

# ProSafe prenatal requisition form

**\*Required information**

**PATIENT INFORMATION:**

Last name:\* \_\_\_\_\_ First name:\* \_\_\_\_\_ MI: \_\_\_\_\_ DOB:\* DD / MM / YYYY

Sex: Female \_\_\_\_\_ Medical Record #: \_\_\_\_\_ Client sample ID: \_\_\_\_\_

Address: \_\_\_\_\_

City/State \_\_\_\_\_ Country: \_\_\_\_\_ Zip: \_\_\_\_\_

<input type="checkbox"/> CA PNS	PDC # _____	State accessioning # _____
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**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: DD/MM/YYYY Date of draw:\* DD/MM/YYYY

Maternal height:  cm  ft in \_\_\_\_\_ Maternal weight:  kgs  lbs \_\_\_\_\_

**DATING METHOD (MUST CHOOSE ONE):\***

LMP  Date of implantation  CRL

Other Specify: \_\_\_\_\_

**TEST INDICATIONS (CHOOSE AT LEAST ONE):**

**Prosafe Prenatal Test (chromosomes 21, 18, 13)**

<input type="checkbox"/> Singleton	<input type="checkbox"/> Twin
Additional option: <input type="checkbox"/> Sex chromosome aneuploidies (MX, XXX, XXY, and XYY)	Additional option: <input type="checkbox"/> Presence of Y chromosome

<input type="checkbox"/> Advanced maternal age (≥ 35 years) <input type="checkbox"/> Positive serum screen <input type="checkbox"/> Abnormal ultrasound <input type="checkbox"/> History suggestive of increased risk for the specified chromosome aneuploidies <input type="checkbox"/> Low risk/maternal anxiety <input type="checkbox"/> Other	<b>Comments</b> _____ _____ _____ _____ _____
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**BILLING INFORMATION (PRIOR AUTHORIZATION MAY BE REQUIRED BY CERTAIN CARRIES):**

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 test is not diagnostic or definitive. Because there is a small possibility that a screening test might be incorrect, it is important to talk to your physician to determine if further tests is needed.  
The XX Prenatal 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 U.S. Food and Drug Administration. The VeriPlus Prenatal Test is validated for singleton and twin pregnancies and VeriPlus 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 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 ProSafe 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. ProSafe has the option to screen for aneuploidies (extra copies) in all chromosomes.

**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.

LB-0078 Rev. D