



Manitoba Requisition for Funded Harmony Testing Following Positive MSS

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

Health Ins. No. _____

Sex F M Weigh _____ kg lbs

Address _____
No Street Apt.

_____ City Province Postal code

Tel _____

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. I understand the informed consent and give permission to Dynacare to provide 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 counselling before signing this consent.

Patient Signature _____

Date _____
Year / Month / Day

BLOOD DRAW INFORMATION

Collection Date _____
Year Month Day

Is this a redraw? Yes No

Collection Centre _____

INDICATION FOR FUNDED TEST*

- Positive Maternal Serum Screen (MSS) Down syndrome and/or trisomy 18**
- AND
- Gestational age confirmed by ultrasound

*The pregnant woman must be Manitoba Health insured (out-of-province referrals are not funded).
**Positive MSS result must be attached to this requisition.

PRESCRIBER INFORMATION

Last Name _____

First Name _____

Clinic _____

Address _____
No Street Office

_____ City Province Postal code

Tel _____

Fax _____

TEST MENU OPTIONS

- Harmony Prenatal Test (T21, T18, T13)
- Additional options:
- Fetal Sex
- Monosomy X^{1,2}
- Sex Chromosome Aneuploidy Panel^{1,2}

¹Singletons only. ²Fetal sex not reported.

CLINICAL INFORMATION

Gestational age

A Gestational age at date of ultrasound: _____ weeks _____ days

Date of ultrasound: _____
Year Month Day

B IVF Transfer Date

Year Month Day

of Fetuses 1 2

IVF Pregnancy No Yes

↳ Egg Donor is: Self Non-self
Donor Age at Retrieval: _____ years

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 _____

Date _____ Licence No. _____
Year / Month / Day

Patient Informed Consent

The Harmony® Prenatal Test is a prenatal screening test that analyzes cell-free DNA (cfDNA) in maternal blood. The test provides a risk 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 or sex chromosome aneuploidy 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 counselling.

The Harmony non-invasive prenatal test is licensed in accordance with Health Canada regulation requirements for a class III license. The Harmony test is based on cell-free DNA analysis and is considered a prenatal screening test, not a diagnostic test. Harmony does not screen for potential chromosomal or genetic conditions other than those expressly identified in this document. All women should discuss their results with their healthcare provider who can recommend confirmatory diagnostic testing where appropriate.

Who is eligible for the Harmony Prenatal Test?

Patients must be of at least 10 weeks gestational age for any of the Harmony Test offerings. Patients with a twin pregnancy are not eligible for monosomy X or sex chromosome aneuploidy 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; or 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 RISK test results apply to at least one fetus; male test results apply to one or both fetuses; female results apply to both fetuses.

Not all trisomic fetuses will be detected. Some trisomic fetuses may have LOW RISK results. Some non-trisomic fetuses may have HIGH RISK results. False negative and false positive results are possible. A LOW RISK result does not guarantee an unaffected pregnancy due to the screening limitations of the test. Harmony provides a risk assessment, not a diagnosis, and 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 such as amniocentesis. It is recommended that results be communicated in a setting designated by your healthcare provider that includes appropriate counselling. For a variety of reasons, including biological, the test has a failure rate. As such, you may be requested to redraw a new sample. In a small number of cases, a result for fetal sex and/or sex chromosome aneuploidy determination may not be obtained. This can be due to biological and technical factors influencing sex chromosome analysis that did not impact trisomy analysis.

Note: Options for Fetal Sex, Monosomy X, and Sex Chromosome Aneuploidy Panel can only be added up to a maximum of 30 days following initial reporting.

What is done with my sample after testing is complete?

No additional clinical testing will be performed on your blood sample other than those authorized by your healthcare provider. Dynacare will disclose the test results only to the healthcare provider(s) listed on the front of this form, or to his or her agent, unless otherwise authorized by you or as required by laws, regulations, or judicial order. Details on Dynacare's policies and procedures governing patient privacy and health information, including patient rights regarding such information, can be found at www.dynacare.ca/privacy-policy.aspx.

Your specimen will be tested in Canada, however, in some cases your sample may be sent to a laboratory in the United States for testing. In this case, personal information, including but not limited to name and date of birth, will accompany the sample. Personal information held in countries outside of Canada could be subject to disclosure to government or other authorities (whether of that country or of another country).

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Patient Instructions for Sample Collection

Please go to one of the following Dynacare Laboratory and Health Services Centres:

Manitoba Clinic	LL-790 Sherbrook St.	Winnipeg	R3A 1M3	Fax 204.783.2254
Sterling Lyon Seasons	1-515 Sterling Lyon Pkwy	Winnipeg	R3P 2S8	Fax 431.808.0523
St. Vital	111-1225 St. Mary's Rd.	Winnipeg	R2M 5E5	Fax 431.808.0517
McPhillips Garden City	D-2211 McPhillips St.	Winnipeg	R2V 3M5	Fax 431.808.0519
SmartCentres	3-3653 Portage Ave.	Winnipeg	R3K 2G6	Fax 431.808.0521
Winkler	130-385 Main St.	Winkler	R6W 1J2	Fax 204.325.6700
Brandon Clinic	620 Dennis St.	Brandon	R7A 5E7	Fax 204.571.1313

Dauphin & Thompson Requisition needs to be faxed to a Shared Health Facility for patient to go for collection. To have a kit shipped to these locations, contact Dynacare Manitoba Logistics 1-800-668-2714 or DispatchMB@dynacare.ca

For any questions, contact Dynacare at 888.988.1888.