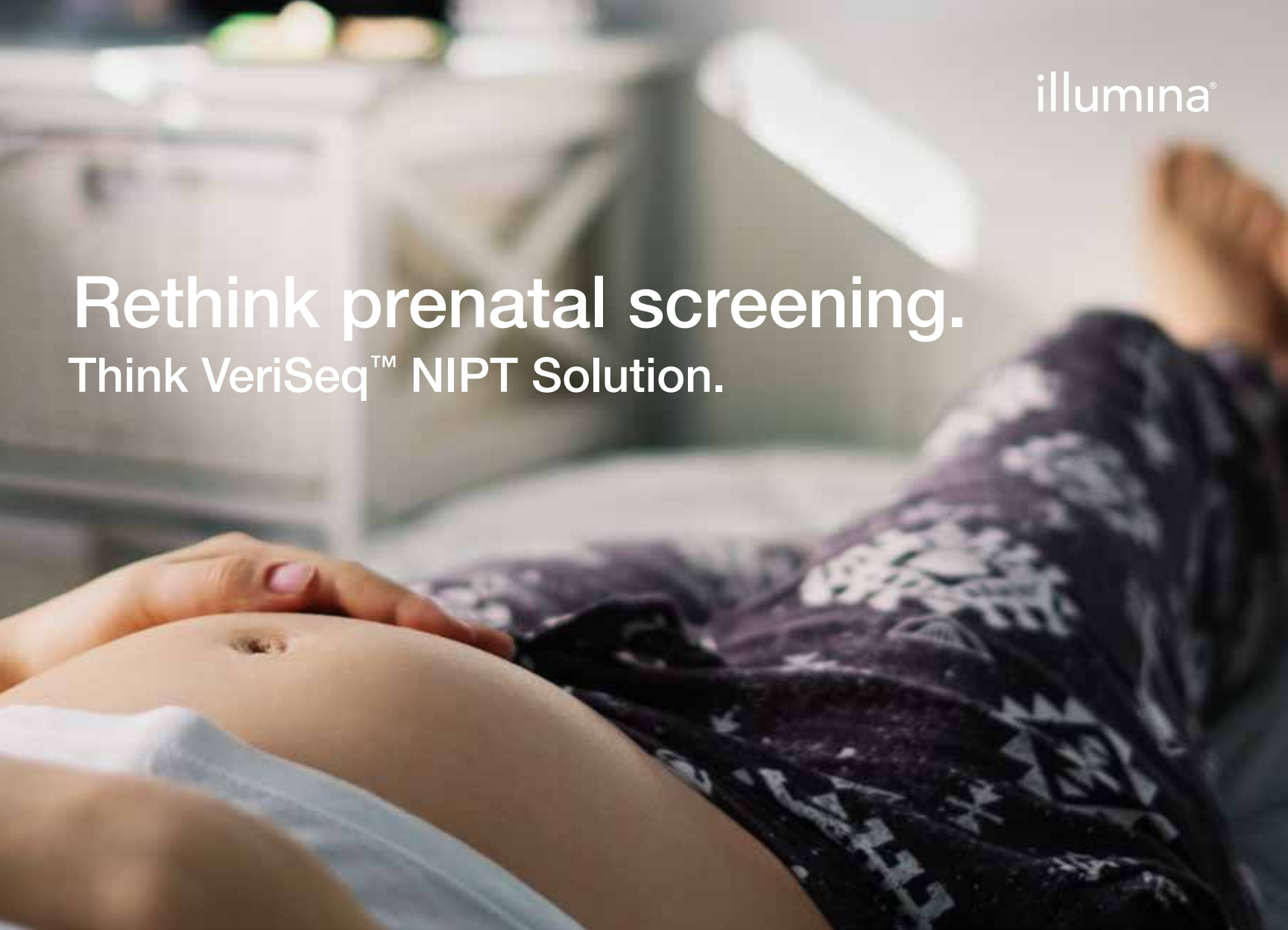

illumina®
Rethink prenatal screening.
Think VeriSeq™ NIPT Solution.

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 more accurate than traditional screening methods for detecting common fetal aneuploidies.

By increasing specificity (ie, reducing false positive rates),[1,2] in addition to higher detection rates, NIPT helps limit invasive procedures—and therefore, the risk of miscarriage—when used as a primary screen.


89%
FEWER INVASIVE TESTS VS
TRADITIONAL SCREENING[1]

1 SOLUTION

The VeriSeq NIPT Solution is validated automated workflow including IVD–marked sample prep and assay software. From sample prep to sequencing to analysis, the VeriSeq NIPT Solution is easy to implement and easy to use in any clinical lab—streamlining your process as one comprehensive workflow.

VeriSeq NIPT Workflow Manager
Specialized software for automated preparation of samples

VeriSeq NIPT Sample Prep Kits
Specially designed kits for full preparation of 48 or 96 samples

VeriSeq NIPT Microlab STAR
Unique liquid handling robot, optimized for the VeriSeq NIPT Solution workflow

VeriSeq Onsite Server
Secure on-site server with revolutionary assay software for NIPT analysis and reporting

2 HOURS HANDS-ON TIME

0 HOURS ON PCR

1.5 DAYS FASTER THAN COMPETING NIPTS*[3]

26 HOURS FROM START TO FINISH

The solution provides results for up to 96 samples, with as little as 2 hours of hands-on time.

With an automated, PCR-free workflow sample to report takes just over 24 hours.

No post-PCR area is required, and only one automated liquid handling system is needed.[4]

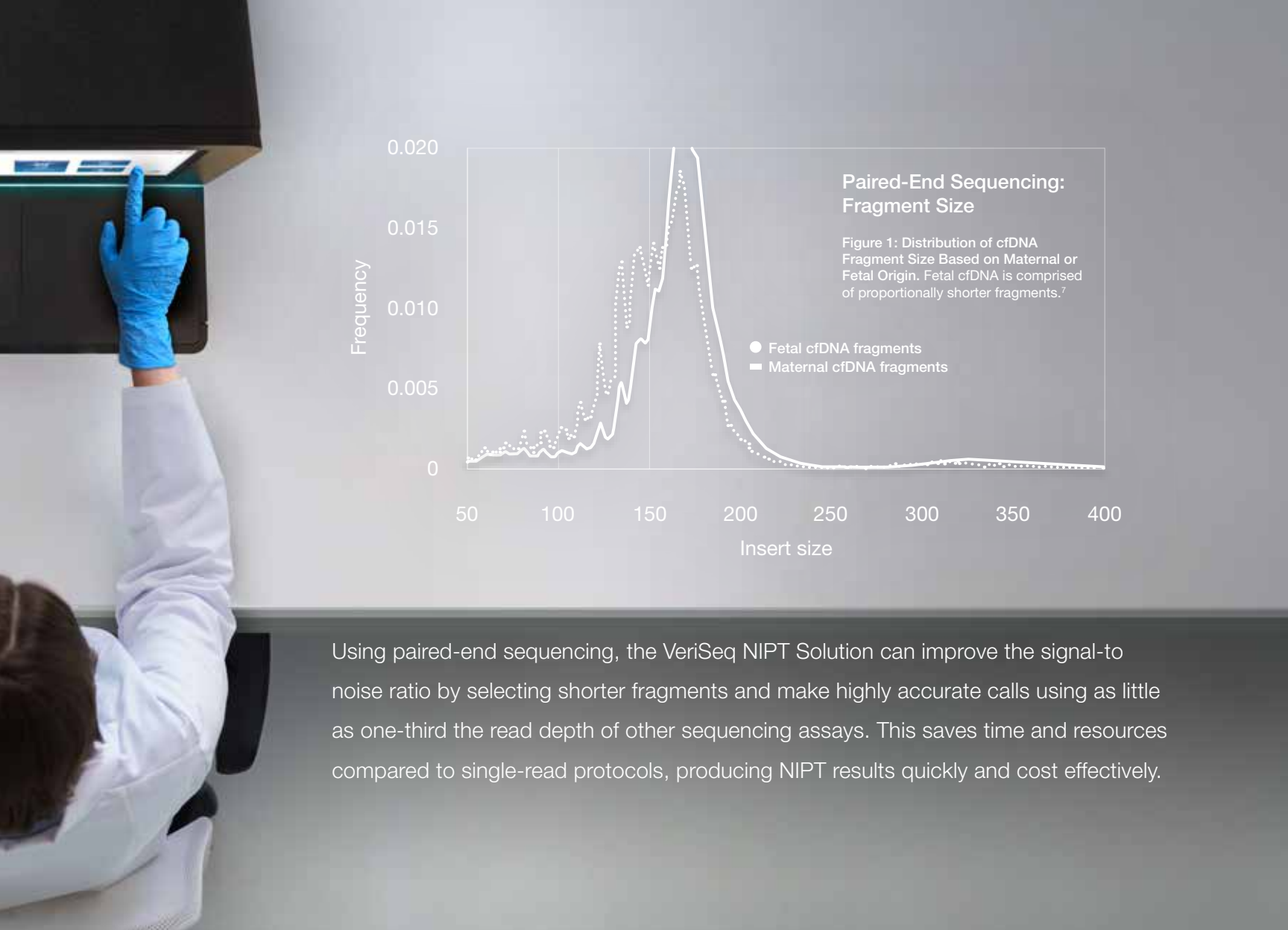
* Assumes one work shift per day


NextSeq 550
Illumina

99.9% ACCURACY[4]

Minimize hands-on time. Maximize efficiency.

The VeriSeq NIPT Solution leverages our paired-end sequencing technology, resulting in a truly revolutionary analysis. During paired-end sequencing, both ends of a DNA fragment are analyzed, allowing for the size determination of each cell-free DNA (cfDNA) fragment in the sample. Studies have shown that in a maternal sample, shorter cfDNA fragments tend to be fetal in origin while longer fragments tend to be maternal (Figure 1).[5,6]



Paired-End Sequencing: Fragment Size

Figure 1: Distribution of cfDNA Fragment Size Based on Maternal or Fetal Origin. Fetal cfDNA is comprised of proportionally shorter fragments.[7]

Using paired-end sequencing, the VeriSeq NIPT Solution can improve the signal-to noise ratio by selecting shorter fragments and make highly accurate calls using as little as one-third the read depth of other sequencing assays. This saves time and resources compared to single-read protocols, producing NIPT results quickly and cost effectively.

Gain confidence.
Get less false positives.

Samples that fail NIPT and provide no result drive a need for further clinical follow-up and additional testing. The International Society for Prenatal Diagnosis (ISPD) states that after a NIPT failure, alternative testing versus repeat NIPT may be considered.[8]

Did you know the VeriSeq NIPT Solution can provide results on a larger proportion of processed samples? Utilizing a simplified workflow and a powerful analysis method aimed toward minimizing failure rate and rescuing low fetal fraction samples, the solution provides results on a larger proportion of processed samples. In fact, the VeriSeq NIPT Solution showed excellent clinical performance with only a 0.68% overall sample failure rate in a 3107 sample clinical study. Other tests with higher failure rates require additional follow up—which may be an invasive procedure. The VeriSeq NIPT Solution aims to greatly reduce the chances of these procedures due to low false positive rate and low sample failure rate.

9X

LOWER FAILURE RATE[9]

Distribution of Fetal Fraction[4]

Figure 2: Distribution of Fetal Fraction of More Than 2000 NIPT Samples.[3] If the system utilized fetal fraction exclusively to exclude samples, a significant proportion would not be analyzed. Because the VeriSeq NIPT Solution is optimized to handle samples at the lower end of the fetal fraction range (highlighted in white), results will be provided to a larger proportion of samples than if these samples were excluded.


99%
OF ALL NIPT STUDY SAMPLES
ARE RUN ON ILLUMINA SYSTEMS[10]

Empowering breakthroughs in genetic screening

Illumina sequencing is the foundational technology powering NIPT. In fact, it has been used in more than 99% of published NIPT samples to date.[10] With breakthrough genetic screening technology, we are well equipped to serve the needs of clinical laboratories, health care professionals, and patients. Together, we can change the perception of prenatal screening options and improve the future of genetic disease detection.

References

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3. Data calculations on file. Illumina, Inc., 2016
4. VeriSeq NIPT Solution Package Insert
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6. Lo YN, Chan KC, Sun H, et al. Maternal plasma DNA sequencing reveals the genome-wide genetic and mutational profile of the fetus. *Sci Transl Med.* 2010;61(2):61-91.
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9. Data calculations on file. Illumina, Inc., 2018
10. Data calculations on file. Illumina, Inc., 2017

The VeriSeq NIPT Solution is an *in vitro* diagnostic test intended for use as a sequencing-based screening test for the detection of fetal aneuploidies from maternal peripheral whole blood samples in pregnant women of at least 10 weeks gestation. The VeriSeq NIPT Solution provides information regarding aneuploidy status for chromosomes 21, 18, 13, X, and Y. 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 to your lab.

www.illumina.com/InLabNIPT

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

CE

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