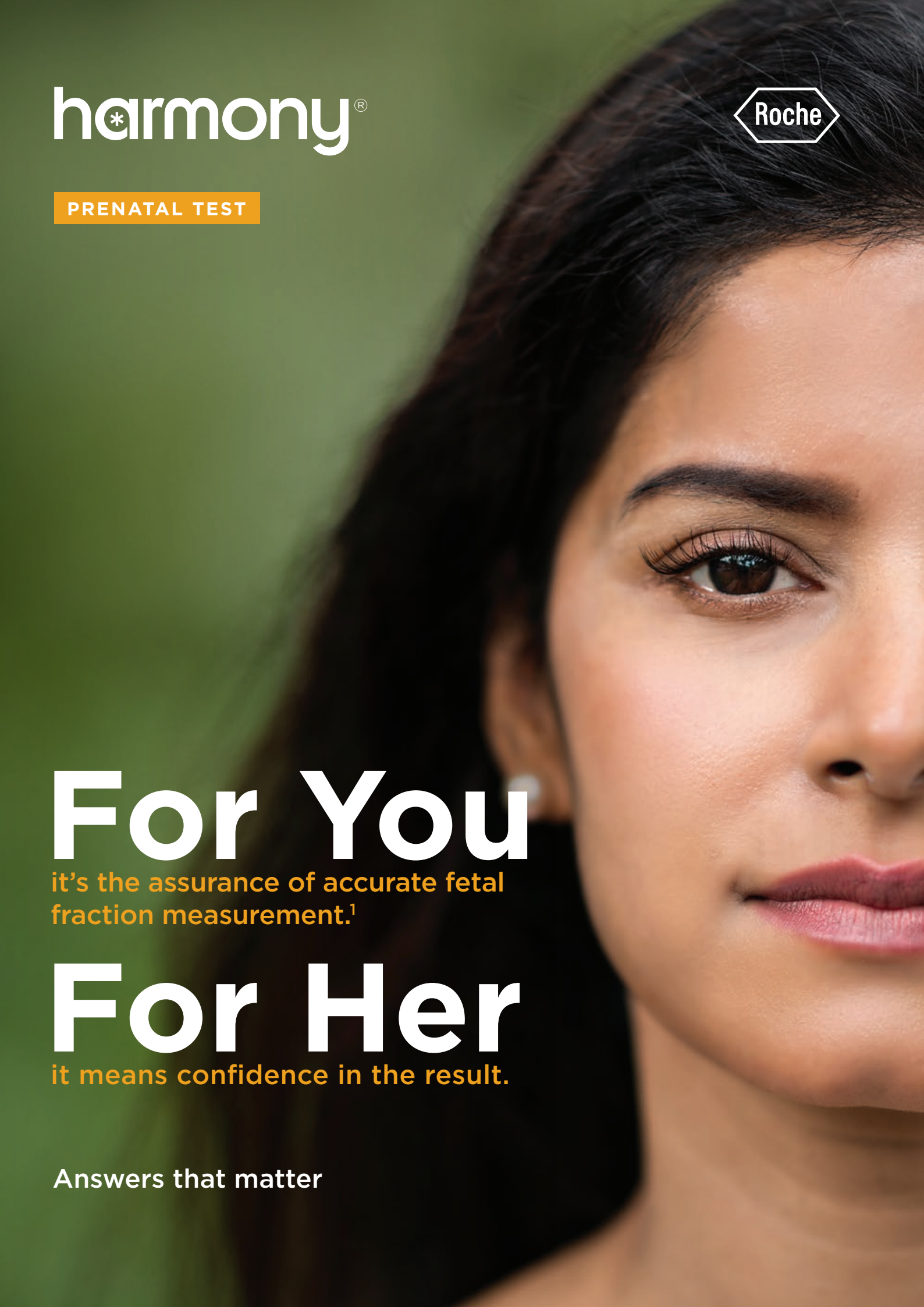

harmony®
Roche
PRENATAL TEST
For You
it's the assurance of accurate fetal fraction measurement.[1]
For Her
it means confidence in the result.
Answers that matter

The reliability you want, and the accuracy you need.

Well proven

The Harmony test is a well proven cell-free DNA-based prenatal blood screen.[2]

Menu options:

- Trisomies 21, 18, and 13
- Sex Chromosome Aneuploidy (SCA)
- Monosomy X
- Fetal sex
- 22q11.2 deletion

For pregnant women aged 18 to 48, anywhere.[3]

The Harmony test can be used in singleton, twin, and egg-donor pregnancies and has been validated for use in pregnant women aged 18 to 48.[3] Clinicians have used Harmony to screen over one million pregnancies in more than 100 countries around the world.[3]

Reliable results for all tested conditions

The Harmony prenatal test delivers consistent, industry-leading performance across clinical studies[1]

	Detection Rate	False-Positive Rate
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)

Greater than

99%

detection rate for trisomy 21.[1]

Less than

1 in 1000

false-positive rate.[1]

Clinical evidence

Cell-free DNA analysis for Non-invasive Examination of Trisomy (NEXT) Study[3]

The Harmony test, as a first-line screen, is supported by extensive clinical evidence.[3]

15,841 women were included in the primary analysis population.[3]

NEXT study design

- Maternal age range: 18 to 48 years old (mean: 31 years old)
- Gestational age range: 10.0 to 14.3 weeks (mean: 12.5 weeks)

All patients in this study received both first-trimester screening (FTS) and the Harmony prenatal test. Pregnancy outcome data was obtained on each pregnancy by genetic testing or newborn examination.

Significantly outperforms

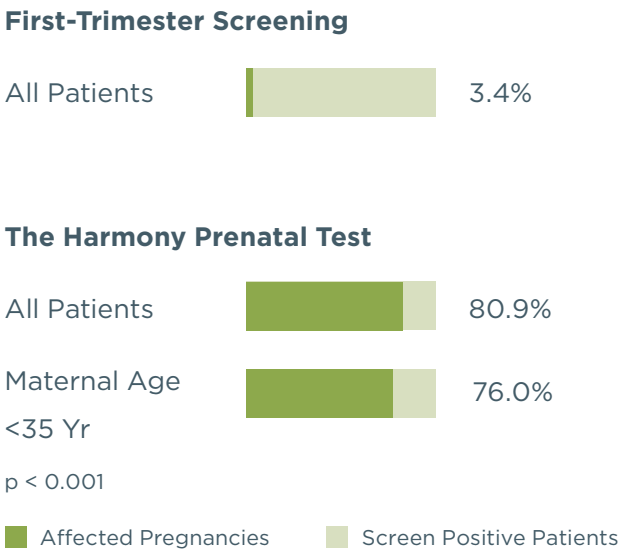
In the largest to date blinded, prospective study of its kind, the Harmony test significantly outperformed first-trimester screening (FTS†) for trisomy 21 in both detection and false-positive rates.[3]

NEXT study results[3]

	Harmony	FTS	P-value
DETECTION RATE (affected pregnanices identified as high chance)	**100%** (38/38)	**79%** (30/38)	**0.008**
FALSE-POSITIVE RATE (unaffected pregnancies incorrectly identified as high chance)	**0.06%** (9/15803)	**5.4%** (854/15803)	**<0.001**

THE HARMONY PRENATAL TEST DEMONSTRATES SUPERIOR POSITIVE PREDICTIVE VALUE (PPV) FOR TRISOMY 21 COMPARED TO FTS[3]

PPV: proportion of screen positive results that accurately reflect an affected pregnancy



A superior first-line screen for Trisomy 21[3]

† Serum PAPP-A, total of free β-hCG & Nuchal Translucency

Clarity is one simple step away

Your patients who are expecting may have many questions. That's why it's important for you to be equipped with the right knowledge at the right time. With the Harmony test, results are clear and focused, so that your conversations can be too.

It's about time

As early as 10 weeks	Answers in 3-5 days	Clear Reports	Fewer False Positives than FTS[3]
The Harmony test can be administered as early as 10 weeks gestation.	Results are usually available within 3-5 days of sample receipt.	Clear reports help pave the way for your conversations. Customer support is available to address any of your needs.	Testing options that focus on clinically relevant conditions mean fewer complex conversations.

It’s about confidence

Superior performance to FTS[3]

to help minimise anxiety and invasive procedures due to false-positive results.[3,4]

Unparalleled evidence

as demonstrated in studies of over 148,000 patients in more than 48 peer-reviewed publications.[2]

Trusted results

the Harmony test will only provide a result when there is sufficient cell-free fetal DNA for an accurate analysis.[5]

May minimise patient anxiety caused by false-positive results.[4]

Our commitment to your care

Information and support

The Harmony test was developed with the belief that all women should have access to the best quality information about their pregnancies.

Patient education – We're committed to developing resources to help your patients understand more about their pregnancy, test results, and more.

Market access initiative – Our team works at the health-system level to provide the clinical evidence necessary to bring testing to your population.

First line screening test – The Harmony test makes superior prenatal screening available to women aged 18 to 48 compared to traditional screening.[3]

Professional medical societies

The Royal College of Obstetricians and Gynaecologists welcome the news that non-invasive prenatal testing has been recommended for the high-chance women on the NHS and states that it reduces unnecessary invasive procedures.[6]

> Performance of cfDNA screening is considerably greater than conventional screening...
>
> *– ISPD Statement 2015*[7]

> ACMG recommends informing **all pregnant women** that NIPS [noninvasive prenatal screening] is the **most sensitive screening option** for T21, 18, 13...
>
> *– ACMG Statement 2016*[8]

> All labs should include clearly visible fetal fraction on all reports...[and] establish clinical validation of fetal fraction...
>
> *– ACMG Statement 2016*[8]

The Harmony test has been demonstrated to provide highly accurate and reproducible assessment of fetal fraction.[10]

Give her the difference of Harmony prenatal test

SUPERIOR PERFORMANCE TO FTS [1,3]

with extremely low false-positive rates for trisomies 21, 18, and 13

Globally available with over

1.4 MILLION

tests performed [10]

Can be administered as early as

10 WEEKS

gestation

Clear results in

3-5 DAYS

from sample receipt

Validated for use in women aged

18-48*

* Pregnancies with more than two fetuses, a history of vanishing twin, maternal organ transplant or maternal aneuploidy are not eligible for the Harmony test.

SUPPORT

for your practice and your patients

For More

information visit www.harmonytest.co.uk

harmony®

Answers that matter

TDL GENETICS

Email: harmony@tdlpathology.com

TAP3930/31-12-18/V4

1. Stokowski et al. Prenat Diagn. 2015 Dec;35(12):1243-6.
2. Demonstrated by 48 peer-reviewed published studies using the Harmony prenatal test as of Jan 2018. For the entire 48 references, please go to harmonytest.com/references
3. Norton ME et al. N Engl J Med. 2015;372(17):1589-1597.
4. Wax et al. J Clin Ultrasound. 2015 Jan;43(1):1-6.
5. Takoudes et al. Ultrasound Obstet Gynecol. 2015 Jan;45(1):112.
6. https://www.rcog.org.uk/en/news/rcog-response-to-uknsc-recommendationon-nipt-testing-for-high-risk-women/ [Accessed 23.08.2018]
7. Benn et al. Prenat Diagn. 2015 Aug;35(8):725-34.
8. Gregg et al. Genetics in Medicine 2016 Oct;18(10):1056-65.
9. Schmid et al. Ultrasound Obstet Gynecol. DOI: 10.1002/uog.19036.
10. Data on file.

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).