Harmony™ PRENATAL TEST

Place the PAT barcode label here

Patient Information

FIRST NAME

LAST NAME:

STREET ADDRESS:

CITY: | STATE/PROVINCE:

COUNTRY: | ZIP/POSTAL CODE:

PHONE:

MEDICAL RECORD NUMBER:

GENDER: ☒ FEMALE ☐ MALE

Weight: _____**** lbs. or _____ kg
Height: _____**** ft/in or _____ m

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

DATE YEAR | MONTH | DAY

Billing Information

☒ BILL CLINIC ☐ BILL PATIENT

Ordering Lab Specimen ID

Clinic Information

Account Number

CLINIC NAME: Fugene Genetics

ORDERING CLINICIAN:

STREET ADDRESS: 43 Brodezky st.

CITY: Tel Aviv | STATE/PROVINCE:

COUNTRY: Israel | ZIP/POSTAL CODE: 6905235

PHONE: 972-3-7620606 | FAX: 972-3-7620609

REFERRING CLINICIAN (COPY OF RESULTS):

REFERRING CLINICIAN FAX:

Required Test Information

☑ HARMONY PRENATAL TEST

☐ With Y Analysis ☐ With X,Y Analysis

- **Is this a redraw?** ☐ Yes ☐ No
- **Mother's birthdate:** YEAR | MONTH | DAY
- **Gestational Age:** _____**wks** _____ **days**
  - ***Determined by:*** ☐ ***U/S*** ☐ ***LMP*** ☐ ***IVF***
- **# of fetuses:** ☐ **1** ☐ **2** ☐ **>2**
- **IVF pregnancy:** ☐ **Yes** ☐ **No**
  - ***If IVF, egg donor is:*** ☐ ***Self*** ☐ ***Non-self***
  - ***Donor age at retrieval:*** _____ ***years***

I deem this test to be medically necessary to assess the risk of fetal aneuploidy and will use the results to guide care. I attest that this patient has been informed about, and has given consent for, the test.

CLINICIAN SIGNATURE

DATE YEAR | MONTH | DAY

Specimen Information

COLLECTION DATE YEAR | MONTH | DAY

Ariosa DIAGNOSTICS

5945 Optical Court
San Jose, CA 95138
U.S.A
www.ariosadx.com
CLIA #05D2032812
CAP #8035656

✆ 1-855-9-ARIOSA (1-855-927-4672)
✆ International customers: +1 (925) 854-6246

ADCLIA

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. Directed analysis of purified cfDNA measures the relative proportion of chromosomes.

The test is intended to aid in the risk determination of fetal trisomy 21, trisomy 18, and trisomy 13 in women with singleton or twin pregnancies of at least 10 weeks gestational age. It is not intended for a twin pregnancy that resulted from a non-self egg donor.

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** 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.

The Harmony Prenatal Test is a screening test and is not intended nor validated for diagnosis. 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 (e.g. Amniocentesis). It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counseling. The test is not intended for use in pregnancies with more than two fetuses and has not been validated to detect mosaicism, partial trisomy or translocations.

The Harmony Prenatal Test with Y analysis is a screening test and offers evaluation for chromosome Y in addition to chromosomes 21, 18, and 13. The test is not intended nor validated for diagnosis. This laboratory-developed test evaluates Y chromosome sequences, providing information on fetal sex and Y aneuploidy. 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 Y analysis is validated for use in singleton pregnancies only.

The Harmony Prenatal Test with X and Y analysis is a screening test and offers evaluation for chromosomes X and Y in addition to chromosomes 21, 18, and 13. The test is not intended nor validated for diagnosis. This laboratory-developed test evaluates the X and Y chromosome sequences, providing information on fetal sex and sex chromosome aneuploidy. 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,Y analysis is validated for use in singleton pregnancies only.

No further clinical testing will be performed and reported 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.

It is standard of care far 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.