verifi® prenatal test Requisition Form

ACCOUNT / ORDERING CLINICIAN

Physician:		Genetic Counselor:	
Account Name:		Account #:	
Address:		City:	
State:	ZIP:	Phone:	Fax:

ADDITIONAL REPORTING TO

Physician:		
Address:		
City:	State:	Zip:
Phone:	Fax:	

PATIENT INFORMATION (Attach face sheet or label when available)

Name: Last:	First:	MI:	DOB: mm/dd/yyyy	Sex: FEMALE	MR #:
Address:	Apt #:	City:	State:	Zip:	Phone:

TEST INFORMATION (Choose only ONE verifi® test)

For **Singleton** Pregnancy

- ☐ verifi® prenatal test for **chromosomes 21, 18, 13**
- ☐ verifi® prenatal test for **chromosomes 21, 18, 13 plus sex aneuploidies**

For **Twin** Pregnancy

- ☐ verifi® prenatal test for **chromosomes 21, 18, 13**
- ☐ verifi® prenatal test for **chromosomes 21, 18, 13 plus presence of Y only**

This test is validated for twin and singleton pregnancies of at least **10 weeks gestational age.**

ICD-9

☐ 659.53 ☐ 659.63 ☐ 655.83 ☐ 655.13 ☐ 796.5 ☐ 655.23

☐ Other:

TEST INDICATIONS

- ☐ Advanced maternal age
- ☐ Positive serum screen
- ☐ Abnormal ultrasound
- ☐ Hx suggestive of increased risk for T21, T18, T13 or sex chromosome aneuploidy

CLINICAL INFORMATION

Gestational age: wks / days on mm/dd/yy

Date of draw: mm/dd/yyyy

Comments:

I attest that I have ordered the verifi® prenatal test based on my professional judgment of medical necessity and that I have addressed the limitations of this test with my patient. I understand that Verinata Health, Inc. or PerkinElmer Labs/NTD or their affiliated companies, agents, or subcontractors may need additional information, and I agree to provide it as needed for purposes of reimbursement.

Physician signature: **Date: mm/dd/yyyy**

BILLING INFORMATION

☐ Private insurance (Attach face sheet / insurance card when available)

Relationship of patient to insured: ☐ Self ☐ Spouse ☐ Dependent ☐ Other

Name of insured: Last: First:

Member ID #: Group #:

Primary insurance: Prior authorization #:

Address: Apt #:

City: State: Zip:

Phone: Fax:

☐ Self pay (select a payment method or call 1-855-266-6563)

Choose one: ☐ Visa ☐ MasterCard ☐ Amex ☐ Discover ☐ Check (attach)

Credit card #:

Exp. date: mm/yyyy CVV #: Amount authorized: $

Name on card:

Billing address:

City: State: Zip:

☐ California PNS patient

PDC #:

☐ Client bill

Account name: Contract #:

PATIENT CONSENT

By signing this form, I voluntarily request that Verinata Health perform the verifi® prenatal test offered through PerkinElmer Labs/NTD. I have received and read a copy of the patient consent included on the back of this form from my provider. The risks, benefits, and limitations of this test have been adequately explained to me. I also accept the Financial Responsibility Statement as stated on the back of this form. I authorize Verinata Health and/or PerkinElmer Labs/NTD (or their affiliated companies or subcontractors) to perform the necessary steps to obtain reimbursement for the verifi® prenatal test, including but not limited to insurance verification and case assessment.

FOR MASSACHUSETTS PATIENTS ONLY: I have discussed with the healthcare provider who is ordering this test the reliability of positive and negative test results for aneuploidy for chromosomes 21, 18, 13, and for sex chromosomes (if ordered) and the level of certainty to which a positive test result predicts the presence of these conditions. I understand that genetic counseling is important when obtaining genetic testing. My healthcare provider has provided me with information identifying a genetic counselor or medical geneticist from whom I may obtain additional counseling.

Patient signature: **Date: mm/dd/yyyy**

Verinata Health (an Illumina company), 800 Saginaw Drive, Redwood City, CA 94063. 1-855-266-6563. CAP: 7519312 CLIA: 05D2013691 www.verinata.com
PerkinElmer Labs, Inc./NTD, 80 Ruland Road, Suite 1, Melville, NY 11747

VERINATA PART NO. LB-0033, REV. G

verifi® prenatal test

Requisition Form

PATIENT INFORMED CONSENT FOR VERINATA HEALTH, INC. VERIFI® PRENATAL TEST

Performed by Verinata Health; Offered through PerkinElmer Labs/NTD

This blood test is designed to measure the combined maternal and fetal DNA present in maternal blood, and is considered a genetic test. Your written consent is required to perform a genetic test. This consent form provides information about the Verinata Health verifi® prenatal test, including what the test is for, the testing process, and what results may mean. Before signing this document, you should ask your healthcare provider to answer any questions you may have about this test.

About the verifi® prenatal test: The verifi® prenatal test looks at the DNA (genetic material) in your blood. The test can tell if there are too many or too few copies (also called an "aneuploidy") of certain chromosomes—21, 18, and 13—present in your fetus. The test can also look at sex chromosomes (X and Y), and can determine if there are too many or too few copies of the sex chromosomes. This test uses a technology called 'massively parallel DNA sequencing' to count the number of copies of these chromosomes, and then uses a calculation method to determine if there are too many or too few copies of these chromosomes in your fetus.

The verifi® prenatal test has been studied in patients who have an increased risk for having a baby with an incorrect change in the number of certain chromosomes. Your healthcare provider has determined that you are an appropriate candidate for this test.

Common Aneuploidies:

Trisomies occur when three, instead of the usual two, copies of a chromosome are present. Trisomy 21, trisomy 18, and trisomy 13 are three of the most commonly occurring trisomies seen in babies at birth.[1] Although the outcomes are variable, these conditions can cause mild to severe intellectual disabilities, and can cause multiple physical problems including congenital heart defects, defects in other organs, and a shortened life span. The chance of having a baby with one of these conditions gets higher as a woman gets older.

Sex Chromosome Aneuploidies[1]: The verifi® prenatal test also gives your healthcare provider the option to test for changes in the number of sex chromosomes. Sex chromosome aneuploidies are conditions in which there is a change from the usual 2 copies of sex chromosomes in males (XY) or females (XX). About 1 in 400 babies that are born will have a sex chromosome aneuploidy. The most common sex chromosome aneuploidies are caused by a missing sex chromosome in girls (45,X or monosomy X, also called Turner syndrome) or an extra chromosome in boys or girls [47,XXY (Klinefelter syndrome), 47,XYY, or 47,XXX]. Children with a sex chromosome aneuploidy can have difficulties with language skills, motor skills, and learning, but can lead healthy and productive lives. For more information on these conditions, please visit our website at http://www.verinata.com. Your healthcare provider or genetic counselor can also give you more information about these conditions.

If your healthcare provider chooses the sex chromosome option, and no sex chromosome aneuploidies are found, then the test report will state whether your baby is expected to be a girl or a boy. If you do not wish to know the gender of your baby, please let your healthcare provider know in advance to not disclose this information to you.

The Testing Process: To analyze the DNA from your blood, your healthcare provider will take a blood sample from you (between 7 and 10mL, in a standard blood draw). The physical risk to you of obtaining the blood sample is usually minimal.

Some important points about the testing and reporting process:

- Your test results are confidential to the extent required by law. The Verinata Health, Inc. and PerkinElmer Labs/NTD respective Notices of Privacy Practices set forth the companies' privacy policies and are available on the respective company websites at http://www.verinata.com and at http://www.ntdlabs.com.
- Only Verinata Health, Inc. and PerkinElmer Labs/NTD laboratory personnel will have access to your blood sample and testing information and results. All results will be kept confidential as per applicable laws and guidelines. Results will only be disclosed to your ordering healthcare provider(s).
- Only authorized tests will be performed on your identified blood sample.
- Your sample will be destroyed at the end of the testing process, in accordance with your state's requirements (e.g., New York State samples will be destroyed within 60 days from the day the test report is released).
- Collecting information on your pregnancy after prenatal diagnosis is part of a laboratory's standard practice for quality purposes, and is required in several states. As such, Verinata Health, Inc. may contact your healthcare provider to obtain this information.

The test is performed after 10 weeks of pregnancy. Adequate DNA in the blood sample is required to complete the test. Additional samples may be needed if the sample is damaged in shipment or incorrectly submitted. After analysis in Verinata Health's California laboratory, the test results will be returned to your healthcare provider who will discuss them with you.

Obtaining and Interpreting Test Results: Your test results will be returned to your healthcare provider after analysis by Verinata Health, Inc. The results will be reported by Verinata Health or PerkinElmer Labs/NTD only to the qualified healthcare provider(s) indicated on the front of this form. Your results will tell your healthcare provider whether too few or too many copies of the chromosomes being tested for are present. It is the responsibility of the healthcare provider ordering this test to understand the specific uses and limitations of this test, and to make sure you understand them as well. If a genetic disorder is detected, follow up testing (such as amniocentesis or chorionic villus sampling) may be recommended to confirm the result.

Your test report will include one of three possible results for chromosomes 21, 18, and 13: No Aneuploidy Detected, Aneuploidy Detected, or Aneuploidy Suspected (Borderline Value). Sex Chromosomes will be reported as No Aneuploidy Detected, or Aneuploidy Detected.

A *No Aneuploidy Detected* test result means that this test identified the expected number of copies of chromosomes.

An *Aneuploidy Detected* test result means that this test identified too many or too few copies of one of the chromosomes. This can indicate either a trisomy or a sex chromosome aneuploidy.

An *Aneuploidy Suspected* test result means that this test identified more copies than expected of one of the chromosomes. This means that your provider should follow up on this result to obtain more information.

The verifi® prenatal test does not test for all health problems. Normal results do not eliminate the possibility that your pregnancy may have other chromosomal/genetic conditions, birth defects, or other complications. A 'No Aneuploidy Detected' result on this test does not completely rule out the presence of the conditions being tested for, and does not guarantee the health of your baby. The verifi® prenatal test has been validated for chromosomes 21, 18, 13 and sex chromosomes only. The verifi® prenatal test is a highly accurate advanced screening test that is non-invasive. Genetic counseling before and after testing is recommended. Results of 'Aneuploidy Detected' or 'Aneuploidy Suspected' are considered positive and patients should be offered invasive prenatal procedures for confirmation. A negative test does not ensure an unaffected pregnancy. Chorionic villus sampling and amniocentesis provide definitive diagnostic information, but may pose harm to the fetus.

Before signing this form, if you have any questions regarding this test or the meaning of possible test results you should ask your healthcare provider.

This test represents the newest service currently available for prenatal testing. However, as with any complex genetic test, there is always a chance of failure or error in sample analysis. Extensive measures are taken to avoid these errors. The verifi® prenatal test was tested in a multi-center clinical study, in a population of high risk patients.

Please see the chart below for detailed performance on the verifi® prenatal test.

verifi® prenatal test performance data**

Chromosome	N	Sensitivity	95% CI	Specificity	95% CI	Accuracy	95% CI
21	500	>99.9% (90/90)	96.0 – 100.0	99.8% (409/410)	98.7 – 100.0	-	-
18	501	97.4% (37/38)	86.2 – 99.9	99.6% (461/463)	98.5 – 100.0		
13	501	87.5% (14/16)	61.7 – 98.5	>99.9% (485/485)	99.2 – 100.0		
Monosomy X	508	95% (19/20)	75.1 – 99.9	99.0% (483/488)	97.6 – 99.7		
XX	508	97.6% (243/249)	94.8 – 99.1	99.2% (257/259)	97.2 – 99.9	98.40%	96.9 – 99.3
XY	508	99.1% (227/229)	96.9 – 99.9	98.9% (276/279)	96.9 – 99.8	99.00%	97.7 – 99.7
XXX/XXY/XYY	Other sex aneuploidies will be reported if detected. (Limited data preclude performance calculations.)						

*** Data on file, Verinata Health, Inc.*

Financial Responsibility Statement

I hereby authorize Verinata Health and/or PerkinElmer Labs/NTD to furnish my designated insurance carrier, health plan or third party administrator the information on this form, verifi® prenatal test results, and other pertinent information provided by my healthcare provider, if necessary for reimbursement. I also authorize all applicable benefits of my plan to be payable to Verinata Health and/or PerkinElmer Labs/NTD for the services provided. I understand that I am responsible for any amounts not paid by insurance for reasons including, but not limited to, non-covered or non-authorized services, to the extent permitted by applicable law and/or Verinata's and PerkinElmer Labs/NTD network provider contracts with insurers.

Sample ICD-9 Diagnosis Codes

659.63 - ELDERLY MULTIGRAVIDA W/ANTPRTM COND/COMPLICATION

659.53 - ELDERLY PRIMIGRAVIDA, ANTEPARTUM

655.13 - CHROMOSOM ABNORM FETUS AFFECT MGMT MOM ANTPRTM

655.83 - OTH KNOWN/SUSPECTED FETAL ABNORMALITY-NEC-APC/C

796.5 - ABNORMAL FINDING ON ANTENATAL SCREENING

655.23 - HEREDITARY DZ POSS AFFCT FETUS ANTPRTM COND/COMPL 19

The ICD-9 diagnosis code(s) must be defined for the most detailed level of specificity available. This list of common ICD-9 diagnosis codes for prenatal testing is not complete. Please refer to the ICD-9 manual for a complete listing. These codes are being provided for informational purposes only; it is ultimately the responsibility of the attending physician to select the appropriate ICD-9 code supported by the patient's medical record.

[1] *Genetic Disorders and the Fetus: Diagnosis, Prevention, and Treatment.* Sixth Edition, ©2010; Milunsky and Milunsky; p 9, Table 1.3, p 197, Table 6.2, p 858, p 4, p 199, p 278

Verinata Health (an Illumina company), 800 Saginaw Drive, Redwood City, CA 94063. 1-855-266-6563. CAP: 7519312 CLIA: 05D2013691 www.verinata.com
PerkinElmer Labs, Inc./NTD, 80 Ruland Road, Suite 1, Melville, NY 11747

VERINATA PART NO. LB-0033, REV. G