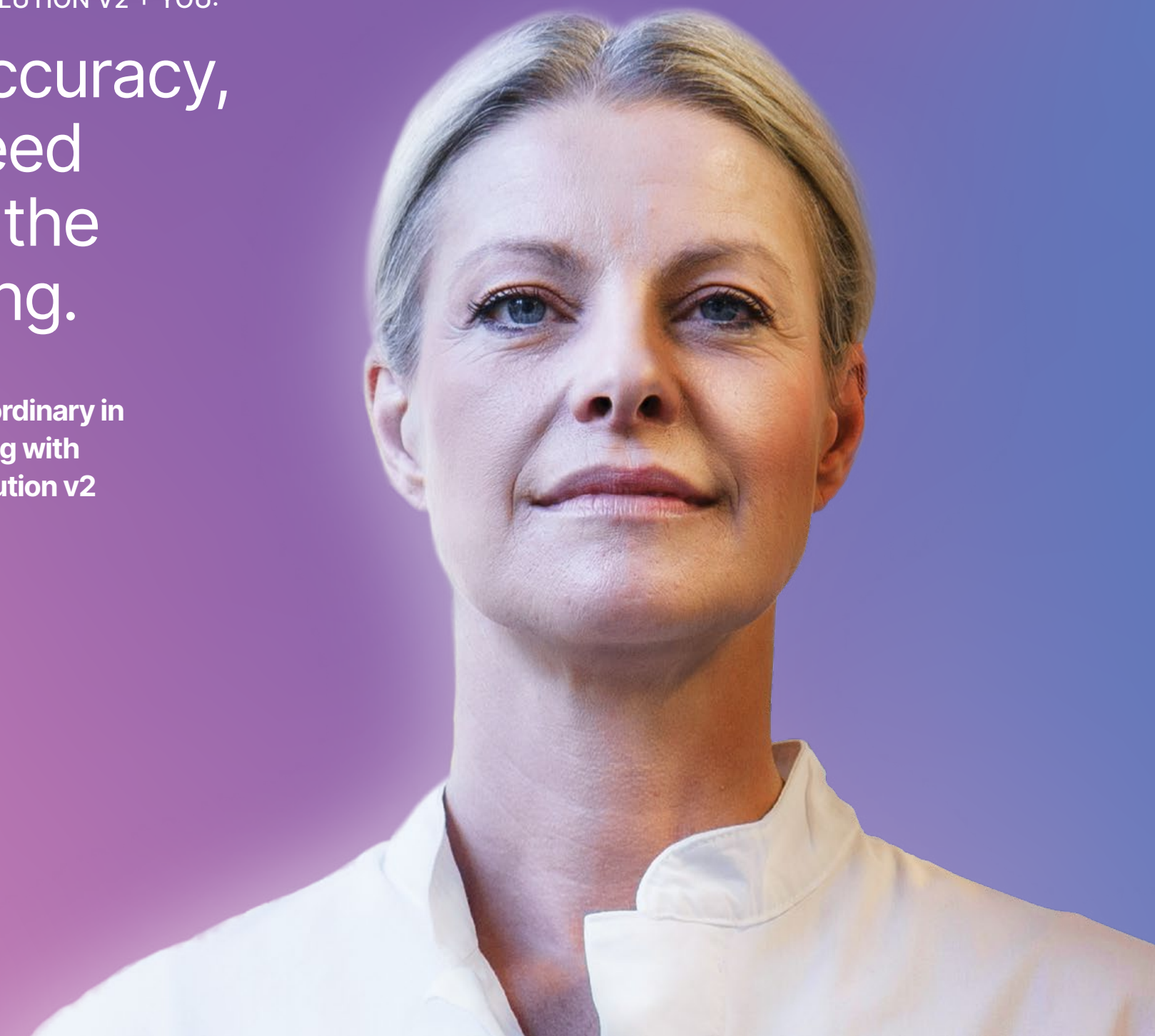
VERISEQ™ NIPT SOLUTION V2 + YOU:

Ease, accuracy, and speed are just the beginning.

Expect the extraordinary in prenatal screening with VeriSeq NIPT Solution v2



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Deliver ease, accuracy, and speed to your lab with an end-to-end workflow, high accuracy, and low failure rates with VeriSeq NIPT Solution v2.[1-3]

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A valuable choice for today and tomorrow.

Offer a comprehensive menu of prenatal screening options with VeriSeq NIPT Solution v2[1]:

Trisomy 21, 18, and 13

Sex chromosome aneuploidies

Rare autosomal aneuploidies (RAAs)

Partial duplications and deletions ≥7 Mb for all autosomes

VeriSeq NIPT Solution v2 scales according to your lab's needs, through customized menu selection for each individual sample and versatile batch options.[1] With a long-lasting partnership committed to your lab's growth and continued success, together we can shape the future of prenatal testing.

VeriSeq NIPT Solution v2 delivers high accuracy with ≥99.9% sensitivity and specificity.[2] Results that you and your clinicians can trust.

Illumina's performance is backed by published clinical experience data from over 40,000 samples studied.[2,4-6]

	Trisomy 21[b2]	Trisomy 18[2]	Trisomy 13[2]	RAA[c2]	Partial duplications and deletions ≥7 Mb[2]
Sensitivity[a]	>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 Cytogenetic results[2]		
Percent concordant	100% XX	100% XY	90.5% XO
	100% XXX	100% XXY	91.7% XYY

A dynamic fetal fraction measurement means lower failure rates, fewer redraws, trusted results for the clinician, and more answers delivered earlier to expecting families.[2]

a. Basic screen performance is reported for T21, T18, and T13 and excludes 16 samples with known mosaics and 49 samples affected with anomalies for the genome-wide screen only; genome-wide screen performance is reported for RAAs and CNVs.[2]
b. Seven twin pregnancies reported correctly as T21 are not shown in the table.[2]
c. RAA excludes chromosomes 21, 18, and 13.[2]

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FOR CLINICIANS AND EXPECTING FAMILIES

Get answers in 26 hours with VeriSeq NIPT Solution v2.[3]

From sample to result, all it takes is 1 technician and 2 hours of hands-on time to deliver results in about 1 day.

Rest assured that you can report timely prenatal screening results to your clinicians. The dedicated service and support team is available for on-site assistance and phone and email communication when you need it the most.

	Sample and library preparation	Sequencing	Data analysis and report generation	Total overall time
Hands-on time	~2 hours	~15 minutes	N/A	**~2.25 hours**
Total time	~8 hours	~14 hours	~4 hours	**~26 hours**

N/A=not available.
Actual times depend on individual lab practices and may vary; the depiction shown represents a 48-sample workflow.


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When you need an NIPT solution that fits easily into your lab.

Choose VeriSeq NIPT Solution v2 for a complete end-to-end IVD system that enables a streamlined workflow[1]:

A simple, easy-to-use, automated prenatal screening solution that easily integrates into your lab's current workflow and flexes with your lab's growing needs. This next-generation, sequencing-based, PCR-free system provides a small footprint and less complexity for the lab.

VeriSeq NIPT Solution v2 scales to fit your lab's needs with[1]:

- Versatile batch options for 24, 48, or 96 samples per run
- Customized menu selections for each sample

IVD=*in vitro* diagnostic.

VERISEQ NIPT SOLUTION V2

A workflow that works with you.

Ease: A simple, easy-to-use, automated system that seamlessly integrates into your lab's current workflow and flexes with your lab's growing needs.[1]

Accuracy: An in-lab IVD NIPT screening assay solution that delivers high accuracy with ≥99.9% sensitivity and specificity.[2] Results that you and your clinicians can trust.

Speed: Results in approximately 26 hours with only 2 hours of hands-on time means clinicians and their expecting families get answers faster.[3]

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MICROLAB STAR
NextSeq 550Dx
Welcome to NextSeqDx
Sequence
illumina
DASHBOARD
PREP
RUNS
PROJECTS
APPS
PUBLIC DATA
VeriSeq NIPT Solution v2

WHEN IT COMES TO NIPT,

VeriSeq NIPT Solution v2 sets a high standard for prenatal screening.

Ease, accuracy, and speed are just the beginning.

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.

References:

1. VeriSeq NIPT Solution v2 [package insert]. San Diego, CA: Illumina; 2021. **2.** Pertile MD, Flowers N, Vavrek D, et al. Performance of a paired-end sequencing-based noninvasive prenatal screening test in the detection of genome-wide fetal chromosomal anomalies. *Clin Chem.* 2021;67(9):1210-1219. doi: 10.1093/clinchem/hvab067. **3.** VeriSeq NIPT Solution v2 [data sheet]. San Diego, CA: Illumina; 2021. **4.** Borth H, Teubert A, Glaubitz R, et al. Analysis of cell-free DNA in a consecutive series of 13,607 routine cases for the detection of fetal chromosomal aneuploids in a single center in Germany. *Arch Gynecol Obstet.* 2021;303:1407-1414. doi: 10.1007/s00404-020-05856-0. **5.** Eiben B, Borth H, Kutur N, et al. Clinical experience with noninvasive prenatal testing in Germany: analysis of over 500 high-risk cases for trisomy 21, 18, 13, and monosomy X. *Obstet Gynecol Rep.* 2021;5:1-7. **6.** Kleinfinger P, Lohmann L, Luscan A, et al. Strategy for use of genome-wide non-invasive prenatal testing for rare autosomal aneuploidies and unbalanced structural chromosomal anomalies. *J Clin Med.* 2020;9(8);2466. doi: 10.3390/jcm9082466.

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