ONCOHELIX

Testing site & Shipping Address:

Hematology Translational Lab (HTL)

ATTN: Dr. Faisal Khan
HMRB 380, 3330, Hospital Drive NW, Calgary, AB T2N 4N1
Phone: +1(403)220-7671, +1(403)210-3935
Fax: +1(403)210-8176, Email: HTL@ucalgary.ca

PATIENT INFORMATION

Name (Last, First) _____

Medical Record # _____

Date of Birth(dd-mmm-yyyy):_____ Gender: M ◯ F ◯

Address:_____ City:_____

Prov./State: _____ Country: _____ Postal/Zip code_____

ORDER INFORMATION

Requesting Physician_____ Location/Facility _____

Address_____ City _____ Prov./State _____ Country: _____ Postal/Zip code _____

Phone _____ Fax_____Email _____ Report delivery method: Email ☐ Fax ☐

INDICATION

Indication (*Specify*)_____ Other Information (*Specify*) _____

Date of Last Delivery (*If yes, specify*)_____ Was the baby born with any health issues? (*If yes, specify*)_____

Family history of genetic disease? (*If yes, specify)* _____

TEST REQUESTS

PRENATAL SCREENING

Serenity NIPT (Non-Invasive Prenatal Screening)

☐ **Serenity**

- Trisomy 21 (Down Syndrome)
- Trisomy 18 (Edwards Syndrome)
- Trisomy 13 (Patau Syndrome)
- Sex Chromosome Aneuploidies

☐ **Serenity +**

- Trisomy 21 (Down Syndrome)
- Trisomy 18 (Edwards Syndrome)
- Trisomy 13 (Patau Syndrome)
- Sex Chromosome Aneuploidies
- All Autosomal Chromosomes

☐ **Microdeletions**

- 1p36 deletion syndrome
- 4p- (Wolf-Hirschhorn syndrome)
- 5p- (Cri-du-chat syndrome)
- 15q11.2 (Prader-Willi syndrome/ Angelman syndrome)
- 22q11.2 deletion (DiGeorge syndrome)

SERENITY NIPT

Please see page 2 for consent form.

Gestational age: _____ weeks _____ days on _____

Dating Method ☐ LMP ☐ CRL Date of Implantation_____

Maternal Height _____cm / ____ft ____in Maternal Weight _____ kgs/lbs

Pregnancy ☐ Singleton ☐ Twin

☐ Fetal gender Identification

SAMPLE REQUIREMENTS & GUIDELINES

SPECIMEN TYPE	SHIPPING & HANDLING INSTRUCTIONS	REJECTION CRITERIA
Peripheral Blood in STRECK Tubes	1. Use OncoHelix provided Streck Cell Free DNA BCT tube (1) 2. Minimum Volume : 7mL. Invert tube 10x to mix blood with preservative reagent. 3. Gestational Age should be at least 10 weeks on the date of draw 4. Place the tube in the biohazard bag provided along with the absorbent sheet. 5. Duly filled TRF (test Requisition Form) to be placed in the outside pouch of the biohazard bag. 6. Sample to be transported in Ambient temp (6°-37° C) to OncoHelix.	• Hemolyzed / clotted specimen. • Frozen sample. • Sample outside stability time. • Leaky sample. • Inappropriate anticoagulant. • Suboptimal quantity/quality

SPECIMEN

◯ Peripheral Blood in Streck (Cell-Free DNA) tube (NIPT)

Date of Collection dd-mm-yyyy) _____ Time of Collection _____

SELF-PAYMENT DETAILS

OncoHelix to bill AvoVita Wellness directly, payment has already been collected.

TEST AUTHORIZATION, CONSENT & SIGNATURES

What is NIPT and Who is Eligible?

The Serenity Non Invasive Prenatal Test (NIPT) offered by OncoHelix is a laboratory-developed screening test that analyzes the cell-free DNA (cfDNA) in the maternal blood to screen and identify the risk of the baby having the most common chromosomal aneuploidies as early as 10 weeks of gestation. Oncohelix Serenity NIPT uses next-generation sequencing technology to screen for common fetal aneuploidies like Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome), Trisomy 13 (Patau syndrome) in addition to sex chromosome aneuploidies in singleton pregnancies and select microdeletions such as 1p36 deletion, 4p- (Wolf-Hirschhorn syndrome), 5p- (cri-du-chat syndrome),15q11.2 (Prader-Willi syndrome/ Angelman syndrome), and 22q11.2 deletion (DiGeorge). Women who are pregnant with at least 10 weeks gestation can take the test with just a single draw of blood. History of active malignancy, pregnancy with fetal demise, bone marrow/solid organ transplantation may not be eligible to take the test. All testing should be ordered by a licensed physician.

What are the limitations of the NIPT test

The Serenity Non-Invasive Prenatal Test (NIPT) offered by OncoHelix analyzes cell-free DNA derived from maternal blood as a screening method during pregnancy. False-positive and false-negative results do occur. Test results must not be used as the sole basis for diagnosis. Further genetic counseling and confirmatory diagnostic testing are necessary with a positive test result. Test results might not reflect the chromosomal status of the fetus but may reflect chromosomal changes of the placenta (CPM) or of the patient, which may or may not have clinical significance. CPM may be associated with a higher chance of pregnancy complications or uniparental disomy (UPD), which may affect the growth and development of the fetus. Some of these rare chromosomal aneuploidies may only occur in mosaic form. Clinical consequences depend on the chromosome involved and cannot be predicted prenatally. A negative test result does not eliminate the possibility of chromosomal abnormalities for the tested chromosomes or microdeletions. In addition, microdeletion conditions caused by other molecular mechanisms cannot be detected with this assay. This test does not screen for polyploidy (e.g. triploidy), birth defects such as open neural tube defects, single gene disorders, or other conditions, such as autism. Patients with a positive Serenity NIPT test result should be offered further genetic counseling and invasive diagnostic testing such as chorionic villus sampling or amniocentesis.

I have explained the nature and purpose of testing to the patient and have obtained informed consent, to the extent legally required, to permit OncoHelix to (a) perform the test/s specified herein, (b) retain de-identified test results as required or permitted by law for internal quality assurance/operational improvement, (c) use/disclose de-identified (without identifiable patient information) results and data for ongoing/future unspecified research and development purposes.

_____	_____	_____
Physician/Allied Health Professional Signature	Printed Name	Date

I permit OncoHelix & partner lab HTL to (a) perform the test/s specified herein, (b) retain test results as required or permitted by law for internal quality assurance/operational improvement, reporting, submissions, publication, research or to improve the program and (c) use/disclose de-identified results and data for ongoing/future unspecified research and development purposes.

_____	_____	_____
Patient's signature **OR** Check for Patient Verbal Consent ☐	Printed Name	Date

Shipping Address	For HTL Laboratory Use Only
ATTN: Dr. Faisal Khan **Hematology Translational Lab (HTL)** HMRB 380, 3330, Hospital Drive NW, Calgary, AB, CANADA T2N 4N1	Sample Received _____(YYYY-MM-DD) _____(AM/PM) Specimen type _____ #Tubes / Amount _____ Lab Acc.# _____