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Verifi™ Prenatal Test

A reliable, easy, fast noninvasive prenatal test

The Verifi Prenatal Test safely and noninvasively screens for the most common chromosomal aneuploidies as early as 10 weeks gestation using a single maternal blood draw, offering the lowest test failure rate in the industry.[1] The Verifi Prenatal Test uses sequencing technology to provide accurate information for pregnant women regardless of age or risk.[1]

The leader in NIPT innovation

While there are different methods for performing noninvasive prenatal testing, sequencing is the most published method.[4] It has demonstrated excellent detection rates and very low false positive rates.[5]

The Verifi Prenatal Test from Illumina uses whole-genome sequencing (WGS) to screen for common fetal aneuploidies, with higher detection rates and significantly fewer false positives than traditional screening methods.[6-9]

Test options

Standard Verifi Test offering	Sex chromosome aneuploidies
• Trisomy 21 (Down syndrome) • Trisomy 18 (Edwards syndrome) • Trisomy 13 (Patau syndrome)	• Monosomy X (MX/Turner syndrome) • XXX (Triple X) • XXY (Klinefelter syndrome) • XYY (Jacob's syndrome) • Fetal Sex may be reported if no sex chromosome aneuploidies are detected

Why choose the Verifi Test?

- Proven superiority to traditional screening methods for the screening of common fetal aneuploidies, with reduced false positive rates (increased specificity) and increased positive predictive values (PPV)[6,7]
- Comprehensive portfolio with expanded panel available
- Fast turnaround time[†]
- Lowest published failure rate in the industry, 0.1%[1-3]

NIPT vs traditional serum screening

- Offers the highest reported detection rate for Down syndrome[6]
- Offers the lowest reported false positive rate for Down syndrome[6]
- Offers the broadest screening window (performed as early as 10 weeks gestation until term)[6-8]

The original Verifi Test* has previously shown excellent performance in a real-life clinical population of over 86,000 patient samples.[1]

Total Cases	86,658
Average Turnaround Time[†] (business days)	3.3
Technical Cancellations	0.1%
Aneuploidy Detected	2.2%
Observed False Positives[‡]	0.12%
Observed False Negatives[‡]	0.02%

* The improved Verifi prenatal test has performance metrics that are equivalent to those as the original Verifi prenatal test.

† Turn around time is defined as the time from sample receipt in the performing laboratory until the report is released to the client.

‡ FP and FN calculations are based on known outcome data.

For performance metrics from the original validation study, visit www.illumina.com/VerifiData

Report example

Verifi prenatal screening report

Verifi™ Prenatal Test

REPORT RELEASED
Date: 09/22/15 Time: 08:45 AM

PROVIDER INFORMATION
University Medical Center
Attn: Dr. John Smith-Gonzalez
1234 Doctor Street, Suite 541
Downtown City, CA 10231
Phone: (800) 555-1212
Fax: (800) 555-1212

SECOND RECIPIENT
Medical Center
Attn: Dr. Mary Smith
Address: 1234 State Street, Downtown City, CA 10231
Phone: (800) 555-1212
Fax: (800) 555-1212

PATIENT INFORMATION
Name: Jane Doe
DOB: 09/07/1971
GA: XXXXXXXX
Indication: XXXXXXXX
Medical record/patient ID: XXXXXXXX

SAMPLE INFORMATION
Client Sample ID: 1234567
Order ID: 1234567
Date of Draw: 09/07/15
Date Received: 09/22/15
Pregnancy Type: Singleton

ANEUPLOIDY DETECTED

RESULTS SUMMARY:

CHROMOSOME	RESULTS	PPV (%)
Chromosome 21	**POSITIVE: Aneuploidy detected** Results consistent with pregnancy at increased risk for trisomy 21.	90%
Chromosome 18	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 18.	
Chromosome 13	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 13.	
Sex Chromosomes	**POSITIVE: Aneuploidy detected** Results consistent with pregnancy at increased risk for XXX (triple X).	

Clear, concise results

Results from the Verifi Prenatal Test are reported as “Positive: Aneuploidy Detected” or “Negative: No Aneuploidy Detected.” Results for chromosomes 21, 18, 13, X, and Y are reported individually.

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. False positive and false negative results do occur. Test results must not be used as the sole basis for diagnosis. Further confirmatory testing is necessary prior to making any irreversible pregnancy decision. A negative result does not eliminate the possibility that the pregnancy has a chromosomal or subchromosomal abnormality. This test does not screen for polyploidy (eg, triploidy), birth defects such as open neural tube defects, single gene disorders, or other conditions, such as autism. There is a small possibility that the test results might not reflect the chromosomal status of the fetus, but may instead reflect chromosomal changes in the placenta (confined placental mosaicism, CPM) or the mother that may or may not have clinical significance.

References

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2. McCullough RM, Almasri EA, Guan X, et al. Non-invasive prenatal chromosomal aneuploidy testing--clinical experience: 100,000 clinical samples. *PLoS One*. 2014;9(10):e109173.
3. Ryan A, Hunkapiller N, Banjevic M, et al. Validation of an enhanced version of a single-nucleotide polymorphism-based noninvasive prenatal test for detection of fetal aneuploidies. *Fetal Diagn Ther*. 2016;40(3):219-223.
4. Data calculation on file. Illumina, Inc. 2016.
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6. Practice Bulletin No. 163: Screening for Fetal Aneuploidy. *Obstet Gynecol*. 2016;127(5):979-981.
7. Gregg AR, Skotko BG, Benkendorf JL, et al. Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics. *Genet Med*. 2016;18(10):1056-1065.
8. Bianchi DW, Parker RL, Wentworth J, et al. DNA sequencing versus standard prenatal aneuploidy screening. *N Engl J Med*. 2014;370(9):799-808.
9. Norton ME, Jacobsson B, Swamy GK, et al. Cell-free DNA analysis for noninvasive examination of trisomy. *N Engl J Med*. 2015;372(17):1589-1597.

The Verifi™ and Verifi™ Plus Prenatal Test were developed by, and their 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. They have not been cleared or approved by the U.S. Food and Drug Administration.

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