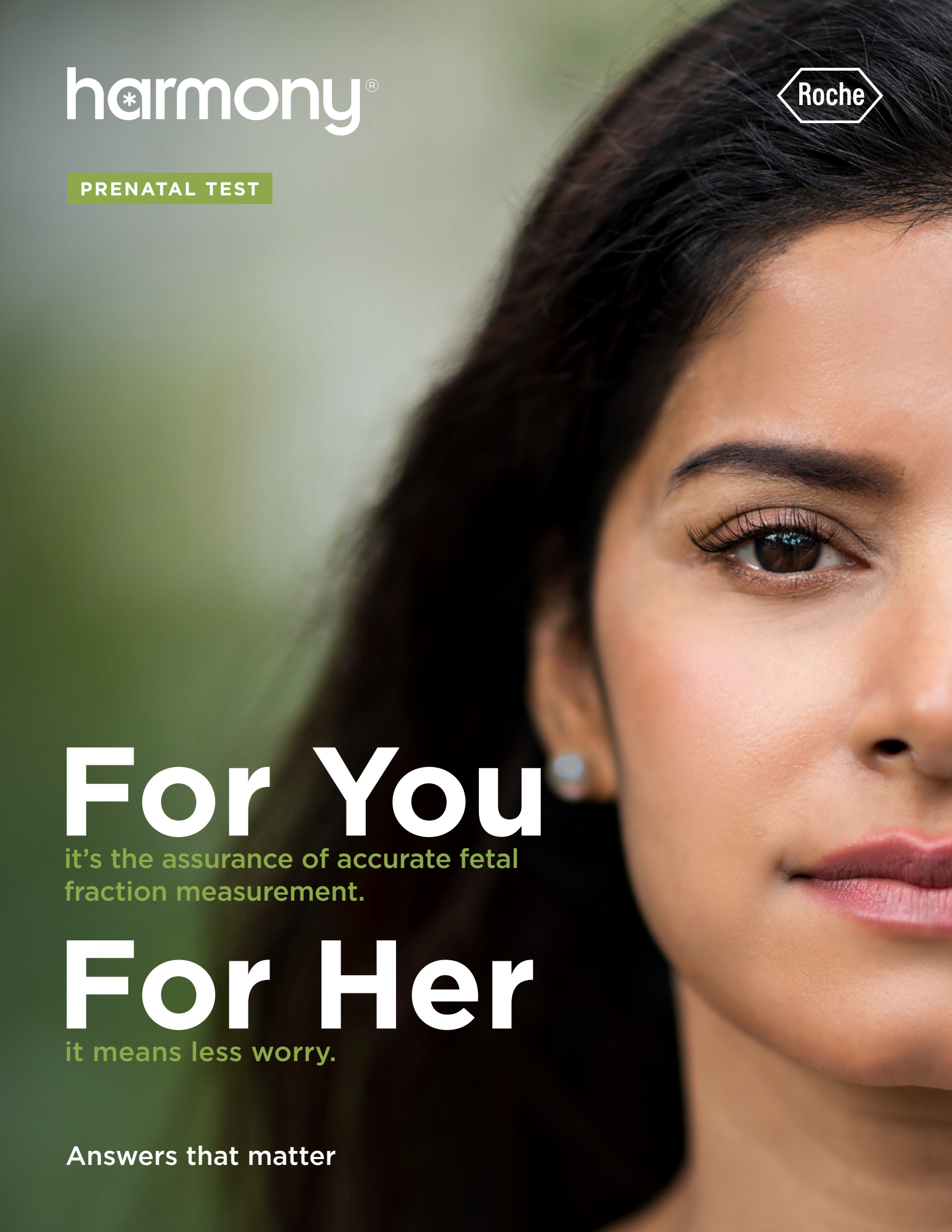

harmony®
Roche
PRENATAL TEST
For You
it's the assurance of accurate fetal fraction measurement.
For Her
it means less worry.
Answers that matter

Most proven

The Harmony test is the most proven cell-free DNA-based prenatal blood screen.[1]

Menu options:

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

For any patient, with any risk*, anywhere.

The Harmony test can be used in singleton, twin, and egg-donor pregnancies and has been validated for use in pregnant women of any age or risk category.*,[2]

Clinicians have used Harmony test to screen over 1.8 million[Ω] pregnancies in more than 100 countries around the world.

*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.

[Ω] Data on file with Roche

Reliable results

The Harmony prenatal test delivers consistent, industry-leading performance across clinical studies[2]

	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.[2]

Less than

1 in 1000

false-positive rate.[2]

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]

Over 250,000 samples

included in peer-reviewed publications[1]

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 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 Prenatal Test	FTS	P-value
DETECTION RATE (affected pregnanices identified as high risk)	**100%** (38/38)	**79%** (30/38)	**0.008**
FALSE-POSITIVE RATE (unaffected pregnancies incorrectly identified as high risk)	**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.

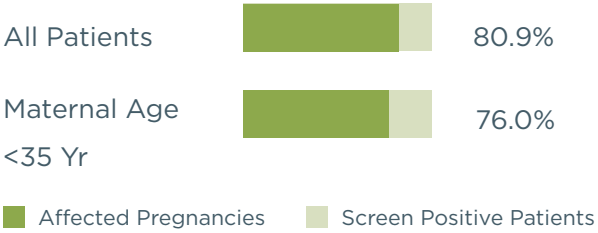
First-Trimester Screening

All Patients — 3.4%

The Harmony Prenatal Test

All Patients — 80.9%

Maternal Age <35 Yr — 76.0%



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.

As early as 10 weeks

The Harmony test can be administered as early as 10 weeks gestation.

Rapid Results

Usually available within one week.

Clear Reports

Clear reports help pave the way for your conversations.

Fewer False Positives

Targeted testing keeps false positive rates low, for fewer complex conversations.

Professional guidelines

Recent positioning statements recommend using NIPT as a first-tier test, which significantly decreases the number of women who will receive an initial false alarm.

> "Performance of cfDNA screening is considerably greater than conventional screening..."
>
> *– ISPD Statement 2015[4]*

> "Cell-free DNA screening is the most sensitive and specific screening test for the common fetal aneuploidies"
>
> *– -ACOG/SMFM 2020[5]*

> "ACMG recommends informing all pregnant women that NIPS [noninvasive prenatal screening] is the most sensitive screening option for T21, 18, 13..."
>
> *– ACMG Statement 2016[6]*

Give her the difference of Harmony prenatal test

SUPERIOR PERFORMANCE TO FTS[2,3]

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

Can be administered as early as

10 WEEKS

gestation

Globally available with over

1.8 MILLION

tests performed[Ω]

SUPPORT

for your practice and your patients

RAPID RESULTS

Typically available within a week from sample receipt.

Validated for use in women of

ANY AGE OR RISK CATEGORY*

For More

information visit www.harmonytest.com
or call 1-855-927-4672
Outside the US, call +1-925-854-6246

harmony®

Answers that matter

*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.

[Ω] Data on file with Roche

1. 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
2. Stokowski et al. Prenat Diagn. 2015 Dec;35(12):1243-6.
3. Norton ME et al. N Engl J Med. 2015;372(17):1589-1597.
4. Benn et al. Prenat Diagn. 2015 Aug;35(8):725-34.
5. ACOG Practice Bulletin 226. Obstet Gynecol. 2020.
6. Gregg et al. Genetics in Medicine 2016 Oct;18(10):1056-65.

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).