the possibility your baby may have Down syndrome, trisomy 18, or trisomy 13.

Positive screen
A positive screen occurs in about 5% of all tests. This means your baby is at increased risk for Down syndrome, trisomy 18, or trisomy 13. When you receive this result in your first trimester, you and your doctor may choose to consider additional testing options such as non-invasive prenatal testing (NIPT), or diagnostic testing options, like chorionic villus sampling (CVS) or amniocentesis.

If I receive a positive screen, what additional tests may I take?
If you are at risk of having a baby with a birth defect based on your family history or the results of a previous screening test, your doctor may recommend additional testing. There are 3 options you can consider.

One type of additional testing, known as non-invasive prenatal testing, or NIPT, is a type of advanced screening test that examines fetal DNA which is present in the mother’s blood. It is performed after 10 weeks of pregnancy by a blood draw from the arm and detects the same type of chromosome abnormalities that are examined by The First Trimester Screen ß. It can also detect problems with the sex chromosomes (the X and Y chromosomes).

Another test, known as chorionic villus sampling, or CVS, is performed at 10 to 12 weeks of pregnancy. A small tube is inserted into your cervix, or a thin needle is inserted through your abdomen in order to remove a small piece of the placenta. The sample is sent to a lab and the cells are checked for chromosome abnormalities such as Down syndrome, trisomy 18, and trisomy 13. CVS does not test for ONTDs. CVS is a diagnostic test. CVS is associated with a small risk of miscarriage.

Another test, known as amniocentesis, is performed between 15 and 20 weeks of pregnancy. A small sample of fluid surrounding the baby is taken through a needle and sent to a lab to be tested. The cells in the fluid are checked for chromosome abnormalities such as Down syndrome, trisomy 18, and trisomy 13. Amniocentesis also tests for ONTDs. Amniocentesis is a diagnostic test. Amniocentesis is associated with a small risk of miscarriage.

Be sure to discuss these additional tests with your doctor to determine which options may be right for you.

If you are screened for chromosome abnormalities in your first trimester, you should be sure to be screened for open neural tube defects (ONTDs) in your second trimester. ONTDs can be detected through a maternal serum alpha-fetoprotein (MSAFP) screening. The maternal serum AFP test is noninvasive. Blood is taken by a finger stick or drawn from the mother’s arm and sent to the lab for analysis. High levels of AFP in the blood may indicate that the developing fetus has an ONTD.

What do the results of the FirstTrimesterScreen ß mean?

Negative screen
A negative screen occurs in about 95% of all tests. This means your baby is at low risk for Down syndrome, trisomy 18, or trisomy 13. If you get a negative screen, your doctor may decide to stop screening or may continue with more tests in your second trimester for additional verification. A negative screen does not completely eliminate the possibility your baby may have Down syndrome, trisomy 18, or trisomy 13.

Positive screen
A positive screen occurs in about 5% of all tests. This means your baby is at increased risk for Down syndrome, trisomy 18, or trisomy 13. When you receive this result in your first trimester, you and your doctor may choose to consider additional testing options such as non-invasive prenatal testing (NIPT), or diagnostic testing options, like chorionic villus sampling (CVS) or amniocentesis.

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Be sure to discuss these additional tests with your doctor to determine which options may be right for you.
Read on to learn more about screening for certain chromosome abnormalities and birth defects and why it is important for you to be tested during the first trimester of your pregnancy to help protect the health of your new baby.

Why should I have prenatal testing?
According to the American College of Obstetricians and Gynecologists (ACOG), almost all children in the United States are born healthy. Only 2 or 3 out of 100 newborns have major birth defects. For the majority of babies the cause is unknown. However, there are certain birth defects that can be tested for prenatally—before a baby is born. These include Down syndrome, trisomy 18, trisomy 13, and open neural tube defects.

The risk of having a baby with a chromosome abnormality, such as Down syndrome, increases with the mother’s age. However, ACOG recommends prenatal testing be offered to all pregnant women, regardless of age.

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Down syndrome often results in developmental problems and a higher risk of conditions including heart defects, mental retardation, breathing and hearing problems, and childhood leukemia. The severity of these conditions varies greatly from individual to individual.

What is trisomy 13?
Trisomy 13, or Patau syndrome, is another well-known chromosome abnormality. It is caused by having an extra copy of chromosome 13—for a total of 3 copies instead of the normal 2.

• 1 in every 16,000 babies is born with trisomy 13.
• Only 5% to 10% of children with trisomy 13 live past their first year.

Trisomy 13 is associated with severe mental and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 13 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

What is trisomy 18?
Trisomy 18, or Edwards syndrome, is the second most common trisomy—a condition in which someone has 3 copies of a certain chromosome. It is caused by having an extra copy of chromosome 18—for a total of 3 copies instead of the normal 2.

• 1 in every 3,000 babies is born with trisomy 18.
• About half of babies with trisomy 18 who reach full term are stillborn.

Trisomy 18 causes developmental problems associated with life-threatening complications in a baby’s first months and years. These may include deformities of the heart, intestines, esophagus, hands, and feet; kidney problems; delayed growth; and mental retardation.

What is trisomy 19?
Trisomy 19 is another chromosome abnormality. It is caused by having an extra copy of chromosome 19—for a total of 3 copies instead of the normal 2.

• Only 1% to 5% of children with trisomy 19 live past their first year.

Trisomy 19 is associated with severe growth and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 19 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

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Being tested during pregnancy will allow you to be informed about the health of your baby, even before she is born. The information you receive will be extremely valuable in helping you plan for your baby’s birth. You and your doctor will also be able to decide if you need more testing later in your pregnancy. If you learn you will have a baby with one of these birth defects, you can proactively prepare your family for the future by making important medical and financial decisions about care.

PerkinElmer Labs/NTD: an innovative leader in prenatal testing for more than 30 years
PerkinElmer Labs/NTD has been providing patients with early prenatal detection and early assurance regarding birth defects for over 30 years. We’re committed to helping protect the health of your family every step of the way.

As the only lab that measures free beta hCG (a hormone in your body with strong predictive power for a Down syndrome fetus when elevated), PerkinElmer Labs/NTD helps ensure the most accurate prenatal detection possible during the first trimester.

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Down syndrome often results in developmental problems and a higher risk of conditions including heart defects, mental retardation, breathing and hearing problems, and childhood leukemia. The severity of these conditions varies greatly from individual to individual.

What is trisomy 13?

Trisomy 13, or Patau syndrome, is another well-known chromosome abnormality. It is caused by having an extra copy of chromosome 13—for a total of 3 copies instead of the normal 2.

• 1 in every 16,000 babies is born with trisomy 13
• Only 5% to 10% of children with trisomy 13 live past their first year

Trisomy 13 is associated with severe mental and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 13 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

What is trisomy 18?

Trisomy 18, or Edwards syndrome, is the second most common trisomy—a condition in which someone has 3 copies of a certain chromosome. It is caused by having an extra copy of chromosome 18—for a total of 3 copies instead of the normal 2.

• 1 in every 3,000 babies is born with trisomy 18
• About half of babies with trisomy 18 who reach full term are stillborn

Trisomy 18 causes developmental problems associated with life-threatening complications in a baby’s first months and years. These may include deformities of the heart, intestines, esophagus, hands, and feet; kidney problems; delayed growth; and mental retardation.

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Trisomy 13, or Patau syndrome, is another well-known chromosome abnormality. It is caused by having an extra copy of chromosome 13—for a total of 3 copies instead of the normal 2.

• 1 in every 16,000 babies is born with trisomy 13
• Only 5% to 10% of children with trisomy 13 live past their first year

Trisomy 13 is associated with severe mental and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 13 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

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Trisomy 13, or Patau syndrome, is another well-known chromosome abnormality. It is caused by having an extra copy of chromosome 13—for a total of 3 copies instead of the normal 2.

• 1 in every 16,000 babies is born with trisomy 13
• Only 5% to 10% of children with trisomy 13 live past their first year

Trisomy 13 is associated with severe mental and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 13 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

What is trisomy 18?

Trisomy 18, or Edwards syndrome, is the second most common trisomy—a condition in which someone has 3 copies of a certain chromosome. It is caused by having an extra copy of chromosome 18—for a total of 3 copies instead of the normal 2.

• 1 in every 3,000 babies is born with trisomy 18
• About half of babies with trisomy 18 who reach full term are stillborn

Trisomy 18 causes developmental problems associated with life-threatening complications in a baby’s first months and years. These may include deformities of the heart, intestines, esophagus, hands, and feet; kidney problems; delayed growth; and mental retardation.

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Being tested during pregnancy will allow you to be informed about the health of your baby, even before she is born. The information you receive will be extremely valuable in helping you plan for your baby’s birth. You and your doctor will also be able to decide if you need more testing later in your pregnancy. If you learn you will have a baby with one of these birth defects, you can proactively prepare your family for the future by making important medical and financial decisions about care.

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• 1 in every 3,000 babies is born with trisomy 18
• About half of babies with trisomy 18 who reach full term are stillborn

Trisomy 18 causes developmental problems associated with life-threatening complications in a baby’s first months and years. These may include deformities of the heart, intestines, esophagus, hands, and feet; kidney problems; delayed growth; and mental retardation.

What is trisomy 13?

Trisomy 13, or Patau syndrome, is another well-known chromosome abnormality. It is caused by having an extra copy of chromosome 13—for a total of 3 copies instead of the normal 2.

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• Only 5% to 10% of children with trisomy 13 live past their first year

Trisomy 13 is associated with severe mental and physical problems that cause many infants to die during their first days or weeks of life. Infants with trisomy 13 often have problems including abnormalities of the heart, brain, or spinal cord; small or poorly developed eyes; extra fingers and/or toes; deformed mouths; and weak muscle tone.

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Positive screen
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If you are screened for chromosome abnormalities in your first trimester, you should be sure to be screened for open neural tube defects (ONTDs) in your second trimester. ONTDs, such as spina bifida, result from improper development of the brain and spinal cord, which may cause an opening to remain along the spine or head after the baby is born.

ONTDs can be detected through a maternal serum alpha-fetoprotein (MSAFP) screening. The maternal serum AFP test is noninvasive. Blood is taken by a finger stick or drawn from the mother’s arm and sent to the lab for analysis. High levels of AFP in the blood may indicate that the developing fetus has an ONTD.

What do the results of the FirstTrimesterScreen Fβ mean?

Negative screen
A negative screen occurs in about 95% of all tests. This means your baby is at low risk for Down syndrome, trisomy 18, or trisomy 13. If you get a negative screen, your doctor may recommend additional testing for ONTDs. A negative screen does not eliminate the possibility your baby may have Down syndrome, trisomy 18, or trisomy 13.

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How is the FirstTrimesterScreen Fβ performed?
The First Trimester Screen Fβ is a simple blood test performed on you with a finger stick when a fetus is between 9 weeks and 13 weeks, 6 days of age. Your blood is analyzed for 2 markers normally found in all pregnant women. The blood test is followed by an ultrasound examination, given when the fetus is between 11 weeks, 1 day and 13 weeks, 6 days of age. The ultrasound confirms your baby’s age and measures the amount of fluid behind the baby’s neck.
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Positive screen
A positive screen occurs in about 5% of all tests. This means your baby is at increased risk for Down syndrome, trisomy 18, or trisomy 13. When you receive this result in your first trimester, you and your doctor may choose to consider additional testing options such as non-invasive prenatal testing (NIPT), or diagnostic testing options, like chorionic villus sampling (CVS) or amniocentesis.

If I receive a positive screen, what additional tests may I take?

If you are at risk of having a baby with a birth defect based on your family history or the results of a previous screening test, your doctor may recommend additional testing. There are 3 options you can consider.

One type of additional testing, known as non-invasive prenatal testing, or NIPT, is a type of advanced screening test that examines fetal DNA which is present in the mother's blood. It is performed after 10 weeks of pregnancy by a blood draw from the arm and detects the same type of chromosome abnormalities that are examined by the The First Trimester Screen Fβ. It can also detect problems with the sex chromosomes (the X and Y chromosomes).

Another test, known as chorionic villus sampling, or CVS, is performed at 10 to 12 weeks of pregnancy. A small tube is inserted into your cervix, or a thin needle is inserted through your abdomen in order to remove a small piece of the placenta. The sample is sent to a lab and the cells are checked for chromosome abnormalities such as Down syndrome, trisomy 18, and trisomy 13. CVS does not test for ONTDs. CVS is a diagnostic test. CVS is associated with a small risk of miscarriage.

Another test, known as amniocentesis, is performed between 15 and 20 weeks of pregnancy. A small sample of fluid surrounding the baby is taken through a needle and sent to a lab to be tested. The cells in the fluid are checked for chromosome abnormalities such as Down syndrome, trisomy 18, and trisomy 13. Amniocentesis also tests for ONTDs. Amniocentesis is a diagnostic test. Amniocentesis is associated with a small risk of miscarriage.

Be sure to discuss these additional tests with your doctor to determine which options may be right for you.

If you are screened for chromosome abnormalities in your first trimester, you should be sure to be screened for open neural tube defects (ONTDs) in your second trimester. ONTDs, such as spina bifida, result from improper development of the brain and spinal cord, which may cause an opening to remain along the spine or head after the baby is born.

ONTDs can be detected through a maternal serum alpha-fetoprotein (MSAFP) screening. The maternal serum AFP test is noninvasive. Blood is taken by a finger stick or drawn from the mother’s arm and sent to the lab for analysis. High levels of AFP in the blood may indicate that the developing fetus has an ONTD.

What do the results of the FirstTrimesterScreen Fβ mean?

Negative screen
A negative screen occurs in about 95% of all tests. This means your baby is at low risk for Down syndrome, trisomy 18, or trisomy 13. If you get a negative screen, your doctor may decide to stop screening or may continue with more tests in your second trimester for additional verification. A negative screen does not completely eliminate the possibility your baby may have Down syndrome, trisomy 18, or trisomy 13.

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Results of the blood test and the ultrasound are combined to estimate the risk of Down syndrome, trisomy 18, and trisomy 13.

• 91% of Down syndrome cases are detected
• 95% of trisomy 18 and trisomy 13 cases are detected

These are the highest available detection rates in the first trimester—only from PerkinElmer Labs/NTD.
How is the FirstTrimesterScreen | Fβ performed?

The First Trimester Screen Fβ is a simple blood test performed on you with a finger stick when a fetus is between 9 weeks and 13 weeks, 6 days of age. Your blood is analyzed for 2 markers normally found in all pregnant women.

The blood test is followed by an ultrasound examination, given when the fetus is between 11 weeks, 1 day and 13 weeks, 6 days of age. The ultrasound confirms your baby’s age and measures the amount of fluid behind the baby’s neck.

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