Mount Sinai SERVICES

MSH PATIENTS & NON-MSH PATIENTS

MSS NIPT Patient Ordering Guide for Self-Pay Patients

Noninvasive Prenatal Testing (NIPT)
One easy test. Five simple steps.

Thank you for your interest in the Verifi Noninvasive Prenatal Testing (NIPT) from Mount Sinai Services (MSS). Available as soon as 10 weeks pregnancy, NIPT is a simple and noninvasive way to shed light on some common genetic concerns, by testing the baby's DNA in the mother's blood.

Step one: Getting started

Speak with your general practitioner, obstetrician, genetic counsellor, or midwife to learn more about the test. Make sure you discuss the following:

- □ Eligibility for OHIP reimbursement
- □ Additional testing of the microdeletion panel and/or all chromosome aneuploidy (Verifi Plus options)

Step two: Private pay

Ministry of Health-approved NIPT for OHIP reimbursement is only performed at LifeLabs and Dynacare laboratories. If you are paying privately, your healthcare provider will need to:

- □ Complete the Prenatal Test Requisition Form
- □ Sign the NIPT Blood Draw Information handout* if they do not sign the Requisition Form

Make sure to provide your consent on the Requisition Form. Your provider is encouraged to make photocopies for your records.

Verifi Prenatal Test = $550 CAD
Verifi Plus add-ons: + $150 (microdeletion panel)
+ $70 (all chromosome aneuploidies)

- □ Complete the Credit Card Authorization Form

Step three: Blood draw

Blood will only be drawn at a minimum 10 weeks pregnancy. For your blood draw, please bring to the MSH outpatient lab the following:

- □ Original, signed Verifi Prenatal Test Requisition Form
- □ Signed NIPT Blood Draw Information handout (if the requisition is not signed by your healthcare provider)
- □ Completed Credit Card Authorization Form in a sealed envelope with your name on the front
- □ Valid health card

Mount Sinai Hospital Outpatient Lab:
600 University Ave, 4th floor
Room 461 "Diagnostic Laboratory"
Monday to Friday: 8:00 am - 5:00 pm
No appointment required.

Step four: Shipping

After the blood draw, the blood sample along with the original Requisition Form (and NIPT Blood Draw Information handout if required) and sealed Credit Card Authorization Form are delivered to the MSS laboratory.

Step five: Results!

Results will be returned to your healthcare provider within 5-10 business days. Contact your healthcare provider to review the results.

You may contact Mount Sinai Hospital for genetic counselling if you have concerns or questions about the results. The Prenatal Diagnosis and Medical Genetics Program can be reached at 416-586-4800 x 4523.

Please, keep in mind that NIPT failures, false positives and false negatives may occur. The Verifi Prenatal Tests report a low observed failure rate of 0.1%[1] because of its robust testing method. Observed false positive and false negative rates are 0.1% and 0.02%, respectively.[1] NIPT is a powerful screening test, but more invasive test methods are required for a definitive diagnosis. Positive test results should be discussed further with a genetic counsellor.

1. Taneja, P.A., Snyder, H.L., de Feo, E., Kruglyak, K.M., Halks-Miller, M., Curnow, K.J., & Bhatt, S. (2016). Noninvasive prenatal testing in the general obstetric population: clinical performance and counseling consideration in over 85 000 cases. *Prenatal Diagnosis, 36*, 237-243.

*The "NIPT Blood Draw Information handout" will be provided by your provider if required. It must be signed if the Requisition Form is not, but otherwise the Requisition Form must be complete.

For further questions, please contact MSS at 416-586-4800 x 8986.

Mount Sinai SERVICES

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ILLUMINA LAB USE ONLY

[OID Label] [Stamp Here]

Prenatal test requisition form

*Required information.

PATIENT INFORMATION:

Last name:* **First name:*** MI: **DOB:*** M M / D D / Y Y Y Y

Sex: Female Medical Record #: Client sample ID:

Address:

City/State: Country: ZIP:

☐ CA PNS	PDC #	State accessioning #

ACCOUNT/ORDERING PROVIDER*:

Health care provider: Genetic counselor:

Account name: Account #:

Phone: FAX: Email:

ADDITIONAL REPORTING TO:

Authorized health care provider: Address:

CLINICAL INFORMATION:

Gestational age:* Weeks: Days: As estimated on: M M / D D / Y Y Y Y **Date of draw:*** M M / D D / Y Y Y Y

Maternal height: ☐ cm ☐ ft in Maternal weight: ☐ kgs ☐ lbs

DATING METHOD (MUST CHOOSE ONE):*

☐ LMP ☐ Date of implantation ☐ CRL ☐ Other Specify:

CHOOSE EITHER TEST (VERIFI OR VERIFI PLUS) AND ALL OPTIONS THAT APPLY):*

Verifi Prenatal Test (chromosomes 21, 18, 13)

☐ Singleton
Additional option:
☐ Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)

☐ Twin
Additional option:
☐ Presence of Y chromosome

OR

Verifi Plus Prenatal Test (chromosomes 21, 18, 13)

Singleton
Additional options:
☐ Microdeletions:
1p36 deletion, 4p- (Wolf-Hirschhorn syndrome), 5p- (cri-du-chat syndrome), 15q11.2 (Prader-Willi syndrome/ Angelman syndrome), 22q11.2 deletion (DiGeorge syndrome)
☐ Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)
☐ All chromosomes (including sex chromosome aneuploidies [MX, XXX, XXY, and XYY])

TEST INDICATIONS (CHOOSE AT LEAST ONE):

☐ Advanced maternal age (≥ 35 years)
☐ Positive serum screen
☐ Abnormal ultrasound
☐ History suggestive of increased risk for the specified chromosome aneuploidies
☐ Low risk/maternal anxiety
☐ Other

Comments:

BILLING INFORMATION (PRIOR AUTHORIZATION MAY BE REQUIRED BY CERTAIN INSURANCE CARRIERS):

☐ Private insurance (Attach face sheet / insurance card when available) Relationship of patient to insured: ☐ Self ☐ Spouse ☐ Dependent ☐ Other

Last name: First name: Member ID:

Group #: Primary insurance: Prior authorization #:

I certify that (i) this test is medically indicated, (ii) the patient (or authorized representative on the patient's behalf) has given informed consent (which includes written informed consent or written authorization when required by law) to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law and Illumina's Patient Informed Consent. I agree to provide Illumina, or its designee, any and all additional information reasonably required for this testing to be performed.

Health care provider signature:* **Date:**

PATIENT CONSENT: By signing this form, I, the patient having this screening performed, acknowledge that: (i) I have been offered the opportunity to ask questions and discuss with my health care provider the benefits, risks, and limitations of the test to be performed; (ii) I have discussed the test limitations (reliability of positive and negative test results; the predictive value of the test results; and that the test is not a diagnostic test, but a screening test and is not definitive) with the health care provider who ordered the test; (iii) I have been informed about the availability and importance of genetic counseling and have been provided with information identifying an appropriate health care provider from whom I might obtain such counseling; (iv) I have received, read, and understood the Patient Informed Consent in its entirety and that I may retain a copy for my records; (v) I consent to the use of the leftover specimen and health information as described in the Patient Informed Consent; (vi) I consent to having this test performed; and (vii) I will discuss the results and appropriate medical management with my health care provider.

Patient signature: **Date:**

Non-invasive prenatal testing (NIPT) based on cell-free DNA analysis from maternal blood is a screening test. Screening tests are not diagnostic or definitive. Because there is a small possibility that a screening result might be incorrect, it is important to talk to your physician to determine if further testing is needed.

The Verifi™ Prental Test was developed by, and its performance characteristics were determined by Verinata Health, Inc. a wholly owned subsidiary of Illumina, Inc. The VHI laboratory is CAP-accredited and certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. It has not been cleared or approved by the U.S. Food and Drug Administration.

The Verifi™ Prenatal Test is validated for singleton and twin pregnancies and Verifi™ Plus Prenatal Test is validated for singleton pregnancies with gestational age of at least 10 weeks 0 days.

Patient informed consent

INTRODUCTION: This form describes the benefits, risks, and limitations of this screening test. You should seek pre-test counseling by a genetic counselor or other experienced health care provider prior to undergoing this test. Read this form carefully – and ask any questions you may have of your health care provider — before making your decision about testing.

PURPOSE: The purpose of the Verifi Test and the Verifi Plus Test is to screen your pregnancy for certain chromosomal abnormalities, also known as "aneuploidies." Both tests give information about whether there may be extra copies (trisomy) of chromosomes 21, 18, and 13, and the option to know if there is an extra copy of a sex chromosome (X or Y), and/or a missing copy of sex chromosome (MX). Fetal sex may also be reported. The Verifi Plus Test has the option to screen for aneuploidies (extra copies) in all chromosomes. In addition, the option to screen for the following microdeletions (small, missing parts of chromosomes) syndromes: 1p36 deletion, 4p- (Wolf-Hirschhorn syndrome), 5p- (cri-du-chat syndrome), 15q11.2 (Prader-Willi syndrome/Angelman syndrome), 22q11.2 deletion (DiGeorge syndrome or velocardiofacial syndrome) is also available. For chromosomes 21, 18, and 13, the Verifi Test is validated in singleton and twin pregnancies. In twin pregnancies, sex chromosome testing can only screen for the presence or absence of the Y chromosome, and not for extra or missing sex chromosomes. Both Verifi and Verifi Plus can be performed as early as 10 weeks 0 days gestational age. Consult your health care provider if you would like more information about this screening test, including risks, limitations, performance data, error rates, descriptions of the conditions being screened, and what these results may mean to your pregnancy.

HOW THIS TEST WORKS: This test screens for specific chromosomal abnormalities by looking at the DNA (genetic material) in your blood. The sample of blood includes a combination of both your DNA and the DNA from the pregnancy. A technology called massively parallel sequencing is used to count the amount of DNA from each test chromosome and/or from specific regions of chromosomes. The laboratory then uses an analysis method to determine if each of the conditions you have elected to test for is likely to be present or absent.

SEX OF PREGNANCY: Depending upon the option you and your health care provider elect, the test results may include the sex of the pregnancy. If you do not wish to know the sex, please tell your health care provider not to disclose this information to you. Depending upon the test ordered, you may not be able to prevent learning the sex of your pregnancy. In rare instances, incorrect sex results can occur.

LIMITATIONS OF THE TEST: These are screening tests that look only for specific chromosomal abnormalities. This means that other chromosomal abnormalities may be present and could affect your pregnancy. A "No Aneuploidy Detected" result does not guarantee a healthy pregnancy or baby and does not eliminate the possibility that your pregnancy may have birth defects, genetic conditions, or other conditions, such as open neural tube defects or autism.

There is a small possibility that the test results might not reflect the chromosomes of the fetus, but may reflect chromosomal changes of the placenta (confined placental mosaicism, CPM) or of you (maternal chromosomal abnormalities). While these tests are not designed to assess your health, in some cases, information about your health may be revealed directly or indirectly (e.g., when combined with other information). Examples include maternal XXX, sex chromosome status or benign or malignant maternal neoplasms. In a twin pregnancy, the status of each individual fetus cannot be determined.

These tests, like many tests, have limitations, including false negative and false positive results. This means that the chromosomal abnormality being tested for may be present even if you receive a negative result (this is called a 'false negative'), or that you may receive a positive result for the chromosomal abnormality being tested for, even though the abnormality is not actually present (this is called a 'false positive').

In the case of a twin pregnancy, the presence or absence of Y chromosome material can be reported. The occurrence of sex chromosome aneuploidies cannot be evaluated in twin pregnancies. In the case of a vanishing twin, the test result may reflect the DNA of the vanishing twin, leading to a higher probability of false positive or false negative results.

No irreversible clinical decisions should be made based on these screening results alone. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis would be necessary. In some cases, other testing may also be necessary. Some rare chromosomal aneuploidies may only occur in mosaic form. Clinical consequences depend on the chromosome involved and can not be predicted prenatally.

Consult your health care provider for more information about your results and what they may mean for your pregnancy, what options you will have for further testing, and whether additional testing is recommended for you based on your clinical history.

TEST PROCEDURE: A tube of your blood will be drawn and sent to Verinata Health, Inc., a wholly owned subsidiary of Illumina, Inc., which will then analyze your blood.

PHYSICAL RISKS: Side effects of having blood drawn are uncommon, but may include dizziness, fainting, soreness, bleeding, bruising, and, rarely, infection.

DISCRIMINATION RISKS: Genetic information could be used as a basis of discrimination. To address concerns regarding possible health insurance and employment discrimination, some countries, U.S. states and the U.S. government have enacted laws to prohibit genetic discrimination in those circumstances. The laws may not protect against genetic discrimination in other circumstances, such as when applying for life insurance or long-term disability insurance. Talk to your health care provider or genetic counselor if you have concerns about genetic discrimination prior to testing.

PREGNANCY OUTCOME INFORMATION: Collecting information on your pregnancy after testing is part of a laboratory's standard practice for quality purposes and is required in several states. As such, Illumina or its designee may contact your health care provider to obtain this information. By executing this informed consent, you agree to allow your health care provider to provide this information to Illumina or its designee.

SECONDARY FINDINGS: In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations, also known as "secondary findings" may become evident. Our policy is to NOT REPORT on any secondary findings that may be noted in the course of analyzing the test data.

PRIVACY: Test results are kept confidential. Your test results will only be released in connection with the testing service, to your health care provider, his or her designee, other health care providers involved in your medical care, or to another health care provider as directed by you (or a person legally authorized to act on your behalf) in writing, or otherwise as required or authorized by applicable law.

CROSS-BORDER DATA TRANSFER: If you are from outside the United States, your specimen and associated health information will be sent to the United States in order for the testing to be completed. As part of the testing, additional health information about you will be created and maintained. Your country may consider the legal privacy protections in the United States to be inadequate.

USE OF INFORMATION AND LEFTOVER SPECIMENS: Pursuant to best practices and clinical laboratory standards, leftover de-identified specimens (unless prohibited by law), as well as de-identified genetic and other information learned from your testing, may be used by Illumina or others on its behalf for purposes of quality control, laboratory operations, laboratory test development, and laboratory improvement. All such uses will be in compliance with applicable laws. Leftover specimens from New York State will be destroyed within 60 days.

RESEARCH: We may use your leftover specimen and your health information, including genetic information, in a de-identified form (unless otherwise allowed by applicable law) for research purposes. Such uses may result in the development of commercial products and services. You will not receive notice of any specific uses and you will not receive any compensation for these uses. All such uses will be in compliance with applicable law. This does not apply to leftover specimens collected from New York State.

TEST RESULTS: Your test results will be sent to the health care provider.

Credit Card Authorization Form

(Canadian Cards only)

Date: _____

Patient Name: _____ _____
First name Last name

Name of Cardholder (as on card): _____ _____

Billing Address: _____
Address line 1

_____
Address line 2

_____
City Province Postal code

Telephone #: _____

Email address: _____

□ Visa □ MasterCard □ Amex Canada

Credit card number: __ __ __ __ - __ __ __ __ - __ __ __ __ - __ __ __ __

Expiration Date: __ __ __ __ / __ __
Y Y Y Y M M

CSC number: _____
(Found on the back of Visa and MasterCard (3 digits), and on the front of Amex (4 digits))

Customer Service phone number from the back of the credit card: _____

Product to be purchased (select *one* order option):

Prenatal Test	21, 18, 13	All chromosomes	Microdeletions	$ (CAN)	Order
Verifi	●			550.00	□
	●	●		620.00	□
Verifi Plus	●		●	700.00	□
	●	●	●	770.00	□

I hereby authorize Mount Sinai Services Inc. to charge my Credit Card for the amount listed above. I certify that I am the authorized Card holder of record and that I have full authority to make purchases on behalf of the account listed above. I understand that Mount Sinai Services Inc. may contact me directly if there will be any issue with the payment.

Printed name: _____

Signature of Card holder: _____

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