GERMANO DE SOUSA
CENTRO DE MEDICINA LABORATORIAL

harmony™
PRENATAL TEST

Ordering Lab Specimen ID
Optional

Place the -PAT barcode label here

Patient Information

Patient Name (Last, First)

Date of Birth YYYY/MM/DD

Address

City/State or Province

Country/Postal Code

Phone

Medical Record Number

Gender ☐ Female ☐ Male

Weight (kg) | Height (m)

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 test(s) 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, as well as my blood sample, to be shipped and transmitted to Ariosa for the purposes of performing the Harmony test(s). I understand and agree to allow my personal data to be processed and stored by Ariosa and its sub-processors in accordance with the information provided on the back of this form and on the Ariosa Privacy Notice, also available at www.ariosadx.com/privacy-policy. I agree to allow my personal data and blood samples to be transferred outside of my country for testing and I understand that this may mean that my personal data will be processed in a country that does not provide the same level of privacy protection as my own. I understand that such a transfer is required in order to perform the Harmony test(s). I understand that failure to consent to the use and processing of my personal data by Ariosa and its sub-processors means that I will be unable to take the Harmony test(s).

Patient Signature

Date YYYY/MM/DD

Opt-In for Sample Retention for Study or Research Use

☐ Opt-In
I understand that if I choose to opt in and allow Ariosa to use my unused sample in this manner, any information that can identify me will be removed. I understand that my unused sample will be stored with some of the non-identifiable clinical data Ariosa or its affiliates received from me (such as number of fetuses).

I understand that if I do not opt in, I will still be able to take the Harmony test(s). If I do not opt in, my unused samples will not be used for these purposes and will be destroyed in accordance with Ariosa's policies and procedures. In all cases, my sample and personal data, including my test results, will be stored, used, and destroyed in compliance with applicable laws, rules, and regulations.

Clinic Information

Account Number 17511:78

Roche Customer ID 3308504960

Account Name CT MEDICINA LAB GERMANO SOUSA SA

Ordering Clinician

Address

City/State or Province

Country/Postal Code

Phone

Referring Clinician

Clinician Signature

I attest that my patient has been fully informed about the capabilities, limitations, and possible risks of the test(s). The patient has given full consent for this test. The tests ordered are medically necessary and will assist in determining the patient's medical management and treatment options. The person listed as the Ordering Clinician is legally authorized to order the test(s) requested herein.

Clinician Signature

Date YYYY/MM/DD

Test Menu Options and Clinical Information

☐ Harmony Prenatal Test (T21, T18, T13)

Please mark any additional test options requested:
- ☐ Fetal Sex
- ☐ Monosomy X[1,2]
- ☐ Sex Chromosome Aneuploidy Panel[1,2]
- ☐ 22q11.2[1]

[1]Singletons only [2]Fetal sex not reported

Gestational Age, choose A or B:

A. ____weeks ____days measured on YYYY/MM/DD

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: ____ Years

Important Blood Draw Information

Complete A & B:

A. Collection Date YYYY/MM/DD

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.

I authorize the sending of the results to the doctor indicated by me

_____

Ariosa DIAGNOSTICS
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Serviços ao Cliente | (855) 927-4672
CLIA #05D2032812 | CAP #8035656

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Mod. 80.05_EN

Patient Informed Consent

The Harmony Prenatal Test is a laboratory-developed screening test that analyzes cell-free DNA (cfDNA) in maternal blood. The test provides a probability assessment, not a diagnosis, of fetal chromosomal or genetic conditions, and fetal sex determination. Consider Harmony results in the context of other clinical criteria. Follow up confirmatory testing based on Harmony results for Trisomy 21, 18, 13, sex chromosome aneuploidy, or 22q11.2 could reveal maternal chromosomal or genetic conditions in some cases. Results from the Harmony Prenatal Test should be communicated in a setting designated by your healthcare provider that includes the availability of appropriate genetic counseling.
For a full test description of the Harmony Prenatal Test and available report options, please visit: **www.harmonytest.com**.

Who is eligible for the Harmony Prenatal Test?

Women who are at least ten weeks pregnant are eligible for the Harmony Prenatal Test offerings. Patients with a twin pregnancy are not eligible for sex chromosome aneuploidy or 22q11.2 options. The Harmony Prenatal Test is not for patients with:

- a history of or active malignancy
- a pregnancy with fetal demise
- a pregnancy with more than two fetuses
- a history of bone marrow or organ transplants

What are the limitations of the Harmony Prenatal Test for Trisomies 21, 18, and 13, sex chromosome aneuploidy, and fetal sex determination?

The Harmony Prenatal Test is not validated for use in pregnancies with more than two fetuses, fetal demise, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18. Harmony does not detect neural tube defects. Certain rare biological conditions may also affect the accuracy of the test. For twin pregnancies, HIGH PROBABILITY test results apply to at least one fetus; male test results apply to one or both fetuses; female test results apply to both fetuses.
Due to the limitations of the test, inaccurate results are possible. A LOW PROBABILITY result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition. Some non-aneuploid fetuses may have HIGH PROBABILITY results. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

What are the limitations of the Harmony Prenatal Test for 22q11.2?

In addition to the limitations discussed above, the 22q11.2 option is not validated for use in pregnancies with more than one fetus or for women with a 22q11.2 duplication or deletion. A 22q11.2 deletion may not be detected in all fetuses. Due to the limitations of the test, a NO EVIDENCE OF A DELETION OBSERVED result does not guarantee result that a fetus is unaffected by a chromosomal or genetic condition . Some fetuses with a 22q11.2 deletion may receive a test result of NO EVIDENCE OF A DELETION OBSERVED. Some fetuses without the 22q11.2 deletion may receive a test result of HIGH PROBABILITY OF A DELETION. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

How is my blood sample and personal data used by Ariosa Diagnostics?

Ariosa Diagnostics, Inc. (Ariosa) and its sub-processors collect and process your blood samples and personal data in order to perform the Harmony Prenatal Test. No additional clinical testing will be performed on your blood sample other than those authorized by your healthcare provider. Your test results will be disclosed only to the healthcare provider listed on this form (or to his or her agent), unless otherwise authorized by you or as required by law, regulations, or judicial order. Due to the nature of the Harmony Prenatal Test, we will be unable to perform the test without your personal data. For this reason, you will be unable to take the test if you do not consent to the use of your personal data for these purposes. Additionally, the Harmony Prenatal Test must be performed at a designated laboratory, which may be located in a country outside of your own. This may mean that your personal data and samples may be transferred to a country that does not offer the same level of legal privacy protection as your own.
Your blood samples will be retained by Ariosa for 60 days, which is the amount of time needed to perform the test and to perform additional testing as directed by your healthcare provider. Your blood samples will be destroyed after this time unless you have consented to allow your sample to be used for validation and research purposes. Your records and test results will be stored and maintained by Ariosa according to its retention schedule. During this time, your personal data will be maintained in a secure system and will not be used or disclosed for purposes outside of what is required or permitted by law.
The Ariosa Privacy Notice describes your rights with regards to the processing of your personal data. This notice can also be found at **www.ariosadx.com/privacy-policy**.

Test Description

The Harmony Prenatal Test® measures the relative proportion of chromosomes to aid in the assessment of fetal trisomies 21, 18, and 13. Harmony® performs a directed analysis of cell-free DNA (cfDNA) in maternal blood and incorporates the fetal fraction of cfDNA in test results. Test results also incorporate maternal age (or egg donor age) and gestational age related probability based on information provided on the test requisition form. Probability of less than 1% is defined as low probability and 1% or greater is defined as high probability. Harmony has been validated in singleton and twin pregnancies of at least 10 weeks gestational age. Harmony is not validated for use in pregnancies with more than two fetuses, demised twin, mosaicism, partial chromosome aneuploidy, translocations, maternal aneuploidy, transplant, malignancy, or in women under the age of 18. Harmony does not detect neural tube defects. Twin results reflect the probability that the pregnancy involves at least one affected fetus. Analysis of cfDNA does not always correlate with fetal genotype. Not all aneuploid fetuses will have a high probability result and some euploid fetuses will have a high probability result. The Harmony Prenatal Test is not a diagnostic test and results should be considered with other clinical criteria and communicated in a setting that includes appropriate counseling.

Fetal Sex test quantifies the Y chromosome. A "female" result indicates absence of Y chromosome and a "male" result indicates presence of Y chromosome. It does not exclude sex chromosome aneuploidy. For twin pregnancies, a male result indicates one or two male fetuses.

Sex Chromosome Aneuploidy (SCA) Panel measures proportions of the X and Y chromosomes. Sex chromosome conditions (Monosomy X, XXY, XYY, XXX, XXYY) are reported at probabilities of 1% or greater. An XYY or XXYY result indicates two or more fetal Y chromosomes. Sex Chromosome Aneuploidy Panel has only been validated in singleton pregnancies..

22q11.2 test uses targeted analysis of chromosome cfDNA fragments from within a 3Mb region of 22q11.21 to determine the probability of a deletion. "High probability of a deletion" indicates that the analysis detected a decrease of cfDNA fragments consistent with a deletion in the 22q11.21 region, which may be fetal, maternal or both. "No evidence of a deletion observed" indicates the analysis does not find an increased probability for a deletion in the 22q11.21 region. Not all fetuses with 22q11.2 deletions will be classified as high probability. This test does not rule out the possibility of other clinically significant aneuploidy, single gene conditions, microdeletions or microduplications being present in the fetus. Women with a known 22q11.2 deletion are not eligible for this test. 22q11.2 test has only been validated in singleton pregnancies.

Clinical Data

	Detection Rate	False Positive Rate
T21	>99% (95% CI: 97.9-99.8%)	<0,1% (95% CI: 0.02-0.08%)
T18	97,4% (95% CI: 93.4-99.0%)	<0,1% (95% CI: 0.01-0.05%)
T13	93,8% (95% CI: 79.9-98.3%)	<0,1% (95% CI: 0.01-0.06%)

Detection and false positive (discordant result) rates based on probability cut-off of 1/100 (1%). Because these conditions are rare, limited numbers of aneuploidy twin and egg donor pregnancies have been evaluated. The negative predictive value for trisomy 21, 18, and 13 is greater than 99%. Positive predictive value (PPV) varies by prevalence. The probability result reported is not equivalent to the PPV. For more information regarding PPV refer to: www.harmonytest.com/PPV

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

SCA Panel SCA Panel provides probability for non-mosaic fetal sex chromosome aneuploidies. Test performance varies by condition. Limited numbers of sex chromosome aneuploidy cases have been evaluated to date.

22q11.2 Limited numbers of 22q11.2 cases have been evaluated to date.