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VERIFI™ PLUS PRENATAL TEST

An expanded NIPT panel for additional insights

Screen for a broad range of aneuploidies

The Verifi Plus Prenatal Test allows you more insights with an expanded elective panel that includes rare autosomal trisomies as well as clinically significant microdeletions.

- Reliable results without the risks of invasive procedures
- Thorough and responsible test expansion – considered in conjunction with clinical context such as abnormal ultrasound or family history[1,2]
- Proven technology that takes advantage of Illumina's next generation sequencing technology, which is the most widely used in the industry[3]
- Additional panel options available to the common trisomy screening

	Incidence
22q11.2 deletion syndrome (DiGeorge syndrome, velocardiofacial syndrome)[4]	1 in 4,000
1p36 deletion syndrome[4]	1 in 4,000 to 1 in 10,000
Angelman syndrome (15q11.2 microdeletion)[4,5]	1 in 12,000
Prader-Willi syndrome (15q11.2 microdeletion)[4,5]	1 in 10,000 to 1 in 25,000
Cri-du-chat syndrome (5p- syndrome)[4,5]	1 in 20,000 to 1 in 50,000
Wolf-Hirschhorn syndrome (4p- syndrome)[4,5]	1 50,000

What are microdeletions?

Microdeletions are chromosomal disorders caused by small missing pieces of chromosome material. Some occur more commonly in a specific area of a particular chromosome and have been linked to known genetic syndromes. Most occur by chance, rather than by being inherited from a parent, and can occur with no prior family history and without other risk factors.

What is the value of microdeletion testing?

Many microdeletion syndromes can cause serious health issues including both physical and intellectual impairment. These conditions cannot be detected by traditional serum screening and may be associated with ultrasound abnormalities. The Verifi Plus Prenatal Test offers a noninvasive option to screen for select microdeletions. If definitive diagnosis is desired, an invasive procedure, such as chorionic villus sampling (CVS) or amniocentesis would be necessary.

Why choose the Verifi Plus Prenatal Test?

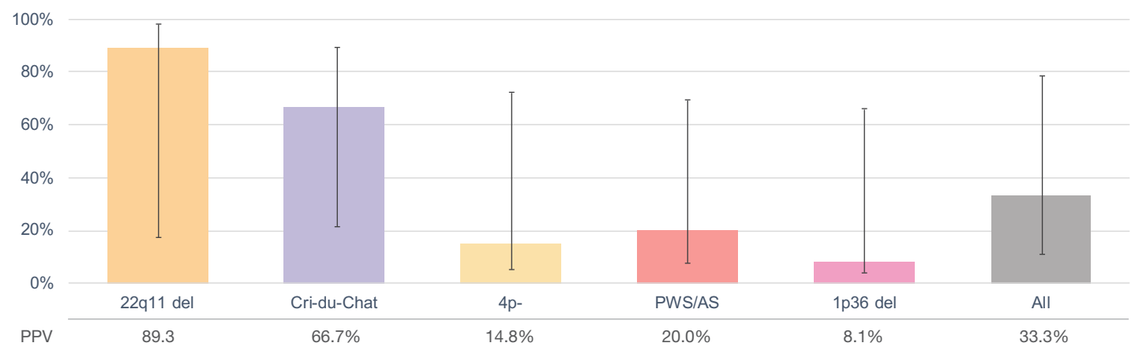
The capabilities of the Verifi Prenatal Test have been expanded to help detect five specific microdeletion regions. By doing so, the Verifi Plus Prenatal Test microdeletion panel can provide valuable information to aid in pregnancy management and preparation for newborn care.

CLINICAL EVIDENCE SUPPORTING THE VERIFI PLUS PRENATAL TEST

The Verifi Plus Prenatal Test microdeletion panel has been validated on both clinical and analytical samples.

In a clinical cohort of more than 368,000 samples, the Verifi Plus Prenatal Test microdeletion panel shows strong overall performance including: a low false positive rate, a low test failure rate, and a positive predictive value (PPV) of 89.3% for 22q11 deletion syndrome, with PPVs ranging from 8.1% to 66.7% for the other microdeletion syndromes.*

Observed Positive Predictive Value (PPV) for 22q deletion and other microdeletions*



	22q11 del	Cri-du-Chat	4p-	PWS/AS	1p36 del	All
PPV	89.3	66.7%	14.8%	20.0%	8.1%	33.3%

*Data calculations on file. Illumina, Inc. 2022

Simple. Fast. More information.

- Performed as early as 10 weeks gestational age
- A deeper approach to the science of sequencing
- Fast turnaround time; results usually available within 3 to 5 business days

Get started with the Verifi Plus Prenatal Test microdeletion panel today. Please Contact (858) 736-8080 or (855) 266-6563 (toll free) or https://ClinicalLabServicesSupport.Illumina.com/ to learn more.

References

1. American College of Obstetricians and Gynecologists. Practice Bulletin no.175: Ultrasound in pregnancy. Obstet Gynecol. 2016; 128(6):e241-e256
2. Dungan, J.S. et al. Noninvasive prenatal screening (NIPS) for fetal chromosome abnormalities in a general- risk population: An evidence-based clinical guideline of the American College of Medical Genetics and Genomics (ACMG). Genet. Med. 25, 100336 (2023)
3. Data on file. Illumina, Inc. October 2022.
4. Gardner RJM, Sutherland GR, Schaffer LG. Chromosome Abnormalities and Genetic Counseling. 4th ed. New York, NY: Oxford University Press; 2012.
5. Jones KL. Smith's Recognizable Patterns of Human Malformation. 5th ed. Philadelphia, PA: Saunders; 1996.

Limitations of the test

Verifi™ Plus 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 diagnostic 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. CPM may be associated with a higher chance for pregnancy complications or for uniparental disomy (UPD), which may affect the growth and development of the fetus. Some of these rare chromosomal aneuploidies may only occur in mosaic form. Clinical consequences depend on the chromosome involved and cannot be predicted prenatally. A negative test result does not eliminate the possibility of chromosomal abnormalities for the tested chromosomes or microdeletions. In addition, microdeletion conditions caused by other molecular mechanisms cannot be detected with this assy. 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™ and Verifi™ Plus 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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