harmony®
PRENATAL TEST
performed in Sweden

WISE Choice

The Harmony Prenatal Test (NIPT) is based on a very simple promise. Our promise is to provide clinicians across the world and pregnant women of any age with a simple, non-invasive screen for common chromosomal abnormalities, such as trisomy 21.

Respected clinicians rely on the timely and accurate results that we deliver every day.

Ken Song, MD

Not all NIPT Providers are the same. The focus of Ariosa Diagnostics' dedicated staff is to provide clear answers to questions that matter. The Harmony Prenatal Test is built on an exceptional foundation of solid clinical studies.[Table 1]

Quality Leadership

Some of the claims being made by participants in the NIPT field lately have been based on limited published data. We seek to set the record straight and continue to provide you with the clear, precise, and accurate information you have come to expect from us.

Within please find

- a comparison of blinded validation studies and published false positive rates
- relative PPV values within average and higher-risk populations
- why we measure fetal fraction in every sample we receive

From the way we run our test, to the way we handle your samples, accuracy and quality are our top priorities. We pride ourselves on providing you and your patients the experience you deserve.

We thank you for your continued support and hope to meet your needs for years to come.

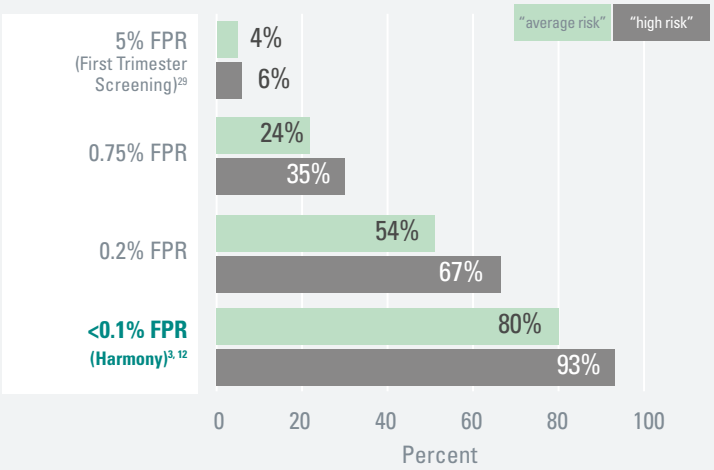
Sincerely,

Ken Song, MD
Co-founder
Ariosa Diagnostics

Exceptional Positive Predictive Value (PPV)

PPV for any screening test will depend upon the incidence of the condition within a specific population and the false positive rate of the test. Figure 2 The Harmony Prenatal Test's low false positive rate of less than 0.1% for trisomy 21 also allows us to deliver exceptional PPV.[12, 28] The Harmony Test is the wise choice for clinicians that wish to efficiently deliver clarity, maximize PPV, and minimize false alarms in both high and lower risk populations.[12, 28]

Figure 2
Theoretical PPV for Trisomy 21 in Average & High Risk Populations*

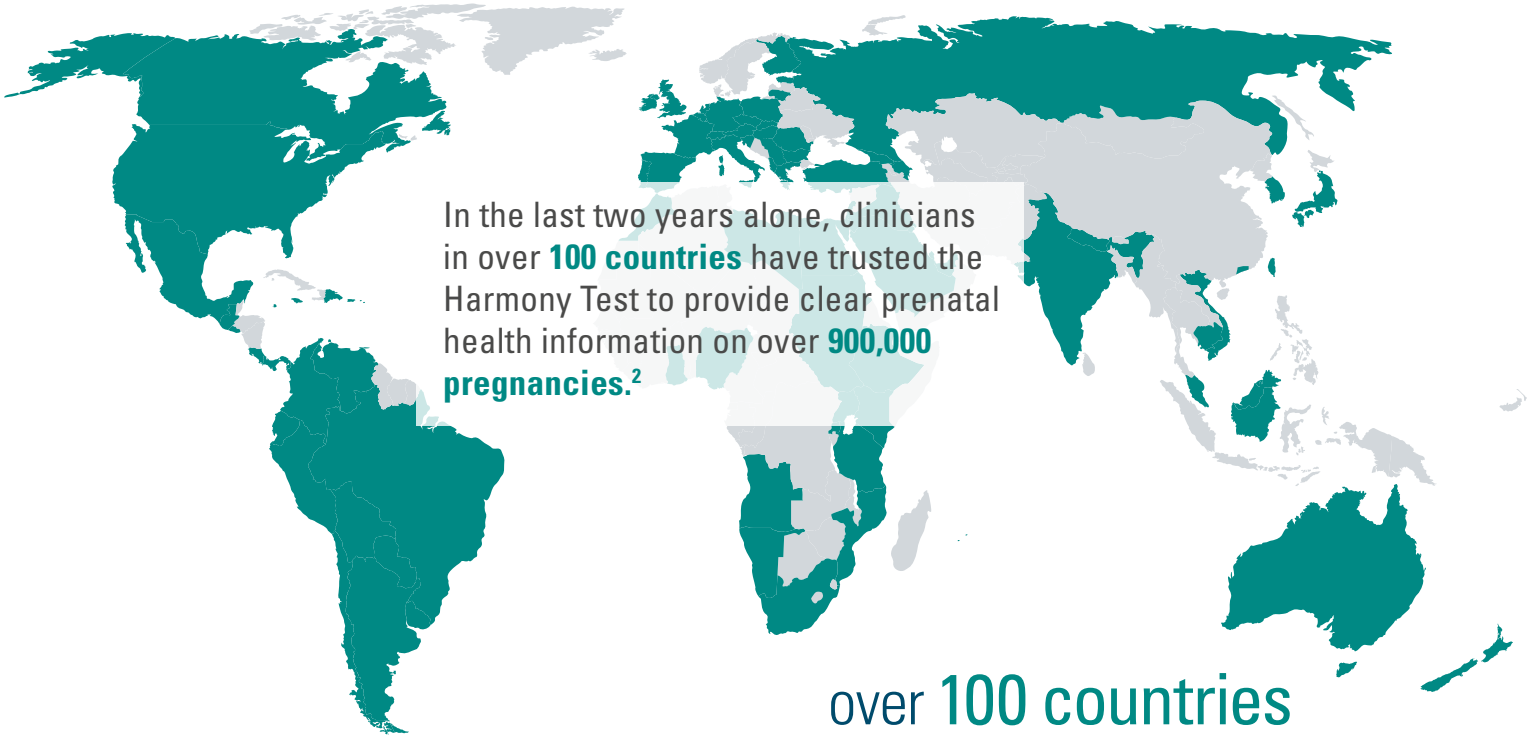


*Theoretical PPV above calculated based on prevalence of trisomy 21 of 1/417 ("average risk" population) and 1/249 ("high risk" population) at differing false positive rates (FPRs).

A Global Leader

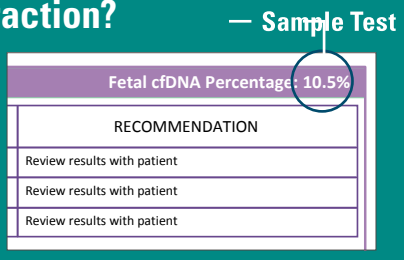
Since entering the market in 2012, access to the Harmony Prenatal Test has expanded swiftly. In 2015, we began the process of transferring our technology to enable the Harmony Test to be run locally. Since 2016, Life Genomics has been a local Harmony provider in Europe, located in Sweden.

900,000+ pregnancies



Focused on Patient Benefits

Accurate Fetal Fraction? Yes, please.



Professional societies like ACOG and SMFM recognize that sufficient fetal fraction is essential for accurate NIPT results.[22] For this reason, **we measure, report, and incorporate fetal fraction into every test result.**[8, 30]

Harmony uses a unique targeted technology that differentiates and quantifies maternal and fetal DNA using single nucleotide polymorphisms (SNPs).[8, 30] By measuring and incorporating fetal fraction into every Harmony Prenatal Test report, **we deliver exceptionally accurate results that include an individualized risk score.**

A recent report showed that three of five commercial NIPT test providers reported a normal female fetus in samples from women who were not even pregnant.[23] For this same set of samples, The Harmony Prenatal Test **correctly reported** insufficient fetal cell-free DNA to report a risk assessment result. When other NIPT providers do not measure fetal fraction, their results may be incorrectly based on the DNA of the mother. We clearly note the percent fetal fraction contained in samples, right at the top of every Harmony Prenatal Test patient report.

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27. Wax et al. J Clin Ultrasound. 2015 Jan;43(1):1-6.
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NIPT Leadership

From our inception, Ariosa® has focused on serving the prenatal screening needs of pregnant women with exceptional accuracy. Harmony is the leading non-invasive prenatal test that assesses the risk of trisomy 21, 18, and 13 in pregnant women of any age or risk category.* In the largest blinded, prospective head-to-head comparative study to date, published in the New England Journal of Medicine, the Harmony Test significantly outperformed First Trimester Screening (FTS) that measures maternal serum for biochemical markers for trisomy 21 within the general pregnancy population.[12]

In this landmark NEXT (Non-Invasive Examination of Trisomy) Study, Harmony's detection rate for Trisomy 21 was >99%, compared with 79% for traditional FTS. The Harmony test's false positive rate was 0.06% compared to 5.4% for traditional screening.[12]

Studies show that the Harmony's false positive rate is also lower than those of most major NIPT providers.[Table 1]

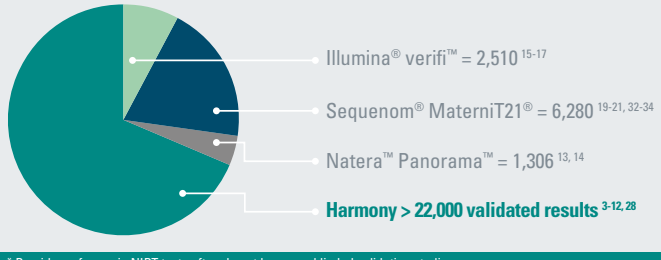
* Both under 35 and over 35 age groups, studies have included women ages 18-48

Extensively Validated

The Harmony Prenatal Test has been validated in published blinded clinical studies conducted on more than 22,000 pregnant patients.[3-12, 28] In 2015, our data set was three times as large as all the major NIPT screening providers combined.

As blinded clinical studies are the appropriate standard for validation, the science supporting the Harmony Prenatal Test is in a class by itself.

Total Patients Tested in Blinded Validation Studies



* Providers of generic NIPT tests often do not have **any** blinded validation studies.

Reducing False Positives Over 90 Times Compared to FTS[12]

First Trimester Screening False Positives = 854 The Harmony Prenatal Test False Positives = 9

Table 1	harmony PRENATAL TEST	Illumina®/ Verinata® verifi ™	Sequenom® MateriT21®	Natera™ Panorama™	Generic Illumina® NIPT
Claimed Cumulative False Positive Rates (T21,T18,T13)	Less than 0.1%[28]	0.21%[24]	0.8%[25]	Less than 0.1%[26]	0.21%[18]
False Positive Rate Claims (forT21,T18,T13) Based Upon	Published Clinical Validation Studies	Limited Published Clinical Validation Studies, Unpublished Data	Limited Published Clinical Validation Studies	Limited Published Clinical Validation Studies	Unpublished Data

Figure 1

PUBLISHED CLINICAL VALIDATION STUDIES[1]

Harmony Benefits

FAST: Lab results in as little as a week from time of receipt.

EARLY: Can be performed as early as 10 weeks gestation.

ACCURATE: Exceptional accuracy in pregnant women of any age or risk. Results proven in published blinded studies of over 22,000 delivered a false-positive rate for trisomy 21 of less than 0.1%.[28]

SAFE: A simple blood draw may minimize invasive procedures caused by false positive results.[27]

TRUSTED: Clinicians in over 100 countries have trusted the Harmony Test to provide clear prenatal health information on 900,000+ pregnancies.[2]

Test Options

The Harmony Prenatal Test is validated for use in singleton, twin, and IVF pregnancies, including self and non-self egg donor pregnancies.[9]

		AVAILABLE FOR		
		SINGLETON	EGG DONOR & IVF	TWINS
Harmony Prenatal Test	Evaluates the risk of fetal trisomy 21, trisomy 18 and trisomy 13.	✓	✓	✓
The following test options are also available from the same blood draw:				
☐ **Fetal Sex**	Provides information regarding fetal sex. Assessment of fetal sex does not include risk assessment of sex chromosome aneuploidy. In twin pregnancies, a female result applies to both fetuses; a male result applies to one or both fetuses.	✓	✓	✓
☐ **Monosomy X**	Provides monosomy X risk assessment, but no information regarding other sex chromosome aneuploidies.	✓	✓	
☐ **Sex Chromosome Aneuploidy Panel**	Provides assessment of risk of X and Y chromosome aneuploidies, including monosomy X, XXX, XXY, XYY and XXYY.	✓	✓	
☐ **22q11.2**	Provides assessment of 22q11.2 deletion syndrome (DiGeorge syndrome).	✓	✓	

For both Monosomy X and the Sex Chromosome Aneuploidy Panel, fetal sex will not be reported unless the Fetal Sex box is checked separately. However if the result indicates a high risk for sex chromosome aneuploidy, then this risk assessment will indirectly provide information regarding fetal sex. The Harmony Prenatal test is not available for more than 2 fetuses.

harmony™ PRENATAL TEST

COMBINED FALSE POSITIVE RATE[28]
<0.1%
Trisomies 21,18, 13

FETAL FRACTION MEASUREMENT
100%
of all eligible samples

DETECTION RATE[28]
Trisomy 21
>99%
False negative rate <1%

Three Simple Steps to Clarity

1 Draw a maternal blood sample at 10 weeks or later in pregnancy

2 Submit sample to Life Genomics through one of our clinical partners.

3 Lab results in as little as a week from time of receipt.

Visit us at nipt.se

For assistance email **info@lifegenomics.se** or call Life Genomics Laboratory **+46 708 58 33 72**

harmony®

PRENATAL TEST

performed in Sweden

LIFE GENOMICS

Ref: MM-00665-101515-Rev1.0
LG-H-NLT-Rev1.0

The Harmony® Prenatal Test was developed by Ariosa Diagnostics (San Jose, California, USA). The Harmony® reagents and Ariosa cell-free DNA System (AcfS) software used as part of the Harmony Prenatal Test are CE Marked under the IVD Directive 98/79/EC. Harmony is a non-invasive prenatal test (NIPT) based on cell-free DNA analysis. The results are intended for prenatal screening and are not intended to be the sole basis for diagnosis. 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.