NIPT

LeoNext cfDNA Library Preparation Kit

for Non-invasive Prenatal Testing

CE IVD

www.genes2me.com

About our NIPT Panel

LeoNext cfDNA Library Preparation kit for Non-invasive Prenatal Testing (NIPT) is aimed to detect common trisomies, sex chromosomal aneuploidies and other rare aneuploidies in all 23 pairs of chromosomes employing next generation sequencing (NGS) Technology. This product is highly sensitive, robust and accurate and can additionally detect the microdeletions & duplications.

This product helps in construction of a cfDNA library which will be compatible with the commonly available sequencer platforms (Illumina, MGI, Element Biosciences (AVITI). The library preparation is performed on isolated circulating fetal DNA (cfDNA) from maternal blood sample which is A-tailed, adapter ligated and amplified to get a library that is ready to be sequenced.

NIPT Offerings by G2M

NIPT- 23 pairs of chromosomes:-

Covers all 23 pairs of chromosomes – including autosomal aneuploidies (like Common trisomies: Down Syndrome (T21) Edward Syndrome (T18) Patau Syndrome (T13) and sex chromosomal aneuploidies.

NIPT- 23 pairs of chromosomes & 90+ Micro-deletions/duplications:-

Covers all 23 pairs of chromosome – including autosomal aneuploidies (like Common trisomies: Down Syndrome (T21) Edward Syndrome (T18) Patau Syndrome (T13), sex chromosomal aneuploidies and 90+ micro-deletions and micro-duplication Syndromes.

Product Name	No of Reads (in Millions)
NIPT-All Chromosome	7-10 Million*
NIPT-All Chromosome + Microdeletions & duplications	20-25 Million

**Note: This corresponds to unique reads generated.*

Advantages of NIPT

- A Non-invasive genetic screening test, completely risk free assessment.
- Allows early accessibility of highly accurate data on all chromosomes of the fetus for informed pregnancy decisions.
- Helps to identify fetuses at risk of any serious chromosomal abnormalities.
- Completely safe and empowers expecting parents to support, manage and access early medical help if required.

Specifications

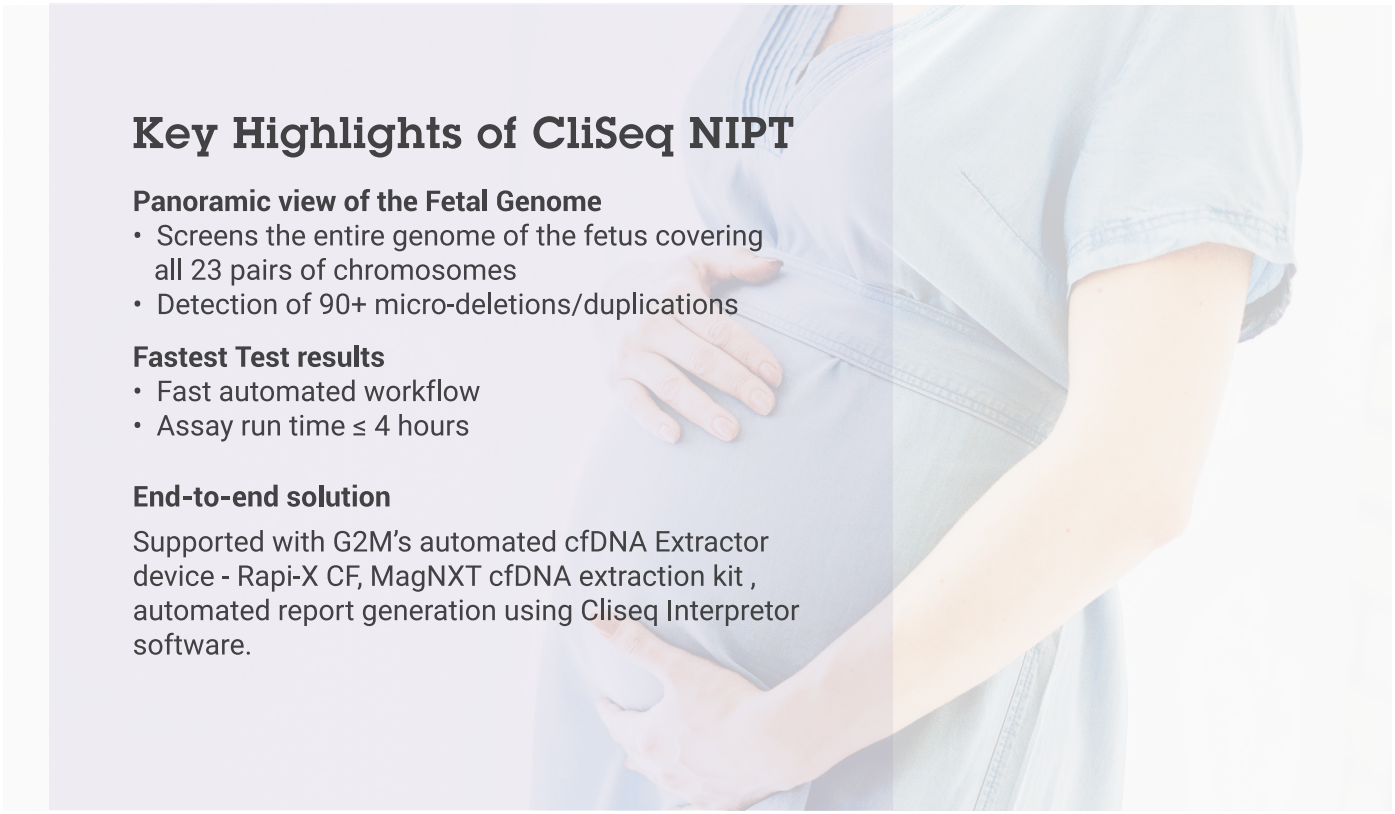
Gestational age	10 weeks onwards
Specimen type	10 ml of Maternal blood sample
Recommended extraction kits and devices	1.Genes2me – MagNXT Cell free DNA extraction kit 2.Genes2me – Rapi-X CF device
Input cfDNA	10-20 ng
Library Avg insert size	275 to 325 bp
Sequencing Methodology	Low depth whole genome sequencing
Sequencer Compatibility	2nd Generation Sequencers – Illumina, MGI, Element Biosciences
Sequencing mode	SE 50 (Single end sequencing)
Fetal Fraction	Min 3%
Pregnancy Type	Acceptable for Singleton & Twin*

*Note: "The assay can detect aneuploidy in a given sample, regardless of whether the pregnancy is singleton or twin. However, it cannot determine the type of pregnancy (e.g., twin) or distinguish between individual fetuses. It will solely report the presence or absence of aneuploidy."

Performance Characterstics

	Trisomy 13	Trisomy 18	Trisomy 21
Sensitivity (%)	100	100	100
Specificity (%)	99.96	99.95	99.96
PPV (%)	78.57	88.54	96.56
NPV (%)	100	100	100

Note : The data mentioned above is for > 3000 samples.



Key Highlights of CliSeq NIPT

Panoramic view of the Fetal Genome
- Screens the entire genome of the fetus covering all 23 pairs of chromosomes
- Detection of 90+ micro-deletions/duplications

Fastest Test results
- Fast automated workflow
- Assay run time ≤ 4 hours

End-to-end solution

Supported with G2M's automated cfDNA Extractor device - Rapi-X CF, MagNXT cfDNA extraction kit , automated report generation using Cliseq Interpretor software.

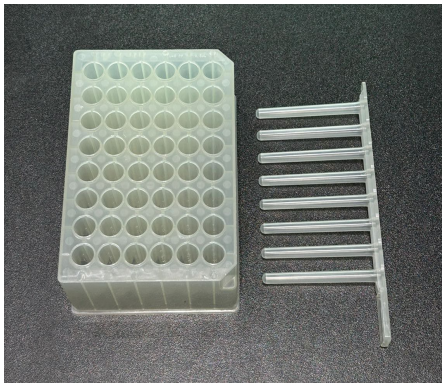
G2M NIPT END-TO-END Workflow

Maternal Plasma	Cf DNA Extraction	LeoNext CfDNA library preparation kit	Sequencing	Data Analysis
10 ml of maternal whole blood	cfDNA extraction with G2M's cell-free DNA extraction kit and extraction platform RAPi-XCF CELL FREE DNA EXTRACTION SYSTEM for NIPT	Using G2M's LeoNext CfDNA library preparation kit on G2M's Ezy Autoprep - automated NGS library preparation workstation EZY-AutoPrep	On the sequencing platform of your choice	G2M's proprietary NIPT data analysis software CliSeq Interpreter

RAPi-XCF

Automated Cell Free DNA Extraction System

Engineered for Maximum Efficiency in isolating Circulating DNA from Plasma/Serum Samples



RAPi-X CF Automated Nucleic Acid System is specifically optimized for Non-Invasive Prenatal Testing (NIPT), ensuring efficient extraction of high-quality cell-free fetal DNA from maternal plasma. Designed to meet the demands of modern molecular laboratories, it supports reliable, contamination-free processing for consistent and reproducible results.

From clinical diagnostics and research to academic applications, RAPi-X CF empowers laboratories to deliver accurate insights in prenatal screening with confidence and precision.

PRODUCT ADVANTAGES

HIGH THROUGHPUT
The system offers full automation of the nucleic acid extraction workflow, with the capability to process up to 32 samples in a single run.

FLEXIBLE
Offers flexible throughput with the capacity to handle sample volumes of up to 700 µL, ensuring efficiency across diverse workloads.

HIGH EFFICIENCY
Efficiency is 4–5 times greater than manual methods, ensuring faster turnaround and consistently reliable results

PRECISE TEMPERATURE
Custom heater module ensures complete contact between the deep-well plates and heating element ensuring precise and uniform temperature control in every well, enabling high efficiency and optimal nucleic acid elution.

STANDARD OPERATION
The intuitive user interface is designed for simplicity, ensuring smooth and effortless operation.

SAFETY
Use of Disposable tips combined with a built-in UV sterilization system effectively prevents aerosol contamination between runs.

cfDNA Nucleic Acid Extraction kit

MAGNXT

G2M MagNXT Nucleic Acid Purification Kits provide a comprehensive solution for high-yield and high-purity DNA/RNA extraction across a range of molecular biology applications, including sequencing, restriction digestion, and Non-Invasive Prenatal Testing (NIPT). Utilizing advanced paramagnetic particle technology, these kits ensure exceptional reproducibility and minimal non-specific binding. The Circulating Cell-Free DNA Extraction Kit enables efficient purification of nucleic acids from human plasma or serum through a magnetic particle and silica-based system, optimized for liquid biopsy, oncology, and prenatal testing workflows.

EZY AutoPrep - 48

Automated **NGS Library Preparation** *Workstation*

Construct upto
48 Sample Libraries
in one run

Simplifying NGS Automation Like Never Before

EZY Autoprep is designed to streamline and automate the entire NGS library construction process. By directly loading nucleic acid samples, the system fully automates critical steps of a library preparation workflow. The workstation is equipped with a built-in thermal cycler and a fluorometer. This end-to-end solution minimizes hands-on time, reduces human errors, and significantly enhances throughput, making it an ideal choice for high-throughput sequencing applications.

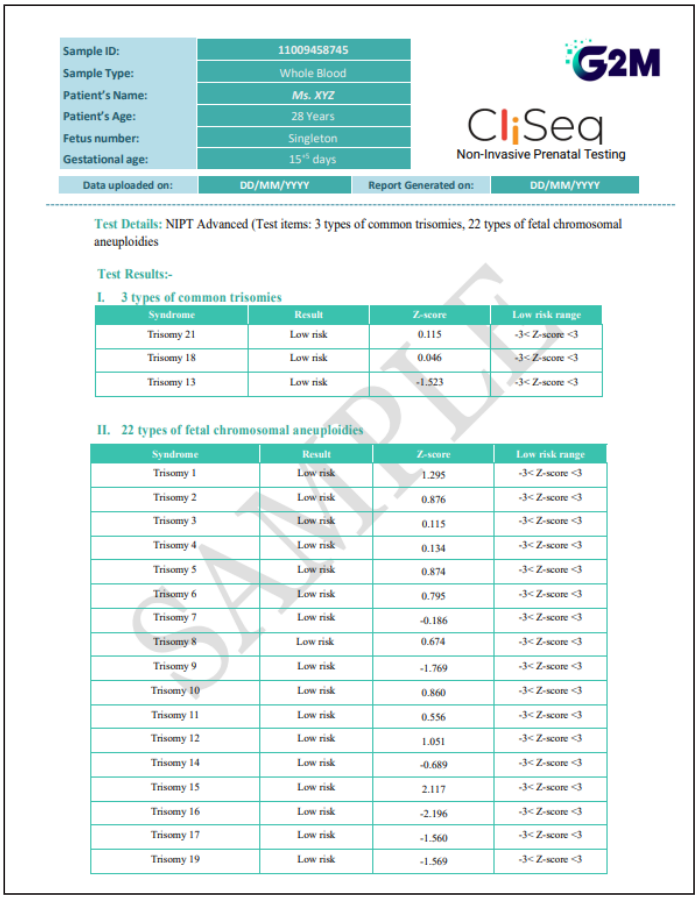
With EZY-AutoPrep 48, one can rely on consistent, reproducible results, allowing them to focus on their scientific discoveries with confidence

- **Flexible to Match Experimental Needs**
- **Precise Pipetting**
- **Integrated Fluorescence Detection**
- **Gripper Arm**
- **Multiple Functional Modules**
- **Flexible Software Interface**

Data Analysis Platform

For Data analytics and reporting, our cloud based platform, Cliseq Interpreter's workflow pipelines are designed and tested to work seamlessly with a variety of G2M NGS Clinical Panels including NIPT. NIPT analysis is based on low-depth Whole genome sequencing. With Cliseq Interpreter software, the time to analyse the NIPT data and reporting is significantly reduced to upto 1 hour per sample.

Sample Report



Sample ID:	11009458745
Sample Type:	Whole Blood
Patient's Name:	*Ms. XYZ*
Patient's Age:	28 Years
Fetus number:	Singleton
Gestational age:	15^{+5} days

G2M

CliSeq Non-Invasive Prenatal Testing

Data uploaded on:	DD/MM/YYYY	Report Generated on:	DD/MM/YYYY

Test Details: NIPT Advanced (Test items: 3 types of common trisomies, 22 types of fetal chromosomal aneuploidies

Test Results:-

I. 3 types of common trisomies

Syndrome	Result	Z-score	Low risk range
Trisomy 21	Low risk	0.115	-3< Z-score <3
Trisomy 18	Low risk	0.046	-3< Z-score <3
Trisomy 13	Low risk	-1.523	-3< Z-score <3

II. 22 types of fetal chromosomal aneuploidies

Syndrome	Result	Z-score	Low risk range
Trisomy 1	Low risk	1.295	-3< Z-score <3
Trisomy 2	Low risk	0.876	-3< Z-score <3
Trisomy 3	Low risk	0.115	-3< Z-score <3
Trisomy 4	Low risk	0.134	-3< Z-score <3
Trisomy 5	Low risk	0.874	-3< Z-score <3
Trisomy 6	Low risk	0.795	-3< Z-score <3
Trisomy 7	Low risk	-0.186	-3< Z-score <3
Trisomy 8	Low risk	0.674	-3< Z-score <3
Trisomy 9	Low risk	-1.769	-3< Z-score <3
Trisomy 10	Low risk	0.860	-3< Z-score <3
Trisomy 11	Low risk	0.556	-3< Z-score <3
Trisomy 12	Low risk	1.051	-3< Z-score <3
Trisomy 14	Low risk	-0.689	-3< Z-score <3
Trisomy 15	Low risk	2.117	-3< Z-score <3
Trisomy 16	Low risk	-2.196	-3< Z-score <3
Trisomy 17	Low risk	-1.560	-3< Z-score <3
Trisomy 19	Low risk	-1.569	-3< Z-score <3
Trisomy 20	Low risk	-0.488	-3< Z-score <3
Trisomy 22	Low risk	1.071	-3< Z-score <3
Turner syndrome (45,X)	Low risk	-2.057	-3< Z-score <3
Klinefelter syndrome (XXY)	Low risk	-2.057	-3< Z-score <3
XYY syndrome	Low risk	-2.057	-3< Z-score <3
XXX syndrome	Low risk	-2.057	-3< Z-score <3

III. Sample quality test

Sample information	Test value	Reference range	Result
Unique reads (M)	25.00	>15	Passed
GC content of unique reads (%)	40.10	37–43	Passed
Fetal Fraction (%)*	12.36		

*If the fetal fraction is lower than 3.5% , the accuracy of the test may be reduced. To ensure the accuracy of the results, we would recommend a re-sampling of the maternal blood one or two weeks later. If the fetal fraction is less than 7%, the detection power of fetal microdeletion/microduplication syndrome (< 5 Mb) is limited. We would recommend a more careful clinical observation or a higher coverage whole genome sequencing re-test.

This report is automatically generated by CliSeq Interpreter.

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Scan for Microdeletion list

ORDERING INFORMATION

Commercial Name	Cat No.
LeoNext cfDNA LibraryPrep Kit for NIPT	NGS3105-01 ; NGS3105-02 ; NGS3105-03
RAPi-X CF - Cell free DNA Extraction System for NIPT	G2M910002
MagNXT Cell free DNA Extraction Kit	G2M810003-96T ; G2M810003-192T
EZY AutoPrep - 48 Automated NGS Library Preparation Workstation	G2MBR4-0712

CE IVD | ISO 13485:2016 | ISO 9001:2015 | GMP Quality

Genes2Me Pvt. Ltd.

1105, 11th Floor, Tower B, SAS Tower, Medicity,
Sector - 38, Gurgaon - 122 001, Haryana, India
Tel : + 91 18001 214030 / + 91 88000 23600
E-mail : contact@genes2me.com
www.genes2me.com