

Patient Informed Consent

Introduction. This form describes the benefits, risks, and limitations of this screening test. You should seek genetic counseling prior to undergoing this testing. Read this form carefully before making your decision about testing.

Purpose. The purpose of this test is to screen your pregnancy for certain chromosomal abnormalities, such as too many or too few copies (this is called an “aneuploidy”) of chromosomes 21, 18, 13 as well as the sex chromosomes (X and Y). It can also test for trisomies (too many copies) of chromosomes 9 and 16, as well as microdeletions of certain chromosomes, which are listed on the front of this form. This test is not intended to be performed prior to the 10th week of pregnancy, as estimated by last menstrual period, crown rump length, or other appropriate method (equivalent to 8 weeks fetal age as determined by the date of conception.) Your healthcare provider has determined that this test is appropriate for you. Consult your healthcare provider for more information about this test, including the limitations and risks of this test, performance data, and error rates, descriptions of the common aneuploidies and sex chromosome aneuploidies, and what the test results may mean to you.

How this Test Works. This test screens for specific chromosomal abnormalities by looking at the DNA (genetic material) in your blood. To determine whether too few or too many chromosomes are present, this test uses a technology called ‘massively parallel DNA sequencing’ to count the number of copies of the specific chromosomes, and then uses a proprietary method to determine if there are too many or too few copies of the chromosomes in your pregnancy.

Sex of Pregnancy. Depending upon what your healthcare provider orders, the test results may include the sex of the pregnancy. If you do not wish to know the sex, please tell your healthcare provider not to disclose it to you. Depending upon the test ordered you may not be able to prevent learning the sex of your pregnancy. In rare instances, incorrect fetal sex results can occur.

Limitations of the Test. This is a screening test that only looks for specific chromosomal abnormalities. This means other chromosomal abnormalities may be present and could cause health concerns. This test does not test the health of the mother. Normal test results do not eliminate the possibility that your pregnancy may have other chromosomal abnormalities, birth defects, or other conditions, such as open neural tube defects. In addition, a normal result does not guarantee a healthy pregnancy or baby. This test, like many tests, has limitations including, false positive and false negative rates. 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 it was not really present (this is called a “false positive”). Further testing of the pregnancy and in some cases you, may be needed to confirm your test results which could result in additional expense to you and additional invasive testing procedures (e.g., amniocentesis or chorionic villus samples). We recommend that no irreversible clinical decisions be made based on these screening results alone. If definitive diagnosis is desired, chorionic villous sampling or amniocentesis would be necessary. Consult your healthcare provider for more information about the limitations of this test, including error rates (false positives and false negatives). Genetic counseling before and after testing is recommended.

Test Procedure. A tube of your blood will be drawn and sent to Verinata Health, Inc., a wholly owned subsidiary of Illumina, Inc., who 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 healthcare 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 healthcare provider to obtain this information.

Incidental Findings. In the course of performing the analysis for the indicated tests, information regarding other chromosomal alterations may become evident (called Incidental Findings). Our policy is to NOT REPORT on any Incidental Findings that may be noted in the course of analyzing the test data.

Privacy. We keep test results confidential. Your test results will only be released in connection with the testing service, to your healthcare provider, his or her designee, other healthcare providers involved in your medical care, or to another healthcare 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.

Use of Information and Leftover Specimens. Pursuant to best practices and clinical laboratory standards leftover de-identified specimens (unless prohibited by law) as well 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 law. 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 an anonymized or 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 healthcare provider that ordered the test. Speak with him/her if you would like a copy of the test results. Your healthcare provider is responsible for interpreting the test results and explaining the meaning to you. Illumina does not provide genetic counseling services directly to patients.

The verifi test is performed by Verinata Health Inc., a wholly owned subsidiary of Illumina, Inc.

Illumina, Inc., 800 Saginaw Drive, Redwood City, CA 94063. 1-855-266-6563. www.verifitest.com
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