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 100, 000 pregnancies

Fast & Convenient

- From sample to report: fast as 16.5 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 nine 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			
Number of samples per run(1 Positive Control +1 Negative Control included)	FASTASeq™ 300	1 FCM: 24 1 FCH: 48 1 FCP: 96	1 FCM: 16 1 FCH: 32 1 FCP: 64	1 FCM: 12 1 FCH: 24 1 FCP: 48	1 FCH: 10 1 FCP: 20
	GenoLab™ M	1 FCM: 48 1 FCH: 96	1 FCM: 32 1 FCH: 64	1 FCM: 24 1 FCH: 48	1 FCM: 10 1 FCH: 20
	SURFSeq™ 5000	1 FCH: 250 1 FCP: 450	1 FCH: 160 1 FCP: 300	1 FCH: 96 1 FCP: 180	1 FCH: 64 1 FCP: 120
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		25-29 h on GenoLab™ M, 16.5-21.5 h on FASTASeq™ 300, and 16-30 h on SURFSeq™ 5000			
Report generation		Local analysis and report system			

NIPT Basic

- Trisomy 21，18，13
- Sex identification, fetal fraction estimation

NIPT Standard

- Trisomy 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

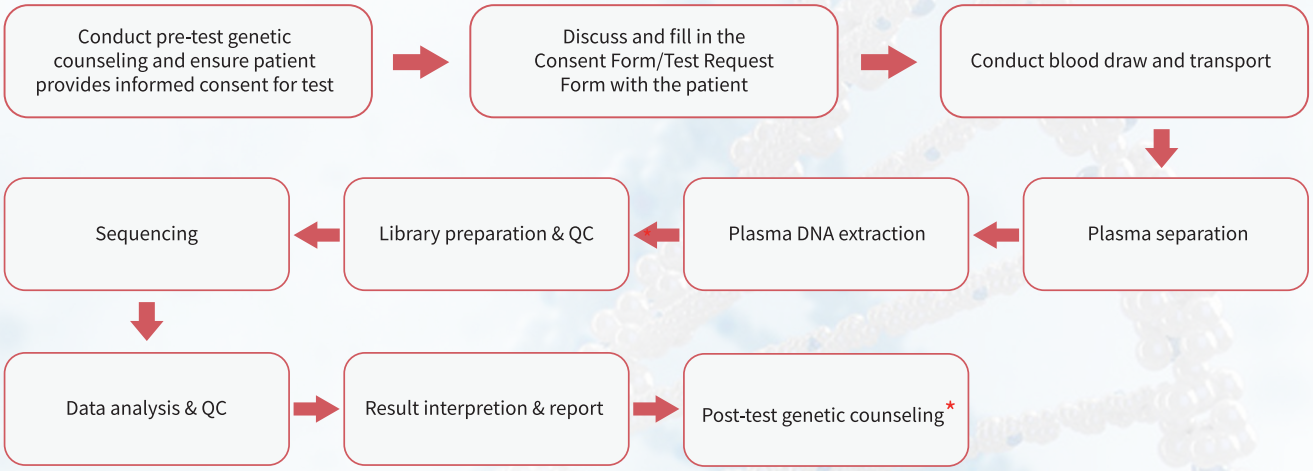
- Trisomy 21，18，13
- 6 Sex Chromosome Aneuploidies (SCAs) (XO/XXX/XXY/XYY/XO+XY/XXX+XY)
- Other 19 autosomal Aneuploidies
- 60 Microdeletion/duplications syndromes
- Sex identification, fetal fraction estimation

NIPT Pro

- Trisomy 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

For twin pregnancies, NIPT Basic is applicable, whereas the Standard, Plus, and Pro versions are not recommended for use.

The Test Workflow



* non-complimentary

Support Both Manual and Automated Solutions (96 samples)

	Sample Collection, Information Registration, and Isolation	DNA Extraction	Library Prepraration	QC, Pooling, and Loading	Sequencing	Analysis and Report
Automated workflow	G Tube* / Streck Tube	Genoscout EM	MrLH-96**			AIRS***
Total 16.5-28 hr	2 h	2 h	4 h	2.5 h	4.5-16 h	1.5 h
Manual workflow	G Tube* / Streck Tube					AIRS***
Total 18.5-30hr	2 h	8 hours (at least 3 technicians)		2.5 h	4.5-16 h	1.5 h

* G Tube: provided and validated by GeneMind

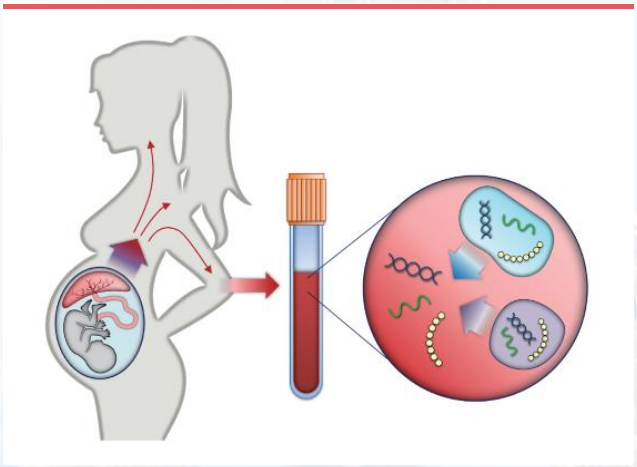
** MrLH-96: Automated Sample Preparation System, consumables (tips and plates) provided and validated by GeneMind

*** AIRS: Automated Integrated Report Server provided and validated by GeneMind

cfDNA Extraction

During pregnancy, cell-free DNA (cfDNA) fragments originating 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.

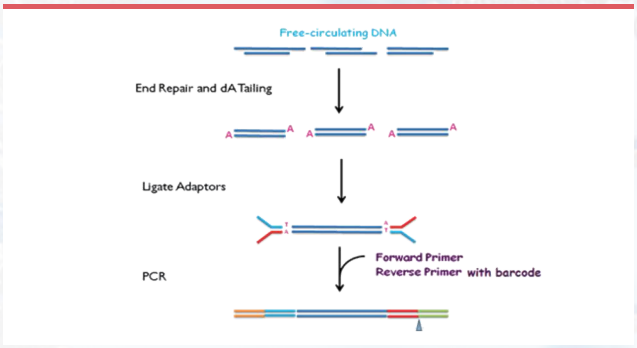
Using paramagnetic particle method, our cfDNA extraction process is compatible with a variety of blood collection vessels with the requirement of as little as 200 μL plasma. The success rate of cfDNA extraction is above 99.9% if the maternal plasma meets the sampling standard.



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 100 pg.

- **High conversion efficiency**
  With significant enrichment effect of fetal concentration, the library yield is sufficient for multiple validation and long-term storage.

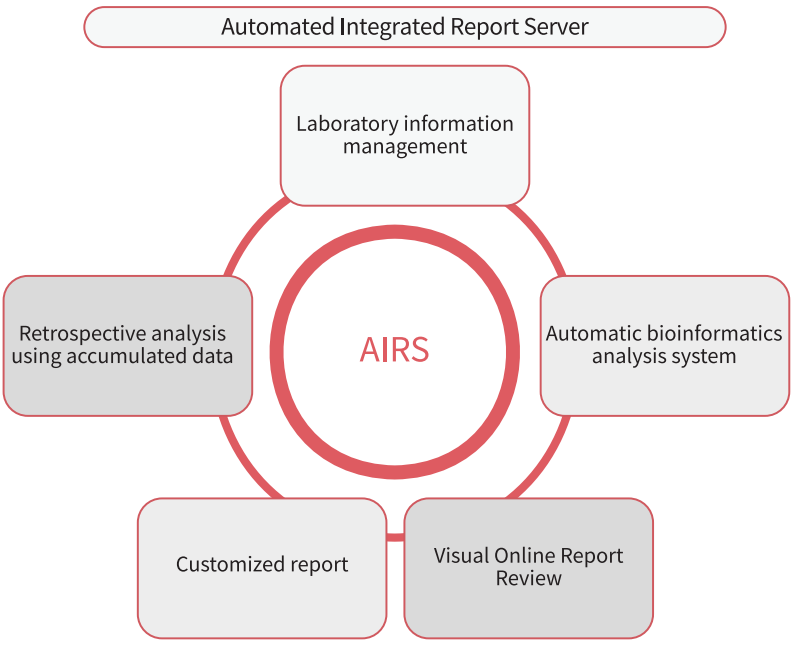


Sequencing

We conduct sequencing on NGS sequencing platforms FASTASeq™ 300, GenoLab™ M, and SURFSeq™ 5000.

- **Accurate**
  High-fidelity sequencing chemistry and unique optical system
- **Cost Effective**
  Competitive instrument and reagent kit prices
  Single and dual-flow cell mode provides flexibility in managing cost efficiency per sample

Automated Bioinformation Analysis and Report



Sample Requirement

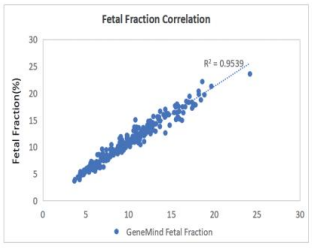
Sample Type	Quantity	Requirements	Shipment
Plasma	2 mL	Stored in four 1.5 mL-Eppendorftubes with 0.5 mL plasma each tube , and sealed with 1 cm wide parafilm	Stored at -80 °C, shipped with dry ice within one week.
Maternal Blood	10 mL	Gently invert the tube ten times immediately after blood sampling	Stored and shipped between 4~30 °C within 7 days. Keep the tubes upright during shipping

Clinical Validation[1]

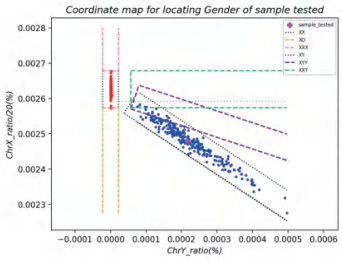
Condition	Positive	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
T21	643	100% (99.37-100.00)	99.95% (99.93-99.96)	90.51% (88.13-92.46)	100% (100.00-100.00)
T18	149	100% (97.11-100.00)	99.98% (99.97-99.99)	84.56% (78.45-89.18)	100% (100.00-100.00)
T13	91	100% (90.75-100.00)	99.95% (99.94-99.96)	41.76% (35.39-48.41)	100% (100.00-100.00)
Autosomes	185	97.73% (92.03-99.72)	99.91% (99.89-99.93)	46.49% (41.58-51.47)	99.998% (99.99-100.00)
SCA	686	97.93% (95.97-99.10)	99.73% (99.69-99.76)	55.25% (52.45-58.01)	99.99% (99.99-100.00)
Total	1754	99.18% (98.50-99.61)	99.51% (99.47-99.55)	69.04% (67.22-70.81)	99.99% (99.98-100.00)

1. It was validated by 112, 118 retrospective clinical samples in April 2025.

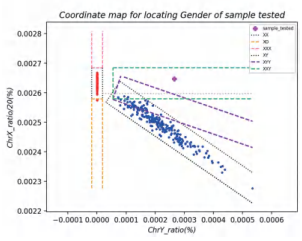
Performance in Sex Identification, Fetal Fraction Estimation and SCAs Detections



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 was established in 2012 and is headquartered in Shenzhen, China. Its facility includes more than 10,000 square meters of research and development laboratories and GMP production lines.

Specializing in the independent R&D and manufacturing of molecular diagnosis technology platform centred on DNA sequencing system, GeneMind is devoted to constructing a precision medicine ecosystem to serve human life and health through collaboration with genetic testing service providers and medical institutions.

GeneMind has launched the high-throughput sequencing platform GenoLab™ M, FASTASeq™ 300, SURFSeq™ 5000, SURFSeq™ Q, and FASTASeq™ S through independent research and innovation, and offers the "equipment -reagent-flowcell-software" total platform solutions. GeneMind is one of the few companies with core upstream technology and independent brand of gene sequencing in the world.

※ Disclaimer

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