

Ordering Lab
Specimen ID



Place the
-PAT barcode
label here

1 Patient Information		2 Clinic Information				
First Name		Account number	Clinic Name			
Last Name		Ordering Clinician				
Street Address		Street Address				
City	State/Province	City	State/Province			
Country	ZIP/Postal Code	Country	ZIP/Postal Code			
Phone:		Phone	Fax			
Medical Record Number	Gender <input type="checkbox"/> Female <input type="checkbox"/> Male	Referring Clinician (Copy of Results)				
Weight (kg)	Height (cm)	Referring Clinician Fax				
3 Patient Informed Consent						
<p>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.</p> <p><input type="checkbox"/> Check to opt-out of laboratory studies and the patient registry (described on page 2)</p> <p><i>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</i></p> <p>Patient Signature _____</p> <table border="1"><tr><td>Year</td><td>Month</td><td>Day</td></tr></table>				Year	Month	Day
Year	Month	Day				
4 Clinician Signature						
<p>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.</p> <p>Clinician Signature _____</p> <table border="1"><tr><td>Year</td><td>Month</td><td>Day</td></tr></table>				Year	Month	Day
Year	Month	Day				
5 Required Test Information						
<input checked="" type="checkbox"/> Harmony Prenatal Test <input type="checkbox"/> with Y Analysis* <input type="checkbox"/> with X,Y Analysis* * Singletons only						
Draw Date	Year Month Day	Is this a redraw? <input type="checkbox"/> Yes <input type="checkbox"/> No	Mother's Birthdate Year Month Day			
Gestational Age _____ weeks _____ days	Measured on Year Month Day	by: <input type="checkbox"/> U/S <input type="checkbox"/> LMP <input type="checkbox"/> IVF				
LMP Date Year Month Day	EDD/EDC Date Year Month Day	by: <input type="checkbox"/> U/S <input type="checkbox"/> LMP <input type="checkbox"/> IVF <input type="checkbox"/> PE	CRL _____ mm			
# of Fetuses <input type="checkbox"/> 1 <input type="checkbox"/> 2	IVF Pregnancy <input type="checkbox"/> Yes <input type="checkbox"/> No	Egg Donor is <input type="checkbox"/> Self <input type="checkbox"/> Non-self	Age at retrieval: _____ years			
Clinical Indications <input type="checkbox"/> Advanced maternal age (>35) (V23.81-23.82) <input type="checkbox"/> Positive maternal serum screen (796.5)	<input type="checkbox"/> Ultrasound abnormality (V28.3) <input type="checkbox"/> Other antenatal screening (V28.89)	<input type="checkbox"/> Other genetic screening (V82.79) <input type="checkbox"/> Other (specify): _____				
6 Billing Information						
<input type="checkbox"/> Bill Clinic <input type="checkbox"/> Bill Patient						



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TP-00056-F1 Rev 9.1 Effective Date 11/10/2014



harmony™

PRENATAL TEST

Patient Informed Consent

The Harmony Prenatal Test is a laboratory-developed test that analyses fetal cell-free DNA (cfDNA) in maternal blood to aid in the risk determination of foetal 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 fetus 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 foetal 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 counselling.

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 foetal 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 counselling.

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 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 X and 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 counselling.

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 IOG



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