- **Simple**
- **Safe**
- **Accurate**

for you and your pregnancy.

The Harmony™ Prenatal Test is an early and accurate test for Down syndrome and other trisomy conditions. The test can also evaluate fetal sex and sex chromosome (X,Y) conditions.

Ariosa® DIAGNOSTICS

CALIFORNIA ARIOSA DIAGNOSTICS UNITED STATES

Harmony™ PRENATAL TEST

A simple, safe blood test that offers highly sensitive results

	Detection Rate	False Positive Rate
T21[6,9]	>99%	<0.1%
T18[6,9]	>98%	<0.1%
T13[10]	8/10	<0.1%

X and Y analysis is >99% accurate for fetal sex. It can also assess risk for sex chromosome conditions with test performance varying by the type of condition detected.[11]

The Harmony Prenatal Test has been developed and is performed as a laboratory test service by Ariosa Diagnostics, a CLIA-certified, CAP-accredited clinical laboratory.

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A non-invasive test that assesses the risk for chromosome conditions such as Down syndrome and includes an optional analysis of fetal sex and sex chromosome (X,Y) conditions.

Ask your provider

The following information is provided to inform you about the Harmony Prenatal Test. Talk to your healthcare provider before you decide if the Harmony Prenatal Test is appropriate for you.

What is a trisomy?

Humans have 23 pairs of chromosomes, which are strands of DNA and proteins that carry genetic information. A trisomy is a chromosomal condition that occurs when there are three copies of a particular chromosome instead of the expected two.

Trisomy 21 is due to an extra copy of chromosome 21 and is the most common trisomy at the time of birth. Trisomy 21 causes Down syndrome, which is associated with mild to moderate intellectual disabilities and may also lead to digestive issues and congenital heart defects. It is estimated that Down syndrome is present in 1 out of every 740 newborns.[1]

Trisomy 18 is due to an extra copy of chromosome 18. Trisomy 18 causes Edwards syndrome and is associated with a high rate of miscarriage. Infants born with Edwards syndrome may have various medical conditions and a shortened lifespan. It is estimated that Edwards syndrome is present in approximately 1 out of every 5,000 newborns.[2]

Trisomy 13 is due to an extra copy of chromosome 13. Trisomy 13 causes Patau syndrome, which is associated with a high rate of miscarriage. Infants born with trisomy 13 usually have severe congenital heart defects and other medical conditions. Survival beyond the first year is rare. It is estimated that trisomy 13 is present in approximately 1 out of every 16,000 newborns.[3]

Sex chromosome conditions. The sex chromosomes (X and Y) are the ones that make us either male or female. X and Y chromosome conditions occur when there is a missing, extra or incomplete copy of one of the sex chromosomes. The Harmony with X,Y test can assess risk for XXX, XYY, XXYY, XXY (Klinefelter syndrome), and for monosomy X (Turner syndrome). There is significant variability in the severity of these conditions, but most individuals have mild, if any, physical or behavioral features. If you are interested in having this optional testing, please talk with your healthcare provider to determine if it is right for you.[4,5]

What will the Harmony Prenatal Test tell me and my provider?

The Harmony Prenatal Test determines the risk of fetal trisomies by measuring the relative amount of chromosomes in maternal blood. The Harmony test assesses the risks of trisomies 21, 18 and 13 in the fetus, but does not rule out all fetal abnormalities.

How is the Harmony Prenatal Test different from other prenatal tests?

The Harmony Prenatal Test is based on the latest advances in non-invasive prenatal testing. It is a simple and safe blood test that has been shown in analytical studies to evaluate the risk of certain fetal trisomies.[6]

Other screening tests such as serum blood tests and ultrasound are also non-invasive, but have false positive rates of up to 5% and miss detection of up to 30% of fetal trisomy 21 cases.[7] Such tests may falsely report a pregnancy as positive for a fetal trisomy when it is in fact negative (a false positive). Or they may falsely report a pregnancy as negative for a fetal trisomy when it is in fact positive (a false negative). The false positive and negative rates are significantly lower for the Harmony test.

Diagnostic tests such as amniocentesis or chorionic villus sampling (CVS) are accurate for detecting fetal trisomies, but they are invasive and pose a risk for fetal loss.[8]

The Harmony Prenatal Test detects >99% of fetal trisomy 21 cases at a false positive rate of <0.1%.[6]

Who can get the Harmony Prenatal Test?

The Harmony Prenatal Test can be ordered by healthcare professionals for women with pregnancies of at least 10 weeks' gestational age. The Harmony test is available for any singleton or twin pregnancy, including all those conceived by IVF. This test does not assess risk for mosaicism, partial trisomies or translocations.

Please let your healthcare team know if you have any additional questions about the Harmony Prenatal Test.

Toll-free: 1-855-9-ARIOSA (855-927-4672)
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