harmony™
PRENATAL TEST
performed in Germany

cenata
safe method. secure result.

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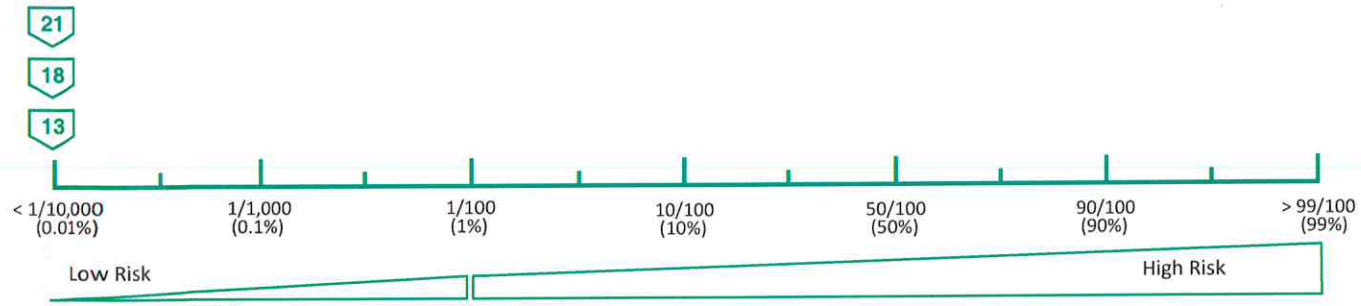
Patient and Provider Information

PATIENT NAME:	ACCOUNT #: -
DATE OF BIRTH: (MM/DD/YYYY)	CLINIC NAME: -
MRN: -	REFERRING/ORDERING CLINICIAN: Freiburg Med.Lab Middle East LLC
ARIOSA ID: 6111898450 / OTHER ID: -	REFERRING/ORDERING CLINICIAN FAX #: -
GESTATIONAL AGE: 12 wks 1 days	OTHER CLINICIAN: -
# OF FETUSES: 1 / IVF STATUS: non-IVF pregnancy	OTHER CLINICIAN FAX #: -
COLLECTION DATE (MM/DD/YYYY): 1/14/16 / RECEIVED DATE (MM/DD/YYYY): 1/19/16	REPORT DATE: (MM/DD/YYYY) 01/22/2016

Test Results

Fetal cfDNA Percentage: 14.1%

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 Fetus	Greater than 99/100 (99%)	Review results with patient
X,Y Analysis	XY	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 assessment 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 provided to Ariosa 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.

X,Y Analysis measures proportions of the X and Y chromosomes. The probability of sex chromosome conditions (Monosomy X, XXY, XYY, XXX, XXYY) are reported at risks of 1% or greater. A XYY or XXYY result indicates two or more fetal Y chromosomes. 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 (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 prengnacies 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

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 chromosome aneuploidies. Test performance varies by condition. Because limited numbers of sex chromosome aneuploidy cases have been evaluated to date, performance claims have yet to be established

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, Gil MM et al. (2013) Fetal Diagn Ther DOI:10.1159/000356495, Nicolaides KH et al. (2014) Fetal DiagnTher;35:1-6;

The Harmony Prenatal Tests are intended for clinical use and should not be regarded as investigational or for research. The tests have been developed, and the performance characteristics determined, by the Ariosa Diagnostics Clinical Laboratory, which is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing. The Harmony Prenatal tests have not been cleared or approved by the U.S. Food and Drug Administration.