harmony™
PRENATAL TEST
www.harmonytest.com

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Questions:

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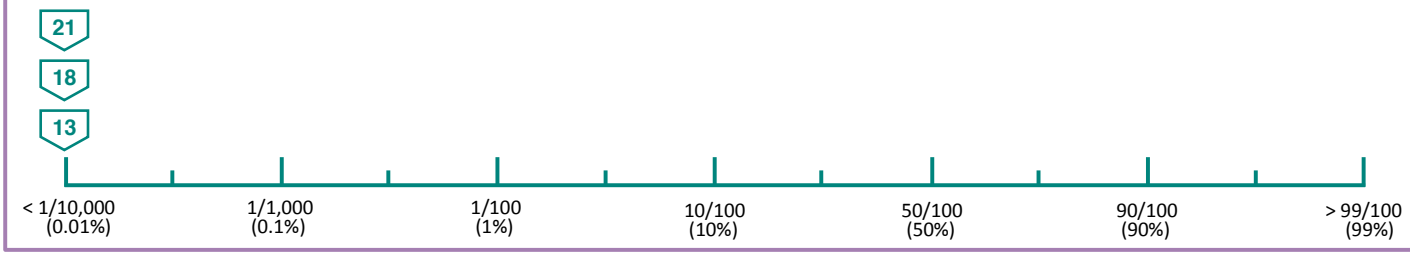
Patient and Provider Information

PATIENT NAME:	Jane Doe
DATE OF BIRTH: (MM/DD/YYYY)	01/01/1970
MRN:	1234567890123456789
LABORATORY ID:	AD12345678-PAT
OTHER ID:	00123456789012345XZY
GESTATIONAL AGE:	10 wks 5 days
# OF FETUSES:	1
IVF STATUS:	non-IVF pregnancy
COLLECTION DATE (MM/DD/YYYY) :	07/20/2015
RECEIVED DATE (MM/DD/YYYY) :	07/21/2015
ACCOUNT #:	7654321
CLINIC NAME:	The Clinic Offering Test
REFERRING/ORDERING CLINICIAN:	Ordering Physician MD
REFERRING/ORDERING CLINICIAN FAX #:	123-456-7890
OTHER CLINICIAN:	Genetic Counselor MA, CGC
OTHER CLINICIAN FAX #:	987-654-3210
REPORT DATE: (MM/DD/YYYY)	07/28/2015

Test Results

Fetal cfDNA Percentage: 10.5%

CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 18 (T18)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient



Fetal Sex **Male**

TEST DESCRIPTION

The Harmony™ Prenatal Tests measure the relative proportion of chromosomes to aid in the risk assessment of fetal trisomies 21, 18, and 13. The laboratory developed tests perform a directed analysis of cell-free DNA (cfDNA) in maternal blood and incorporate the fetal fraction of cfDNA in test results. Test results also incorporate maternal age (or egg donor age) and gestational age related risk based on information provided on the test requisition form. Tests have been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Tests are neither intended nor validated for diagnosis or for use in pregnancies with more than two fetuses, mosaicism, partial chromosome aneuploidy, translocations, or maternal aneuploidy. 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 be classified as high risk and some euploid fetuses will have a high risk result. The Harmony Prenatal Tests are not diagnostic tests and results should be considered with other clinical criteria and communicated in a setting that includes appropriate counseling.

Fetal Sex test quantifies the Y chromosome. A "female" result indicates absence of Y chromosome and a "male" result indicates presence of Y chromosome. It does not exclude sex chromosome aneuploidy. For twin pregnancies, a male result indicates one or two male fetuses.

CLINICAL DATA

	Detection Rate	False Positive Rate
T21	> 99% (95% CI: 97.9-99.8%)	< 0.1% (95% CI: 0.02-0.07%)
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 risk cut-off of 1/100 (1%) and on singleton, non egg donor pregnancies. 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.ariosadx.com

Fetal Sex: > 99% accuracy for male or female sex (95% CI: 99.2-100%)

REFERENCES: Sparks AB et al. Am J Obstet Gynecol 2012; 206:319.e1–9; Norton ME et al. Am J Obstet Gynecol 2012; 207:137.e1–8; Nicolaides KH et al. Am J Obstet Gynecol 2012; 207:374.e1–6; Ashoor G et al. Ultrasound Obstet Gynecol 2013; 41(1):21–5; Verweij EJ et al. Prenat Diagn 2013; 33:996–1001; Gil MM et al. Fetal Diagn Ther 2013; 35:1-6; Juneau K et al. Fetal Diagn Ther 2014; 36:282–6; Norton ME et al. N Engl J Med 2015; 372:1589–97; Data on file.