harmony™ PRENATAL TEST
performed in Canada

Yukon Health and Social Services

yukon hospitals
whitehorse
dawson city
watson lake

Dynacare® next

PATIENT INFORMATION

Last Name _____

First Name _____

Date of Birth _____
Year / Month / Day

Health Ins. No. _____

Sex ☒ F ☐ M Weight _____ ☐ kg ☐ lbs

Address _____
No Street Apt.

_____
City Province Postal code

Tel _____

PRESCRIBER INFORMATION

Last Name _____

First Name _____

Clinic _____

Address _____
No Street Office

_____
City Province Postal code

Tel _____

Fax _____

Copy Results To Fax CASY 867-667-5714

PATIENT CONSENT

My signature on this form indicates that I give permission to Dynacare 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 counselling before signing this consent. I know that my personal information is being collected, used and disclosed in accordance with Yukon's *Health Information Privacy and Management Act* (www.hss.gov.yk.ca/healthprivacy.php), it will be shared with Congenital Anomalies Support Yukon (CASY) for program evaluation purposes.

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 NIPT

- ☐ Age ≥ 35 years at EDD
- ☐ Positive screen from SIPS/Quad/FTS
- ☐ Serum screen + ultrasound markers risk ≥ 1/300
- ☐ Ultrasound abnormality highly suggestive of T21, T18, or T13
- ☐ Either biological parent had previous pregnancy with aneuploidy
- ☐ Personal / family history that increases risk of T21, T18, or T13
- ☐ Twin pregnancy
- ☐ Carrier of X-linked condition where gender ID is indicated
- ☐ HIV / HBV / HCV positive
- ☐ IVF with ICSI
- ☐ **Low/med risk: NOT eligible for NIPT funding**

TEST MENU OPTIONS

☒ Harmony Prenatal Test (T21, T18, T13)

Additional options:

- ☐ Fetal Sex
- ☐ Monosomy X*
- ☐ Sex Chromosome Aneuploidy Panel*

*Singletons only. Fetal sex not reported.

CLINICAL INFORMATION

Gestational age: complete **A** or **B**

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

Date of ultrasound: Year Month Day

B ☐ LMP Date; or ☐ 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

harmony™ PRENATAL TEST
performed in Canada

Dynacare® next

Patient Informed Consent

The Harmony Prenatal Test and the available test options are laboratory-developed screening tests that analyze cell-free DNA (cfDNA) in maternal blood. The tests aid in the risk determination of fetal chromosomal or genetic conditions, and fetal sex determination, if selected. In some cases, follow-up confirmatory testing based on these test results could uncover maternal chromosomal or genetic conditions.

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 who have received bone marrow or organ transplants or those who have metastatic cancer are not eligible for the Harmony Prenatal Test. Please see below for additional eligibility criteria:

	Harmony (Trisomy 21, 18,13) with or without Fetal Sex Option	Harmony with Sex Chromosome Aneuploidy Panel or Monosomy X
Singleton Pregnancies including IVF	✓	✓
Twin Pregnancies including IVF	✓	Not eligible
More than 2 Fetuses	Not eligible	Not eligible

What are the limitations of the Harmony Prenatal Test?

The Harmony Prenatal Test is not intended nor validated for diagnosis or detection of mosaicism, partial trisomy, or translocations. Certain rare biological conditions may also affect the accuracy of the test. Limited numbers of aneuploidy twin and egg donor pregnancies have been evaluated because these conditions are rare. Results for twin pregnancies reflect the probability that the pregnancy involves at least one affected fetus. For twin pregnancies, male results apply to one or both fetuses, and 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.

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).