GeneMind

NIGM

Non-invasive Prenatal Testing (NIPT) of GeneMind

Simple

Test from a tube of 10ml maternal blood sample as early as 9 gestational weeks

Accurate

Proven >99% sensitivity based on a test of more than 70,000 pregnancies.

Fast & Convenient

- Quick test from sample preparation to issue report within 24 hours
- Simplified operation: Automated and localized data analysis and report

Flexibility

- Compatible with low,medium and high throughput sequencing platforms
- Offering flexible options for both manual and automated workflows

Introduction to NIGM

Noninvasive prenatal testing (NIPT) performed with NGS sequencing system GenoLab M*, FASTASeq 300* and SURFSeq 5000* provides reliable screening results for fetal chromosomal aneuploidies as early as 9 gestational weeks—from a single tube of 10 mL maternal blood. Support G tube (Provided by GeneMind) and Streck Tube.

Parameter		NIPT Basic	NIPT Standard	NIPT Plus	NIPT Pro
Sample Volume		10 mL of a single tube of maternal blood			
Library preparation		PCR			
Method		Low-pass whole genome sequencing			
No. of samples per run(1 PC +1 NC included)	GenoLab M*	1 FCM : 48 2 FCM/1 FCH : 96 1 FCM+1 FCH : 144 2 FCH : 192	1 FCM : 32 2 FCM/1 FCH : 64 1 FCM+1 FCH : 96 2 FCH : 128	1 FCM : 24 2 FCM/1 FCH : 48 1 FCM+1 FCH : 72 2 FCH : 96	1 FCM : 10 2 FCM/1 FCH : 20 1 FCM+1 FCH : 30 2 FCH : 40
	FASTASeq 300*	1 FCH : 48 1 FCM : 24	1 FCH : 32 1 FCM : 16	1 FCH : 24 1 FCM : 12	1 FCH : 10 1 FCM : 5
	SURFSeq 5000*	1 FCH : 250	1 FCH : 160	1 FCH : 96	1 FCH : 64
Read length		SE 75 on GenoLab M* and FASTASeq 300* SE 50 on SURFSeq 5000*			
Average Unique Reads / sample	GenoLab M* and FASTASeq 300*	⩾3.5 M	⩾5 M	⩾7 M	⩾16 M
	SURFSeq 5000*	⩾5 M	⩾7 M	⩾12 M	⩾20 M
Turnaround time		25 h on GenoLab M*, 21.5 h on FASTASeq 300*, and 26 h on SURFSeq 5000*			
Report generation		Local analysis and report system			

NIPT Basic

- Trisomies 21/18/13
- Sex identification, fetal fraction estimation

NIPT Standard

- Trisomies 21/18/13
- 6 Sex Chromosome Aneuploidies (SCAs) (XO/XXX/XXY/XYY/XO+XY/XXX+XY)
- Other 19 autosomal Aneuploidies
- Sex identification, fetal fraction estimation

NIPT Plus

- Trisomies 21/18/13
- 6 Sex Chromosome Aneuploidies (SCAs) (XO/XXX/XXY/XYY/XO+XY/XXX+XY)
- Other 19 autosomal Aneuploidies
- 60 Microdeletion/duplications syndromes
- Sex identification, fetal fraction estimation

NIPT Pro

- Trisomies 21/18/13
- 6 Sex Chromosome Aneuploidies (SCAs) (XO/XXX/XXY/XYY/XO+XY/XXX+XY)
- Other 19 autosomal Aneuploidies
- 90 Microdeletion/duplications syndromes (Including Di-George Syndrome)
- Sex identification, fetal fraction estimation

*NIPT Basic and Standard can be performed in twin pregnancies, but Plus or Pro is NOT applicable.

Support Both Manual and Automated Solutions

Sample Collection, information registration, isolation	Extraction, Library Prep	QC, pooling, Loading	Sequencing	Analysis and Report
G Tube / Streck Tube	MrLH-96		GenoLab M*	AIRS
				
Automated workflow	2 h	6 h	2.5 h	13 h	1.5 h	25 hours in total
G Tube / Streck Tube			FASTASeq 300*	AIRS		
						
Manual workflow	2 h	8 hours (at least 3 technicians)	2.5 h	7.5 h	1.5 h	21.5 hours in total
G Tube / Streck Tube	MrLH-96		SURFSeq 5000*	AIRS		
						
Automated workflow	2 h	6 h	2.5 h	14 h	1.5 h	26 hours in total

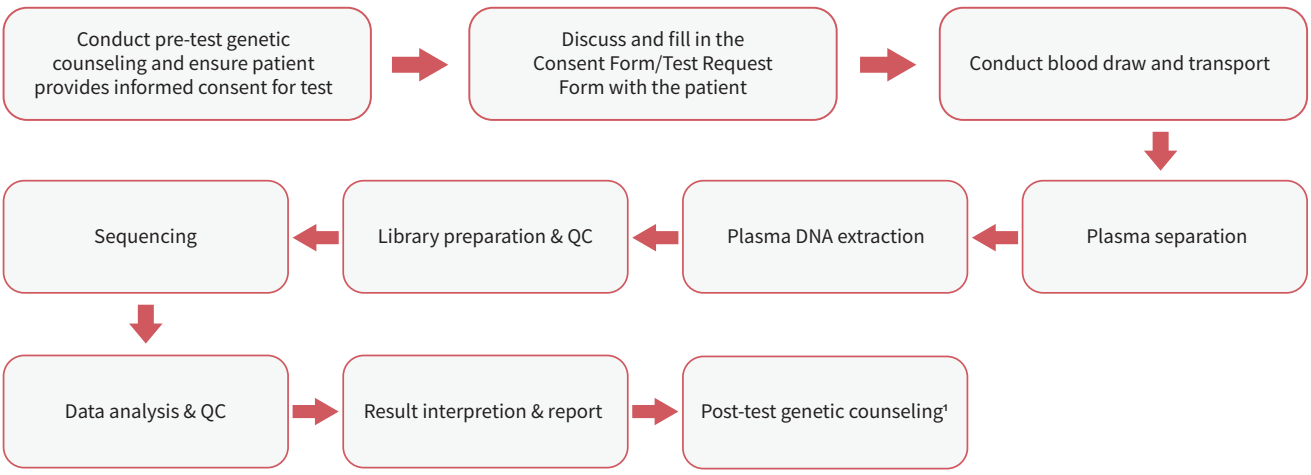
►G Tube: provided and validated by GeneMind

►MrLH-96: Automated Sample Preparation System, consumables (tips and plates) provided and validated by GeneMind

►GenoLab M*, FASTASeq 300* and SURFSeq 5000* : sequencing device from GeneMind

►AIRS: Automated Integrated Report Server provided and validated

The Test Workflow and Advantages

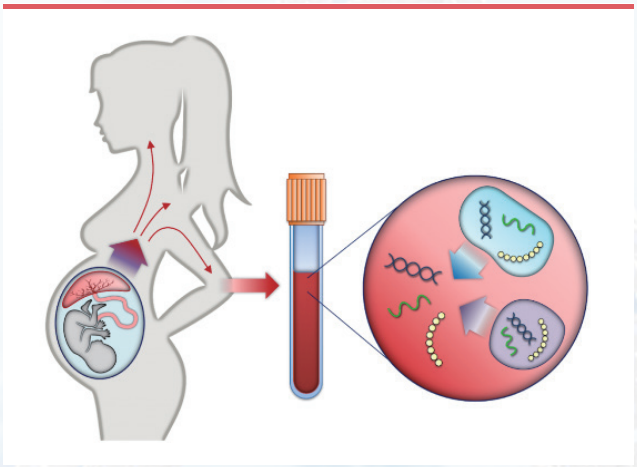


1. non-complimentary

cfDNA Extraction

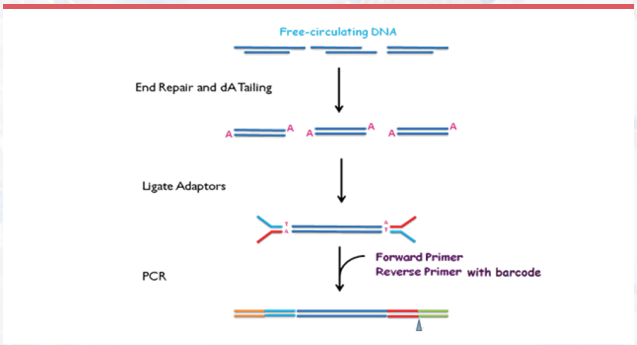
During pregnancy, cell-free DNA (cfDNA) fragments originate from both the mother and fetus are present in maternal blood circulation. Cell-free fetal DNA (cffDNA) is present only as a minority component of the total cfDNA in maternal plasma, which poses a significant technical challenge for some NIPT detection methods.

Using paramagnetic particle method, our cfDNA extraction process is compatible with a variety of blood collection vessels with the requirement of as little as 200uL plasma. The success rate of cfDNA extraction is above 99.9% if the maternal plasma meets the sampling standard.



Library preparation

- **Low-input**
  The success rate of cfDNA library construction is above 99.9% even if the amount of cfDNA is as little as 100pg.
- **High conversion efficiency**
  With significant enrichment effect of fetal concentration, the library yield is sufficient for multiple validation and long-term storage.



Sequencing

We conduct sequencing on High-throughput DNA Sequencing Platform GenoLab M*.

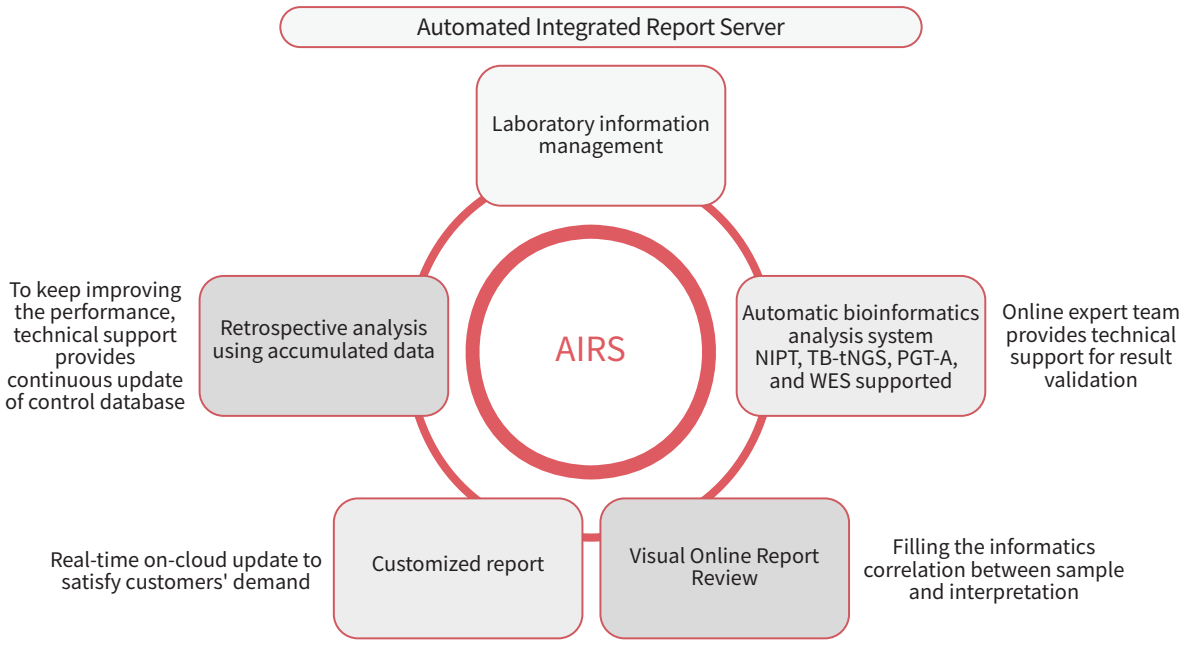
Accurate

- High-fidelity sequencing chemistry and unique optical system

Cost Effective

- Competitive instrument and reagent kit prices
- Single-flow cell and dual-flow cell mode give customer more control over per-sample cost

Automated Bioinformation Analysis and Report



Sample Requirement

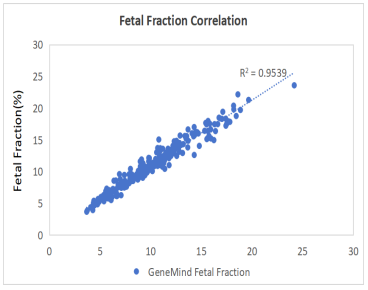
Sample Type	Quantity	Requirements	Shipment
Plasma	2ml (4 tubes required)	Stored in 1.5ml Eppendorf tubes, and sealed with 1cm wide parafilm	Stored at -80 °C, shipped with dry ice within one week.
Whole Blood	10ml	Gently invert the tube ten times immediately after blood sampling	Stored and shipped between 6~35 °C within 7 days. Keep the tubes upright during shipping

Clinical Validation[2]

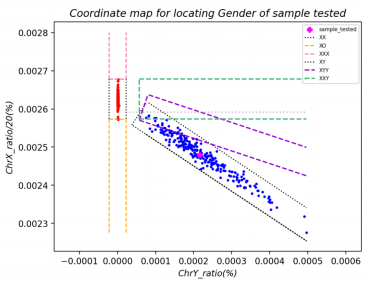
Trisomy	Positive	Sensitivity	Specificity	PPV	NPV
T21	402	100.00%	99.94%	90.03%	100.00%
T18	93	100.00%	99.98%	84.95%	100.00%
T13	57	100.00%	99.95%	42.11%	100.00%
Autosomes	116	98.18%	99.91%	46.55%	99.99%
SCAs	429	97.93%	99.73%	55.24%	99.99%
Total	1097	99.21%	99.51%	69.01%	99.99%

2. validated by 70,075 retrospective clinical samples

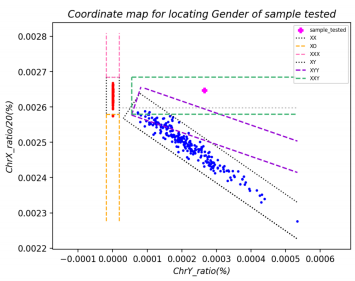
Performance in Sex Identification, Fetal Fraction Estimation and SCAs Detections



Fetal fraction estimation is highly consistent with existing products



Accruacy of Sex identification is 99.3%



Reliable performance in sex chromosome aneuploidies detection

About GeneMind

GeneMind Biosciences Co., Ltd. (hereinafter referred to as 'GeneMind') was founded in 2012 and is headquartered in Luohu, Shenzhen. Its facility includes more than 8,000 square meters of research and development laboratories and GMP production lines.

From the company's inception, GeneMind aimed at the research and development of the DNA sequencer: the core instrument of the modern molecular diagnostic platform. GeneMind is committed to building a precision medical ecosystem that serves healthcare through collaborations with genetic testing service providers and medical institutions. We has launched high-throughput sequencing platform GenoLab M*, FASTASeq 300*, and SURFSeq 5000*, which can provide 'instrument-reagent-chip-software' full-platform solutions. With nearly 200 technical patents, covering mainland China , Hong Kong, Europe, and the United States, GeneMind is one of the few companies in the world that possess core DNA sequencing technologies and independent products.

After several years of hard work, GeneMind has mastered the key technologies of the DNA sequencing, and realized production of core materials such as enzymes, nucleic acids, dyes, and biochips in China, providing research and medical institutions with competent domestically produced sequencing solutions.

*Unless otherwise informed, GeneMind sequencing platform and related sequencing reagents are not available in the USA, Canada, Australia, Japan, Singapore, Western Europe, Southern Europe and Nordic countries yet.

GeneMind

GeneMind Biosciences Co., Ltd.

Technical Support: **+86-400-822-3660**

Website: en.genemind.com Email: info@genemind.com

Address: Room 502A/502B/602, Luohu Investment Holding Building, 112 Qingshuihe 1st Road, Luohu District, Shenzhen, Guangdong, China