Harmony™ PRENATAL TEST
www.harmonytest.com

Ariosa Diagnostics, Inc.
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Integrated GENETICS
Laboratory Specialty Testing Group

Questions
(800) 345-4363

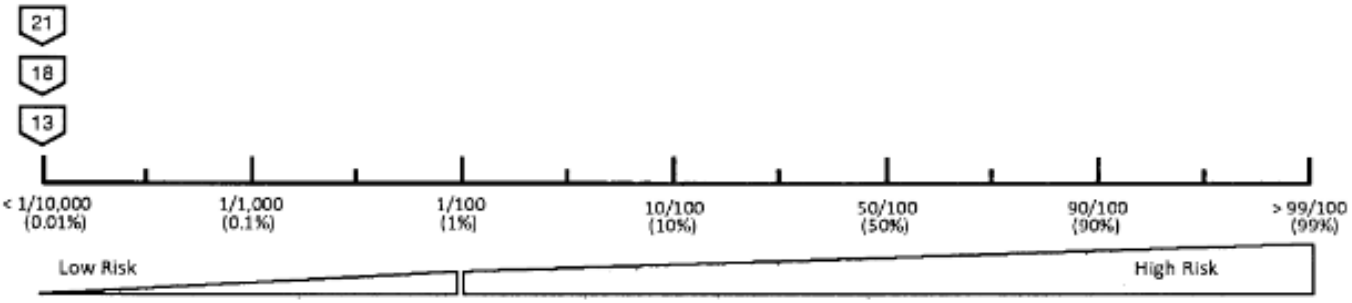
Patient and Provider Information

PATIENT NAME:	ACCOUNT #:
DATE OF BIRTH (MM/DD/YYYY):	CLINIC NAME: SMC Perinatal Medicine
MRN:	REFERRING/ORDERING CLINICIAN: S PETERSON
ARIOSA ID: OTHER ID:	REFERRING/ORDERING CLINICIAN FAX #:
GESTATIONAL AGE: 13 wks 1 days	OTHER CLINICIAN:
# OF FETUSES: 1 IVF STATUS: non-IVF pregnancy	OTHER CLINICIAN FAX #:
COLLECTION DATE (MM/DD/YYYY): 06/19/2014 RECEIVED DATE (MM/DD/YYYY): 06/21/2014	REPORT DATE (MM/DD/YYYY): 06/27/2014

Test Results

Fetal cfDNA Percentage: 15.9%

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	Female Fetus	Greater than 99/100 (99%)	Review results with patient
X,Y Analysis	XX	Greater than 99/100 (99%)	Review results with patient



TEST DESCRIPTION

The Harmony Prenatal Tests measure the relative proportion of chromosomes to aid in the risk determination of fetal trisomies 21, 18, and 13. The Ariosa 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 from 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 chromosomal aneuploidy, translocations, or maternal aneuploidy. 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. Results should be considered with other clinical criteria and communicated in a setting that includes appropriate counseling.

X,Y Analysis measures proportions of the X and Y chromosomes. Fetal sex is reported and the risk of sex chromosomal conditions (Monosomy X, XXY, XYY, XXX, XXYY) are also reported at risks of 1% or greater. X,Y Analysis has only been validated in singleton pregnancies.

CLINICAL DATA

	Detection Rate	False Positive Rate
T21	> 99% (95% CI: 95-100%)	< 0.1% (95% CI: 0.0-0.2%)
T18	> 98% (95% CI: 93-100%)	< 0.1% (95% CI: 0.0-0.3%)
T13	• Given rarity of condition, limited T13 cases analyzed • Detection rate: 8 of 10 with Harmony • False positive rate: < 0.1% (95% CI: 0.0-0.3%)	

Detection and false positive rates based on risk cut-off of 1/100 (1%) and are based on singleton, non egg donor pregnancies. Negative predictive value for Trisomy 21, 18, and 13 is greater than 99%. Positive predictive value varies by prevalence.

X,Y Analysis	>99% accuracy for male or female sex (95% CI: 99.2-100%)

X,Y Analysis also provides probability for non-mosaic fetal sex chromosomal aneuploidies. Test performance varies by condition.

REFERENCES: Norton ME et al. (2012) Am J Obstet Gyn 207(2):137.e1-8, Nicolaides KH et al. (2012) Am J Obstet Gyn 207(5):374.e1-6; Ashoor G et al. (2013) Ultrasound Obstet Gynecol 41(1):21-5, data on file