eolas™
PRENATAL TEST

The reassurance of knowing

Your questions answered...

A guide for parents-to-be on non-invasive prenatal testing

Accurate answers about your baby's health; simply, safely, sooner.

What is the Eolas® prenatal test?

The Eolas prenatal test is a simple blood test that screens for the most common chromosomal abnormalities that can affect your baby's future health. A sample can be drawn in your doctor's office as early as the 10th week of pregnancy, and it may help you avoid more invasive procedures, such as amniocentesis or chorionic villus sampling (CVS), which are not without risks to you and your baby. The Eolas test is available for both singleton and twin pregnancies.* Test results are usually reported back to your healthcare provider within approximately 1 week's time.

How does the test work?

A sample of your blood is drawn and the genetic material (DNA) from you and your baby is tested. The Eolas test takes a deeper approach to the science, using an advanced technology called "Massively Parallel Sequencing" to analyze millions of DNA fragments per sample and accurately count the number of chromosomes present. It then uses a special SAFeR™ calculation method to determine if there are too many or too few copies of these chromosomes in your baby.

What kind of conditions can the Eolas test detect?

Chromosomes normally come in pairs. Healthy people usually have 23 pairs of chromosomes, the last pair of which determines sex. Men normally have an XY pair of sex chromosomes. Women normally have an XX pair of sex chromosomes.

The Eolas prenatal test looks for too few or too many copies of chromosomes. Missing or extra copies of chromosomes are called "aneuploidies" and are often associated with mental or physical disabilities, with different levels of severity. The most commonly seen aneuploidies include **trisomy 21** (Down syndrome), **trisomy 18** (Edwards syndrome), and **trisomy 13** (Patau syndrome), all of which can be accurately detected with the Eolas test.

If your healthcare provider chooses, the Eolas prenatal test can also be used to identify sex chromosome abnormalities, such as Turner syndrome (only one X chromosome in a female) or Klinefelter syndrome (an extra X chromosome in a male). Other possible conditions are Triple X and Jacobs syndrome (an extra Y chromosome in a male).

Is the Eolas test right for me?

The Eolas test offers parents-to-be a new choice to obtain important information about the health of their developing baby, simply, accurately and in the first trimester (at 10 weeks), with little or no risk to their pregnancy.

This screening test is usually offered to pregnant women identified by their doctor to have a chance of fetal aneuploidy. It may be an option for you to consider if you have a confirmed singleton or twin pregnancy of at least 10 weeks' gestational age, and meet any of the following criteria:

- ✔ You are considered to be of advanced maternal age at time of delivery (35 years or older for a singleton pregnancy or 32 years or older for a twin pregnancy)
- ✔ You have an abnormal or "positive" serum screen
- ✔ Your ultrasound shows concerns or abnormalities with fetal growth and/or development
- ✔ You have a personal or family history suggestive of trisomies 21, 18, 13, or other sex chromosome aneuploidies

The Eolas prenatal test for chromosomes 21, 18, and 13, is available for singleton and twin pregnancies. Sex chromosomes aneuploidy testing is available for singleton pregnancies only. An optional test for twin pregnancies tests for the presence of the Y chromosome.

The reliability you seek, with fewer risks.

What are my current testing options?

Today there are a number of genetic testing options available for expectant women and their healthcare providers. Some tests are called “screening” tests and others are called “diagnostic” tests.

Traditional screening tests are used to predict the chance of a pregnancy having certain chromosomal conditions. Some screening tests require more than one office visit to perform multiple blood draws, and you would undergo ultrasound examinations at very specific times during pregnancy. Results from screening tests usually provide a “risk score” (such as 1 in 500 or 1 in 50) that describes the *chance* of a baby developing a certain chromosome problem. They do not provide definitive answers and can have a relatively high rate of “false negative” or “false positive” results. But not all screening tests are the same in terms of accuracy and convenience.

Diagnostic tests, such as amniocentesis or CVS, can accurately determine whether a pregnancy has trisomy 21 (Down syndrome) or other chromosomal conditions. However, the invasive nature of these procedures is not without the risk of complications, including miscarriage.

Why should I choose the Eolas testover other tests?

The Eolas test sheds much needed light on the chromosomal health of your unborn baby – providing the reassurance of reliable answers no other screening test can quite match. Compared to similar options, the Eolas prenatal test offers accurate information, rather than calculating chances or risk scores. And, it does not carry the risk of complications that an invasive procedure can. It also:

- ✔ Uses a simple, single blood draw from your arm » just 1 tube of blood is all that’s needed
- ✔ Can be drawn conveniently in your doctor’s office » as early as 10 weeks (your 1st trimester)
- ✔ Provides reliable answers about the most common chromosomal abnormalities
- ✔ Can test for sex chromosome conditions » for singleton pregnancies) if ordered by your healthcare provider. If you’re carrying twins, however, the test cannot test for sex chromosome conditions. There is an option that can determine if the Y chromosome is present
- ✔ Has the lowest test failure in its class (0.1%)[1] » which means there is no need for additional blood draws and the inconvenience of another office visit or a delay in getting test results
- ✔ Delivers results fast » reports are usually sent to your healthcare provider within 2–4 business days from receipt in our lab[2]

How quickly will I get my results?

Your results will be sent to your healthcare provider, who will usually receive them within 2–4 business days from receipt in our lab.

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Performance you can trust, we've got you covered.

What do my Eolas test results mean?

Your results will tell your doctor whether or not trisomies 21, 18, 13 or sex chromosome abnormalities (if ordered) are highly likely to be present in your pregnancy. In the case of a positive result, your healthcare provider will discuss what the results mean to your pregnancy as well as further testing options to consider.

Your test report will include one of three possible results for chromosomes 21, 18, and 13:

- No Aneuploidy Detected » means the expected number of chromosomes was found
- Aneuploidy Detected » means too many or too few copies of one of the chromosomes have been identified. This can indicate a chromosome abnormality. Your provider may advise a diagnostic test for confirmation
- Aneuploidy Suspected » a borderline result, which occurs infrequently, and suggests there might be too many copies of a chromosome present. Your provider may advise a diagnostic test for confirmation

If the sex chromosome option is ordered, results will be reported as either No Aneuploidy Detected or Aneuploidy Detected.

How do I know I can trust the Eolas test to be effective?

The performance of the Eolas prenatal test was evaluated in a major scientific study in which more than 60 leading US medical research and teaching institutions participated. The study findings were reviewed and published in the leading journal read by obstetricians and gynecologists.[3] A second study, published subsequently, presented the test's performance under regular clinical conditions and found similar results.[4]

Do normal Eolas test results mean that my baby will be perfectly healthy?

The Eolas prenatal test is a highly accurate advanced screening test that is non-invasive. No test, however, can guarantee a baby will not have any medical issues. The Eolas test only addresses aneuploidies of chromosomes 21, 18, 13, and sex chromosomes,† if ordered. It does not test for or report all genetic and non-genetic problems that may be present in a baby. If the test result is *No Aneuploidy Detected*, indicating a negative result, it does not completely rule out all potential problems with chromosomes 21, 18, and 13, or all sex chromosome aneuploidies in your baby.

Genetic counseling before and after testing is recommended. Results of *Aneuploidy Detected* or *Aneuploidy Suspected* are considered positive and women who receive such results should be offered invasive prenatal procedures for confirmation. A negative test does not ensure an unaffected pregnancy.

CVS and amniocentesis provide definitive diagnostic information, but the invasive nature of these procedures can give rise to concern among some women.

Does insurance cover the Eolas prenatal test?

The Eolas prenatal test has been added to a list of in-network tests with major insurers. This means that if you are a member of major plans such as Aetna, Cigna, or United Healthcare, the Eolas prenatal test may be a covered benefit. Members pay the lowest cost determined by their plan. The best way to confirm if the Eolas prenatal test is covered by your particular insurance plan is to contact your insurance provider.

The reassurance of reliable answers; simply, safely, sooner.

- A simple, in-office blood test
- Safe from procedural risks of invasive procedures (amniocentesis/CVS)
- Lowest test failure rate among non-invasive prenatal tests
- Fast results – usually available to your doctor within 2–4 business days

To learn more about the Eolas prenatal test, please visit www.p4ml.com

References

1. Bhatt S, Parsa S, Snyder H, Taneja P, Halks-Miller M, Seltzer W, DeFeo E. Clinical Laboratory Experience with Noninvasive Prenatal Testing: Update on Clinically Relevant Metrics. ISPD 2014 poster.
2. Data on file.
3. Bianchi DW, Platt LD, Goldberg JD, et al. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. Obstet Gynecol. 2012;119:890–901.
4. Futch T, Spinosa J, Bhatt S, de Feo E, Rava RP, Sehnert AJ. Initial clinical laboratory experience in noninvasive prenatal testing for fetal aneuploidy from maternal plasma DNA samples. Prenat Diagn. 2013;33:569-574.

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