

About this test

This test tells you if your baby is at risk for certain genetic diseases.

A **chromosome** is made up of DNA, and chromosomes play an important role in our health. People typically have two copies of most chromosomes. However, some people have an extra or missing chromosome that can cause disease. The diseases included in this test are trisomy 21 (Down syndrome), trisomy 18, and trisomy 13. Others may be tested for at the request of your provider. The **genetic diseases** on this test were chosen because they have harmful health effects that often start at a young age and do not have a cure. **Having a baby with one of these diseases can happen to a parent of any age.** There is usually no family history of the disease.

What test results mean

- ⊕ **Positive (abnormal) results** mean that your baby's risk to have a certain genetic disease is **higher** than most other babies. Follow-up testing would be needed to know for sure whether your baby has the genetic disease.
- ⊖ **Negative (normal) results** mean that your baby's risk to have the diseases tested is **low**, but not zero.

Benefits

- ▶ Finding out these results will help you understand your baby's risk to have the diseases tested.
- ▶ Negative results are reassuring. Positive results let you and your provider determine the next steps for the identified risk(s).

Your privacy is protected

- ▶ We keep your results and information private. We only send results to the ordering provider, unless you give us permission to send elsewhere. You can contact us for a copy of your results.
- ▶ No other test will be performed or reported on your sample, unless ordered by your provider. Samples received from New York State will be destroyed within 60 days after testing.
- ▶ We may contact your provider to obtain follow-up information after your test is complete. This is a standard lab practice, and is required in several states.

Limitations

- ▶ Negative results do not guarantee a healthy pregnancy or baby. This test looks for specific changes to certain chromosomes. Changes not targeted by this test will not be detected.
- ▶ False positive, false negative, and failed results are rare, but possible.

Before signing this form, I had the chance to talk about this test with my healthcare provider or someone he/she chose, and genetic counseling has been recommended before and after testing. My questions have been answered and I have all of the information that I need to decide. I understand that this test is voluntary. I have decided that:

- Yes, I want to receive the **Innatal[®] Prenatal Screen**.
- No, I do not want to receive the **Innatal[®] Prenatal Screen**.

PATIENT NAME *(please print)*

DATE OF BIRTH

PATIENT SIGNATURE

DATE

DISEASES TESTED

Trisomy 21 (Down syndrome)

Every year, about 6,000 babies in the United States are born with trisomy 21 (an extra chromosome 21). Children with trisomy 21 have distinct facial features. They require special care due to below average intelligence, difficulty achieving life skills, and a higher risk for certain health problems.

Trisomy 18 (Edwards syndrome)

Every year, about 1,100 babies in the United States are born with trisomy 18 (an extra chromosome 18). Children with trisomy 18 have severe, life-threatening health problems. Miscarriage of a pregnancy with trisomy 18 is common. Babies who survive birth often do not live past the first few weeks of life.

Trisomy 13 (Patau syndrome)

Every year, about 500 babies in the United States are born with trisomy 13 (an extra chromosome 13). Children with trisomy 13 have severe, life-threatening health problems. Miscarriage of a pregnancy with trisomy 13 is common. Babies who survive birth often do not live past the first few weeks of life.

Monosomy X (Turner syndrome)

Every year, about 800 babies in the United States are born with monosomy X (a missing chromosome X). People with monosomy X have some distinct features, such as a short neck, low hairline, and a broad chest. They are at a higher risk for certain health and reproductive problems, but typically have normal intelligence. Miscarriage of a pregnancy with monosomy X is common.

47, XXY (Klinefelter syndrome)

Every year, up to 4,000 babies in the United States are born with 47, XXY (an extra chromosome X). People with 47, XXY may be taller than average and have delayed or incomplete puberty. They are at a higher risk for certain health and reproductive problems and may have some problems with learning.

47, XYY (Jacob's syndrome)

Every year, about 2,000 babies in the United States are born with 47, XYY (an extra chromosome Y). People with 47, XYY may be taller than average, but otherwise have no distinct features. They are at a higher risk for certain health problems and may have some problems with learning. However, some people with 47, XYY have no symptoms.

47, XXX (Triple X syndrome)

Every year, about 2,000 babies in the United States are born with 47, XXX (an extra chromosome X). People with 47, XXX may be taller than average, but otherwise, have no distinct features. They are at a higher risk for certain health problems and may have some problems with learning. However, some people with 47, XXX have no symptoms.