



illumina®

# Rethink prenatal screening

Think VeriSeq™ NIPT

## Change the way you think about NIPT

Think you know everything about prenatal screening? Think again.

Noninvasive prenatal testing (NIPT) can be offered as early as 10 weeks and has been proven to be more accurate than traditional screening methods for detecting common fetal aneuploidies.

With VeriSeq NIPT Solution v2, NIPT has never performed better. It also provides the most comprehensive view of the fetal genome, covering all 23 pairs of chromosomes—more than any other available prenatal screening solution. It's the only IVD NIPT solution offering genome-wide coverage of partial deletions and duplications  $\geq 7$  Mb for all autosomes.

**>99.9%**  
ACCURACY  
FOR T21, T18, T13

**26**  
HOURS FROM  
START TO FINISH

**98.8%**  
FIRST PASS  
SUCCESS



# Superior performance.<sup>1</sup> More confidence.

It's time to change the way you think about prenatal testing. The VeriSeq NIPT Solution v2 offers superior performance to any *in vitro* diagnostic (IVD) noninvasive prenatal testing (NIPT) solution available.<sup>1</sup> With unparalleled accuracy, a start to finish run time of just 26 hours, and low sample failure rate, experience the confidence that comes with the best performing NIPT.

	Trisomy 21	Trisomy 18	Trisomy 13	Rare autosomal aneuploidy (RAA)	Partial deletions and duplications
Sensitivity	>99.9%	>99.9%	>99.9%	96.4%	74.1%
Specificity	99.90%	99.90%	99.90%	99.80%	99.80%

Fetal sex classification concordance		
100% XX	100% XY	90.5% XO
100% XXX	100% XXY	91.7% XYY





# 23

**CHROMOSOME  
PAIRS AND MORE**

## More insights from every sample

Most NIPTs only give information on the status of common aneuploidies of chromosomes 21, 18 and 13. In addition to a basic screen, VeriSeq NIPT Solution v2 has the option for screening for aneuploidy for all chromosomes and partial duplications and deletions  $\geq 7$  Mb for all autosomes, providing the most comprehensive, genome-wide view of fetal chromosomal anomalies among all IVD screening tests.

With its expanded screening option, VeriSeq NIPT Solution v2 is able to detect RAAs and CNVs, which have been associated with clinically-relevant outcomes like development delays, and fetal anomalies.<sup>2,3</sup> The combined incidence rate of these conditions in early pregnancy is estimated to be 0.44%.<sup>2,3</sup> Compare that to 0.50% estimated incidence rate of trisomies 21, 18, and 13 combined.<sup>4</sup> That means you may be missing something if you're not looking genome-wide.

# 24 | 48 | 96

SAMPLE BATCH  
FLEXIBILITY

## A single platform. Maximum flexibility.

With batching flexibility of 24, 48, and 96 samples per run, VeriSeq NIPT Solution v2 flexes with your lab's needs. You can start small and scale up as demand grows. Or you can easily manage your workflow if you're already processing samples at high capacity. Easily switch between kits on a single platform to make sure the solution is meeting the needs of your lab and not the other way around.



# 1 SOLUTION

If you think NIPT is too complicated, it's time to rethink it. VeriSeq NIPT Solution v2 is an easy, turnkey, sample-to-result, complete *in vitro* diagnostic (IVD) workflow. The PCR-free, automated and validated workflow is IVD-marked and fully integrated—from sample prep to sequencing with the NextSeq™ 550Dx Sequencing System to VeriSeq NIPT Assay Software v2. With an end-to-end IVD workflow, you have everything you need for NIPT using next-generation sequencing (NGS). It's the only solution you need.





## Empowering breakthroughs in genetic screening

As evidence for the clinical utility of screening for chromosome aneuploidies, including RAAs, and CNVs continues to grow, the VeriSeq NIPT Solution v2 prepares your lab for future trends in genetic screening. You can prepare your lab to offer more as customer needs and reimbursement coverage continues to evolve. VeriSeq NIPT Solution v2 offers flexible, modular reporting that allows you to customize testing options. Are you ready for a solution today that prepares your lab for the needs of the future?

## References

1. Data on file. Illumina, Inc, 2019.
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3. Shaffer LG, Rosenfeld JA, Dabell MP, Coppinger J, Bandholz AM, Ellison JW, et al. Detection rates of clinically significant genomic alterations by microarray analysis for specific anomalies detected by ultrasound. *Prenat Diagn*. 2012;32(10):986-995.
4. Liang D, Cram DS, Tan H, Linpeng S, Liu Y, Sun H, et al. Clinical utility of noninvasive prenatal screening for expanded chromosome disease syndromes. *Genet Med*. 2019. doi: 10.1038/s41436-019-0467-4.
5. Galjaard R-J, Henneman L, Macville M, Bax C, Bekker MN, Die-Smulders C, et al. Implementing NIPT as part of a national prenatal screening program: The Dutch TRIDENT studies [Abstract]. *Prenat Diagn*. 2018;38(S1):8.

## Intended Use

The VeriSeq NIPT Solution v2 is an *in vitro* diagnostic test intended for use as a screening test for the detection of genome-wide fetal genetic anomalies from maternal peripheral whole blood specimens in pregnant women of at least 10 weeks gestation.

VeriSeq NIPT Solution v2 uses whole-genome sequencing to detect partial duplications and deletions for all autosomes and aneuploidy status for all chromosomes. The test offers an option to request the reporting of sex chromosome aneuploidy (SCA).

This product must not be used as the sole basis for diagnosis or other pregnancy management decisions.

Noninvasive prenatal testing (NIPT) based on cell-free DNA analysis from maternal blood is a screening test; it is not diagnostic.

Test results must not be used as the sole basis for diagnosis. Further confirmatory testing is necessary prior to making any irreversible pregnancy decision.

Contact your Illumina sales representative to find out how to bring the VeriSeq NIPT Solution v2 to your lab.

[www.illumina.com/InLabNIPT](http://www.illumina.com/InLabNIPT)

**For *in Vitro* Diagnostic Use. Not available in all regions and countries.**

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