Harmony™ PRENATAL TEST

Harmony Prenatal Test Sample Reports

A simple, safe blood test

- Highly accurate, individualized results for you, your practice and patients[1-6]
- Performed anytime after 10 weeks' gestation
- Lowest cumulative false positive rate[1-6]

www.harmonytest.com

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San Jose, CA 95138

For Questions:

clientservices@ariosadx.com

US: (855) 927-4672

Intl: +1 (925) 854-6246

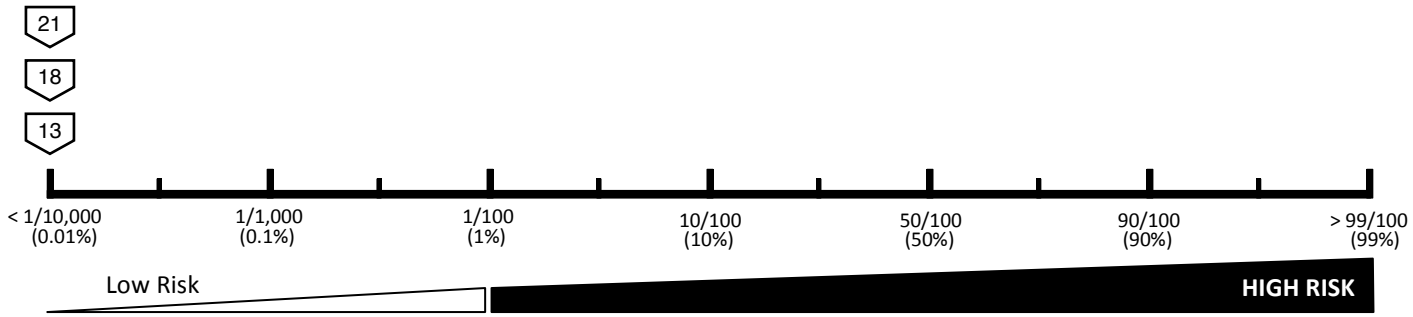
Patient and Provider Information

PATIENT NAME:	Jane Doe
DATE OF BIRTH:	01/01/1970
MRN:	1234567890123456789
ARIOSA ID:	AD12345678-PAT
OTHER ID:	00123456789012345XZY
GESTATIONAL AGE:	10 wks 5 days
# OF FETUSES:	1
IVF STATUS:	non-IVF pregnancy
COLLECTION DATE:	01/20/2013
RECEIVED DATE:	01/21/2013
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:	01/28/2013

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



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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.

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CLIA # 05D2032812 STATE # CLF 341864

Laboratory Director: M. Junaid Shabbeer, PhD, FACMG

TP-00115-F1 Rev 9.0

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Test Results

Fetal cfDNA Percentage: 10.5%

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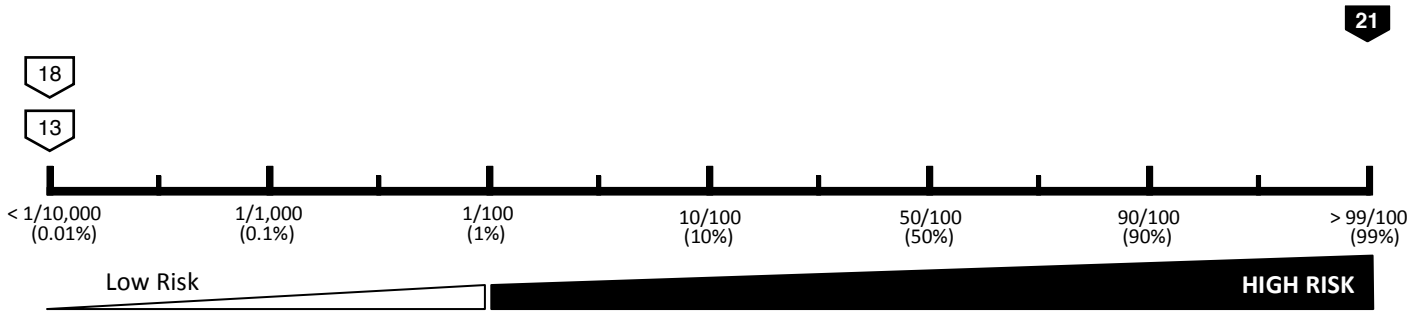

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GESTATIONAL AGE: 10 wks 5 days	REFERRING/ORDERING CLINICIAN FAX #: 123-456-7890
# OF FETUSES: 2	IVF STATUS: 25.0 yr old non-self egg donor
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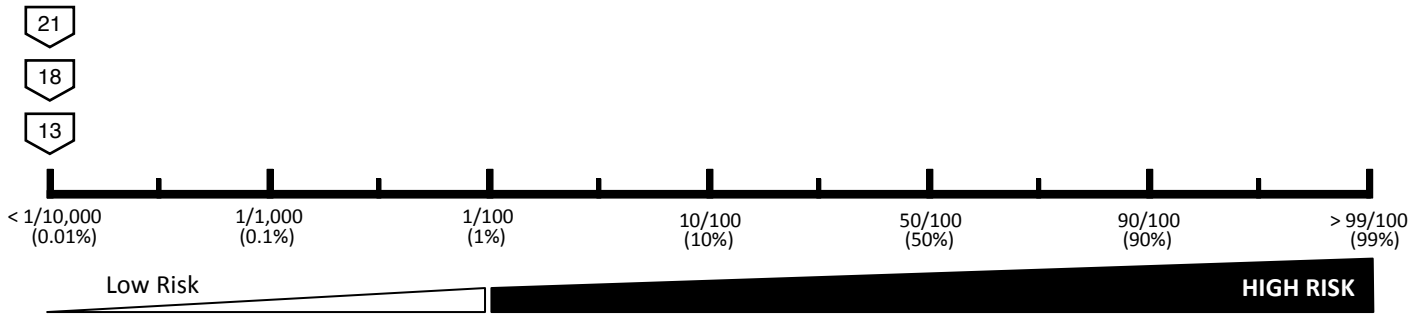

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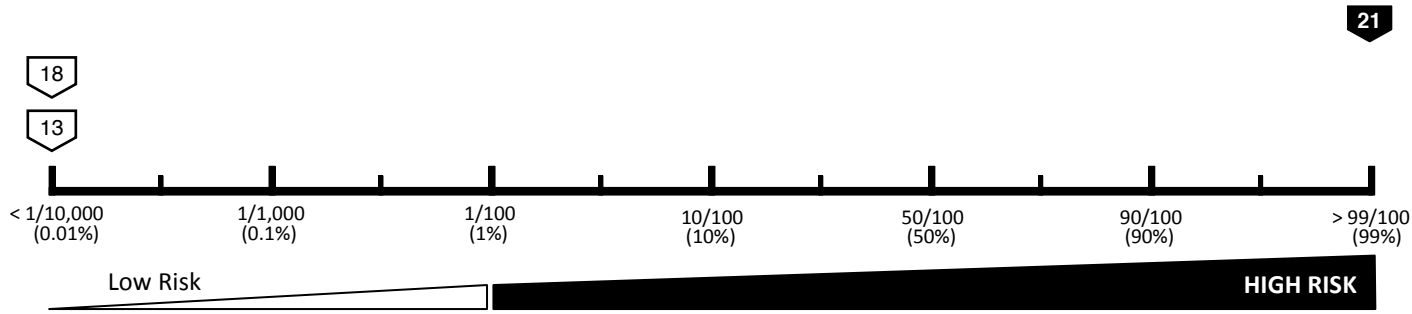
CHROMOSOME	RESULT	PROBABILITY	RECOMMENDATION
Trisomy 21 (T21)	**High Risk**	**Greater than 99/100 (99%)**	**Genetic counseling and additional testing**
Trisomy 18 (T18)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Risk	Less than 1/10,000 (0.01%)	Review results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



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Y Analysis provides no information on the X chromosome. A "Female Fetus" result indicates a lack of significant Y chromosome sequences and does not exclude Monosomy X. A "Male Fetus" result does not exclude XXY. A Y "Aneuploidy" result indicates two or more fetal Y chromosomes. This test 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

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Detection and false positive rates based on risk cut-off of 1/100 (1%) and are based on singleton, non egg donor pregnancies.

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

Y Analysis also provides probability for non-mosaic Y aneuploidy.

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*

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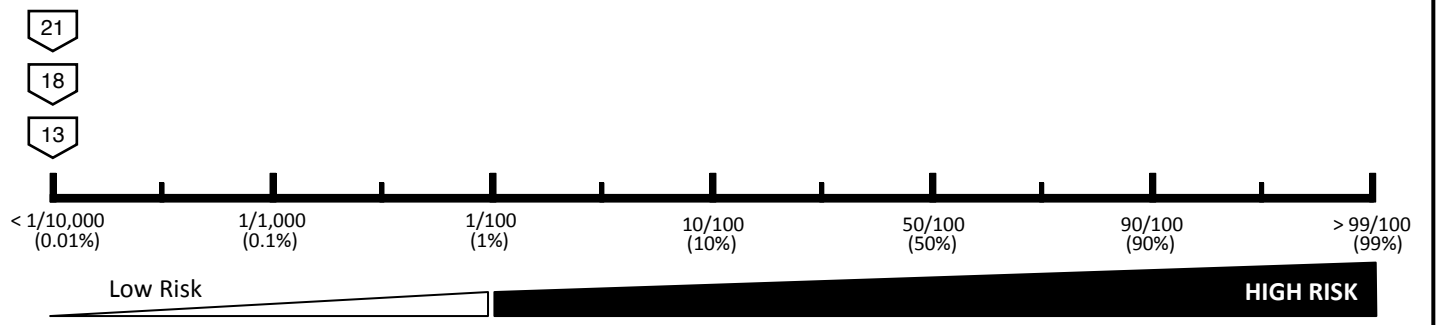
Trisomy 21 (T21)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 18 (T18)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Trisomy 13 (T13)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Fetal Sex	Female Fetus	Greater than 99/100 (99%)	Review results with patient
X,Y Analysis	XX	Greater than 99/100 (99%)	Review results with patient



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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 evaluated. The test has only been validated in singleton pregnancies.

CLINICAL DATA

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T21	>99% (95% CI: 95-100%)	<0.1% (95% CI: 0.0-0.2%)
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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*

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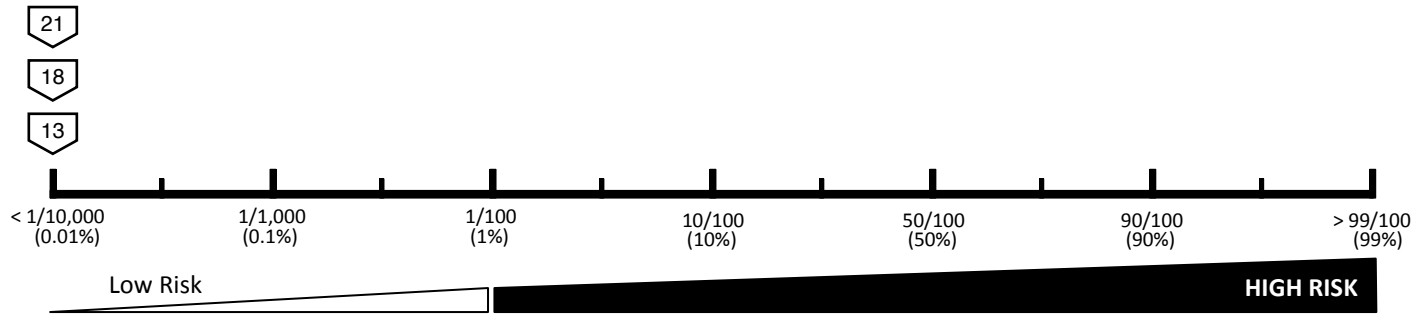
Trisomy 13 (T13)	Low Risk	Less than 1/10,000 (0.01%)	Review results with patient
Fetal Sex	Female Fetus	Greater than 99/100 (99%)	Review results with patient
X,Y Analysis	Monosomy X	Greater than 99/100 (99%)	Genetic counseling



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For Questions:

clientservices@ariosadx.com

US: (855) 927-4672

Intl: +1 (925) 854-6246

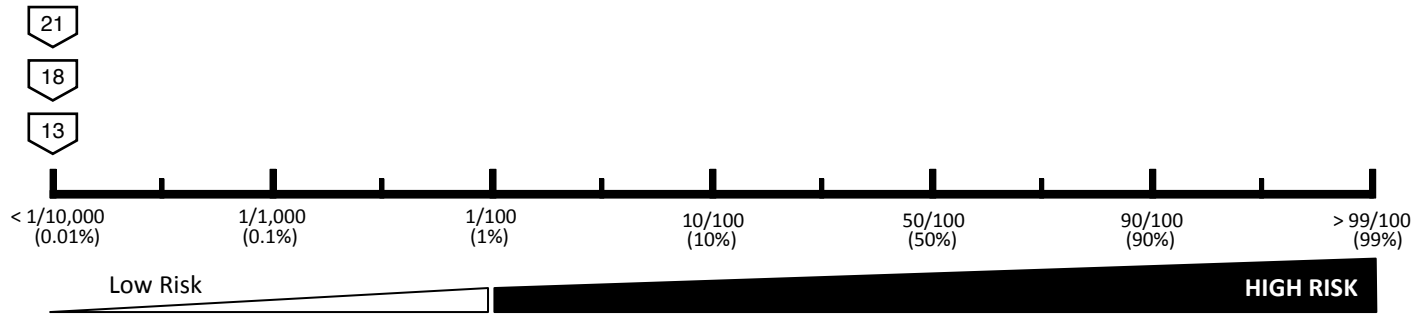
Patient and Provider Information

PATIENT NAME: Jane Doe	ACCOUNT #: 7654321
DATE OF BIRTH: 01/01/1970	CLINIC NAME: The Clinic Offering Test
MRN: 1234567890123456789	REFERRING/ORDERING CLINICIAN: Ordering Physician MD
ARIOSA ID: AD12345678-PAT / OTHER ID: 00123456789012345XZY	REFERRING/ORDERING CLINICIAN FAX #: 123-456-7890
GESTATIONAL AGE: 10 wks 5 days	OTHER CLINICIAN: Genetic Counselor MA, CGC
# OF FETUSES: 1 / IVF STATUS: non-IVF pregnancy	OTHER CLINICIAN FAX #: 987-654-3210
COLLECTION DATE: 01/20/2013 / RECEIVED DATE: 01/21/2013	REPORT DATE: 01/28/2013

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 Fetus	Greater than 99/100 (99%)	Review results with patient
X,Y Analysis	XXY	Greater than 99/100 (99%)	Genetic counseling



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 detected and some euploid fetuses may have high probability results for aneuploidy. 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 evaluated. The test 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.

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*

The Harmony Prenatal Test is intended for clinical use and should not be regarded as investigational or for research. It was developed, and its 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 test has not been cleared or approved by the U.S. Food and Drug Administration.

CLIA # 05D2032812 STATE # CLF 341864

Laboratory Director: M. Junaid Shabbeer, PhD, FACMG

TP-00115-F1 Rev 9.0

Harmony™ PRENATAL TEST
www.harmonytest.com

Ariosa DIAGNOSTICS
Ariosa Diagnostics, Inc.
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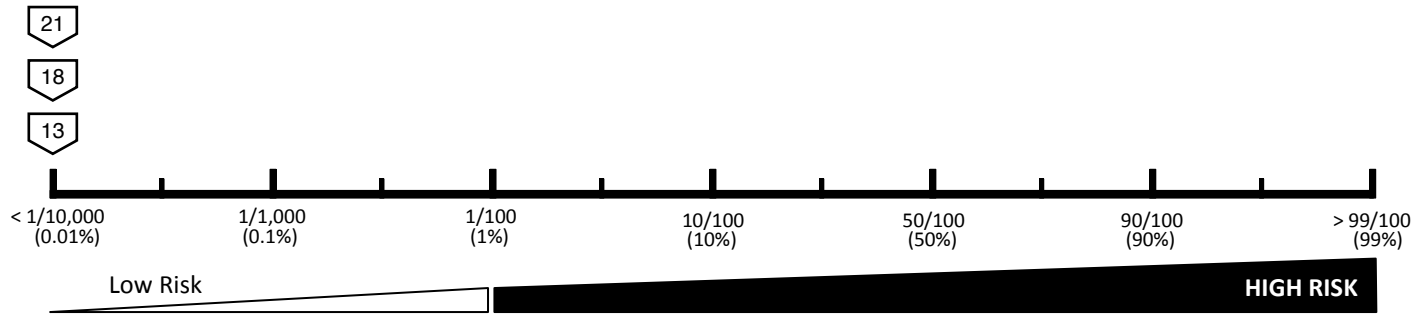
X,Y Analysis	XXX	Greater than 99/100 (99%)	Genetic counseling



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CLIA # 05D2032812 STATE # CLF 341864

Laboratory Director: M. Junaid Shabbeer, PhD, FACMG

TP-00115-F1 Rev 9.0

SAMPLE TEST REQUISITION FORM

Ordering Lab Specimen ID

Harmony™ PRENATAL TEST

Place the -PAT barcode label here

1 Patient Information

First Name

Last Name

Street Address

City | State/Province

Country | ZIP/Postal Code

Phone:

Medical Record Number | Gender ☐ Female ☐ Male

Weight (lbs.) | Height (ft./in)

2 Clinic Information

Account number | Clinic Name

Ordering Clinician

Street Address

City | State/Province

Country | ZIP/Postal Code

Phone | Fax

Referring Clinician (Copy of Results)

Referring Clinician Fax

3 Patient Consent

My signature on this form indicates that I have read, or had read to me, the informed consent on the back of this form, and I understand it. I have had the opportunity to ask questions and discuss the test, including the purposes and possible risks, with my healthcare provider or someone my healthcare provider has designated. I know that I may obtain professional genetic counseling if I wish, before signing this consent. I give permission to Ariosa Diagnostics to perform the Harmony Prenatal Test.

Details on Ariosa's policies and procedures governing patient privacy and health information, including patient rights regarding such information, can be found at www.ariosadx.com/patient

Patient Signature Year | Month | Day

4 Clinician Signature

ally necessary to e the results to guide care. I attest that ed about, and ha

linician Signature Day

Evaluates the risk of trisomies 21, 18, and 13

Check this box to request the evaluation of X & Y chromosomes, which can provide information on fetal sex and sex chromosome aneuploidy

Check this box to request the evaluation of Y chromosome, which can provide information on fetal sex and Y aneuploidy

5 Required Test Information

☑ Harmony Prenatal Test ☐ With Y Analysis ☐ With X, Y Analysis

Collection Date Year | Month | Day

Is this a redraw? ☐ Yes ☐ No

Month | Day

_____ Days Determined by: ☐ U/S ☐ LMP ☐ IVF

☐ >2 IVF Pregnancy: ☐ Yes ☐ No

Egg Donor is ☐ Self ☐ Non-self Age at retrieval: _____ years

6 Billing Information

☐ Bill Clinic ☐ Bill Patient

Ariosa DIAGNOSTICS

ADCLIA

5945 Optical Court I San Jose I California I USA
Client Services +1 925 854 6246
CLIA #05D2032812 I CAP #8035656

TP-00056-F1 Rev 7.1 Effective Date 08/03/2013

All three options are available for singleton pregnancies.

Harmony with Y and Harmony with X,Y are not available for twin pregnancies.

Harmony™
PRENATAL TEST
www.harmonytest.com

Ariosa®
DIAGNOSTICS

Customer Service: 1-855-9-ARIOSA (855-927-4672)