARE PROVIDER STATEMENT

I confirm that the patient understands the purpose, limitations, potential risks, scope and performance of the test explained by myself. The patient has given full consent for this test.

Doctor Signature

Date DD | MM | YY

IMPORTANT BLOOD COLLECTION INFORMATION

Date DD | MM | YY	Time ..... : ..... AM PM

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NON-INVASIVE PRENATAL SCREENING PATIENT CONSENT FORM

NIFTY

PURPOSE

NIFTY® & NIFTY® Pro are intended to screen fetal trisomy 21, 18, and 13 for pregnancies. Depending on your choice, further details about the clinical condition of the fetus can also be provided, including information on trisomy 22, 9, and 16, sex chromosome aneuploidy, other autosomal trisomy, 92 kinds of microdeletion/microduplication syndromes, and Y chromosome conditions (for sex inference).

TEST PROCEDURE

For each test option you choose, a tube of blood will be drawn and sent to NRL laboratory, which will then analyze your DNA using molecular genetics technology. Before and after undertaking the tests, you should consult with the healthcare professionals regarding any risks, diagnoses, treatment and/or any other potentially relevant healthcare issues.

ELIGIBILITY

Patients should be at least 10 weeks' gestational age. Perform the test before 24 gestational weeks of pregnancy to have enough time for further diagnosis or procedure.

Patients who have the following situations are NOT ELIGIBLE for NIFTY® or NIFTY® Pro:

- Have chromosomal abnormality (couples);
- Pregnancy with triplets or more fetuses;
- Have malignant tumors;
- Received transplant surgery or stem cell therapy;
- Received allogeneic blood transfusion within one year;
- Received human serum albumin therapy and/or exogenous DNA cells introduced immunotherapy within four weeks;
- Fetal ultrasound scan indicates structural abnormality;
- Have vanishing twin syndrome, unless it has been identified that the developmental arrest occurred within the first eight weeks of pregnancy and more than eight weeks prior to the date of the test.

Patients with the following conditions have a high risk of maternal genetic background for abnormalities which may cause inaccurate test results. Please check the patients' genetics and medical reports, if any, prior to their test. In these cases, the decision to undergo the tests or not should be made by the patients and/or their health provider in conjunction with local medical and bioethics guidelines, laws and/or regulations. Signing this form means you are fully aware of and willing to accept the risks:

- Patients received Assisted Reproductive Technology therapy (including *In- Vitro* Fertilization & Embryo Transfer, Intracytoplasmic Sperm Injection, *In- Vitro* maturation, *In-Vitro* Gametogenesis, Germinal Vesicle Transfer, Egg/Sperm Donation, Surrogacy);
- Patients who have a history of abnormal pregnancy, or family history of genetic disease or abnormal phenotype;
- Another screening result indicates fetal abnormality.
- Pregnancy with twins or vanishing twin.

TEST LIMITATION

The tests are NOT intended nor validated for diagnostic purposes; thus, the result cannot be used as the sole evidence for a diagnostic conclusion. The sensitivity and specificity of the tests are based on singleton pregnancies. According to studies and theory, the tests perform similarly in twin and singleton pregnancies. The tests cannot be used to predict diseases that are not in the test scope or rule out risks in patients' families.

A false negative/positive result cannot be totally excluded. Due to the limitations of current medical detection technology and individual differences of the subject, potential sources of false positive or false negative results include, but are not limited to: maternal, fetal and/or placental mosaicism, low fetal fraction, blood transfusion.

'Vanishing twin syndrome' may also cause test inaccuracy in the event of twin pregnancy testing.

Abnormalities caused by chromosomal polyploid (triploid, tetraploid, etc.), chromosomal translocation, inversion, ring, UPD, monogenic/polygenic disease, imprinting disorders, etc., cannot be detected by this test; this test cannot exclude the fetal chimeric chromosomal abnormalities.

	Sensitivity Rate Singleton		Sensitivity Rate Twin
Trisomy 21	99.17%		90.91%
Trisomy 18	98.24%		100.00%
Trisomy 13	>99.90%		Not available
Gender identification	99.53%		Not available
Sex Chromosome Aneuploidies	99.60%		Not available
Microdeletions/ Microduplications	>10Mb	88.89%	Not available
	<10Mb	72.73%	

Reference:

- Zhang H, Gao Y, Jiang F, et al. Non-invasive prenatal testing for trisomies 21, 18 and 13: clinical experience from 146 958 pregnancies[J]. Ultrasound in Obstetrics & Gynecology, 2015, 45(5): 530-538.
- Pan X, Zhang C, Li X, et al. Non-invasive fetal sex determination by maternal plasma sequencing and application in X-linked disorder counseling[J]. The Journal of Maternal-Fetal & Neonatal Medicine, 2014, 27(18): 1829-1833.
- Rose N C, Barrie E S, Malinowski J, et al. Systematic evidence-based review: The application of noninvasive prenatal screening using cell-free DNA in general-risk pregnancies[J]. Genetics in Medicine, 2022, 24(7): 1379- 1391.
- Liu H, Gao Y, Hu Z, et al. Performance evaluation of NIPT in detection of chromosomal copy number variants using low-coverage whole-genome sequencing of plasma DNA[J]. PLoS One, 2016, 11(7): e0159233.
- Wu HY, Wang H, Zhao QM, et al. Performance analysis of non-invasive prenatal testing in twin pregnant women[J]. Maternal and Child Health Care of China, November 2022,Vol 37,No 22.

RESULTS

Reports will be available within 7-10 working days from the time the laboratory receives the sample. Results will be sent only to the undersigned healthcare provider due to their complexity and implications. Patients should contact their healthcare provider for test results and interpretation. High-risk results should be followed by confirmatory diagnostic tests.

Occasionally samples fail quality control and/or the initial analysis cannot reach a conclusion. This may require resampling and/or reanalysis, which will be offered free but may delay your report as extra days may be needed for processing. You will be notified by your healthcare provider if this happens.

PRIVACY POLICY

By signing the consent you agree and give permission for the personal data and clinical information included in this test requisition form as well as your blood sample, to be sent to National Reference Laboratory LLC. (NRL) to perform the NIFTY screening test. NRL may store your personal data (including the test results) and remaining sample (if any).

The NIFTY screening test will be performed in the UAE by NRL. Under certain circumstances NRL may subcontract with other laboratories approved to perform the NIFTY test and/or may need to use technical support and maintenance services in relation to the equipment used to perform the test. Under these circumstances, should NRL need to transfer your personal data to countries outside the UAE, the transfer will be made in accordance with all UAE laws and relevant authorities regulations.

USE OF LEFTOVER SPECIMENS AND INFORMATION

In compliance with better practices, your de-identified specimens may be utilized for the statistics database for the laboratory's quality improvement, research and validation purposes.

RIGHT OF REVOCATION

You may contact your service provider to revoke your consent to the test in full or in part at any time, without providing a reason. You have the right not to be informed of test results (right not to know), to halt testing processes at any time prior to receiving the results, and to request the destruction of all test materials and results.