harmony®
cliniqueovo

Consent

LIS Label

PATIENT

Date of birth ____ (YYYY) ____ (MM) ____ (DD)

First name, last name

____ Sex ____ Weight ☐ kg ☐ lb Email

Telephone ____ File# ____ Health card number

PRESCRIBING PHYSICIAN

First name, last name ____ Licence# ____

Institution ____

Email or telephone ____ Fax ____

Physician cc ____

CLINICAL INFORMATION To be completed

Gestational Age on the most recent ultrasound date ____ wks ____ days

As of: ____ (YYYY) ____ (MM) ____ (DD)

or

☐ LMP or ☐ EDD ____ (YYYY) ____ (MM) ____ (DD)

# of fetuses: ☐ 1 ☐ 2

In vitro fertilization: ☐ Yes ☐ No

If IVF: 1) the oocyte is from: ☐ Itself ☐ Donor

2) Age of patient/donor on the oocyte collection day____yrs

ANALYSIS OPTION

☒ Prenatal Test Harmony (T21, T18, T13)

Additional Option(s):

- ☐ Fetal Sex
- ☐ Monosomy X[1]
- ☐ Sex chromosome aneuploidies (Monosomy X included)[1]
- ☐ 22q11.2 microdeletion (DiGeorge Syndrom)[1]

1 Single pregnancy only.

IMPORTANT:
Gestational age must be ≥ 10 weeks at the time of collection
Patient age must be ≥ 18 years

BLOOD SAMPLING

Collection date ____ (YYYY) ____ (MM) ____ (DD) Is it a redraw? ☐ Yes ☐ No Collection Center ____

AGREEMENT TO KEEP THE SAMPLE FOR STUDY OR RESEARCH PURPOSES

With your agreement, the remaining part of your sample can be used by ovo labo for laboratory validation studies, development processes, quality control, and/or other research purposes. If you agree and authorize ovo labo to use the remaining portion of your sample, all information that could be linked to this sample will be deleted (anonymized) while some of the non-identifiable clinical data you provided (e.g., gestational age, number of fetuses, etc.) will be retained for use in these activities.

If you do not agree, the remaining portion of your sample will not be used for these purposes and will be destroyed in accordance with ovo labo policies and procedures. In all cases, your sample and personal data, including your test results will be retained, used or destroyed in accordance with applicable laws, rules and regulations.

☐ Initials: ____

PATIENT'S CONSENT

My signature on this form certifies that I have read, or have been read, the informed consent on the back of this form. I understand the terms of the informed consent and authorize ovo labo to provide the selected laboratory test(s). I have had the opportunity to ask questions and discuss the capabilities, limitations, and potential risks of the test(s) with my physician or a designated representative of my physician. I know that I can, if I wish, obtain professional genetic counseling prior to signing this consent. I hereby expressly authorize the use of my personal data included in this analysis request form (including, but not limited to, my name, address, pregnancy-related information, and other relevant details) for identification purposes, its transmission to the prescribing physician, and its storage in ovo labo's systems. I also authorize my blood sample to be sent to and processed by a partner laboratory of ovo labo, if applicable.

Patient's signature ____ Date (YYYY/MM/DD) ____

SIGNATURE OF THE PROFESSIONAL WHO PERFORMED BLOOD SAMPLING

I certify that I have fully explained the details, capabilities and limitations of this test(s)

Signature ____ Title ____ License # ____ Date (YYYY/MM/DD) ____

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Informed consent of the patient

The Harmony® Prenatal Test is a prenatal screening test that analyzes cell-free DNA (cdDNA) in maternal blood. The test provides a risk assessment, not a diagnosis, of chromosomal or genetic conditions in the fetus, as well as a determination of fetal sex. The results should be considered in the context of other clinical criteria. In some cases, follow-up tests for confirmation of Harmony® test results for trisomy 21, 18, 13, sex chromosome aneuploidies, or 22q11.2 deletion may reveal chromosomal or genetic conditions in the mother. It is recommended that the results of the Harmony® prenatal test be communicated in the setting chosen by your physician and accompanied by appropriate genetic counseling.

The Harmony® non-invasive prenatal test is licensed under the regulatory requirements of Health Canada for a Class III license. The Harmony® test, based on free DNA analysis, is considered a prenatal screening test and not a diagnostic test. It does not detect chromosomal or genetic abnormalities other than those explicitly mentioned in this document. Patients should discuss their results with their health care provider, who may recommend diagnostic testing if necessary.

Who is eligible for a Harmony® prenatal test?

Gestational age of patients must be at least 10 weeks for any Harmony® test. The options of monosomy X, sex chromosome aneuploidy panel are not available for twin pregnancies. The Harmony® prenatal test is not suitable for patients with a history of cancer or active cancer, pregnancy with fetal loss, pregnancy with more than two fetuses, and a history of bone marrow and/or organ transplantation.

What are the limitations of the Harmony® prenatal test for trisomy 21, 18, 13, sex chromosome aneuploidies and fetal sex determination?

The Harmony® prenatal test is not validated for pregnancies with more than two fetuses, death of a fetus, mosaicism, partial chromosomal aneuploidy, translocation, maternal aneuploidy, bone marrow or organ transplantation, maternal cancer, or in women under the age of 18. The Harmony® test does not detect neural tube defects. Certain rare biological conditions may also affect the accuracy of the test. For twin pregnancies, “HIGH RISK” results apply to at least one fetus; “male” results apply to one or both fetuses; “female” results apply to both fetuses.

Not all cases of Down syndrome will be detected. Some fetuses with Down syndrome may have a “LOW RISK” result. Some fetuses without Down syndrome may have a “HIGH RISK” result. False negatives and false positives are possible. A “LOW RISK” result does not guarantee an unaffected pregnancy due to the screening limitations of the test. The Harmony® test provides a risk assessment, not a diagnosis, and results should be considered in the context of other clinical criteria. It is recommended that a result of “HIGH RISK” and/or other clinical indications of chromosomal abnormality be confirmed by fetal karyotype analysis, such as amniocentesis. It is recommended that the results be communicated in a setting chosen by your physician and accompanied by appropriate genetic counseling. For various reasons, including biological, the test has a failure rate. In these cases, you may be asked to submit a new sample. In a small number of cases, no results are obtained for the fetal sex and/or the sex chromosome aneuploidy panel. This may be due to biological or technical factors influencing the sex chromosome analysis that do not affect trisomy analysis.

Note: Fetal sex, monosomy X and sex chromosome aneuploidy panel options can be added up to a maximum of 30 days after the initial report is issued.

What will happen to my sample after the test is over?

If you agree, the remaining portion of your sample may be used by ovo labo for validation laboratory studies, development processes, quality control, and/or other research purposes. If you agree and authorize ovo labo to use the remaining part of your sample, all information that could be linked to this sample will be deleted (anonymized) while some of the non-identifiable clinical data you have provided (e.g. gestational age, number of fetuses) will be retained for use in these activities.

If you do not agree, the remaining portion of your sample will not be used for these purposes and will be destroyed in accordance with ovo labo’s policies and procedures. In any case, your sample and personal data, including your test results will be retained, used or destroyed in accordance with applicable laws, rules and regulations.

To find the collection center nearest you, please contact us

Book an appointment on our website at cliniqueovo.com

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