NIPT

LeoNext CfDNA Library Prep Kit

for Non-invasive Prenatal Testing

CE IVD

www.genes2me.com

About our NIPT Panel

LeoNext CfDNA Library Prep 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 & 80+ deletions and duplications (large & micro) :-

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 66 Large deletions, duplications & 20 microdeletions and micro-duplication Syndromes.

Product Name	No of Reads (in Millions)
NIPT-All Chromosome	10-15 Million
NIPT-All Chromosome + Microdeletions & duplications	20-25 Million

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.

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.

CliSeq Interpreter

Specifications

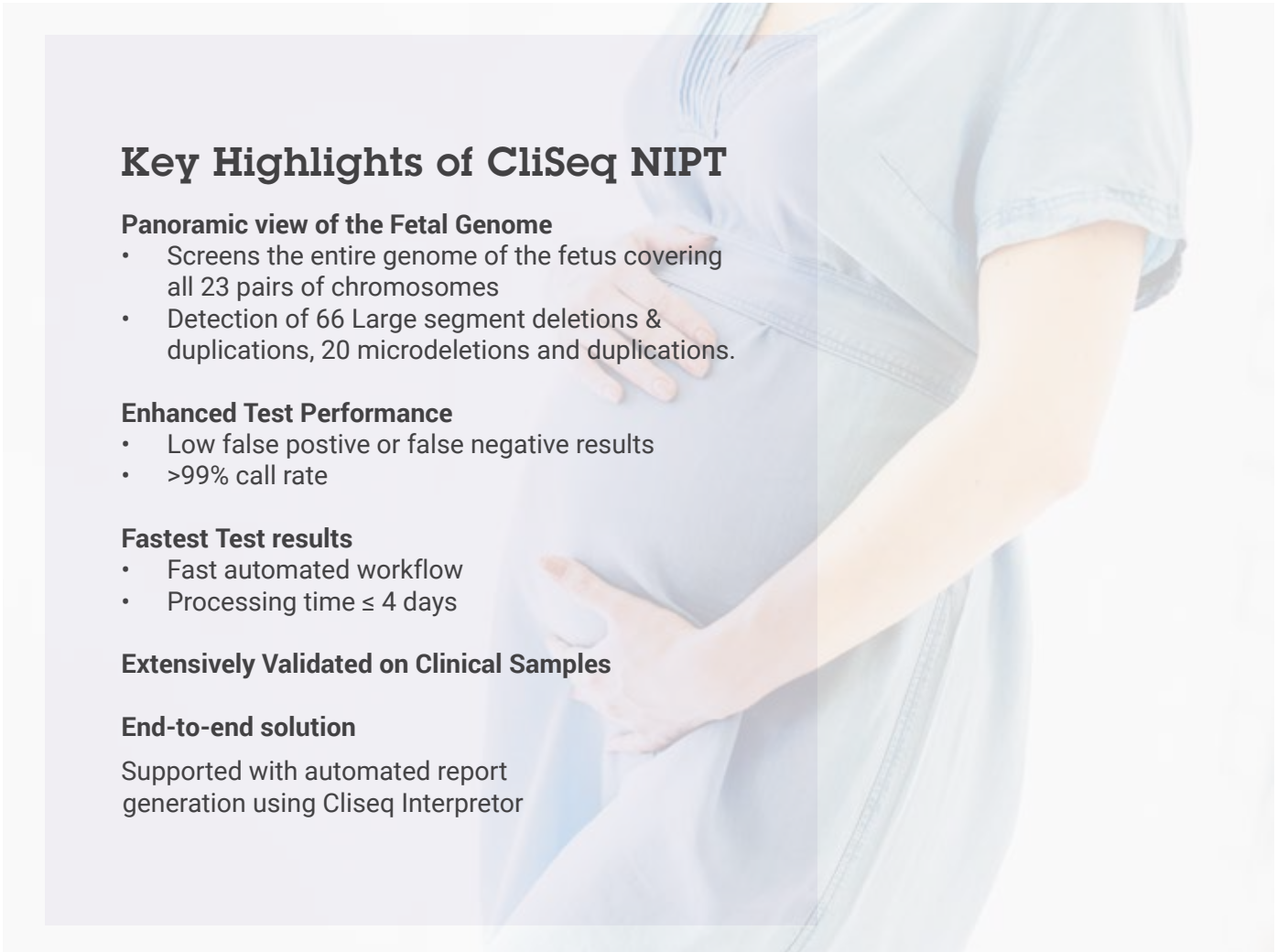
Methodology	Low-depth whole-genome sequencing
Sample collection	10 ml Whole blood in Streck tube or BD cell free DNA tube (10 - 20 ng of cfDNA)
Shipping temperature	4 - 8°C
Fetal Fraction	Min 3%
Gestational Age	10 weeks onwards

Note : The plasma sample should be stored at -80°C and checked prior for hemolysis

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 66 Large segment deletions & duplications, 20 microdeletions and duplications.

Enhanced Test Performance

- Low false postive or false negative results
- >99% call rate

Fastest Test results

- Fast automated workflow
- Processing time ≤ 4 days

Extensively Validated on Clinical Samples

End-to-end solution

Supported with automated report generation using Cliseq Interpretor

G2M NIPT END-TO-END Workflow

Maternal Plasma

10 ml of maternal whole blood

Cf DNA Extraction

cfDNA extraction with G2M's cell-free DNA extraction kit and extraction platform

RAPi-XCF
CELL FREE DNA EXTRACTION SYSTEM for NIPT

LeoNext CfDNA library preparation kit

Using G2M's LeoNext CfDNA library preparation kit on G2M's Ezy Autoprep - automated NGS library preparation workstation

EZY-AutoPrep

Sequencing

On the sequencing platform of your choice

Data Analysis

G2M's proprietary NIPT data analysis software

CliSeq Interpreter

Scan for NIPT Sample Report

ORDERING INFORMATION

Commercial Name	Cat No.
LeoNext cfDNA LibraryPrep Kit for NIPT	NGS3105-01 ; NGS3105-02 ; NGS3105-03

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

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