

Introducing

# Harmony™

PRENATAL TEST

An advanced blood test to detect common fetal trisomies in pregnant women



## Simple

Non-invasive testing via a standard blood draw

## Accurate

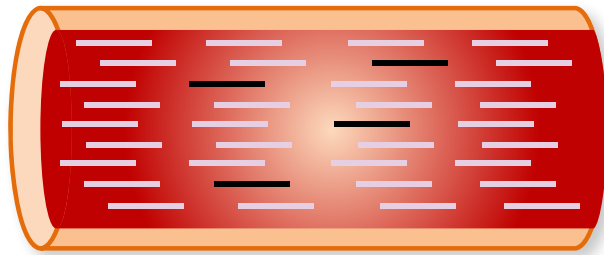
Enhanced performance with individualized results<sup>1-4</sup>

**Ariosa™**  
DIAGNOSTICS

 **Integrated**  
GENETICS  
.....  
LabCorp Specialty Testing Group

# Advanced Technology Behind the Harmony Test

## CELL-FREE DNA AND THE ADVANTAGES OF DIRECTED ANALYSIS



### Cell-free DNA in blood

— Chromosome 21, 18, 13 cell-free DNA

— Other chromosome cell-free DNA

- Cell-free DNA are short DNA fragments from chromosomes found in circulation
- In pregnancy, cell-free DNA from the fetus and mother are both present in maternal blood<sup>3</sup>

Harmony™  
PRENATAL TEST



DIRECTED ANALYSIS



MORE EFFICIENT

### MPSS (shotgun)

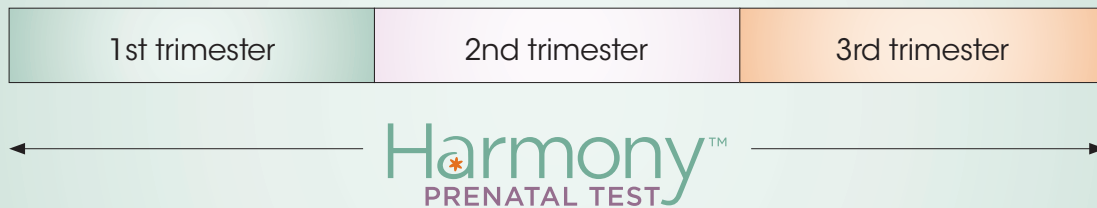
Random analysis of cell-free DNA



- Efficient, directed analysis for accurate and affordable trisomy detection
- Individualized risk results incorporate fetal DNA fraction, gestational age and maternal age<sup>3</sup>

# Simple

## SINGLE TEST AT 10 WEEKS OR LATER

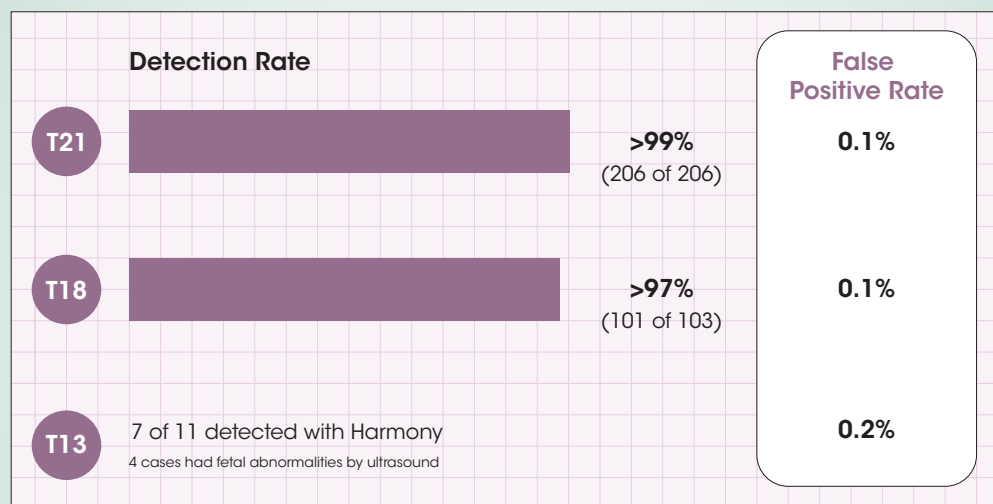


- Simple binary results with individualized risk score for each trisomy
- Access to more than 1,700 patient service centers

# Accurate

## HIGH DETECTION RATES WITH LOW FALSE POSITIVES

Directed analysis evaluated in over 4,400 patients across 5 studies<sup>1-5</sup>



Detection and false positive rates calculated based on risk cut-off of 1/100 (1%)<sup>4</sup>

- Test validated and studied in over 4,400 patients, with 206 out of 206 T21 cases accurately detected and 101 out of 103 T18 cases correctly identified<sup>1-5</sup>
- Only non-invasive prenatal test (NIPT) that has been exclusively evaluated in 1st trimester pregnant women
- Backed by extensive clinical data on cell-free DNA<sup>1-5</sup>

# Harmony Prenatal Test Advantage in Your Practice

## Indications for Use

Harmony is intended for detection of common fetal trisomies in pregnancies of at least 10 weeks' gestation.

The test is not intended for use in women with multiple fetus or egg-donor pregnancies.

## Specimen Requirements

### Whole blood

- Use only the black and tan cap blood collection tubes
- Two tubes, 8-10ml each
- Store samples at room temperature and transport at ambient temperature

### Turnaround Time:

- 8-10 days

## Simple

- One blood draw performed at 10 weeks or later in pregnancy
- In-network laboratory

## Accurate

- Highly accurate detection of common fetal trisomies<sup>4</sup>
- Low false positive rate<sup>4</sup>
- Individualized results on trisomy risk for each patient

## Accessible

- Access to more than 1,700 patient service centers
- Team of more than 150 genetic counselors

**Client Services** 8am to 5pm Monday to Friday 1-800-848-4436

### References

1. Sparks, A.B., Struble, C.A., Wang, E.T., Song, K., Oliphant, A., Non-invasive Prenatal Detection and Selective Analysis of Cell-free DNA Obtained from Maternal Blood: Evaluation for Trisomy 21 and Trisomy 18, *Am J Obstet Gynecol.* (2012), doi: 10.1016/j.ajog.2012.01.030.
2. Ashoor, G., Syngelaki, A., Wagner, M., Birdir, C., Nicolaides, K.H., Chromosome-selective sequencing of maternal plasma cell-free DNA for first trimester detection of trisomy 21 and trisomy 18, *Am J Obstet Gynecol.* (2012), doi: 10.1016/j.ajog.2012.01.029.
3. Sparks, A.B., Wang, E.T., Struble, C.A., Barrett, W., et al. Selective analysis of cell-free DNA in maternal blood for evaluation of fetal trisomy. *Prenat Diagn* (2012);32(1):3-9. doi: 10.1002/pd.2922. Epub 2012 Jan 6.
4. Norton, M., Brar, H., Weiss, J., Karimi, A., et al. Non-Invasive Chromosomal Evaluation (NICE) Study: Results of a Multicenter, Prospective, Cohort Study for Detection of Fetal Trisomy 21 and Trisomy 18, *Am J Obstet Gynecol.* (2012), doi:10.1016/j.ajog.2012.05.021.
5. Data on file.

The Harmony Prenatal Test has been developed and is performed as a laboratory test service by Ariosa Diagnostics, a CLIA-certified clinical laboratory.



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