SagePath®
Excellence In Health Care

Consent Form

☐ **Non-Invasive Prenatal Test - NIPT**
☐ **Non-Invasive Prenatal Test - NIPT Microdeletion**

(To be filled in by patient) Vial ID:

Patient	Name	KUTUBUN NESSA		Date of Birth	DD/MM/YYYY 02/03/2022	ID/Passport No	835945319186
	Address	YEAZEKHWRA. IRANI, KAILASHAHAR, UNAKOTI TRIPURA.				Contact number	9612303060
	Weight	61 kg	Blood Type	O+	Inherited Disease ☑NO ☐YES		
Pregnancy	Gestation Period 29 Weeks 4 Day				Pregnancy type ☑Singleton ☐Multiple		
	Past history of Gestation Abnormality ☐No ☐Yes						

(To be filled in by Clinical/Medical Institution)

Pregnancy profile	Doctor	Sujit Das.		Undergoing IVF ☐No ☐Yes (Number of embryos: Implantation____Blighted ovum____Fetal reduction____)			
	Down Syndrome test	☑ none so far ☐ NT_____Notes:					
		T21_____T18_____T13 _____					
Sample info	Medical Institution		Contact number		Blood taken by		Blood quantity ml
	Blood collection date	DD/MM/YYYY		Blood pick up date		DD/MM/YYYY	
Collection agent			Condition of blood		Blood ID		

Purpose and method of the test

The Firstvue NIPT (Non Invasive Prenatal Testing) was developed by PathCare Labs. This test is designed to screen for Trisomy 13 (Patau syndrome), Trisomy 18 (Edwards syndrome) and Trisomy 21 (Down syndrome). The test is performed by first collecting a 10 ml blood sample from an expecting mother at least 10 weeks into the pregnancy. Cell-free fetal DNA is then extracted from the blood sample for subsequent DNA sequencing. Through innovative next-generation DNA sequencing technology, and specialized bioinformatics analysis, this test platform has a detection rate of over 99.9% for the above-mentioned genetic anomalies.

Recommended use of this test:

The Firstvue NIPT should be considered after close consultation with your physicians and if possible a genetic counselor.

The test is recommended in cases where:

1. Patients are concerned about the risk of invasive prenatal diagnosis; and/or
2. Patients have unusual ultrasonography findings which suggest chromosome abnormality; and/or
3. Patients are of advanced maternal age and/or have a higher risk of their fetus being diagnosed with Down syndrome.

Test Results:

The test report will indicate a Positive (aneuploidy detected) or Negative (aneuploidy not detected) result for each of the conditions listed above.

In very few cases, the test does not report any results. In these circumstances, PathCare Labs will provide a free re-test. If the re-test produces no results, the patient will be refunded the initial cost of the test.

Important considerations:

This test does not reveal the gender of the fetus.

If one or both of the parents have a balanced Robertsonian Translocation involving chromosome 21, please consult your physician about the applicability of this test.

Although the detection rate of this test is very high, like all other non-invasive prenatal tests (NIPTs) based on the analysis of cell-free fetal DNA, this test is currently classified as a screening test. A diagnostic test such as Amniocentesis or Chorionic Villus Sampling (CVS) is typically recommended for tests that return positive results. Therefore, the results of this NIPT serve as a reference for your physicians to suggest further treatment.

The accuracy and quality of the test may be adversely affected by improper blood sample collection, storage and transportation. The accuracy and quality of the test may also be adversely affected by samples taken from patients that have received medical treatment including allogeneic blood transfusion, transplant operations, and stem cell therapy within 30 days of sample collection.

This test is not suitable for:

-Patients with dizygotic multiple gestation.
-Patients with diagnostic results that have revealed chromosomal aneuploidy.
-Patients who have previously accepted blood transfusions from other than themselves, or have undergonetransplantation surgery, stem cell therapy or egg donation.
-Patients at less than 10 weeks gestation.
-Patients who have tested positive for HIV and/or Hepatitis B/C.

Limitations of the test:

Chromosomal abnormalities such as chromosomal rearrangements, duplications, copy number variations, balanced translocations, inversions, imbalanced translocations, uniparental disomy, mosaicism etc., are not within the scope of detection. Therefore, this test does not guarantee that a fetus will be free from a genetic disease. NIPT Microdeletion test is a risk assessment test only and does not guarantee that a fetus will be free from genetic microdeletion.

Informed consent:

If the NIPT test result is high risk, PathCare will reimburse the cost of further confirmatory diagnostic tests including amniocentesis, CVS and chromosome fluorescence in situ hybridization (FISH).

Privacy and confidentiality:

PathCare Labs respects the privacy and confidentiality of your personal information. The information collected on this form (including any relevant medical history) is collected only for the sole purpose of conducting this test and will not used in any manner to the contrary.

If you have any questions or would like further clarification, please call the local PathCare Labs representative orthe relevant partner laboratory

Patient Signature_____DD/MM/YYYY

Doctor's Signature_____DD/MM/YYYY

Patient E-mail_____

Doctor's E-mail:_____