About the Harmony prenatal test

The Harmony prenatal test was developed to be a more accurate prenatal Down syndrome screening test compared to traditional screening. Harmony outperformed First Trimester Screening in the general pregnancy population.[3]

Harmony vs Traditional Down Syndrome Tests[3]

	FALSE-POSITIVE RATE*	DETECTION RATE**
HARMONY Prenatal Test	Less than 1 in 1,600	More than 99 in 100
TRADITIONAL First Trimester Screening***	1 in 20	79 in 100

* Reports a high risk for Down syndrome when it is NOT actually present
** Correctly indicates a high risk for Down syndrome when it IS present
***Serum PAPP-A, total or free ß-hCG & Nuchal Translucency

The Harmony prenatal test has been validated for use in twins and IVF pregnancies, including self and non-self egg donor pregnancies.[4]

Test offerings:

— Trisomy 21, 18, and 13 (singleton and twins)
— Fetal sex (singleton and twins)
— Monosomy X (singleton only)
— Sex chromosomes aneuploidy panel (singleton only)
— 22q11.2 (singleton only)

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Testing Services by Ariosa Diagnostics

Why Harmony

The Harmony prenatal test is a screening test. It can tell if there is a high or low chance for the common chromosomal conditions: Down syndrome (trisomy 21), trisomy 18 and trisomy 13. It can also tell the chance of having an extra or missing sex chromosome (X or Y), and the sex of your baby.

For more information, talk to your healthcare provider or visit **harmonytestusa.com**

1. Bassett et al. J Pediatr. 2011 Aug;159(2):332-9.
2. ACOG/SMFM Committee Opinion No. 640. September 2015.
3. Norton et al. N Engl J Med. 2015 Apr 23;372(17):1589-97.
4. Gil et al. Fetal Diagn Ther. 2014;35:204-11.

The Harmony prenatal test measures a woman's risk of carrying a baby with chromosomal conditions such as Trisomies 21, 18 and 13. If your test indicates a high-probability result, talk with your healthcare provider about what further diagnostic testing is needed to confirm the result. The Harmony Prenatal Test was developed by Ariosa Diagnostics, a laboratory certified by the federal government to perform highly complex tests. This test is a lab-developed test and has not been reviewed or approved by the FDA.

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PRENATAL TEST

For You

Answers that matter

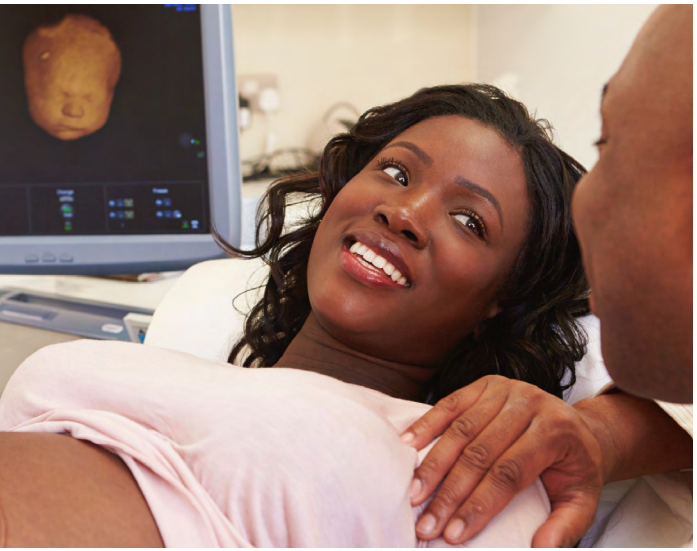
What is non-invasive prenatal testing (NIPT)?

NIPT is a blood test that looks at fetal DNA found in the mother's bloodstream. This screening test helps determine if your baby is at increased risk for a number of chromosomal abnormalities, including Down syndrome (trisomy 21), Edwards syndrome (trisomy 18), Patau syndrome (trisomy 13) and sex chromosome abnormalities. NIPT can also assess the likelihood your baby has a condition linked to a few selected microdeletions.

What is 22q11.2 deletion syndrome?

There are many different types of microdeletions, a group of disorders caused by missing a small amount of genetic information. The most common microdeletion is 22q11.2 deletion syndrome. It affects as many as 1 in 1,000 to 1 in 2,500 pregnancies, making it almost as common as Down syndrome.[1]

Early detection of 22q11.2 deletion syndrome can help ensure your baby receives any necessary treatment from the moment the baby is born.



How is NIPT and screening for 22q11.2 performed?

The Harmony prenatal test is done using a simple blood draw at your doctor's office.

A blood sample is taken at 10 weeks or later in pregnancy.

Your sample is sent to the laboratory, where it is analyzed.

Your results are sent to your healthcare provider within 3-5 days from sample receipt.

Who talks to me about my results?

Your healthcare provider will discuss your Harmony prenatal test results with you. The test results will provide information about the risk of genetic conditions for your pregnancy. In order to confirm a high-probability NIPT result during pregnancy, your physician may recommend diagnostic testing: chorionic villus sampling (CVS) or amniocentesis.

What are my possible Harmony test result outcomes?

There are three potential Harmony test outcomes:

High-probability result. This means there is a higher probability than expected for a chromosomal condition in the pregnancy. Additional testing during the pregnancy and/or evaluation after delivery may be recommended.

Low-probability result. This means there is a low probability for the chromosomal conditions that were screened for in the pregnancy. Routine prenatal management would continue as usual.

No result is able to be obtained. In a small percentage of cases, a Harmony result is unable to be obtained. In this instance, your provider may discuss options for an additional blood sample to be drawn or offer other screening or diagnostic testing options.

Is the Harmony prenatal test right for me?

The risk of Down syndrome in a pregnancy increases with maternal age; however, most cases occur in women who are under age 35, because there are more total pregnancies in women under age 35. The Harmony Prenatal Test has been validated in women both over and under 35. Leading medical societies support offering NIPT to all pregnant women.[2]

How much does the Harmony prenatal test cost?

Harmony is covered by many insurance plans. We are committed to access for all pregnant women and working with you to help provide access to the test regardless of age* or risk category.

Call 1-855-927-4672 to speak with a Harmony Care Specialist.

*Both under 35 and over 35 groups. Studies have included women ages 18-48.