Harmony™ PRENATAL TEST
www.harmonytest.com

Ariosa DIAGNOSTICS
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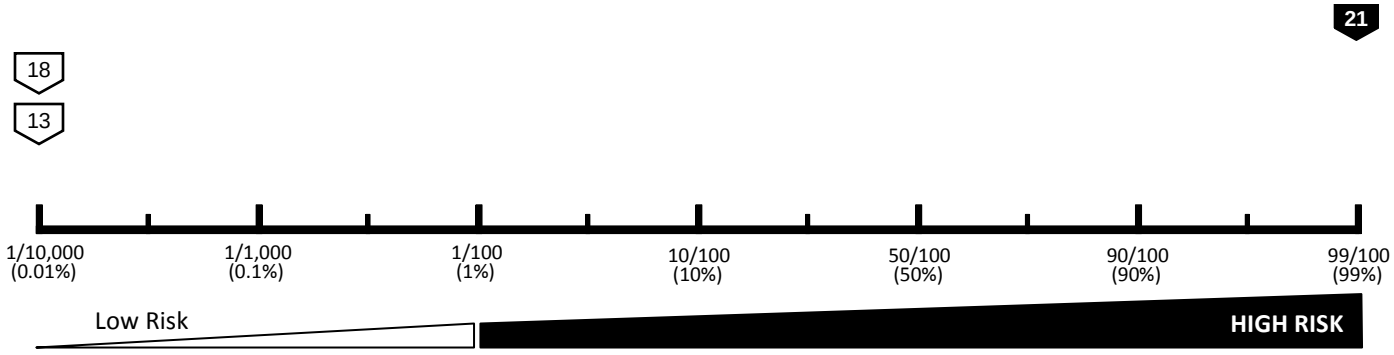
Patient and Provider Information

PATIENT NAME:	Jane Doe
DATE OF BIRTH:	01/01/1970
MRN:	1234567890123456789
SPECIMEN ID:	AD12345678-PAT
GESTATIONAL AGE:	10 wks 5 days
# OF FETUSES:	1
IVF STATUS:	25.0 yr old non-self egg donor
COLLECTION DATE:	01/01/2012
RECEIVED DATE:	01/02/2012
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:	01/10/2012

Test Results

CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	**HIGH RISK**	**Greater than 99/100 (99%)**	**Genetic counseling and additional testing**
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



TEST DESCRIPTION

The Harmony Prenatal Test is a laboratory developed test that analyzes cell-free DNA (cfDNA) in maternal blood. Directed analysis of cfDNA measures the relative proportion of chromosomes. The test is intended to aid in the risk determination of fetal trisomies 21, 18, and 13 in women with singleton pregnancies of at least 10 weeks gestational age. Trisomy test results incorporate maternal age (or egg donor age) and gestational age-related risk and IVF status provided on the test requisition form.

Probability of aneuploidy is based on cfDNA in blood which may not correlate with fetal genotype. The test is neither intended nor validated for diagnosis or use in cases of multiple pregnancy (e.g. twins), mosaicism, partial chromosomal aneuploidy, and translocations. Not all aneuploid fetuses will be detected, and some euploid fetuses may have "HIGH RISK" results. Results should be considered with other clinical criteria. Results should be communicated with appropriate counseling.

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 cut-off of 1/100 (1%)

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. (2012) Ultrasound Obstet Gynecol [epub ahead of print], data on file

Laboratory Director: M. Junaid Shabbeer, PhD, FACMG

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