

harmony[®]

Roche

Your First Choice for NIPT

For You

it's delivering high quality results.

For Her

it's not worrying about false positives.

Answers that matter

Meeting your high standards with high performance.

When it comes to delivering high-quality results for noninvasive prenatal testing (NIPT), the Harmony test on AcfS is your answer.



The AcfS is a set of instrumentation that provides a comprehensive CE-IVD NIPT solution for your lab.*

The Harmony test has a less than
0.1%
false-positive rate for trisomies 21, 18, and 13.¹

Exceptional sensitivity and specificity

The Harmony test delivers consistent, proven performance across clinical studies.¹

	Detection Rate (DR)	False-Positive Rate (FPR)
Trisomy 21	99.3% (418/421)	<0.1% (10/23,155)
Trisomy 18	97.4% (147/151)	<0.1% (5/22,399)
Trisomy 13	93.8% (30/32)	<0.1% (3/14,243)

High quality. Proven accuracy.

**Harness the
combined power
of DANSR assays
and FORTE
algorithm**

**Assays targeted to
regions of interest**

- Increased efficiency²
- Greater depth of analysis²

**Proven accurate
fetal fraction
assessment using
proprietary SNP
analysis³**

**Individualized
probability score
incorporates**

- Fetal fraction
- Chromosome quantification
 - Maternal age
 - Gestational age

YOUR BENEFITS

**Low false
positive rates**

Greater confidence⁴

Scalable methodology





Your advantages with the Harmony test.

Inspire confidence with clearer answers

The providers you work with, and their patients, count on your lab to provide the clarity they need with confidence. The Harmony test was designed to focus on relevant conditions in order to minimize the rate of false-positive results.

Deliver high quality results

The reputation of your lab is only as good as the accuracy and reliability of the results you provide. The Harmony test has stringent quality metrics and is the most proven NIPT on the market, with industry-leading performance for trisomy 21, 18, and 13.^{1,5}

Maximize opportunity

Choosing Harmony NIPT means offering your providers confidence, value and proven quality. Whether you process five samples or 5000, NIPT is a growth opportunity for your lab.

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BRAND AWARENESS⁶

95%.....Physicians

94%.....Patients

Backed by a partnership that you can trust.

Support for where you are, and where you're going.

The Harmony test is fully backed by the resources and expertise of Roche, an industry leader and global pioneer in personalized healthcare. From dedicated technical support, marketing, and sales, you can count on us to provide training and help you drive volume and value to your NIPT offering.

Customized implementation to meet your needs.



OUR HARMONY TEST SEND OUT SERVICE

allows you to easily access the NIPT market and start building demand quickly with a minimal investment. Our central lab will ensure a timely turnaround; Harmony test results are usually available within a week from receipt.

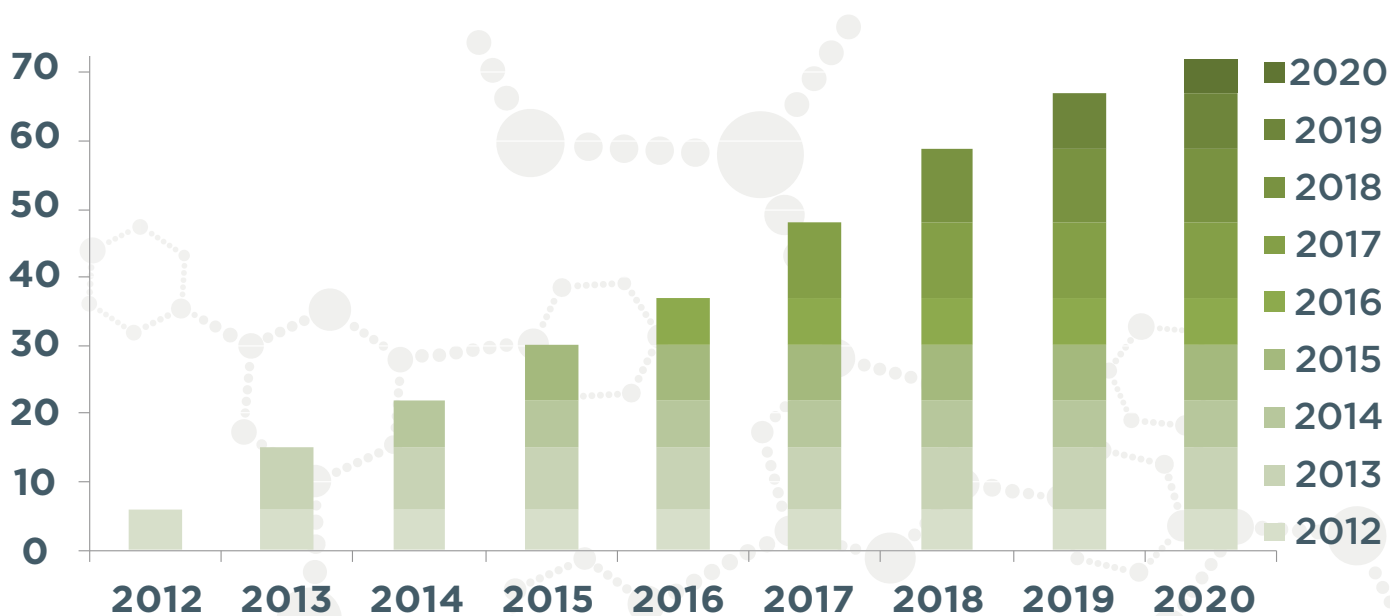


OUR DISTRIBUTED LAB SOLUTION

brings the Harmony test into your lab through AcfS. Our support and technical team will be with you every step of the way, from installation to training and post-launch support. AcfS provides ready scalability to address your growing NIPT demand.

Offer the most proven NIPT on the market.

With evidence from 72 peer-reviewed publications over 9 years, the Harmony test has been validated for use in women of any risk category, including twins and self/non-self egg donors.^{1,8,9}



**THE HARMONY TEST
HAS BEEN TRUSTED
IN OVER
2 MILLION
PREGNANCIES
WORLDWIDE.⁵**

Align your NIPT offering with professional society guidelines.

Given the evolution toward more routine use of cfDNA NIPT, demand for the Harmony prenatal test is on the rise.

2015

**Harmony NEXT study:
18,955 pregnancies¹**

ISPD^D: appropriate to offer NIPT as primary screening test to all¹²

ACOG/SMFM: NIPT should be offered to all¹³

ESHG^E/ASHG^F: NIPT offers improved accuracy compared with existing tests¹⁴

2014

ISUOG^C: NIPT for high risk¹¹

2013

ACOG^A/SMFM^B: NIPT for high risk¹⁰

2020

ACOG/SMFM:
NIPT for average risk¹⁵
ACOG/SMFM/ISPD:
NIPT for twins^{15,16}

**NO PROFESSIONAL
SOCIETY CURRENTLY
RECOMMENDS
GENOME-WIDE SCREENING
WITH NIPT.**

- A. American College of Obstetricians and Gynecologists
- B. Society for Maternal-Fetal Medicine
- C. International Society of Ultrasound in Obstetrics & Gynecology
- D. International Society for Prenatal Diagnosis
- E. European Society of Human Genetics
- F. American Society of Human Genetics

Deliver the Harmony® test.



For More

Contact your Roche representative to learn more about adding the Harmony test to your laboratory.

*Any risk refers to the average risk population (under age 35) and high risk population (over age 35). Pregnancies with more than two fetuses, a history of vanishing twin, maternal organ transplant or maternal aneuploidy are not eligible for the Harmony test.

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Answers that matter

The Harmony non-invasive prenatal test is 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. All women should discuss their results with their healthcare provider who can recommend confirmatory, diagnostic testing where appropriate.

MC--07387

The Harmony prenatal test was developed and its performance characteristics determined by Ariosa Diagnostics, Inc. a CLIA-certified and CAP-accredited clinical laboratory in San Jose, CA USA. This testing service has not been cleared or approved by the US Food and Drug Administration (FDA).

*Not available in all countries. The Harmony IVD Kit, AcFS Software and the Concerto Imager IVD are CE Marked under the IVD Directive 98/79/EC.

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1. Stokowski et al. *Prenat Diagn.* 2015;35(12):1243-6.
2. Sparks et al. *Prenat Diagn.* 2012;32(1):3-9.
3. Schmid et al. *Ultrasound Obstet Gynecol.* DOI: 10.1002/uog.19036.
4. Sparks et al. *Am J Obstet Gynecol.* 2012;206(4):319e1-9
5. Demonstrated by 72 peer-reviewed published studies using the Harmony prenatal test as of Jan 2020. for the entire 72 references, please go to harmonytest.com/references.
6. December, 2016, market research in Germany, n=300 patients; n=100 OBGYN physicians
7. Data on file.
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12. Benn et al. *Prenat Diagn* 2015; 35: 725-734
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14. Dondorp et al. *Eu J Human Genetics.* 2015 Nov;23(11):1438-50
15. ACOG Practice Bulletin Summary, Number 226. *Obstet Gynecol.* 2020 Oct;136(4):859-867
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