NTD | Eurofins Clinical Diagnostics
80 Ruland Rd, Suite 1 ▪ Melville, NY ▪ 11747 ▪ (855) 754-5221 ▪ Fax (631) 425-0864 ▪ reporting@ntd-eurofins.com

verifi® from NTD Labs

Physician ID #: 9999
Physician Tel #: (999) 999-9999
OB/GYN SPECIALISTS
SUIT 100
SOMEWHERE, US, 99999

Patient Name: DOE, JANE
Client ID #: 1234567
Patient ID #: 18SE5999999
Date of Birth: 09/07/71
Draw Date: 09/07/15
Date Received: 09/09/15
Report Date: 09/22/15

verifi® from NTD Labs was performed at:

Illumina, Inc. 800 Saginaw Drive, Redwood City, CA 94063

See attached report.

Jonathan B. Carmichael, Ph.D
Laboratory Director,
Eurofins NTD, LLC

Terrence W. Hallahan, Ph.D
Laboratory Director,
Eurofins NTD, LLC

Verifi Plus™ prenatal screening report

Verifi Plus™ Prenatal Test

REPORT RELEASED
Date: 09/22/15 Time: 08:45 AM

PROVIDER INFORMATION
Eurofins NTD, Inc
Attn: Terrence Hallahan, Ph.D.
80 Ruland Road
Melville, NY 11747
Phone: (888) 754-5221
Fax: (631) 425-0864

SECOND RECIPIENT

PATIENT INFORMATION
Name: Jane Doe
DOB: 09/07/1971
GA: XXXXXXXX
Indication: XXXXXXXX
Medical record/patient ID: XXXXXXXX

SAMPLE INFORMATION
Client Sample ID: 1234567
Order ID: 1234567
Date of Draw: 09/07/15
Date Received: 09/22/15
Pregnancy Type: Singleton

ANEUPLOIDY DETECTED

RESULTS SUMMARY:

CHROMOSOME	RESULTS	PPV (%)
Chromosome 21	**POSITIVE: Aneuploidy detected** Results consistent with pregnancy at increased risk for trisomy 21.	XX
Chromosome 18	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 18.	
Chromosome 13	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of chromosome 13.	
All Other Autosomal Chromosomes	**NEGATIVE: No aneuploidy detected** Results consistent with two copies of all other autosomes.	NA*
Sex Chromosomes	**POSITIVE: Aneuploidy detected** Results consistent with pregnancy at increased risk for XO (monosomy X), XXX, XYY, XYY.	NA**
Microdeletions (1p36, 4p16.3, 5p15.2, 15q11.2, 22q11.2)	**POSITIVE: Abnormality detected** Results consistent with a microdeletion in the 22q11.2 region. **NEGATIVE: No aneuploidy detected** Results consistent with no microdeletions detected in the regions of 1p36, 4p16.3, 5p15.2, 15q11.2, 22q11.2	NA***

CLINICAL COMMENTS: This is a screening test; therefore, false positive and false negative results can occur. Results may be reflective of fetal, placental, or maternal conditions. No irreversible clinical decisions should be made based on these screening results alone. Clinical correlation is indicated. If definitive diagnosis is desired, chorionic villus sampling or amniocentesis would be necessary. Genetic counseling is recommended. The fetal fraction (FF) is estimated to be 23%. FF estimation is one component of the Verifi Plus™ algorithm and is combined with other quality metrics to determine the confidence in the results. The FF estimate is not used in isolation to exclude samples.

Positive predictive value (PPV) is calculated based on stated performance, maternal and gestational age as provided on the Test Requisition Form (TRF). Other factors may impact the patient specific PPV. For more information about PPV please visit us at www.illumina.com/ppv.

*Aneuploidies involving chromosomes other than 21, 13, 18, X, or Y are rare, and prevalence is not available, which precludes accurate calculation of PPV.
**Performance data for sex chromosome aneuploidy is limited, precluding accurate calculation of PPV.
***Performance data for microdeletion analysis is limited, precluding accurate calculation of PPV.

OTHER COMMENTS: Verifi Plus™ comments will be in this section...Lorem ipsum dolor sit amet, ad dicat repudiare ius, est ridens oporteat definiebas te, odio munere possit an vel. Velit legere vim eu, vix maiestatis reprehendunt ei, eripuit blandit detracto eos at. Elit legere vim eu, vix maiestatis reprehendunt ei, eripuit blandit detracto eos a dolor consetetur dissentiet usu, an mei aliquam reformidans.

PERFORMANCE AND LIMITATIONS

LIMITATIONS OF THE TEST: The Verifi Plus™ Prenatal Test is validated for aneuploidy of any chromosome, including 21, 13, 18, X, and Y and for specific deletions in chromosomal regions 1p36, 4p16.3, 5p15.2, 15q11.2, 22q11.2, in singleton pregnancies, with gestational age of at least 10 weeks 0 days. This is a screening test that looks only for specific chromosomal abnormalities. A normal result does not eliminate the possibility that the pregnancy is associated with other chromosomal or subchromosomal abnormalities, 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). Examples include maternal XXX, sex chromosome status, or benign and malignant maternal neoplasm. CPM may be associated with a higher chance for pregnancy complications or for uniparental disomy (UPD), which may affect the growth and development of the fetus. Some of these rare chromosomal aneuploidies may only occur in mosaic form. Clinical consequences depend on the chromosome involved and can not be predicted prenatally. This test, like many tests, have limitations, including false negative and false positive results. A negative test result does not eliminate the possibility of chromosomal abnormalities for the tested chromosomes or microdeletions. See performance metrics for test performance.

PERFORMANCE METRICS:†

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	_	_
Chromosome	N	Sensitivity	95% CI	Specificity	95% CI	Accuracy	95% CI
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 of these more rare aneuploidies preclude performance calculations.)						
Microdeletions & other autosomal aneuploidies	Microdeletions and other autosomal aneuploidies if requested and detected will be reported. (Limited data of these more rare abnormalities preclude performance calculations.)						

†Data on file at Illumina, Inc. regarding Performance and Method Comparison studies

TEST METHOD: Nucleic Acid extraction, DNA sequencing, and analysis of sequencing results to determine fetal aneuploidy.

DISCLAIMER: The manner in which this information is used to guide patient care is the responsibility of the health care provider, including advising for the need for genetic counseling or diagnostic testing. Any test should be interpreted in the context of all available clinical findings.

DISCLOSURE: The Verifi Plus 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. The verifi test has not been cleared or approved by the U.S. Food and Drug Administration.

This prenatal test is performed by Verinata Health, Inc., a wholly owned subsidiary of Illumina, Inc.
Illumina, Inc., 800 Saginaw Drive, Redwood City, CA 94063 1-855-266-6553
CAP: 7519312 CLIA: 05D2013691 California License #: CLF00340177
Laboratory Directors: Meredith Halks Miller, MD, William K. Seltzer, PhD, FACMG, Eileen De Feo, PhD, Beki Sanderson

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