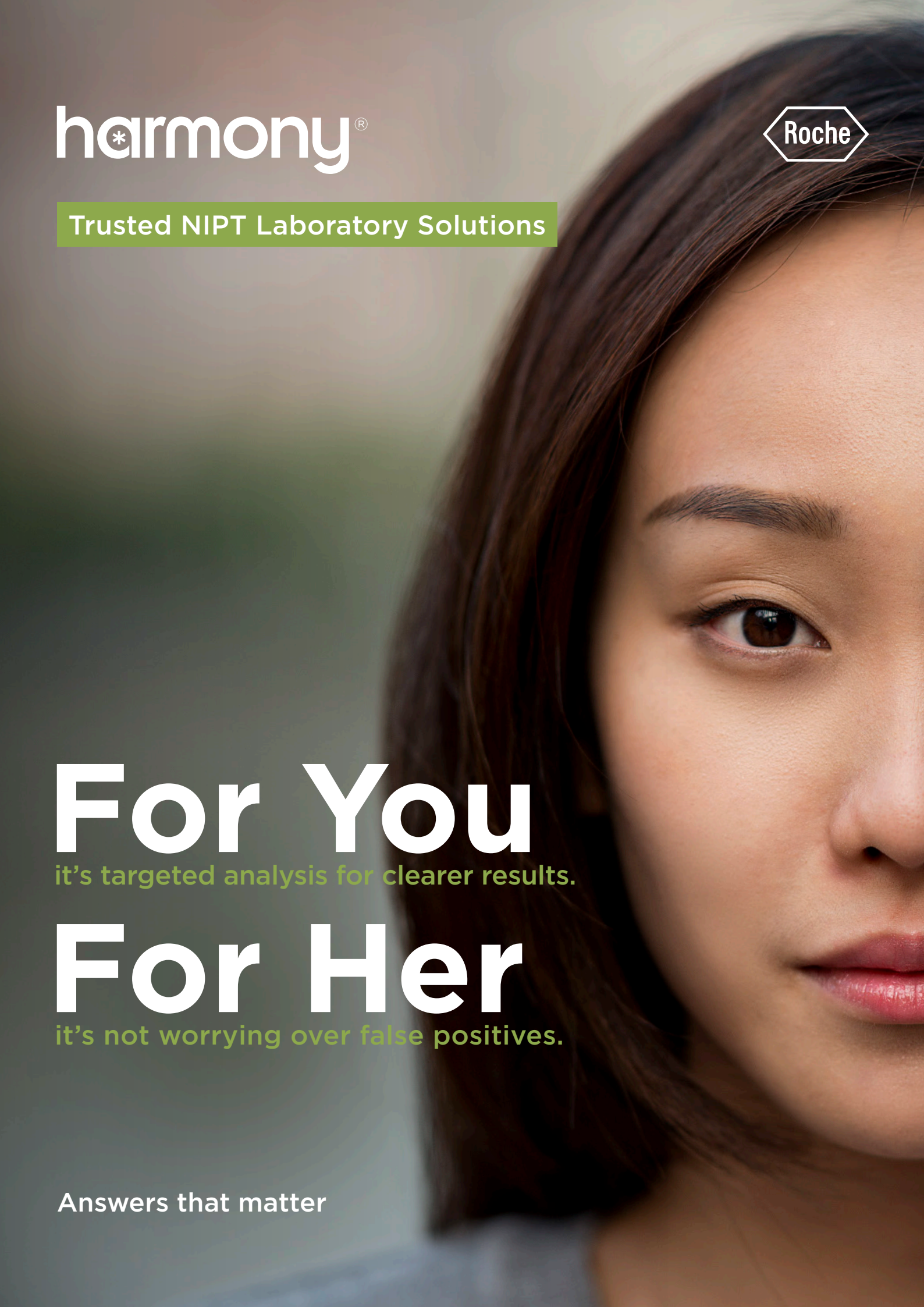

harmony®
Roche
Trusted NIPT Laboratory Solutions
For You
it's targeted analysis for clearer results.
For Her
it's not worrying over false positives.
Answers that matter

Proven accuracy. Trusted quality. Focused technology.

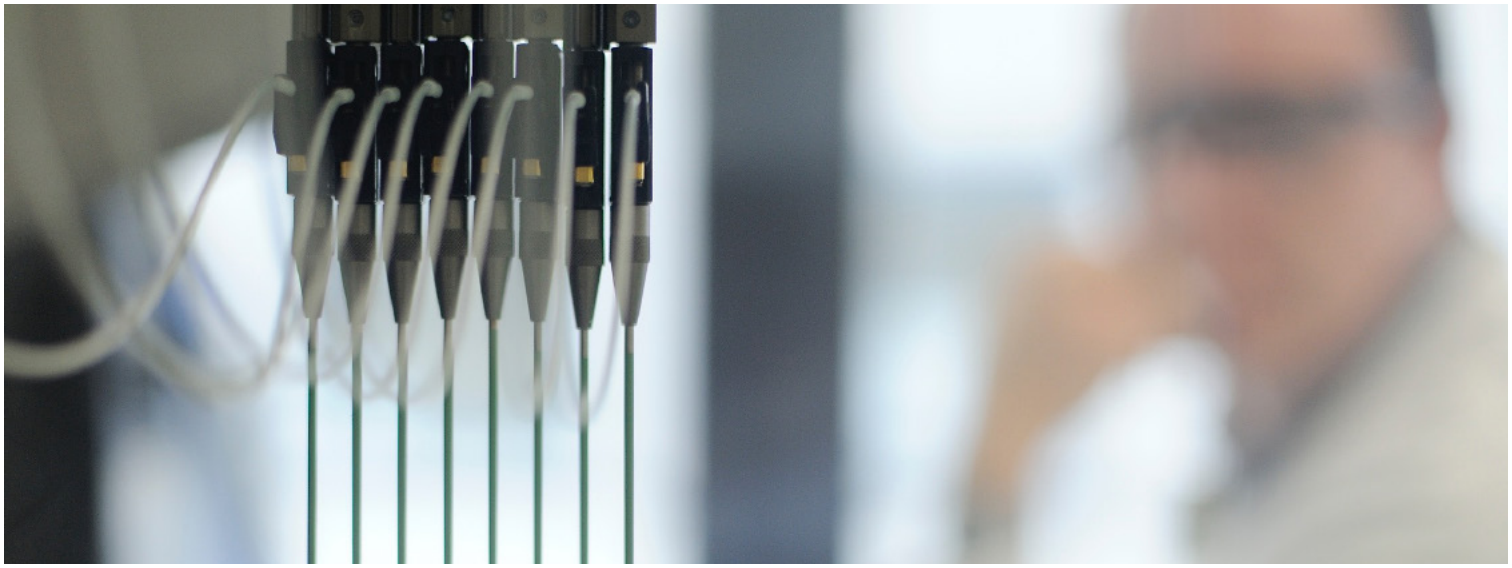
When it comes to delivering consistently high-quality results for noninvasive prenatal testing (NIPT), the Harmony test is your answer. The Harmony test, a validated and extensively studied NIPT, is trusted by labs and clinicians worldwide and has been used to screen more than 1.8 million pregnancies.[1] Backed by the commitment and quality of Roche Diagnostics, the Harmony test is your opportunity to maximize your offering in the NIPT market.

Comprehensive CE-IVD solution for your lab, including the Harmony IVD Kit, AcfS Software, and Concerto Imager IVD, inclusive of Annex II, list B for trisomy 21.*

The Harmony test has a less than

0.1%

false-positive rate for trisomies 21, 18, and 13.[2]



*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.

Meeting your high standards with higher performance.

The Harmony test is run on the Ariosa cell-free DNA System (AcfS), a modular, automated system powered by DANSR and FORTE technology. Our clinically validated, targeted method of DNA analysis achieves a detection rate of greater than 99% and a false-positive rate of less than 0.1% for trisomy 21.[2]

DANSR

Assays for targeted analysis of selected regions[3,4]

Specifically targets fragments from only the chromosomes of interest enabling deep analysis

Precisely quantifies and distinguishes fetal fraction by using single nucleotide polymorphism (SNP) analysis

Simultaneous performance of fetal-fraction and chromosome-fragment quantification assays using the same reagents in the same tubes

FORTE

Algorithm to evaluate probability of trisomy[4,5]

Explicitly accounts for fetal fraction in calculating trisomy probability with stringent quality metrics to ensure confidence in the results

Incorporates maternal and gestational age, two of the strongest factors influencing risk for trisomy

BENEFITS

A robust and accurate assessment of trisomy probability

Minimizes false-positive rates

A scalable approach[4] with a substantive advantage in cost and throughput

Reduces complexity of unutilized sequencing data compared to massively parallel shotgun sequencing (MPSS) techniques[3,4]

Provides greater confidence with clearer separation between positive and negative results[6]

Exceptional sensitivity and specificity

The Harmony test delivers consistent, proven performance across clinical studies.[2]

	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)

CE-IVD performance based on a subset of the above data: for trisomy 21 DR 99.1% (107/108), FPR 0% (0/641). For trisomy 18 DR 100% (29/29), FPR 0% (0/641). For trisomy 13 DR 100% (12/12), FPR 0% (0/641).

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 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. The modular system approach for AcfS provides ready scalability to address your growing NIPT demand.

Your advantages with the Harmony test.

Keep pace with changing technology

NIPT is a growth opportunity that you can now afford to pursue, with a partnership that allows you to choose the adoption method that is most appropriate for your lab.

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 consistently exceptional 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, demonstrating reliable performance for trisomy 21, 18, and 13.[7]

CONTACT

your local Roche representative to learn more about the Harmony prenatal test and AcfS.

Backed by a partnership that maximizes opportunity and productivity.

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.

Deliver the Harmony® test difference.

EXTENSIVELY STUDIED

with evidence from 67 published, peer-reviewed publications.[7]

EXCEPTIONAL PERFORMANCE

with exceedingly low false-positive rates for trisomies 21, 18, and 13.[2]

DEEPER ANALYSIS FOR CLEARER RESULTS

powered by DANSR technology.[3,4]

FOCUSED ON QUALITY

powered by FORTE,[5] which incorporates stringent quality metrics including a fetal-fraction threshold.

REPRODUCIBLE ANALYSIS

with precisely quantified fetal fraction using single nucleotide polymorphism (SNP) analysis.[3-5,8]

VALIDATED FOR USE IN WOMEN OF ANY RISK+ CATEGORY

including twins and self/non-self egg donors.[2,9,10]

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.

harmony®

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.

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).

MC--05679

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3. Sparks et al. Prenat Diagn. 2012;32(1):3-9.
4. Juneau et al. Fetal Diagn Ther. 2014;36(4):282-6.
5. Sparks et al. Am J Obstet Gynecol. 2012;206(4):319e1-9
6. Ashoor G et al. Am J Obstet Gynecol. 2012;206(4):322.e1-5.
7. Demonstrated by 67 peer-reviewed published studies using the Harmony prenatal test as of Jan 2020. for the entire 67 references, please go to harmonytest.com/references.
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