NIPT REQUEST AND CONSENT FORM

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GeneLabs X

Lab ID:	Date:

1. PATIENT INFORMATION

Patient Name	Patient DOB	Age
	Address	
E-mail ID	Contact No.	

2. CLINICAL INFORMATION

GESTATIONAL AGE (WEEKS)

CONCEPTION DETAILS ☐ Natural ☐ IVF

SPECIFIC CLINICAL HISTORY NT Value if available

PREGNANCY TYPE: ☐ Singleton ☐ Twins ☐ Other

3. BLOOD SAMPLE INFORMATION

Sample Type ☐ Streck Tube ☐ EDTA Blood Collection Date __ / __ / _____

Fetal Sex

Wish to know the gender Yes ☐ No ☐

(Please note the accuracy for sex determination is more than 99.5% but not 100%)

4. REQUESTING DOCTOR

Name and Visited Hospital

5. PATIENT ACKNOWLEDGEMENT

I understand that NIPT is a screening test with >99% accuracy for detection of trisomies and sex chromosomes. However this test is not diagnostic and therefore does not claim 100% accuracy

I hereby consent to the NIPT test performed at GeneLabs X and confirm that I have been informed about the purpose, scope and limitations of the test (Outlined in the opposite page).

Date __ / __ / _____

Signature of Patient

Non Invasive Prenatal Test (NIPT)

Limitation of the test

1. NIPT is intended to detect fetal Trisomy from 10 weeks of gestation onwards, and mainly detects trisomies of chromosome 13, 18, 21 and sex chromosomes.
2. NIPT is based on whole genome sequencing technology and is able to detect additional abnormalities such as other autosomal chromosomes & sub-chromosomal abnormalities. Please note, however, that there are currently limited independently published clinically validated studies associated with screening for these abnormalities, due to their low incidences worldwide.
3. The test has a fetal DNA limit cutoff of 3.5%. Any sample with less than 3.5% fetal DNA will require repeat testing. Higher BMI of the mother is a known reason for low fetal DNA in the sample, and in such case the result might be inconclusive even after repeat testing.

Patients Informed Consent

1. I have provided true and reliable personal information, and fully understand the indication, intended purpose and potential risk of this test. I understand the limitations of this test, in particular:
   i. This test carries out genome-wide aneuploidy detection, but is mainly intended for the detection of Trisomy 13, Trisomy 18, Trisomy 21, and sex chromosomes
   ii. The detection rate is close to, but is not 100%
2. I understand that a repeat blood sampling (up to 5%) may be required due to insufficient concentration of fetal DNA or other sample-specific factors. I understand that in the case of repeat sample also failing due to same reason (Eg: high maternal weight), the lab may not be able to issue an aneuploidy report.
3. I understand that this test may not be suitable if I (the mother) have had blood transfusion within 12 months of the test date.
4. GeneLabs X (Pvt) Ltd is committed to the continuous monitoring and Improvement of the next generation sequencing platform for better patient reporting and outcomes. I understand that collecting information on my pregnancy is part of the laboratory's practice for quality purposes and test evaluation, and the data may be used for Research and Development purposes.
5. I acknowledge that when I opt out of receiving results for sex chromosome Aneuploidies and/or deletion syndrome and/or fetal sex, GeneLabs X will not report these results. I understand that whole genome sequencing platform may detect other incidental findings not listed on the test request form. I understand that Genelabs will not report on these additional incidental findings.

TO BE COMPLETED BY GENELABS X

Date Received: __ / __ / _____ Time Received: __ : __

Signature