

Don't settle for failure

The Verifi™ Prenatal Test uses proven NGS technology to provide accurate NIPT results with the lowest failure rate

What is test failure?

For noninvasive prenatal testing (NIPT), test failure indicates that no call of chromosomal status can be made. This is an important factor in the reliability and clinical utility of NIPT. NIPT failure rates vary significantly based on the type of test used. Using whole-genome next-generation sequencing (NGS), the Verifi Prenatal Test from Illumina achieves the lowest test failure rate in NIPT (Figure 1).

The impact of test failure

As test failure is really an inconclusive result, it can lead to increased anxiety on the part of the patient and the physician, and it can potentially lead to an increased number of follow-up invasive procedures to obtain information. Although ordering a second blood draw to repeat NIPT is an option, there are no guarantees that repeated NIPT will provide a result. In fact, as many as 65% of patients who receive a test failure result on their first draw fail to receive a conclusive result, even after factoring in repeat attempts.^{1,*}

Whole-genome sequencing (WGS) methods for NIPT have lower test failure rates than targeted methods. According to the Society for Maternal-Fetal Medicine (SMFM), “women with failed cfDNA tests are at an increased risk for aneuploidy, and therefore need careful counseling about further testing, including the offer of diagnostic testing.”² With a lower test failure rate, whole-genome NGS-based assays are more likely to detect these aneuploidies the first time.

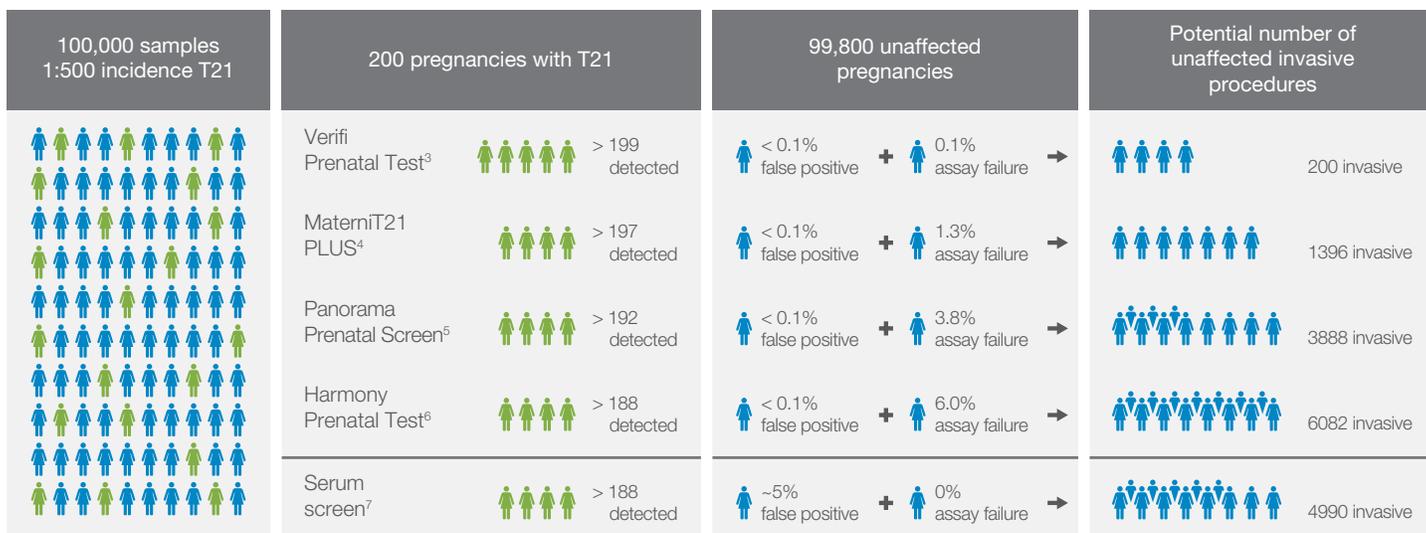


Figure 1: Test Failures May Lead to Invasive Procedures.¹—Theoretical example of the number of invasive procedures requested due to NIPT failure and false positive rates of the assays. Failure rates include assay failures and samples rejected due to low fetal fraction.³⁻⁷

* This 65% includes test failures from redraws and patients that either chose not to submit a second sample or are ineligible for a redraw due to specific features that prevent resolution with SNP-based NIPT (ie, large regions exhibiting loss of heterozygosity [LOH]).

¹ Affected pregnancies with a screening test failure were excluded from the number of detected T21.

To learn more about NIPT using the Verifi Prenatal Test, visit www.illumina.com/Verifi.

References

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Limitations of the test

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 genetic counseling and confirmatory diagnostic testing is necessary prior to making any irreversible pregnancy decision. Limited data exist regarding the clinical outcome of pregnancies with rare autosomal trisomies, especially for those detected through NIPT. Health care providers should be aware of the limitations of the test and understand that limited outcome data may confound pregnancy counseling and management.

The Verifi™ Prenatal Test was developed by, and its performance characteristics were determined by Verinata Health, Inc. (VHI) a wholly owned subsidiary of Illumina, Inc. The VHI laboratory is CAP-accredited and certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. It has not been cleared or approved by the U.S. Food and Drug Administration.