

SequentialScreenSM

Early information and
high detection rates for
birth defects



What is SequentialScreen?

SequentialScreen is a screening test which shows if you are at increased risk of having a baby with Down syndrome, trisomy 18, or an open neural tube defect.

It requires a sample of your blood and an ultrasound measurement performed in the first trimester of pregnancy, and a second blood sample taken during the second trimester.

It is the only screen that can provide you with two answers—an early, preliminary result in the first trimester, and a final result in the second trimester.

How is SequentialScreen performed?

Part 1

Between your 10th and 14th week of pregnancy, a blood sample and an ultrasound measurement, called nuchal translucency, will be taken. SequentialScreen will use these pieces of information to provide you with your risk of having a baby with Down syndrome or trisomy 18. If you are found to be at increased risk, your doctor will offer diagnostic testing to confirm the results of your screen.

Part 2

If you are not identified to be at increased risk in part 1, you will come back between your 15th and 22nd week of pregnancy for a second blood test. The second part of this screen will use the information collected during both part 1 and part 2 of the test to provide you with a final screening result. This final result will tell you what your risk is of having a baby with Down syndrome, trisomy 18, or an open neural tube defect.

What do SequentialScreen results mean?

Part 1

Final result pending second trimester sample: This result means that your pregnancy is not in the highest risk group for Down syndrome or trisomy 18. You will be asked to complete the second part of this screen.

Screen positive: If the results show abnormal measurements, there is an increased chance of you having a baby with Down syndrome or trisomy 18. This is called a *screen positive* result. If your result is screen positive, your doctor will offer diagnostic testing to determine if your baby is affected with one of these birth defects.

SequentialScreen part 1 leads to the detection of approximately 70% of Down syndrome cases and 80% of trisomy 18 cases, according to several large, multi-center studies.

Part 2

Screen negative: If the results show measurements within normal range, the chance of having a baby with Down syndrome, trisomy 18, or an open neural tube defect is low. This is called a “screen negative” result. In rare instances, screening will not detect these birth defects as it cannot detect all high-risk pregnancies.

Screen positive: If the results show abnormal measurements, there is an increased chance of you having a baby with Down syndrome, trisomy 18, or an open neural tube defect. This is called a “screen positive” result. If your result is screen positive, your doctor will offer diagnostic testing to determine if your baby is affected with one of these birth defects.

SequentialScreen part 2 leads to detection of approximately 90% of Down syndrome cases, 90% of trisomy 18 cases and 80% of open neural tube defects, according to several large, multi-center studies.

Additional testing options if you screen positive

If a screening test is abnormal, it does not necessarily mean that the baby has one of these birth defects. In fact, most women who have abnormal screening results will have normal, healthy babies. If you screen positive, your doctor will offer you one of the following procedures:

- Chorionic villi sampling (CVS) is a procedure that takes a small amount of tissue from the developing placenta. The tissue is then sent to a laboratory for chromosome analysis. CVS is performed between 10 and 12 weeks of pregnancy. CVS is associated with a small risk of miscarriage.
- Amniocentesis is a procedure that withdraws a small amount of fluid that surrounds the fetus. The fluid is then sent to a laboratory to test for chromosome abnormalities and open neural tube defects. An amniocentesis is usually performed around the 16th week of pregnancy. Amniocentesis is also associated with a small risk of miscarriage; however, the risk is lower than that for CVS.



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