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Verifi™ Prenatal Test

A reliable, easy, and fast non-invasive prenatal test (NIPT)

The Verifi Prenatal Test non-invasively screens for the most common chromosomal aneuploidies as early as 10 weeks gestation using a single blood draw from the patient, offering a low test failure rate.[1-3] The Verifi Prenatal Test uses sequencing technology to provide accurate information for pregnant patients regardless of age or risk.

A leader in prenatal screening innovation

- While there are different methods for performing non-invasive prenatal screening, 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 next-generation sequencing technology to screen for common fetal aneuploidies, with higher detection rates and significantly fewer false positives than traditional screening methods.[6,7]

Test options

Standard Verifi test offering

- Trisomy 21 (Down syndrome)
- Trisomy 18 (Edwards syndrome)
- Trisomy 13 (Patau syndrome)

Sex chromosome aneuploidies

- Monosomy X (MX/Turner syndrome)
- XXX (Triple X)
- XXY (Klinefelter syndrome)
- XYY (Jacob's syndrome)
- Fetal Sex prediction may be reported if no sex chromosome aneuploidies are detected

Why choose the Verifi test?

- Improved performance compared 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 an expanded panel available
- Fast turnaround time[8]
- Proceed with confidence of a low failure rate of 0.6%[1]

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]

The original Verifi Test* has previously shown excellent performance in a real-life clinical population of over 86,000 patient samples.[8]

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

* The improved Verifi prenatal test has performance metrics that are comparable 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 https://emea.illumina.com/clinical/reproductive-genetic-health/nipt/sendout-testing-for-labs.html

Verifi™ prenatal test report

Verifi™ Prenatal Test

REPORT RELEASED
Date: 10/13/22 Time: 12:09 PM

PROVIDER INFORMATION
Attn: Jane Doctor, MD
123 Fake Street
Downtown City, CA 10231
Phone: (123) 456-7890
Fax: (123) 456-7899

SECOND RECIPIENT
Dr. Mary Smith
Address: 1234 State Street
Downtown City, CA 10231
Fax: (800) 555-1213

PATIENT INFORMATION
Jane Patient
DOB: 11/08/1984
GA: 11 weeks
Indication: AMA
Medical record/patient ID: 123456789

SAMPLE INFORMATION
Client Sample ID:
Order ID: 742352
Date of Draw: 05/18/22
Date Received: 05/20/22
Pregnancy Type: Singleton

ANEUPLOIDY DETECTED

RESULTS SUMMARY:

CHROMOSOME	RESULTS	PPV (%)
Chromosome 21	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 21	
Chromosome 18	**POSITIVE: Aneuploidy detected** Results consistent with pregnancy at increased risk for trisomy 18	30.3%
Chromosome 13	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 13	
Sex Chromosomes	**NEGATIVE: No aneuploidy detected** Results consistent with two sex chromosomes (XX)	

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.

References

1. Data on file. Illumina, Inc 2022
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. Dar, Pe’er et al. Cell-free DNA screening for trisomies 21, 18, and 13 in pregnancies at low and high risk for aneuploidy with genetic confirmation. Am. J. Obstet. Gynecol. (2022) doi:10.1016/j.ajog.2022.01.019
4. Data calculation on file. Illumina, Inc. 2022.
5. Gil MM, Quezada MS, Revello R, Akolekar R, Nicolaides KH. Analysis of cell-free DNA in maternal blood in screening for fetal aneuploidies: updated meta-analysis. Ultrasound Obstet Gynecol. 2015;45(3):249-266.
6. Rose, N. C. et al. Screening for Fetal Chromosomal Abnormalities: ACOG Practice Bulletin, Number 226. Obstet. Gynecol.136, e48–e69 (2020).
7. Bianchi DW, Parker RL, Wentworth J, et al. DNA sequencing versus standard prenatal aneuploidy screening. N Engl J Med. 2014;370(9): 799-808.
8. Taneja PA, Snyder HL, de Feo E, et al. Noninvasive prenatal testing in the general obstetric population: clinical performance and counseling considerations in over 85 000 cases. Prenat Diagn. 2016;36(3):237-243.

Limitations of the test

Verifi™ based on cell-free DNA analysis from maternal or pregnant patients’ blood is a screening test. False positive and false negative results do occur. Test results must not be used as the sole basis for diagnosis. Further genetic counseling and confirmatory testing is necessary with a positive test result. Test results might not reflect the chromosomal status of the fetus but may reflect chromosomal changes of the placenta (CPM) or of the patient, which may or may not have clinical significance. A negative test result does not eliminate the possibility of chromosomal abnormalities for the tested chromosomes. This test does not screen for polyploidy (e.g. triploidy), birth defects such as open neural tube defects, single gene disorders, or other conditions, such as autism.

Verifi™ was developed by, and the 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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