

harmony[®]

PRENATAL TEST

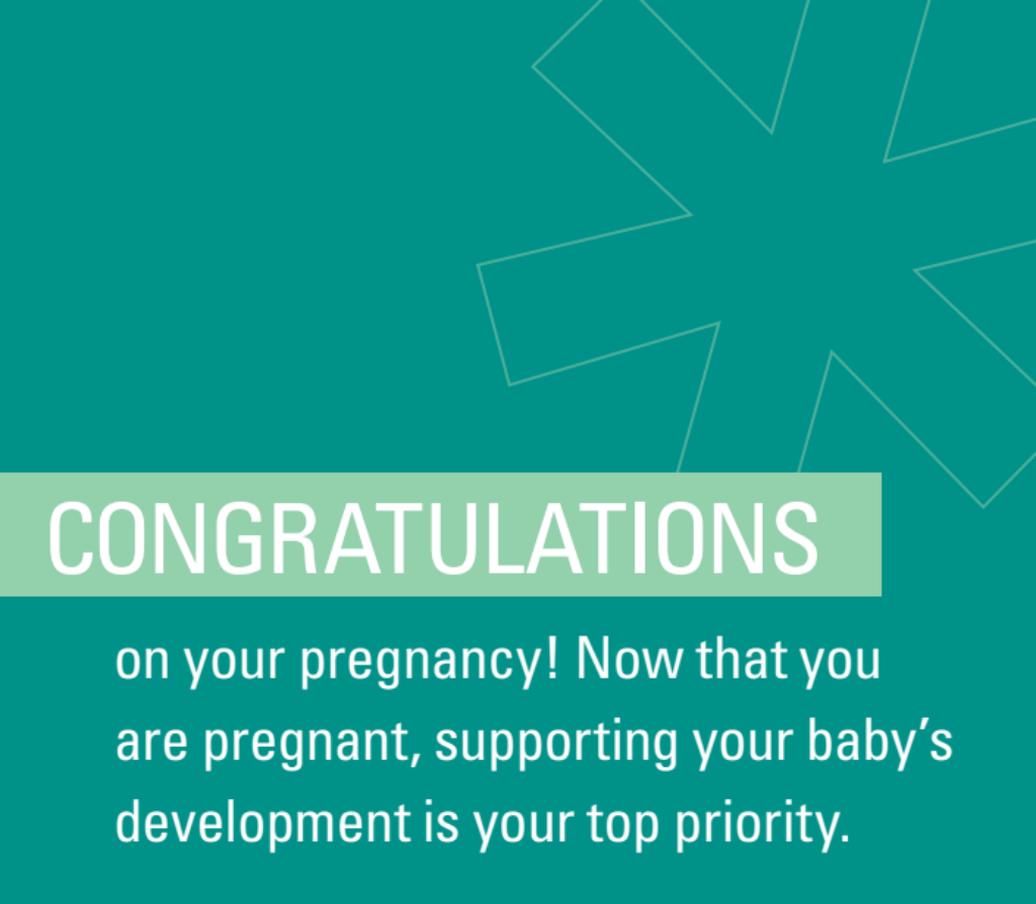
Clear **ANSWERS**
to Questions that Matter



HARMONY PRENATAL TEST is a DNA-based blood screening test for Down syndrome. Harmony is more accurate than traditional tests and can be performed as early as 10 weeks in pregnancy.¹

The Harmony Prenatal Test was developed, and its performance characteristics determined by Ariosa Diagnostics Clinical Laboratory in San Jose, CA USA, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. This testing service has not been cleared or approved by the US FDA.





CONGRATULATIONS

on your pregnancy! Now that you are pregnant, supporting your baby's development is your top priority.

Introduction

During your pregnancy, your healthcare providers will offer various screening tests to help you assess the baby's health.

As part of your care, you will be given the option to screen for Down syndrome, a rare genetic condition that affects physical and mental development.

Experts Support Down Syndrome Screening

Some genetic conditions run in families. Others, like Down syndrome, typically do not. They can happen in any pregnancy.

Although the risk of Down syndrome increases with age, most babies with Down syndrome are born to women under 35 years of age.⁵

The American College of Obstetricians and Gynecologists (ACOG) now recommends that all pregnant women be offered screening and diagnostic testing for Down syndrome.⁶



What is the Harmony Prenatal Test?

When you're pregnant, your blood contains fragments of your baby's DNA.

Harmony Prenatal Test is a new type of screening test that analyzes this DNA in a sample of your blood to assess the risk of Down syndrome (trisomy 21) and two other genetic conditions, trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome).

For Women of Any Age or Risk Category

Traditional blood tests can miss as many as 20% of Down syndrome cases in pregnant women.¹

The Harmony Prenatal Test was developed to be a more accurate prenatal Down syndrome screening test for women of any age or risk category. It is a DNA-based blood test that has been extensively tested in both the under 35 and over 35 age groups, studies have included pregnant women ages 18-48 for trisomy 21.¹⁻²

A More Accurate Screening Test

Harmony has been demonstrated in clinical study to be superior to first trimester screening test for women of any age or risk categories¹

Harmony versus Traditional Down Syndrome Tests¹

	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 β -hCG & Nuchal Translucency

Clarity Early

Harmony Prenatal Test requires a single blood draw and can be done as early as 10 weeks or later in pregnancy.

Results are usually available in about seven business days. Other commonly used screening tests for Down syndrome are performed later in pregnancy and may require multiple office visits.

Minimizes Need for Follow-up Tests

The greater accuracy and low false-positive rate of Harmony compared to traditional tests may minimize the chance that further testing would be recommended due to a false-positive result. Follow-up testing might include an invasive procedure, such as amniocentesis.

Additional Testing Options

In addition to screening for the risks of trisomy 21 (Down syndrome), trisomy 18 and 13, the following opt-in tests are available during the same blood-draw:

- Fetal Sex
- X and Y chromosome conditions



Contact your healthcare provider for more information related to these tests.



ASK Your Prenatal Healthcare Provider

What can I learn from the Harmony test?

How does Harmony differ from other Down syndrome screening tests?

What are the advantages of using Harmony rather than traditional tests?

Do you offer the Harmony test in your office or through a laboratory?

How can I find out how much the Harmony test costs?

When and how will you notify me of the Harmony test result?

Visit us at harmonytest.com, where you can find more questions to ask your doctor about Harmony.

Three Simple Steps to Clarity



1. At 10 weeks or later, you get a simple blood screening test.



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



3. Your results are sent to your healthcare provider in about seven business days.

Your Results

Harmony is a screening test. It screens for conditions listed in this brochure. As with all screening tests, false-positives and false-negatives may occur.

Once you have your Harmony test results, you can discuss your pregnancy care with your healthcare provider.

For help, email clientservices@ariosadx.com or call **1-855-9-ARIOSA** (855-927-4672)

Outside the USA, call **+1 925-854-6246**

www.harmonytest.com

1. Norton et al. N Engl J Med. 2015 Apr 23;372(17):1589-97
2. Nicolaides et al. Am J Obstet Gynecol. 2012 Nov;207(5):374.e1-6.
3. Nicolaides et al. Fetal Diagn Ther. 2014;35(1):1-6.
4. Hooks et al. Prenat Diagn. 2014 May;34(5):496-9.
5. The California Prenatal Screening Program. March 2009. Provider Handbook 2009.
6. ACOG Practice Bulletin 77. ACOG Committee on Practice Bulletins. Obstet Gynecol. 2007 Jan;109(1):217-27

Harmony is a non-invasive prenatal test (NIPT) based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. Before making any treatment decisions, all women should discuss their results with their healthcare provider, who can recommend confirmatory, diagnostic testing where appropriate.



© 2016 Ariosa Diagnostics, Inc. All Rights Reserved.

HARMONY and HARMONY and Design are trademarks of Ariosa Diagnostics, Inc. in the US. HARMONY is a trademark of Roche in other countries. All other trademarks are the property of their respective owners.

MM-00315-06062016-Rev7.0