PREQUEL GENETICS®

REQUEST & CONSENT FORM

PLEASE WRITE CLEARLY USING CAPITAL LETTERS

*Mandatory Fields

REQUESTING CLINIC INFORMATION

REFERRING HEALTHCARE PROFESSIONAL NAME*	CLINIC NAME*	CLINIC TELEPHONE
CLINIC EMAIL*	**CLINIC ADDRESS**	**CLINIC POSTCODE**

PATIENT, PREGNANCY & SAMPLE INFORMATION

FIRST NAME*	SURNAME*	DATE OF BIRTH* (DD/MM/YY)
PATIENT ADDRESS	**PATIENT ZIPCODE**	**PATIENT TELEPHONE***
MATERNAL WEIGHT (KG)	**MATERNAL HEIGHT** (CM)	**E-MAIL***
ULTRASOUND DATE* (DD/MM/YY)	**BLOOD DRAW DATE*** (DD/MM/YY)	**GESTATION AT DRAW*** (WEEKS/DAYS)

PREGNANCY TYPE* ☐ Single ☐ Dichorionic Twin ☐ Monochorionic Twin

VANISHING TWIN (IF APPLICABLE) ☐ Yes

REPEAT SAMPLE (IF APPLICABLE) ☐ Yes

IVF (IF APPLICABLE) ☐ Homologous ☐ Embryo Donation ☐ Sperm Donation ☐ Egg Donation

PATIENT, PREGNANCY & SAMPLE INFORMATION

INDICATION FOR TESTING/RISK FACTORS* (TICK ALL THAT APPLY)	EXPECTANT MOTHER AFFECTED BY/HAS UNDERGONE*
☐ Fetal abnormalities in previous pregnancies *(please give details)*	☐ Immunotherapy *(excluding intravenous immunoglobulin (IVIg) treatment)*
☐ High serum screen result *(please give details)*	☐ Maternal genetic condition *(please give details)*
☐ Maternal age > 35 years	☐ Organ transplant/Stem cell therapy
☐ Patient choice	☐ Recent transfusion *(<4 months)*
☐ Ultrasound abnormalities for current pregnancy *(please give details)*	☐ Tumour/Fibromas *(please give details)*
PREVIOUS NO. OF PREGNANCIES	**MEDICAL NOTES** *Provide details of relevant medical history, e.g., risk score for T21, T18, T13 if known*
PREVIOUS NO. OF MISCARRIAGES	

TEST TYPE REQUIRED* (Tick one only)

☐ Prequel NIPT Basic®	**Chromosomes 21, 18, 13 only**
☐ Prequel NIPT 5®	**Chromosomes 21, 18, 13, X, Y**
☐ Prequel NIPT DiGeorge®	**Chromosomes 21, 18, 13, X, Y + DiGeorge syndrome**
☐ Prequel NIPT Advance®	**Chromosomes 21, 18, 13, X, Y + panel 6 Microdeletions + Trisomies 9 + 16**
☐ Prequel NIPT Karyo®	**Genome-wide NIPT that provides karyotype-level insight**
☐ Prequel NIPT Karyo Advance®	**Genome-wide NIPT that provides karyotype-level insight + panel 9 Microdeletions**
☐ Prequel NIPT Risk 100®	Prequel NIPT Karyo® + **Prequel 100 Gene Analysis (Father's sample required)**
☐ Prequel NIPT Risk 100 Advance®	Prequel NIPT Karyo Advance® + **Prequel 100 Gene Analysis (Father's sample required)**
☐ Prequel NIPT MonoGene®	Prequel NIPT Karyo® + **16 Fetal Monogenic diseases**
☐ Prequel NIPT MonoGene Advance®	Prequel NIPT Karyo Advance® + **16 Fetal Monogenic diseases**
☐ Prequel NIPT Total®	Prequel NIPT Karyo® + **16 Fetal Monogenic diseases + Carrier mother**
☐ Prequel NIPT Total Advance®	Prequel NIPT Karyo Advance® + **16 Fetal Monogenic diseases + Carrier mother**

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☐ Prequel NIPT Total Family®

Prequel NIPT Karyo Advance® + **16 Monogenic diseases + Carrier mother and father** (Father's sample required)

DO YOU WISH TO KNOW THE FETAL SEX? *, [4] ☐ YES ☐ NO

[2] Sex chromosome aneuploidies are not reported for twin pregnancies (including single with vanishing twin). A Prequel Nipt Basic report will be issued instead.

[4] Sex determination is reported as presence/absence of Y chromosome for single pregnancies with vanishing twin or twin pregnancies.
When sex chromosome aneuploidies are tested and detected with Prequel NIPT 5, fetal sex will be disclosed if an anomaly is reported. If no sex chromosome aneuploidy is detected, fetal sex will not be reported unless requested.

HEALTHCARE PROFESSIONAL CONSENT*

- I confirm I am a registered Healthcare professional.
- I verify that the patient and prescriber information in this form is complete and accurate to the best of my knowledge.
- I verify that I have requested this screening test based on my professional judgement of medical necessity.
- I have addressed the limitations of this test and have answered any questions to the best of my ability.
- I understand that Prequel may need additional information from the healthcare provider and I agree to provide it as needed for purposes of reimbursement.
- I have given the patient information leaflet.
- I have taken and packed the sample in accordance with the kit instructions.

BILLING (IF APPLICABLE)

☐ Patient mail:_____

☐ Clinic/Consultant mail:_____

Full Name (USE CAPITAL LETTERS) Signature Date: DD/MM/YYYY

X_____ X_____

FATHER'S DETAILS

NAME*	SURNAME*	DATE OF BIRTH(DD/MM/YY)
PATIENT ADDRESS	**POSTCODE**	**DATE OF SAMPLE COLLECTION(DD/MM/YY)**

FATHER'S CONSENT

• I consent to the selected test, understand where it will be processed, and confirm I was informed about its purpose, scope, and limitations by my doctor.
• I understand this is a screening for specific conditions and does not rule out other possible abnormalities.
• I acknowledge that results should be reviewed with my doctor.
• I had the chance to ask questions, received the patient leaflet, and know I can request more information or genetic counselling.
• I agree my data may be used for quality control and audits, and I understand I can withdraw consent at any time.

Full Name (USE CAPITAL LETTERS) Signature Date: DD/MM/YYYY

X_____ X_____

TEST LIMITATIONS

NIPT is a screening test with a residual risk of false positive and false negative results (<0.1%) and is neither intended nor validated for diagnosis. This test is not validated for pregnancies with more than two fetuses and is not designed to detect chromosomal mosaicisms and triploidies. This test is not intended to identify pregnancies at risk for open neural tube defects. The result of this test does not exclude the possibility that the chromosomes harbour abnormalities other than those included in the test, and it does not detect abnormalities of untested chromosomes, genetic disorders, birth defects or congenital complications of other origin. A low-chance result does not completely exclude the presence of one of the chromosomal abnormalities investigated. The test result may not reflect the real state of the fetus, as it can detect chromosomal abnormalities arising from confined placental mosaicisms, vanishing twin or maternal condition. When an aneuploidy result is detected in a twin pregnancy, the status of each individual fetus cannot be determined. Although the presence or absence of Y chromosome material can be reported in a twin pregnancy, the detection of sex chromosome aneuploidies such as Monosomy X, XXX, XXY, and XYY is not possible. The results of the test can be confounded by certain maternal and fetal factors including but not limited to: recent maternal blood transfusion; maternal organ transplant; maternal surgical procedure; maternal immunotherapy, stem cell therapy; maternal malignancy; maternal mosaicism; fetal placental mosaicism; fetal demise; nonviable twin.

To withdraw any of the consents above, please email: legal@prequel-nipt.com