ALBERTA PRECISION LABORATORIES

Leaders in Laboratory Medicine

SHADED AREAS ARE REQUIRED INFORMATION

ORDERING PHYSICIAN (Include Full Name, Client # and Provider #)

Third Party Client
Facility: 05100
Provider: 009999A

THIRD PARTY REQUISITION

SEE REVERSE FOR ADDITIONAL INFORMATION

PROVINCE	PERSONAL HEALTH NUMBER (PHN) (OPTIONAL)	REGIONAL HEALTH RECORD NUMBER
	____ ____ ____ ____ ____ – ____ ____ ____ ____	

PATIENT LAST NAME | FULL FIRST NAME | MIDDLE NAME

PATIENT ADDRESS | CITY, PROVINCE | POSTAL CODE

CHART NUMBER	GENDER	DATE OF BIRTH	PATIENT PHONE NUMBER
		__ __ __ __ / __ __ / __ __ (Y Y Y Y M M M D D)	(__ __ __) __ __ __ - __ __ __ __

INVOICE TO

CLINICAL DATA

Dynacare Genetics and Specialty Services – HARMONY KIT

This Kit must be collected at an APL location

Physician Information	• **Complete patient information section of APL Third Party Requisition**
	• **Complete Dynacare Harmony Prenatal Test Requisition**
	  o Patient information section
	  o Have patient sign patient consent area.

Patient Information	**Note: Patient must be of at least 10 weeks gestational age at the time of collection**
	• **Appointments are recommended and can be made through the Patient Appointment Line.**
	  o Book an appointment by calling 403-770-5136 and indicate you have a **Kit Collection,** or on line at www.albertaprecisionlabs.ca
	  o Walk-Ins are also acceptable
	• Complete Dynacare Payment Authorization Form (all sections, including credit card information).

Data Entry	Encounter Type: **Community** Financial Class: **Company Bill** Company Name: **I601907** ✓ | **Mnemonic**: KIT1 | **Test**: Kit1 – Blood Collection and Shipping

Collections	**Note: Patient must be of at least 10 weeks gestational age at the time of collection**
	• Collect specimen as per Kit directions.
	• Complete Kit collection tube labels with patient's full name, DOB and collection date.
	• **Ensure patient has completed credit card information and signed patient consent area on requisition.**
	• Package specimens as per kit directions; **ensure the following paper work is in the Harmony Kit Box**:
	  1) Dynacare Harmony Prenatal Test Requisition
	  2) Dynacare Payment Authorization Form
	  3) Original APL Third Party requisition
	• Send copy of APL Third Party Requisition to Optical Scanning
	• Place pre-filled waybill on provided shipping package and send to DSC for shipping.

DSC Accession	• Deliver to Referrals upon receipt • If outside of Referral hours, store at room temperature. Specimens cannot be refrigerated.
DSC Referrals	• Use Purolator waybill provided • Ship same day if received before shipping cut off Monday-Thursday • If after cut off store at room temperature until next available shipping day

Address: Dynacare Genetics and Specialty Services
c/o 115 Midair Court
Brampton, ON L6T 5V1

For questions contact Dynacare Genetics and Specialty Services at 1-888-988-1888.

COLLECTED BY:	FASTING (HOURS PC)	PATIENT COLLECTED SPECIMENS:	ACCESSION NUMBER
DATE COLLECTED	TIME COLLECTED	DATE OF COLLECTION: _____ (YYYY-MMM-DD) TIME OF COLLECTION: _____ : _____ AM / PM (circle one)	

harmony®

performed in Canada

Dynacare®

Harmony Prenatal Test Requisition

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 _____

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

TEST MENU OPTIONS

☒ Harmony Prenatal Test (T21, T18, T13)

Additional options:

- ☐ Fetal Sex
- ☐ Monosomy X[1,2]
- ☐ Sex Chromosome Aneuploidy Panel[1,2]
- ☐ 22q11.2[1] (additional cost for this option)

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

BLOOD DRAW INFORMATION

Collection Date | Year | Month | Day |

Is this a redraw? ☐ Yes ☐ No

Collection Centre _____

IMPORTANT: Patients must be of at least 10 weeks gestational age at the time of collection.

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

115 Midair Court, Brampton, ON L6T 5M3 T 888.988.1888 F 450.663.4428 DynacareGenetics@dynacare.ca

harmony®

performed in Canada

Dynacare®

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, 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 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, 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; 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 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 LOW PROBABILITY result does not guarantee that a fetus is unaffected by a chromosomal or genetic condition. Some fetuses with a 22q11.2 deletion may receive a test result of LOW PROBABILITY. Some fetuses without the 22q11.2 deletion may receive a test result of HIGH PROBABILITY. In cases of HIGH PROBABILITY results and/or other clinical indications of a chromosomal condition, confirmatory testing is necessary for diagnosis.

Note: The 22q11.2 test is not part of the Health Canada approval of the Harmony Prenatal Test and is performed at a CLIA approved laboratory in the United States. **This test must be requested at the time of the order and cannot be added after submission of the original test requisition/specimens.**

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).

HARMONY is a trademark of Roche.

Patient Instructions for Sample Collection

To know the location of the nearest collection centre, call us at **888.988.1888** or visit **dynacare.ca**. You also have the option of having your sample collected in the comfort of your own home at no extra charge.* One of our specially trained medical technicians will come to your home to perform the blood draw. To book your home collection appointment, contact Dynacare at 888.988.1888.

*Depending on distance, additional charges may apply.

Dynacare®

Payment Authorization Form

PATIENT INFORMATION

Last Name: _____

First Name: _____

Date of birth: _____ (Year/Month/Day)

Referring physician: _____

Address: _____
No Street Apt.

_____
City Province Postal code

Tel (primary): _____

Tel (secondary): _____

TEST INFORMATION

☐ Harmony Prenatal Test $495

☐ Harmony Prenatal Test + 22q11.2 Option $670

PAYMENT

☐ VISA ☐ Certified cheque (No personal cheques accepted)

☐ MasterCard

☐ AMEX

Credit Card Number: __ __ __ __ / __ __ __ __ / __ __ __ __ / __ __ __ __

Expiry date: _____ / _____ Security code: __ __ __
MM YY

Cardholder: _____ _____
Name Signature

Date: _____
(Year/Month/Day)

INTERNAL USE

Date: _____ Lab #: _____

3885, boul. Industriel, Laval (QC) H7L 4S3 T 888.988.1888 F 450.663.4428 DynacareGenetics@dynacare.ca