NON-INVASIVE PRENATAL TEST REQUEST

PLEASE SEND TOP COPY WITH SAMPLE

For Laboratory use only

Place the FORM barcode label here

TAP5284/11-07-23/V6

Patient Information

Patient Name (First)

Patient Name (Last)

Date of Birth (DD/MM/YYYY)

Address

City/State or Province

Country/Postcode

Phone Medical Record Number

Gender ☐ Female ☐ Male

Weight (kg) Height (m)

Patient Signature for informed consent

My signature on this form indicates that I have read, or had read to me, the informed consent on the back of this form including the eligibility criteria under the heading 'Who is eligible for the VeriSeq NIPT Solution v2?'. I understand and agree to the informed consent and give permission for the laboratory tests selected to be performed in accordance with the informed consent. I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider or someone my healthcare provider has designated. I know that if I wish, I may obtain professional genetic counselling before signing this consent.

☐ Tick to consent to having your personal data transferred outside the UK, for the limited purposes described on the back of this form.

☐ Tick to opt-in to anonymised laboratory development and validation studies.

If I tick the opt-in box regarding anonymised laboratory development and validation studies, I agree and consent to allow TDL Genetics Limited or its subcontractor to use the unused portions of my sample for laboratory validation, process development, quality control studies and/or other research purposes as described in the informed consent. I understand that if I choose to opt in and allow TDL Genetics Limited or its subcontractor to use my unused sample in this manner, my sample will be anonymised, meaning that information that can identify me will be removed. I understand that my unused sample will be stored with some of the non-identifiable clinical data TDL Genetics Limited or its subcontractor received from me (e.g., gestational age, number of fetuses), which will be retained for use in these activities. The unused samples and non-identifiable clinical data may be stored for longer than 60 days.

I understand that if I do not opt in, my unused sample will not be used for these purposes and will be destroyed in accordance with TDL Genetics Limited's or its subcontractor's policies and procedures. In all cases, patient samples and personal data, including results will be stored, used, and destroyed in compliance with applicable laws, rules, and regulations.

Patient signature Date (DD/MM/YYYY)

Clinician signature

I confirm that my patient has been fully informed about capabilities, limitations, and possible risks of the test(s). The patient has given full consent for this test.

Clinician signature Date (DD/MM/YYYY)

Clinic Information

Account Name

Ordering Clinician

Address

Postcode

Phone

Referring Clinician

Test menu options

☑ Trisomy 21, 18 and 13

Please mark any additional test options requested:

Fetal sex to be reported (now available for twins)

☐ Yes ☐ No

☐ Monosomy X only[1]

☐ Sex chromosome aneuploidy panel[1]

(X and Y – assesses the risk of monosomy X, XXX, XXY & XYY)[1]

Note: [1] Available for singleton pregnancies only.

Fetal sex will be apparent if a high risk sex chromosome aneuploidy is indicated even when fetal sex has not been reported. For twin pregnancies, male results apply to one or both fetuses, female results apply to both fetuses.

Essential clinical information*

Gestational Age* weeks days measured on (DD/MM/YYYY)

Number of Fetuses* ○ 1 ○ 2

IVF Pregnancy?* ○ No ○ Yes

U/S findings or biochemical risk

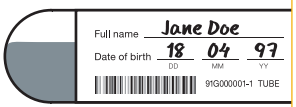
Is this a redraw?* ○ Yes

IMPORTANT BLOOD DRAW INFORMATION

Complete A & B:

A. Blood collected on: (DD/MM/YYYY) by:

B. Write the patient's full name and date of birth on tube barcode. Name, barcode and date of birth must match the Request Form. Place label lengthwise on the cfDNA tube as shown in the example.



Billing Information

○ Bill Patient ○ Bill Doctor

TDL GENETICS

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1 Mabledon Place, London WC1H 9AX
T +44(0)20 7307 7409 | E tdlgenetics@tdlpathology.com
www.tdlpathology.com

Patient Informed Consent

The VeriSeq Non-invasive Pregnancy Test (NIPT) Solution v2 is an in vitro diagnostic test intended for use as a screening test for the detection of fetal genetic anomalies from maternal peripheral whole blood specimens in pregnant women of at least 10 weeks gestation. VeriSeq NIPT Solution v2 uses whole-genome sequencing to detect aneuploidy status. The test offers an option to request the reporting of sex chromosome aneuploidy (SCA). This product must not be used as the sole basis for diagnosis or other pregnancy management options.

Who is eligible for the VeriSeq NIPT Solution v2?

Patients must be of at least 10 weeks gestational age for a VeriSeq NIPT Solution v2. Patients who have received bone marrow or organ transplants or those who have metastatic cancer are not eligible for the VeriSeq NIPT Solution v2. Please see below for additional eligibility criteria:

- Women who are at least ten weeks pregnant are eligible for the VeriSeq NIPT Solution v2.
- Women with IVF pregnancies and twin pregnancies are eligible.

The VeriSeq NIPT Solution v2 is not suitable for patients with:

- Recent maternal blood transfusion
- Maternal prior organ transplant / stem cell transplant
- Maternal autoimmune disease
- Maternal neoplasms (benign and malignant)
- Twin pregnancies are not eligible for sex chromosome aneuploidy
- Maternal mosaicism
- Maternal copy number variations
- Fetoplacental mosaicism / confined placental mosaicism
- Fetal demise / vanishing twin

What are the limitations of the VeriSeq NIPT Solution v2 for Trisomies 21, 18, and 13, sex chromosome aneuploidy, and fetal sex determination?

The VeriSeq NIPT Solution v2 is not validated for use in pregnancies with more than two fetuses, fetal demise, mosaicism, partial chromosome aneuploidy, triploidy, translocations, maternal aneuploidy, transplant or malignancy. VeriSeq NIPT Solution v2 does not detect neural tube defects. Certain rare biological conditions may also affect the accuracy of the test. For twin pregnancies, HIGH PROBABILITY test results apply to at least one fetus; male test results apply to one or both fetuses; female test results apply to both fetuses.

Due to the limitations of the test, inaccurate results are possible. A LOW PROBABILITY result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition. Some non-aneuploid fetuses may have HIGH PROBABILITY results. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

What is done with my sample after testing is complete?

No additional clinical testing will be performed on your blood sample other than those authorised by your healthcare provider. Your test results will be disclosed only to the healthcare provider(s) listed on the front of this form (or to his or her agent) or to its permitted subcontractors unless otherwise authorised by you or as required by laws, regulations, or judicial order.

Personal data

By signing the consent overleaf you expressly agree and give permission for your personal data included in this test request form (including, without limitation, your name, address, information about your pregnancy, and other relevant information), as well as your blood sample, to be sent to TDL Genetics Limited for the purpose of performing the VeriSeq NIPT Solution v2. In the event you withdraw your consent or request not to receive the results of the VeriSeq NIPT Solution v2, TDL Genetics Limited will use commercially reasonable efforts to promptly destroy your blood sample in compliance with applicable UK laws and regulations, and TDL Genetics Limited's standard protocols for sample destruction. You agree that in the event TDL Genetics Limited performs the VeriSeq NIPT Solution v2 selected on this form, TDL Genetics Limited may store your personal data (including the test results) and remaining sample (if any) for the applicable legally required time period.

The VeriSeq NIPT Solution v2 will usually be performed in the UK by TDL Genetics Limited. Under certain circumstances TDL Genetics Limited may subcontract with other laboratories approved to perform the VeriSeq NIPT Solution v2 (for example if TDL Genetics was not able to process your blood sample in its or its UK-based subcontractors laboratories) and/or may need to use technical support and maintenance services in relation to the equipment used to perform VeriSeq NIPT Solution v2. For these purposes TDL Genetics Limited may need to transfer your personal data to countries outside the United Kingdom (UK) which may not offer the same rights in respect of your personal data as countries within the UK. When this is necessary any transfer will be made in full compliance with all aspects of applicable data protection legislation.

By signing the consent form overleaf, you:

- give permission for your personal data included in this form, as well as your blood sample, to be shipped and transmitted to laboratories outside the UK to perform the VeriSeq NIPT Solution v2 and to have your test results transmitted to TDL Genetics Limited and your ordering healthcare provider;
- give permission for your personal data to be transmitted to Germany, America and/or Singapore for the purposes of TDL Genetics Limited processing your blood sample for testing and/or obtaining technical support and maintenance services in relation to the equipment used to perform the VeriSeq NIPT Solution v2;
- consent to the treatment, handling, and retention of your patient data and samples by the laboratory subcontracted by TDL Genetics Limited in accordance with applicable regulations and laws. For information on the TDL group privacy policy please visit: https://tdlpathology.com/about-tdl/tdl-group-privacy-notice/.

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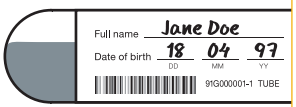

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