mfine /diagnostics

MFine's - Jananya

Non Invasive Prenatal Test

The Future of Proactive & Precise Prenatal Screening is here!

The latest evidence based Practice Guideline by ACMG strongly recommends NIPT over traditional screening for all pregnant patients with Singleton or Twin Gestations.

-Conditional Recommendation to offer NIPT for 22q11.2 Deletion Syndrome

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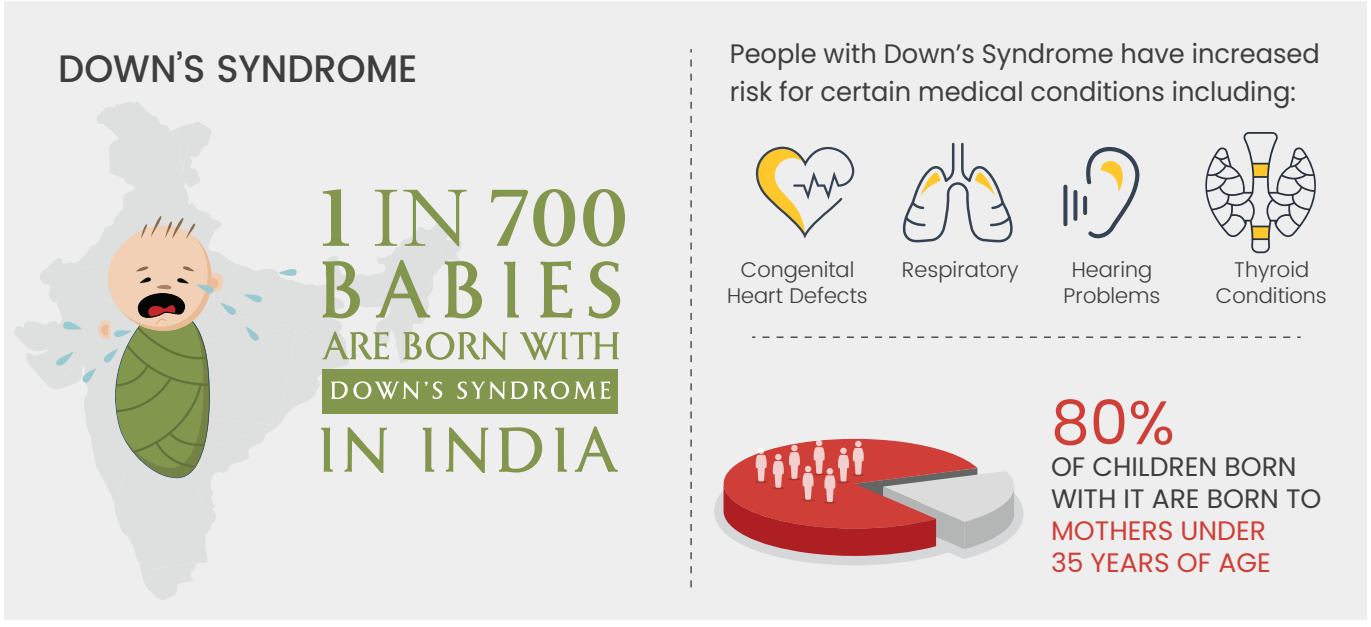
What Are Aneuploidies?

Aneuploidy is a condition in which the growing fetus has an abnormal number of chromosomes causing disruption of the normal course of development and cellular function. Below are some common disorders and their associated clinical findings and incidences.

Disorder	Clinical Findings	Incidence
Patau Syndrome (Trisomy 13)	Multiple congenital malformations and severe to profound intellectual disability. Babies have high prenatal, neonatal, and infant mortality, approximately 10% survive past 5 years of age	1/5000
Down syndrome (Trisomy 21)	Hypotonia, a characteristic facial appearance, developmental delays/intellectual disability, approximately 88% survive past 20 years of age.	1/700
Edwards syndrome (Trisomy 18)	Intrauterine growth restriction with low birth weight; multiple congenital anomalies involving the brain, spinal cord, heart, abdominal wall, and kidneys; hypotonia; and severe to profound intellectual disability. Babies with trisomy 18 have high prenatal, neonatal, and infant mortality, approximately 12% survive past 5 years of age	1/5000
Turner syndrome (Monosomy X)	Fluid accumulations (cystic hygroma, lymphedema), short stature, low-set ears, broad chest, cardiac, renal anomalies and infertility	1/2,500 female births
Klinefelter syndrome (XXY syndrome)	Males with Klinefelter syndrome, or 47,XXY, are typically taller than average, with delayed or incomplete puberty and infertility	1/500 male births



What Is Prenatal Aneuploidy Screening?

Maternal serum screening (MSS) and cell-free DNA (cfDNA) screening or NIPT is offered early in a pregnancy to estimate the risk of the mother carrying a fetus with a chromosomal abnormality. Being simple, safe and noninvasive this test requires only the maternal blood sample.

> "International and National Medical Societies agree that all pregnant women should be offered prenatal screening for chromosomal aneuploidies."

With Jananya NIPT, Delve Deeper For The Answers That Matter The Most!

What Is Jananya NIPT?

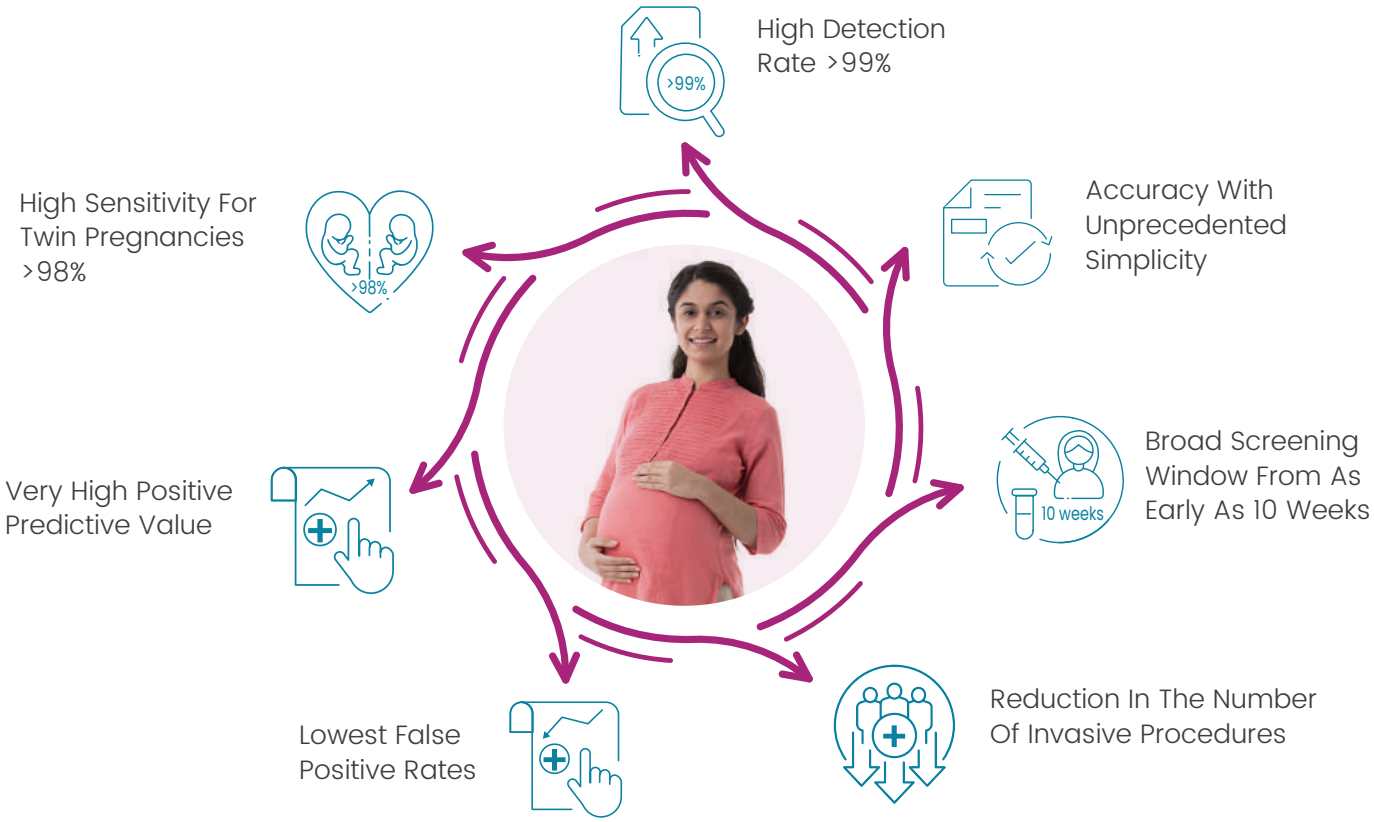
Jananya Non-invasive Prenatal Test (NIPT) is a simple and safe method to determine whether your baby is at the risk of having certain chromosomal abnormalities during pregnancy. What makes this test unique is the fact that it analyzes the small, circulating fragments of DNA in the mother's blood originating from the placenta. It is a reliable test with high sensitivity and specificity and just requires 10 ml of maternal blood.

Who Is Jananya NIPT Intended For?

- All pregnant women with single or twin pregnancies
- All pregnancies involving IVF, surrogacy and egg donation

Limitations Of Serum Screening (Double/Triple/Quadruple Marker) That Jananya NIPT Overcomes

Jananya NIPT Offers The Following Unmatched Advantages:



Looking Beyond Common With Jananya NIPT

MFine uses the potential of next-generation sequencing (NGS) to bring a whole-genome sequencing (WGS) approach to NIPT, expanding test options beyond chromosomes 21, 18, and 13 to include rare autosomal aneuploidies (RAAs), sex chromosome aneuploidies (SCAs).

AUTOSOMAL ANEUPLOIDIES:

• Down syndrome (Trisomy 21) • Edwards syndrome (Trisomy 18)
• Patau syndrome (Trisomy 13)

SEX CHROMOSOME ANEUPLOIDIES:

• Turner syndrome (Monosomy X) • Triple X syndrome (Trisomy X) • Klinefelter syndrome (XXY)
• Jacobs syndrome (XYY)

RARE AUTOSOMAL ANEUPLOIDIES:

• 19 additional chromosomes

MICRODELETIONS:

• DiGeorge syndrome (22q11.2) • 1p36 deletion syndrome • Prader-Willi syndrome/Angelman Syndrome • Wolf-Hirschhorn syndrome (4p16.3) • Cri-du-Chat Syndrome

Choose From Comprehensive Jananya NIPT Options To Get Unmatched Clarity:

	Jananya-NIPT Basic (Required Fetal Fraction >3.5%)	Jananya-NIPT All Chromosomes (Required Fetal Fraction >3.5%)	Jananya – NIPT Microdeletions (Required Fetal Fraction >5%)
Chromosomes 13,18 and 21	✓	✓	✓
Sex Chromosomes	✓	✓	✓
All Other Chromosomes		✓	✓
Microdeletions			✓

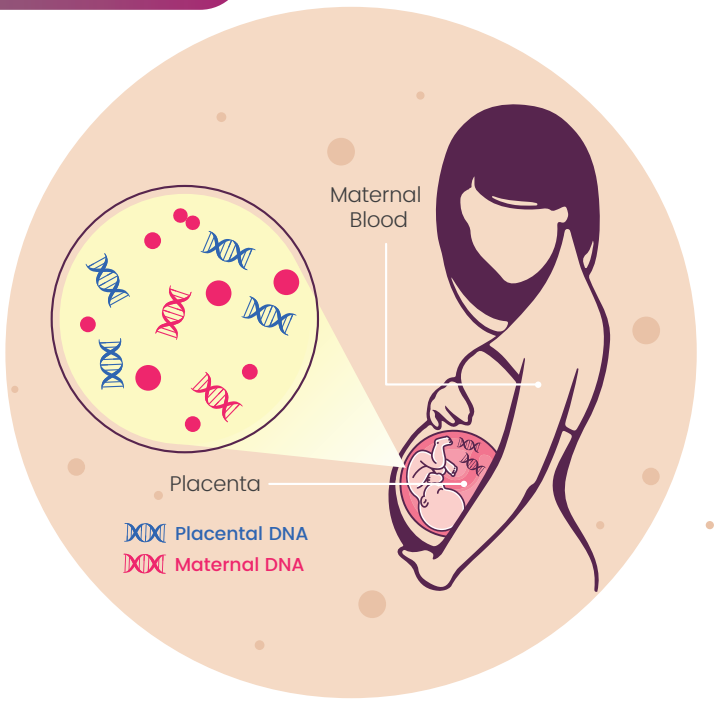
Consult your healthcare provider to choose the right option for you.

Why Choose Jananya NIPT Over Others?

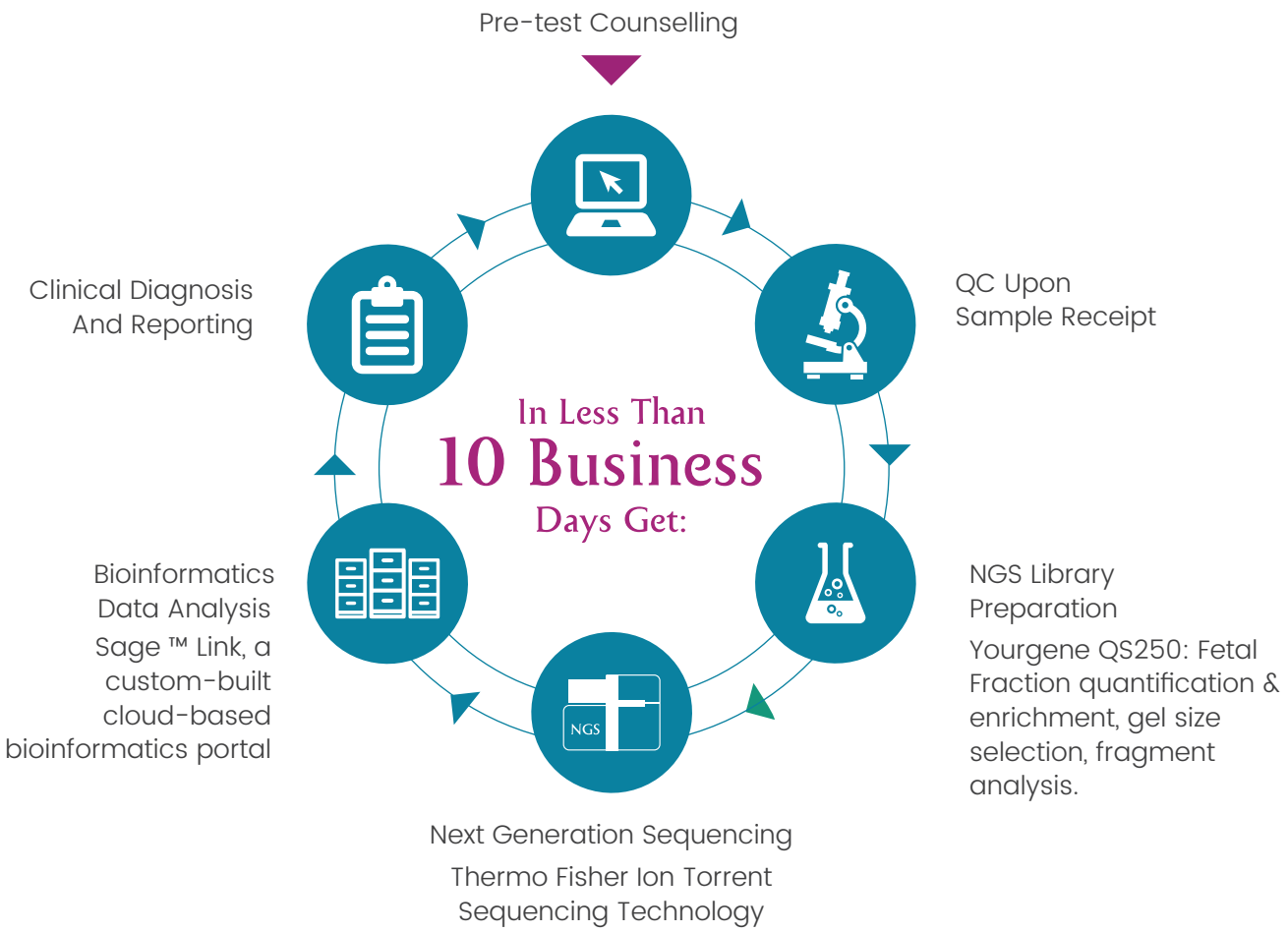
- Genome-Wide NIPT With Next Generation Sequencing Technology
- Powered By Yourgene Health, A Leading Global Provider of NIPT
- Use Of Sage™ 32 Plex Fully Automated Workflow
- Yourgene QS250 For High Level Cell Free DNA Fragment Enrichment
- Proprietary Bioinformatics Pipeline Sage Link For High Quality Analysis
- Extensively Validated By Published Study Of >10000 Samples
- Lowest Test Failure Rates In The Industry
- Trusted As >2000 NIPT Samples Processed Monthly
- Faster Turnaround Time To Result (7-8 Days)
- Complimentary Genetic Counseling To Understand The Results
- Reflex Diagnostic Testing For Screen Positive Cases
- NABL & CAP Accredited Laboratory.

Get Complete Reassurance With Jananya NIPT

Fetal fraction is the percentage of circulating cell free DNA of fetal origin in the maternal blood. Correct measurement of Fetal Fraction is an indispensable requirement for attaining quality analysis. Jananya NIPT is exclusively powered with intelligent Ranger® Technology for accurate Fetal Fraction quantification and high throughput enrichment for accurate results and extremely low test failure rates.



LifeCell's Jananya NIPT Workflow



The Sage Advantage

SageTM QS 32plex Test performance observed following Post-market surveillance on 10,640 samples.

Sage 32™
Highly efficient NIPT workflow

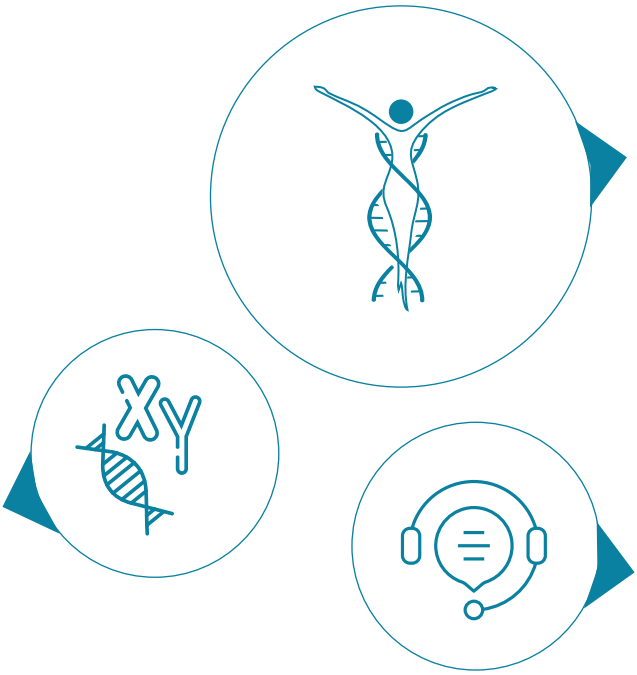
	Sensitivity	Specificity	PPV	NPV	FPR	FNR
Trisomy 21 (173)	>99.99%	99.97%	87.50%	>99.99%	0.028%	<0.01%
Trisomy 18 (48)	>99.99%	99.96%	91.67%	>99.99%	0.038%	<0.01%
Trisomy 13 (24)	>99.99%	>99.99%	>99.99%	>99.99%	<0.01%	<0.01%
SCAs (107)	>99.99%	99.91%	91.59%	>99.99%	0.085%	<0.01%

International Society Guidelines Supporting NIPT

ACOG
The American College of Obstetricians and Gynecologists

Society for Maternal-Fetal Medicine

ACOG and SMFM (Practice Bulletin 226, 2020)



cfDNA screening is an option for all pregnant women, regardless of maternal age or background risk

cfDNA screening is the most sensitive and specific screening option for the common aneuploidies

Patients with a positive screening test result for fetal aneuploidy should undergo genetic counseling and a comprehensive ultrasound evaluation with an opportunity for diagnostic testing to confirm results

ispd

ISPD (Position Statement-10,2020) "The use of first trimester cfDNA screening for the common autosomal trisomies is appropriate for twin pregnancies due to sufficient evidence showing high detection and low false positive rates with high predictive values"

Limitations Of The Test

NIPT is a screening test with probability of false-positive and false-negative results therefore a positive NIPT screen result mandates confirmation by invasive testing. This test does not screen for birth defects such as open neural tube defects, triploidy ,or other genetic disorders like thalassemia. Pregnant women should make an informed choice regarding further testing options after discussion with their health care provider and genetic counselor.