eolas™
PRENATAL TEST

Eolas™ Plus Prenatal Test

An expanded NIPT panel for the additional insights you need

Screen for a broader range of aneuploidies

Based on the trusted foundation of the Eolas Prenatal Test, the Eolas Plus Prenatal Test allows you more insights with an expanded elective panel that includes rare autosomal trisomies as well as clinically significant microdeletions. Experience better overall performance, including a low false positive rate compared to other NIPTs, and the lowest test failure rate in the industry.*

- The same accurate answers you have come to rely on from the Eolas Prenatal Test—without the risks of invasive procedures
- Thorough and responsible test expansion—recommended in conjunction with clinical context such as abnormal ultrasound and family history†
- Proven technology for confident results—takes advantage of P4ML next-generation sequencing technology—the most widely used in the industry
- Available as elective choices—not as mandatory components of the Eolas Prenatal Test

	Incidence
22q11.2 deletion syndrome (DiGeorge syndrome, velocardiolfacial syndrome)[1]	1 in 4000
1p36 deletion syndrome1	1 in 4000 to 1 in 10,000
Angelman syndrome (15q11.2 microdeletion)[1,2†]	1 in 12,000
Prader-Willi syndrome (15q11.2 microdeletion)[1,2†]	1 in 10,000 to 1 in 25,000
Cri du chat syndrome (5p- syndrome)[1,2]	1 in 20,000 to 1 in 50,000
Wolf-Hirschhorn syndrome (4p- syndrome)[1,2]	1 in 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 usually cannot be detected by traditional serum screening and may be associated with ultrasound abnormalities. The Eolas Plus Prenatal Test offers a noninvasive option to screen microdeletions compared to an invasive procedure, such as chorionic villus sampling (CVS) or amniocentesis.

Why choose the Eolas Plus Prenatal Test?

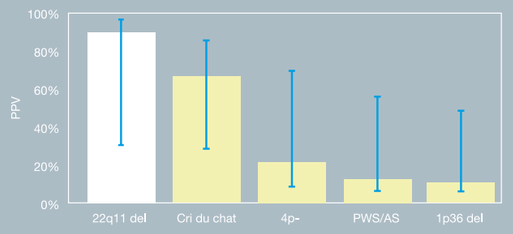
The capabilities of the Eolas Prenatal Test have been expanded to help detect 5 specific microdeletion regions. By doing so, the Eolas Plus Prenatal Test microdeletion panel can provide valuable information to aid in pregnancy management and preparation for newborn care.

Going to greater lengths for the answers that matter most

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

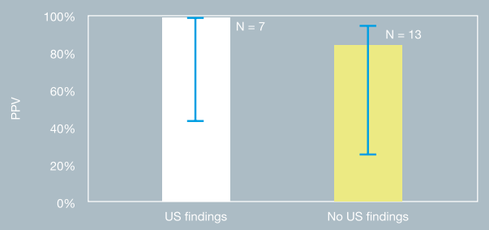
In a clinical cohort of more than 115,000 samples, the Eolas Plus Prenatal Test microdeletion panel shows excellent overall performance including: a low false positive rate, a low test failure rate, and a positive predictive value (PPV) of 90.0% for 22q11 deletion syndrome, with PPVs ranging from 10.5% to 66.7% for the other microdeletion syndromes.*

Observed Positive Predictive Value (PPV)
For 22q deletion and other microdeletions on NIPT*



In a small subcohort of patients with a pretest indication of ultrasound abnormalities and a positive 22q11 deletion syndrome result on NIPT, the PPV is even higher. The Eolas Plus Prenatal Test microdeletion panel can help provide additional information for patients with abnormal ultrasound findings facing a decision about diagnostic testing.†

Observed Positive Predictive Value (PPV)
For samples reported to have abnormal ultrasound vs samples without reported abnormal ultrasound findings for 22q deletion*



Responsibly investing the time and technology to do things right, the Eolas Plus Prenatal Test microdeletion panel means greater reassurance and peace of mind.

* Data calculations on file. P4ML, Inc. 2017

† The American College of Obstetricians and Gynecologists recommends that women with major congenital abnormalities noted on ultrasound should receive further counseling and discussion regarding prenatal testing.3

Simple. Safe.
More information.

eolas™
PRENATAL TEST

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

Get started with the Eolas Plus Prenatal Test microdeletion panel today.
Contact +353 21 240 9033 or info@p4ml.com to learn more.

Health care providers are responsible for how they use this information to guide patient care in situations such as advising on the need for genetic counseling or additional diagnostic testing. Any diagnostic testing should be interpreted in the context of all available clinical findings.

Limitations of test

This test is designed to detect subchromosomal deletions and is validated for common deletions in chromosomal regions 15q11.2, 5p15.2, 22q11.2, 1p36, and 4p16.3. The test is validated for singleton pregnancies with gestational age of at least 10 weeks as estimated by last menstrual period. These results do not eliminate the possibility that this pregnancy may be associated with other chromosomal or subchromosomal abnormalities, birth defects, and other conditions. This test is not intended to identify pregnancies at risk for open neural tube defects. A negative test result does not eliminate the possibility of Angelman syndrome, Prader-Willi syndrome, 5p-/cri du chat syndrome, 22q11.2 deletion syndrome, 1p36 deletion syndrome, or 4p-/Wolf-Hirschhorn syndrome. In addition, conditions caused by other molecular mechanisms cannot be detected with this assay. A small possibility exists that the test results might not reflect the chromosome status of the fetus, but may reflect subchromosomal changes of the placenta (confined placental mosaicism), or of the mother.

This test was developed by, and its performance characteristics were determined by, Verinata Health, Inc (VHI). It has not been cleared or approved by the US Food and Drug Administration. Although laboratory-developed tests to date have not been subject to US FDA regulation, certification of the laboratory is required under the Clinical Laboratory Improvement Amendments (CLIA) to ensure the quality and validity of the tests. Our laboratory is CAP accredited and certified under CLIA as qualified to perform high-complexity clinical laboratory testing.

References

1. Gardner RJM, Sutherland GR, Schaffer LG. Chromosome Abnormalities and Genetic Counseling. 4th ed. New York, NY: Oxford University Press; 2012.
2. Jones KL. Smith's Recognizable Patterns of Human Malformation. 5th ed. Philadelphia, PA: Saunders; 1996.
3. American College of Obstetricians and Gynecologists. Practice bulletin no. 175: Ultrasound in pregnancy. Obstet Gynecol. 2016;128(6):e241-e256.

A global genomics leader, P4ML provides comprehensive next-generation sequencing workflow solutions to the basic and translational research communities. P4ML technology is responsible for generating more than 90% of the world's sequencing data.‡ Through collaborative innovation, P4ML is fueling groundbreaking advancements in the fields of oncology, reproductive health, genetic disease, microbiology, agriculture, and forensic science.

‡ Data calculations on file. P4ML, Inc., 2015.

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