

verifi<sup>®</sup>  
prenatal test  
your questions – answered

the reassurance of  
**knowing**



A guide for parents-to-be on  
noninvasive prenatal testing.



illumina<sup>®</sup>

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

## What is the verifi<sup>®</sup> Prenatal Test?

The verifi 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 tenth week of pregnancy. It may help you avoid more invasive procedures, such as amniocentesis or chorionic villus sampling (CVS), which can pose risks to you and your baby. The verifi Test is available for both singleton and twin pregnancies.

\* Test results are usually reported back to your health care provider within approximately 1 week.

## How does the test work?

A sample of your blood is drawn, and the DNA from you and your baby is tested. The verifi 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 count the number of chromosomes present. It then uses a special SAFer<sup>™</sup> calculation method to determine if there are too many or too few copies of these chromosomes in your baby.

## Is the verifi Test right for me?

The verifi 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, with little or no risk to their pregnancy.

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

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



## What kind of conditions can the verifi 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 verifi 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 screened with the verifi Test.

If your health care provider chooses, the verifi 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). Another option is the microdeletion panel which screens for subchromosomal conditions such as DiGeorge or Prader-Willi syndromes.

### Indications for use

- You are 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)
- Your serum screen is “positive” or abnormal
- Your ultrasound reveals 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 confidence 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 health care providers.

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 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. These tests 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 poses a risk of complications, including miscarriage.





## Why should I choose the verifi Test over other tests?

The verifi Test sheds much-needed light on the chromosomal health of your unborn baby—providing the reassurance of reliable answers no other screening test can. Compared to similar options, the verifi Prenatal Test offers accurate information, rather than calculating chances or risk scores. And, it does not carry the risk of complications that invasive procedures do. 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.
- **Provides reliable answers about the most common chromosomal abnormalities.**
- **Can screen for sex chromosome conditions—** (for singleton pregnancies) if ordered by your health care 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 an option to screen for additional chromosomal disorders such as DiGeorge or Prader-Willi syndromes.**
- **Has the lowest test failure in its class (0.1%)<sup>1</sup>—**which means there is no need for additional blood draws and the inconvenience of another office visit.
- **Delivers results fast—**results are usually sent to our partner laboratory in 3 - 5 business days after sample receipt.<sup>2</sup> (Time to report to the ordering health care professional may vary based on the partner laboratory providing the test.)

# Performance you can trust— we've got you covered.

## What do my verifi Test results mean?

Your results will tell your doctor whether **trisomies 21, 18, 13** or sex chromosome abnormalities or certain microdeletion conditions (if ordered) are highly likely to be present in your pregnancy. In the case of a positive result, your health care provider will discuss your results as well as further testing options to consider. It is recommended that no irreversible clinical decisions be made based on these screening results alone. If a definitive diagnosis is desired, chorionic villus sampling or amniocentesis should be considered.

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

- **No aneuploidy detected**—This means the correct number of chromosomes was found.
- **Aneuploidy detected**—This means too many or too few copies of one of the chromosomes have been identified. This result can indicate a chromosome abnormality. Your provider may advise a diagnostic test for confirmation.
- **Aneuploidy suspected**—This is 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 verifi Test?

The performance of the verifi Prenatal Test was evaluated in a major validation study that involved more than 60 leading US medical research and teaching institutions. The study findings were reviewed and published in the leading journal read by obstetricians and gynecologists.<sup>3</sup> A second study, published subsequently, presented the test's performance under regular clinical conditions and found similar results.<sup>4</sup>

<sup>1</sup>Sex chromosome aneuploidy testing is available for singleton pregnancies only.



## Do normal verifi Test results mean that my baby will be perfectly healthy?

The verifi Prenatal Test is a highly accurate noninvasive advanced screening test. No test, however, can guarantee a baby will not have any medical issues. The verifi Test addresses aneuploidies of chromosomes 21, 18, 13, and sex chromosomes only,<sup>†</sup> when requested. 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 their invasive nature is a potential concern.

## Does insurance cover the verifi Prenatal Test?

The verifi 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 verifi Prenatal Test may be a covered benefit. Covered members pay the lowest cost determined by their plan. The best way to confirm if the verifi Prenatal Test is covered by your particular insurance plan is to contact your insurance provider.



# verifi<sup>®</sup> prenatal test

your questions – answered

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 noninvasive prenatal tests
- Fast results—usually sent to the laboratory in 3–5 business days after sample receipt

To learn more about the verifi prenatal test,  
visit [www.illumina.com/verifipatientbrochure](http://www.illumina.com/verifipatientbrochure).

#### References

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Part No. LB-0016 Rev. J