

HIGH PROBABILITY RESULT

Patient and Provider Information

Ariosa Diagnostics, Inc.
 5945 Optical Court
 San Jose, CA 95138

Contact Line 1^
 Contact Line 2^
 Contact Line 3^
 Contact Line 4^
 Contact Line 5^
 Contact Line 6^
 Contact Line 7^
 Contact Line 8^

PATIENT NAME:	Jane Doe	ACCOUNT #:	7654321
DATE OF BIRTH: (MM/DD/YYYY)	01/01/1980	CLINIC NAME:	The Clinic Offering Test
MRN:	1234567890123456789	REFERRING/ORDERING CLINICIAN:	Ordering Physician MD
LABORATORY ID:	AD12345678-PAT	REFERRING/ORDERING CLINICIAN FAX #:	123-456-7890
GESTATIONAL AGE:	10 wks 5 days	OTHER CLINICIAN:	Genetic Counselor MA, CGC
# OF FETUSES:	1	OTHER CLINICIAN FAX #:	987-654-3210
IVF STATUS:	non-IVF pregnancy	REPORT DATE: (MM/DD/YYYY)	07/28/2015
COLLECTION DATE (MM/DD/YYYY) :	07/20/2015		
RECEIVED DATE (MM/DD/YYYY) :	07/21/2015		

Test Results

Fetal cfDNA Percentage: 10.5%

CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	High Probability	Greater than 99/100 (99%)	Genetic counseling and additional testing
Trisomy 18 (T18)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Probability	Less than 1/10,000 (0.01%)	Review results with patient

TEST DESCRIPTION

The Harmony Prenatal Test® measures the relative proportion of chromosomes to aid in the assessment of fetal trisomies 21, 18, and 13. Harmony® performs a directed analysis of cell-free DNA (cfDNA) in maternal blood and incorporates the fetal fraction of cfDNA in test results. Test results also incorporate maternal age (or egg donor age) and gestational age related probability based on information provided on the test requisition form. Probability of less than 1% is defined as low probability and 1% or greater is defined as high probability. Harmony has been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Harmony is not validated for use in pregnancies with more than two fetuses, demised twin, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18. Harmony does not detect neural tube defects. Twin results reflect the probability that the pregnancy involves at least one affected fetus. Analysis of cfDNA does not always correlate with fetal genotype. Not all aneuploid fetuses will have a high probability result and some euploid fetuses will have a high probability result. The Harmony Prenatal Test is not a diagnostic test and results should be considered with other clinical criteria and communicated in a setting that includes appropriate counseling.

CLINICAL DATA

	Detection Rate	False Positive Rate
T21	> 99% (95% CI: 97.9-99.8%)	< 0.1% (95% CI: 0.02-0.08%)
T18	97.4% (95% CI: 93.4-99.0%)	< 0.1% (95% CI: 0.01-0.05%)
T13	93.8% (95% CI: 79.9-98.3%)	< 0.1% (95% CI: 0.01-0.06%)

Detection and false positive (discordant result) rates based on probability cut-off of 1/100 (1%). Because these conditions are rare, limited numbers of aneuploidy twin and egg donor pregnancies have been evaluated. The negative predictive value for trisomy 21, 18, and 13 is greater than 99%. Positive predictive value (PPV) varies by prevalence. The probability result reported is not equivalent to the PPV. For more information regarding PPV refer to: <http://www.harmonytest.com/PPV>

REFERENCES: Stokowski R et al. Prenatal Diagnosis 2015; 35, 1-4; Data on file.

The Harmony Prenatal Test was developed, and its performance characteristics determined, by the Ariosa Diagnostics Clinical Laboratory in San Jose, CA USA, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. This testing service has not been cleared or approved by the US FDA. Harmony is a non-invasive prenatal test (NIPT) 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. Before making any treatment decisions, all women should discuss their results with their healthcare provider, who can recommend confirmatory, diagnostic testing where appropriate.

HARMONY and HARMONY PRENATAL TEST and design are trademarks of Ariosa Diagnostics, Inc. in the US. HARMONY is a trademark of Roche in other countries. All other trademarks are the property of their respective owners.