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 (kg) | Height (cm)

2 Clinic Information

Account number 16624 | Clinic Name Canberra Fetal Assessment Centre

Ordering Clinician Dr Meiri Robertson Dr Ken Tan

Street Address 1/21 Napier Close

Deakin

City Canberra | State/Province ACT

Country Australia | ZIP/Postal Code 2600

Phone 02 6162 1649 | Fax 02 6162 1659

Referring Clinician (Copy of Results)

Referring Clinician Fax

3 Patient Informed 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.

☐ Check to opt-out of laboratory studies and the patient registry (described on page 2)

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

I attest that this patient has been informed about details of the test and its capabilities and limitations, and has given consent for this test.

Clinician Signature | Year | Month | Day

5 Required Test Information

☑ Harmony Prenatal Test
☐ with Y Analysis*
☐ with X,Y Analysis*
* Singletons only

Draw Date | Year | Month | Day

Is this a redraw? ☐ Yes ☐ No

Mother's Birthdate | Year | Month | Day

Gestational Age _____weeks _____days | Measured on | Year | Month | Day | by: ☐ U/S ☐ LMP ☐ IVF

LMP Date | Year | Month | Day

EDD/EDC Date | Year | Month | Day | by: ☐ U/S ☐ LMP ☐ IVF ☐ PE

CRL ____mm

# of Fetuses ☐ 1 ☐ 2

IVF Pregnancy ☐ Yes ☐ No

Egg Donor is ☐ Self ☐ Non-self

Age at retrieval: _____ years

Clinical Indications
☐ Advanced maternal age (>35) (V23.81-23.82)
☐ Positive maternal serum screen (796.5)
☐ Ultrasound abnormality (V28.3)
☐ Other antenatal screening (V28.89)
☐ Other genetic screening (V82.79)
☐ Other (specify): _____

6 Billing Information

■ Bill Clinic ☐ Bill Patient

Ariosa® DIAGNOSTICS

ADCLIA

5945 Optical Court | San Jose | California | USA
Client Services | (855) 927-4672 US | +1 925 854 6246 Intl
CLIA #05D2032812 | CAP #8035656

harmony™
PRENATAL TEST

Patient Informed Consent

The Harmony Prenatal Test is a laboratory-developed test that analyzes fetal cell-free DNA (cfDNA) in maternal blood to aid in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13. The term "trisomy" refers to a chromosomal condition that occurs when there are three copies of a particular chromosome instead of the expected two.

- Trisomy 21 is due to an extra copy of chromosome 21. Trisomy 21 causes Down syndrome. Infants born with Down syndrome may have mild to moderate intellectual disabilities, a heart defect or other medical conditions. It is estimated that Down syndrome is present in 1 out of every 740 newborns.

- Trisomy 18 is due to an extra copy of chromosome 18. Trisomy 18 causes Edwards syndrome and is associated with a high rate of miscarriage. Infants born with Edwards syndrome may have various medical conditions and a shortened lifespan. It is estimated that Edwards syndrome is present in approximately 1 out of every 5000 newborns.

- Trisomy 13 is due to an extra copy of chromosome 13. Trisomy 13 causes Patau syndrome and is associated with a high rate of miscarriage. Infants born with Patau syndrome may have severe congenital heart defects and other medical conditions. Survival beyond the first year is rare. It is estimated that Patau syndrome is present in approximately 1 out of every 16,000 newborns.

Eligible patients are of at least 10 weeks' gestational age with a singleton or twin pregnancy resulting from natural conception or in vitro fertilization (IVF). Patients who are pregnant with more than two fetuses are not eligible for the Harmony Prenatal Test. The test is not intended nor validated for diagnosis, detection of mosaicism, partial trisomy, or translocations. Clinical studies demonstrate high accuracy for fetal trisomy detection, but not all trisomy fetuses will be detected. Some trisomy fetuses may have "LOW RISK" results. Some euploid (not trisomic) fetuses may have "HIGH RISK" results. Results should be considered in the context of other clinical criteria. It is recommended that a HIGH RISK result and/or other clinical indications of a chromosomal abnormality be confirmed through fetal karyotype analysis by invasive procedure such as amniocentesis. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

The Harmony Prenatal Test with Y analysis is a laboratory-developed test that aids in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13, and evaluates Y chromosome sequences, providing information on fetal sex and Y chromosome aneuploidy. Eligible patients are of at least 10 weeks' gestational age with a singleton pregnancy resulting from natural conception or IVF. Patients who are pregnant with more than one fetus are not eligible for the Harmony Prenatal Test with Y analysis. The test is not intended nor validated for diagnosis, detection of mosaicism, partial aneuploidy, or translocations. Results should be considered in the context of other clinical criteria. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

The Harmony Prenatal Test with X and Y analysis is a laboratory-developed test that aids in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13 and evaluates X and Y chromosome sequences, providing information on fetal sex and sex chromosome aneuploidy. Eligible patients are of at least 10 weeks' gestational age with a singleton pregnancy resulting from natural conception or IVF. Patients who are pregnant with more than one fetus are not eligible for the Harmony Prenatal Test with X and Y analysis. The test is not intended nor validated for diagnosis, detection of mosaicism, partial trisomy, or translocations. Results should be considered in the context of other clinical criteria. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling.

No additional clinical testing will be performed on my blood sample other than those authorized by my healthcare provider. Ariosa Diagnostics, Inc. will disclose the test results only to the healthcare provider listed on the front of this form, or to his/her agent, unless otherwise authorized by me or as required by laws, regulations, or judicial order.

Unless you check the opt-out box on the front page, you acknowledge and agree that after the completion of your selected test(s), the remaining unused portion of your sample may be anonymized and stored for longer than 60 days for use in internal laboratory validation, process development, and/or quality control studies at Ariosa. In addition, your results may be included in a confidential data registry to validate the performance of Ariosa's tests and to assist Ariosa with improving its services to patients. In all cases, your samples and results will be stored, used, and destroyed in compliance with applicable US laws, rules, and regulations.

It is standard of care for physicians to obtain informed consent for genetic testing. This form is designed to address the requirements of New York State Civil Rights Law Section 79-1 and Massachusetts General Law Chapter 111, Section lOG