harmony™ PRENATAL TEST performed in Canada

Dynacare® next

MOH Criteria for Eligibility Form

Instructions: The Provincial Council for Maternal and Child Health (PCMCH) has recommended specific indications for NIPT funding. Please complete Patient Information and Indication Category I **or** II sections of the form, and attach to the completed Harmony™ Prenatal Test requisition.

PATIENT INFORMATION

Last Name _____

First Name _____

Health Ins. No. (OHIP #) _____

Date of birth (Year/Month/Day) _____

INDICATION CATEGORY I

For investigation of trisomy 21, 18 or 13 ONLY.

☐ Singleton gestation (NIPT in the context of twin pregnancies requires consultation with a geneticist or maternal fetal medicine specialist (see Indication Category II)) with appropriate pre-test counselling including a discussion of the limitations of the test.

And any one of the following:

☐ A maternal multiple marker screening test (eg. FTS/IPS/Quad etc.) positive for aneuploidy
☐ Women of advanced maternal age, defined as ≥ 40 years of age at expected time of delivery
☐ Fetal nuchal translucency (NT) ≥ 3.5mm
☐ Pregnancy history of aneuploidy / previous child with aneuploidy

Physician Signature _____ Date (Year/Month/Day) _____ CSN# _____

INDICATION CATEGORY II

There are several situations where additional specialist consultation is necessary to determine whether NIPT is warranted and to provide appropriate pre and post-test counselling. **NIPT funding for the following indications must be submitted by a genetics or maternal fetal medicine (MFM) specialist.**

Risk Indicators:

A/

☐ Fetal congenital anomalies identified on ultrasound, which are suggestive of trisomy 21, 18 or 13.

Specify: _____

OR:

B/

☐ Risk of aneuploidy for trisomy 21, 18 or 13 > than that of a positive maternal multiple marker screen.

- Women less than 40 years of age at expected date of delivery must have at least one other risk factor noted.
- The risk of aneuploidy can be calculated by including any combination of risk indicators including soft markers, biochemistry, maternal age, etc.

Please indicate all risk factors present

☐ Twin pregnancy (if additional risk factors are identified, submit one checklist per fetus)
☐ Soft markers (check all that apply):

☐ Absent nasal bone	☐ Hyperechogenic bowel	☐ Intracardiac echogenic focus / foci
☐ Choroid plexus cysts	☐ Hypoplastic nasal bone	☐ Short femur
☐ Clinodactyly	☐ Increased nuchal fold / edema	☐ Short humerus
☐ Cystic hygroma	☐ Increased nuchal translucency	☐ Ventriculomegaly

☐ Maternal age _____

☐ Other, specify: _____

OR:

C/

☐ NIPT for sex chromosome determination (at least one of the following):

☐ Risk of a sex-limited disorder
☐ Ultrasound findings suggestive of either a sex chromosome aneuploidy
☐ Ultrasound findings suggestive of a disorder of sex determination (DSD).

Genetics or MFM specialist's name (Please print) _____

Specialist's Signature _____ Date (Year/Month/Day) _____ CSN# _____

Genetics or MFM Centre _____