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Sinai Health

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NONINVASIVE PRENATAL TEST REQUISITION FORM

To be completed by healthcare provider

CHOOSE *ONE* NIPT TEST (NIPTB)

PRENATAL TEST $(CAN)

○ **NIPTB: Singleton Verifi Prenatal Test** $495 – Chromosomes 21, 18, 13

○ **NIPTC: Verifi Plus with Microdeletions** (Singleton Pregnancy Only)
$750 – All chromosomes including sex chromosome aneuploidies
(Monosomy X, XXX, XXY and XYY) and Microdeletion panel 1p36 deletion, 4p- (Wolf Hirschhorn syndrome), 5p- (cri-du-chat syndrome), 15q11.2 (Prader-Willi syndrome / Angelman syndrome), 22q11.2 deletion (DiGeorge/VCF syndrome)

PATIENT INFORMATION

LAST NAME	FIRST NAME	MIDDLE	DATE OF BIRTH (DD/MM/YYYY)	SEX
				Female

ADDRESS	CITY	COUNTRY	POSTAL CODE

PHONE	EMAIL

ACCOUNT/ORDERING PROVIDER*

HEALTH CARE PROVIDER	GENETIC COUNSELLOR
ACCOUNT NAME	ACCOUNT #

PHONE	FAX	EMAIL

ADDITIONAL REPORTING TO

AUTHORIZED HEALTH CARE PROVIDER	ADDRESS

I certify that (i) this test is medically indicated, (ii) the patient (or substitute decision maker on the patient's behalf) has given informed consent to have this testing performed, and (iii) the informed consent obtained from the patient meets the requirements of applicable law and Mount Sinai Services' Patient Informed Consent. I agree to provide Mount Sinai Services any and/or its designee all additional information reasonably required for this testing to be performed.

HEALTH CARE PROVIDER SIGNATURE*	DATE (DD/MM/YYYY)
X	

CLINICAL INFORMATION

Gestational age*	WEEKS	DAYS	AS ESTIMATED ON (DD/MM/YYYY)	DATE OF DRAW (DD/MM/YYYY)

DATING METHOD(DAME) (must choose one)*

☐ 0 LMP ☐ 1 U/S ☐ 2 CRL ☐ 3 Date Implant ☐ 4 Other ☐ 5 Unknown

DATING METHOD DESCRIPTION (DAMED)

☐ 0 Ultrasound ☐ 2 LMP ☐ 1 Self ☐ 3 Other

SEX CHROMOSOME – NO ADDITIONAL COST (SEXC)

☐ 0 Yes ☐ 1 No

PATIENT CONSENT: By signing this form, I, the patient having this screening performed, acknowledge that: (i) I have discussed with my health care provider the benefits, risks, and limitations of the test to be performed; and have been offered the opportunity to ask questions; (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 counselling and have been provided with information identifying an appropriate health care provider from whom I might obtain such counselling; (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 will discuss the results and appropriate medical management with my health care provider and (vi) consent to having this test preformed.

CONFIRMATION NUMBER (**MANDATORY** FOR BLOOD DRAW)	PATIENT SIGNATURE	DATE (DD/MM/YYYY)
	X	

OPTIONAL: PLEASE PROVIDE INITIAL TO CONSENT	I consent to the use of the leftover specimen and health information as described in the Patient Informed Consent. For additional information please see optional use of leftover specimen and research below.	PATIENT INITIALS

Samples sent to:
Illumina, Inc.
200 Lincoln Centre Dr.
Foster City, CA 94404
T 416-586-4800 x8797 **F** 416-586-5859
info@mountsinaiservices.com

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 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.

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PATIENT INFORMED CONSENT

INTRODUCTION: This form describes the benefits, risks, and limitations of this screening test. You should seek pre-test counselling by a genetic counsellor 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. If you wish to know the sex of the pregnancy, this can be reported at your request.

The Verifi Plus Test has two screening options in pregnancy. In addition to screening for trisomy 21, 18 and 13, the Verifi Plus Test has the option to screen for specific microdeletions. A microdeletion is a small missing part of a chromosome. The Verifi Plus Test can screen for 1p36 deletion, 4p- (Wolf-Hirschhorn syndrome), 5p- (cri-du-chat syndrome), 15q11.2 (Prader-Willi Syndrome/ Angelman syndrome), and 22q11.2 deletion (DiGeorge syndrome or velocardiofacial syndrome). With the Verifi Plus Test, you may also choose to screen for extra copies of all the chromosomes.

Both Verifi and Verifi Plus can be performed as early as 10 weeks gestation. 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, based in the United States, 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: You may elect to have the sex of the pregnancy reported as part of the screening test. This is optional. For twin pregnancies results will report male for one or both fetuses, and female results apply to both fetusus.

If you do not wish to know the sex, please tell your health care provider not to disclose this information to you. Depending on the test ordered, you may not be able to prevent learning the sex of your pregnancy. In rare instances, incorrect sex results 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 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 cannot be predicted prenatally.

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 counsellor or other professional advisors 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. 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.

INCIDENTAL FINDINGS: In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations, also known as "incidental findings" may become evident. Our policy is to NOT REPORT on any incidental 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: 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.

OPTIONAL USE OF INFORMATION AND LEFTOVER SPECIMENS: Pursuant to best practices and clinical laboratory standards, with your consent, 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.

OPTIONAL RESEARCH: With your consent, 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.

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

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