BambniTest™

Streamlining your Non-Invasive Prenatal Testing (NIPT)

BambniTest™ NIPT

Background

Non-Invasive Prenatal Testing (NIPT) is an advanced prenatal screening method that analyzes cell-free DNA (cfDNA) circulating in the maternal bloodstream. This testing offers a highly accurate and non-invasive approach to assessing the risk of fetal chromosomal abnormalities.

NIPT significantly reduces the need for invasive diagnostic procedures like amniocentesis or chorionic villus sampling (CVS), which carry a small risk of miscarriage. Compared to traditional Down syndrome screening methods, such as the combined first-trimester or second-trimester quadruple test, NIPT has a higher detection rate and a lower false-positive rate.

BambniTest™ NIPT

Berry Genomics provides a comprehensive solution for NIPT technology transfer with next-generation sequencing, encompassing plasma DNA extraction, library preparation, high-throughput sequencing, bioinformatics analysis, and report management. This enables laboratories to conduct their tests efficiently and conveniently. BambniTest™ NIPT service has been adopted by more than 100 clinical institutions.

Panel

By default, BambniTest™ NIPT is offered in 2 panels. Beyond these standard panels, BambniTest™ NIPT empowers you to define your own reporting scope with CNVs (>3Mb) based on local regulations and business strategy.

NIPT Basic

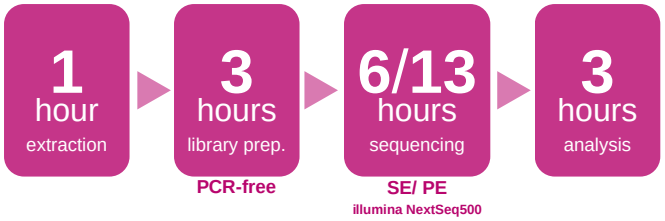
Trisomy 21, Trisomy 18, and Trisomy 13

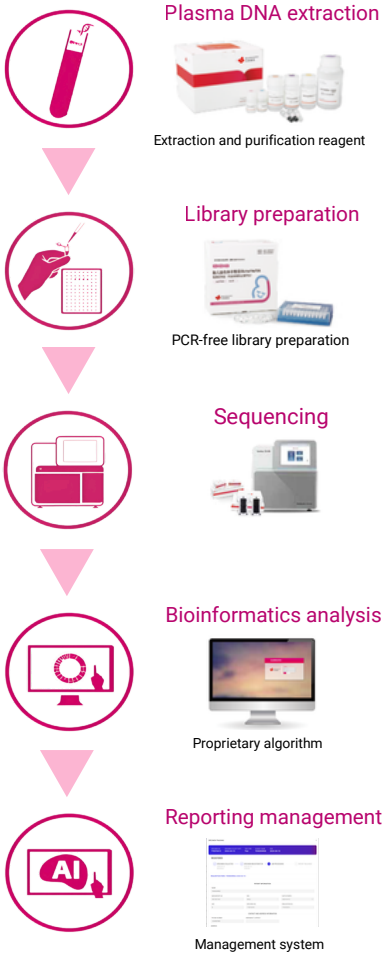
NIPT Plus

Covers an expanded range of conditions:

- 3 trisomies: Trisomy 21, Trisomy 18, and Trisomy 13
- 4 sex chromosome aneuploidies: Triple X syndrome (47,XXX), Klinefelter syndrome (47,XXY), Turner syndrome (45,X), and Jacobs syndrome (47,XYY)
- 7 microdeletion syndromes (>3 Mb): 1p36 Deletion, 2q33.1 Deletion, 5p Deletion (Cri-du-chat), 8q24.1 Deletion (Langer-Giedion), 15q11.2 Deletion (Angelman), 15q11.2 Deletion (Prader-Willi), and 22q11.2 Deletion (DiGeorge)
- Other autosomal aneuploidies: Trisomy 7, 8, 9, 14, 19, 20, 22 and Monosomy 18, 21, 22
- 76 large chromosomal deletion/ duplication syndromes (>10 Mb)

Parameters	Description
Technology	Low-coverage whole-genome sequencing
Platform	Illumina or Salus SBS sequencing system
Sample type	Maternal blood
Operation Time	13/20 hours (from sample preparation to report generation)





BambniTest™

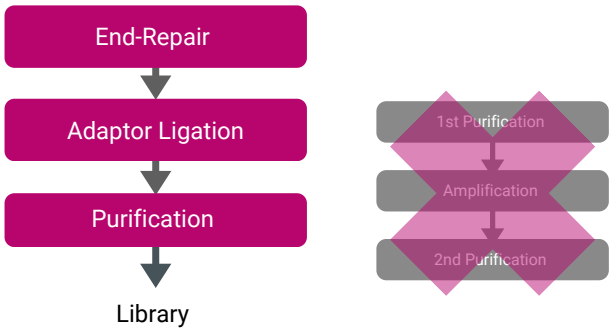
Highlighted Technology

EZ-PALO™ Rapid Library Construction Method

At the core of BambniTest™ NIPT is EZ-PALO™, our patented rapid library preparation technology. Unlike standard NIPT methods that require time-consuming amplification and secondary purification, our method is completely PCR-free.

- PCR-free, no amplification bias
- No need for a dedicated pre-PCR clean room
- Reduced cfDNA loss by eliminating the post-amplification purification step
- Single-tube operation
- Library preparation success rate >99.5%
- Completion in 3 hours

EZ-PALO™ library prep.



RUPA™ Ultra-Fast Information Analysis Method

RUPA™ is a proprietary bioinformatics algorithm for full automation and is optimized for data processing efficiency.

- Automation-friendly

Proven Performance at Scale

BambniTest™ NIPT delivers outstanding test performance, validated by 1,008,703 cases with clinical follow-up information.

Items	Sensitivity	Specificity	PPV	NPV
Trisomy 21	99.51%	99.97%	94.47%	99.99%
Trisomy 18	99.54%	99.98%	86.30%	99.99%
Trisomy 13	100.00%	99.97%	55.79%	100.00%

The positive cases (percentages) were 5,526 (0.55%) for Trisomy 21, 1,525 (0.18%) for Trisomy 18, and 313 (0.06%) for Trisomy 13.

Enhanced Precision: Paired-End (PE) Sequencing Upgrade

While Single-End (SE) sequencing remains a proven method for cost-efficiency, BambniTest™ NIPT now offers an optional upgrade to Paired-End (PE) Sequencing with bioinformatics size-based enrichment.

This upgrade can distinguish fetal DNA from maternal DNA based on fragment size to improves CNV calling without the drawbacks associated with wet-lab enrichment, such as poor ccfDNA recovery and specificity [1].

In our internal parallel testing:

- 60% fewer redraws and 30% lower test-failure rates
- Accurate differentiation between maternal and fetal CNVs, significantly reducing false-positives and false-negatives
- >60% reduction in false positives for sex chromosome aneuploidies

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Reference:

[1] Hu P, Liang D, Chen Y, et al. An enrichment method to increase cell-free fetal DNA fraction and significantly reduce false negatives and test failures for non-invasive prenatal screening: a feasibility study. J Transl Med. 2019;17(1):124.

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