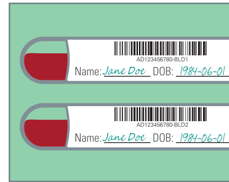
harmony™ PRENATAL TEST

Completing the Harmony Prenatal Test Requisition Form (TRF)

COMPLETE ALL REQUIRED TRF FIELDS TO ENSURE ON-TIME REPORT DELIVERY.



Barcodes and Patient Identifiers

Required:

- Place the PAT barcode label in the upper right corner of the TRF.
- Write the patient's full name and date of birth on the barcoded collection tube labels.
- The identifiers on the tube (barcode, patient name, date of birth) must match the barcode, patient name, and date of birth on the TRF.
- Place one label lengthwise onto each of the two blood tubes.

Patient Information

Required:

- Patient's full name
- Date of birth

Clinical Information

Required:

- Account Number, Account Name and Ordering Clinician

Clinical Signature

Required:

- Clinician signature and date

Patient Consent

Required:

- Patient signature and date

Required Test Information

Required:

- All fields
- To report fetal sex, select the Fetal Sex test option.
- If reporting for sex chromosome aneuploidy is desired, select either Monosomy X or Sex Chromosome Aneuploidy Panel (includes Monosomy X).
- Gestational age (Only one measurement required)
  - For ultrasounds, use option A, specifying gestational age (weeks/days) and ultrasound date.
  - If providing LMP, EDD, or IVF date, choose option B.

Important:

- Fetal Sex option: Singleton or twin pregnancies
- Monosomy X or Sex Chromosome Aneuploidy Panel: Singletons only
- For all IVF pregnancies, specify age of egg at time of transfer and source of egg used in transfer (patient or donor)

Billing Information

Required:

- Select one billing option

Important Blood Draw Information

Required:

- Fill in the blood collection date here

Sample TRF

harmony™ PRENATAL TEST

Ordering Lab Specimen ID — Optional

Place the -PAT barcode label here

Patient Information

Patient Name (Last, First) Doe, Jane
Date of Birth 1984/06/01
Address 1 Main Street
City/State or Province San Jose CA
Country/Postal Code USA 95138
Phone (408) 555-1212 Medical Record Number 12346
Gender ☒ Female ☐ Male
Weight (kg) 145 Height (m) 5'6"

Patient Signature for 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. I understand the informed consent and give permission to Ariosa to perform the laboratory tests selected. I have had the opportunity to ask questions and discuss the capabilities, limitations, and possible risks of the test(s) with my healthcare provider or someone my healthcare provider has designated. I know that if I wish, I may obtain professional genetic counseling before signing this consent.

I expressly agree and give permission for my personal data included in this test requisition form (including, without limitation, my name, address, information about my pregnancy, and other relevant information), as well as my blood sample, to be shipped and transmitted to Ariosa in the United States for the purpose of performing the Harmony test(s). In the event I withdraw my consent or request not to receive the results of the Harmony test(s), Ariosa will use commercially reasonable efforts to promptly destroy my blood sample in compliance with applicable US laws and regulations, and Ariosa's standard protocols for sample destruction. I agree that in the event Ariosa performs the Harmony test(s) selected on this form, Ariosa may store my personal data (including my test results) and remaining sample (if any) for the applicable legally required time period.

☒ Opt-In ☐ Opt-Out
Check to indicate whether you consent to anonymized laboratory development and validation studies. If you check the opt-in box, you acknowledge and agree that after the completion of your selected test(s), your personal data (including, without limitation, information included on the test requisition form and test results) and the remaining unused portion of your sample, which may be stored for longer than 60 days, will be anonymized and may be used in laboratory validation, process development, and/or quality control studies at Ariosa, its affiliates, or a third party. If you do not check the opt-in box, your personal data and the remaining unused portion of your sample will not be used in laboratory development or validation studies. In all cases, patient samples and personal data, including results will be stored, used, and destroyed in compliance with applicable US, Federal, and state laws, rules, and regulations.

Patient Signature Jane Doe
Date 2015/06/10

Billing Information

● Credit Card
○ Client/Provider

Clinic Information

Account Number 12346 Account Name Ob-Gyn Specialists
Ordering Clinician Janice Smith, M.D.
Address 1 Oak Street
City/State or Province San Jose CA
Country/Postal Code USA 95138
Phone (408) 555-1000
Referring Clinician Jennifer Jones, MS, CGC

Clinician Signature

I attest that my patient has been fully informed about details, capabilities, and limitations of the test(s). The patient has given full consent for this test.

Clinician Signature Janice Smith MD
Date 2015/06/10

Test Menu Options and Clinical Information

☑ Harmony Prenatal Test (T21, T18, T13)
Please mark any additional test options requested:
☐ Fetal Sex
☐ Monosomy X (Singletons only)[1]
☐ Sex Chromosome Aneuploidy Panel (Singletons only)[1]
[1]Fetal sex not reported

Gestational Age, choose A or B:
A. 10 weeks 3 days measured on 2015/06/10
B. ○ LMP ○ EDD ○ IVF Date YYYY/MM/DD
Number of Fetuses ● 1 ○ 2
IVF Pregnancy? ○ No ● Yes → Egg used in IVF: ● Patient ○ Donor; Patient/donor age at egg retrieval: 31 Years

Important Blood Draw Information

Complete A & B:
A. Collection Date 2015/06/10
B. Write the patient's full name and date of birth on tube barcodes. Name, barcode, and date of birth must match the TRF. Place labels lengthwise on the blood tubes as shown in the example.

TP-I

Ariosa DIAGNOSTICS

Questions? Please contact Ariosa Diagnostics Client Services
+1 925 854 6246 clientservices@ariosadx.com
www.HarmonyTest.com

5945 Optical Court
San Jose, California, USA
CLIA #05D2032812 | CAP #8035656

WI-00504-081015-Rev2.0

© 2015 Ariosa Diagnostics, Inc. All Rights Reserved.

ARIOSA, the Ariosa Logo, ARIOSA DIAGNOSTICS, the Ariosa Diagnostics Logo, HARMONY PRENATAL TEST and HARMONY are trademarks or registered trademarks of Ariosa Diagnostics, Inc. in the U.S.A. and other countries. All other trademarks are the property of their respective owners.