## TEST REPORT

**Patient Name:** A Patient  
**Date of Birth:** 01/01/1970  
**Maternal Age at EDD:** 20  
**Gestational Age:** 18 weeks/6 days

### RESULTS

<table>
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</tr>
</tbody>
</table>

**SEX OF FETUS:** Male  
**Fetal fraction:** xx%

### LOW RISK for Trisomies 21, 18, 13, and Monosomy X and Triploidy.

**Interpretation:** Reasons for uninformative DNA pattern can include: higher than expected levels of homoygosity (i.e. haploblocks) that affect the test bioinformatics, clarity of maternal SNP profile, or use of egg donors and/or surrogates. Quality metrics include, but are not limited to total DNA amount (maternal and fetal combined), number of SNP reads, and other metrics that are in place to ensure good quality data for accurate, consistent results. Results indicating presence of vanishing twins/triploidy may require additional clinical evaluation such as ultrasound and/or review of medical records along with invasive testing to confirm presence of triploidy. Multiple gestations may complicate these results and are considered out of test specifications.

**Testing Methodology:** DNA isolated from the maternal blood, which contains fetal DNA, is amplified at 15,500 loci using a targeted PCR assay, and sequenced using an Illumina HiSeq high-throughput sequencer. Where available, paternal genomic DNA is amplified and sequenced using the same protocol. Sequencing data is analyzed using the NATUS algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X and Y, thereby identifying any whole chromosome abnormalities or triploidy at those chromosomes. If a sample fails to meet the quality threshold, no result will be reported for that chromosome and a redraw may be requested. **Limitations:** This test has been validated on women with a singleton pregnancy, and of at least nine weeks gestational age. Tests run prior to 9 weeks have an increased no result rate. This test will not return results on pregnancies conceived with an egg donor or those which used a surrogates and cannot be performed on women who have received a bone marrow transplant. If a maternal sample is submitted and non-paternity is identified, it will not be reported and the paternal sample will not be used in the analysis. Samples are analyzed for aneuploidy of chromosomes 13, 18, 21, X and Y only. Abnormalities on other chromosomes or those involving only a portion of the chromosome tested cannot be excluded. This test may not be able to identify abnormalities or may report a positive result in the presence of mosaicism (which may be confined to the placenta). Fetal sex will be reported as male or female based on presence or absence of Y chromosome and does not confirm presence or absence of SRY. Gender will not be reported in cases consistent with triploidy/vanishing twins. Prenancies involving multiples or abnormal ultrasound findings may be better served by other screening or testing options. There is a chance of detecting maternal sex chromosome abnormalities during this testing process (either in full or mosaic form), which, if present, may interfere with the accuracy of the results on the fetal sex chromosomes. Although this test has a high accuracy, the results are not diagnostic. These results should always be interpreted by a clinician in the context of clinical and familial data.

### Test Specifications

<table>
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<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>T21</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>T18</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>T13</td>
<td>&gt;99%</td>
<td>&gt;99%</td>
</tr>
<tr>
<td>MX</td>
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This test has been validated on women who have received a bone marrow transplant. If a paternal sample is submitted and non-paternity is identified, it will not be reported and the paternal sample will not be used in the analysis. Samples are analyzed for aneuploidy of chromosomes 13, 18, 21, X and Y only. Abnormalities on other chromosomes or those involving only a portion of the chromosome tested cannot be excluded. This test may not be able to identify abnormalities or may report a positive result in the presence of mosaicism (which may be confined to the placenta). Fetal sex will be reported as male or female based on presence or absence of Y chromosome and does not confirm presence or absence of SRY. Gender will not be reported in cases consistent with triploidy/vanishing twins. Prenancies involving multiples or abnormal ultrasound findings may be better served by other screening or testing options. There is a chance of detecting maternal sex chromosome abnormalities during this testing process (either in full or mosaic form), which, if present, may interfere with the accuracy of the results on the fetal sex chromosomes. Although this test has a high accuracy, the results are not diagnostic. These results should always be interpreted by a clinician in the context of clinical and familial data.

**References:**
- Snijders et al. Maternal age and gestational age specific risk for chromosomal defects. Fetal Dign

**APPROVED BY:**  
Susan Zneimer, Ph.D., FACMG, Laboratory Director

**IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 650-249-9092 AND ASK FOR THE GENETIC COUNSELOR ON CALL.**

**CLIA ID:** 05D1082992

**Natera, Inc., 1-855-866-NIP T (6478) 201 Industrial Road Suite 410, San Carlos, CA 94070**
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**TEST REPORT**

**Patient Name:** A Patient  
**Date of Birth:** 01/01/1970  
**Maternal Age at EDD:** 20  
**Gestational Age:** 18 weeks/6 days

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**Results are consistent with a possible triploid or vanishing twin pregnancy. Follow-up counseling and testing is recommended.**

Although these results increase the risk for a triploid fetus, the possibility of a vanishing twin pregnancy (or unrecognized multiple gestation) cannot be excluded. Review of clinical history along with ultrasound findings and possible diagnostic prenatal testing is recommended to fully interpret results.

### RESULTS

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<td>1/665 (0.22%)</td>
<td>N/A</td>
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<td>Trisomy 13</td>
<td>1/1,481 (0.07%)</td>
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<td>Monosomy X</td>
<td>1/255 (0.39%)</td>
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<td>No result</td>
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<tr>
<td>Triploidy/Vanishing twins</td>
<td></td>
<td>Increased risk</td>
<td>Follow up counseling and testing recommended</td>
<td></td>
</tr>
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**SEX OF FETUS: N/A**  
**Fetal fraction:** xx%

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**Interpretation:** Reasons for uninformative DNA pattern can include: higher than expected levels of homoygosity (i.e. haploblocks) that affect the test bioinformatics, clarity of maternal SNP profile, or use of egg donors and/or surrogates. Quality metrics include, but are not limited to total DNA amount (maternal and fetal combined), number of SNP reads, and other metrics that are in place to ensure good quality data for accurate, consistent results. Results indicating presence of vanishing twins/triploidy may require additional clinical evaluation such as ultrasound and/or review of medical records along with invasive testing to confirm presence of triploidy. Multiple gestations may complicate these results and are considered outside of test specifications. **Testing Methodology:** DNA isolated from the maternal blood, which contains fetal DNA, is amplified at 19,500 loci using a targeted PCR assay, and sequenced using an Illumina HiSeq high-throughput sequencer. Where available, paternal genomic DNA is amplified and sequenced using the same protocol. Sequencing data is analyzed using the NATUS algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X and Y, thereby identifying any whole chromosome abnormalities at those chromosomes. If a sample fails to meet the quality threshold, no result will be reported for that chromosome and a redraw may be requested. **Limitations:** This test has been validated on women with a singleton pregnancy, and of at least nine weeks gestational age. Tests run prior to 9 weeks have an increased no result rate. This test will not return results on pregnancies conceived with an egg donor or those which used a surrogate and cannot be performed on women who have received a bone marrow transplant. If a paternal sample is submitted and non-paternity is identified, it will not be reported and the paternal sample will not be used in the analysis. Samples are analyzed for aneuploidy of chromosomes 13, 18, 21, X and Y only. Abnormalities on other chromosomes or those involving only a portion of the chromosomes tested cannot be excluded. This test may not be able to identify abnormalities or may report a positive result in the presence of mosaicism (which may be confined to the placenta). Fetal sex will be reported as male or female based on presence or absence of a Y chromosome and does not confirm presence or absence of SRY. Gender will not be reported in cases consistent with triploid/vanishing twins. Pregnancies involving multiples or abnormal ultrasound findings may be better served by other screening or testing options. There is a chance of detecting maternal sex chromosome abnormalities during this testing process (either in full or mosaic form), which, if present, may interfere with the accuracy of the results on the fetal sex chromosomes. Although this test has a high accuracy, the results are not diagnostic. These results should always be interpreted by a clinician in the context of clinical and familial data.

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**References:**


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APPROVED BY: [Signature]

**IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 800-247-7072 AND ASK FOR THE GENETIC COUNSELOR ON CALL.**

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**Report date:** 4/4/2013  
**Case file ID:** 20  
**Collection kit bar code:**

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**CLIA ID:** 05D01602992  
**Natera, Inc., 1-855-866-NIP T (6478)**  
**201 Industrial Road Suite 410, San Carlos, CA 94070**

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**Natera® panaromaa prenatal test™**

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**Greg M. Enns MB, CHB, FAAP**

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**Susan Znaimer, Ph.D., FACMG, Laboratory Director**

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**natera®**

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**Collections (continued)  
**2** May be performed on a maternal sample.  
**3** May be performed on a maternal sample.  
**4** May be performed on a patient who has received a bone marrow transplant.  
**5** May be requested.  
**6** May be requested.  
**7** May be requested.
LOW RISK for Trisomies 21, 18, and 13, and Monosomy X.

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1Excludes cases with evidence of fetal and/or placental mosaicism. 2Based on maternal age and gestational age where applicable. 3Based on a priori risk and test results.

Interpretation: Reasons for uninformative DNA pattern can include: higher than expected levels of homoygosity (i.e. haploblocks) that affect the test bioinformatics, clarity of maternal SNP profile, or use of egg donors and/or surrogates. Quality metrics include, but are not limited to total DNA amount (maternal and fetal combined), number of SNP reads, and other metrics that are in place to ensure good quality data for accurate, consistent results. Results indicating presence of vanishing twins/triploidy may require additional clinical evaluation such as ultrasound and/or review of medical records along with invasive testing to confirm presence of triploidy. Multiple gestations may complicate these results and are considered outside of test specifications. Testing Methodology: DNA isolated from the maternal blood, which contains fetal DNA, is amplified at 18,500 loci using a targeted PCR assay, and sequenced using an Illumina HiSeq high-throughput sequencer. Where available, paternal genomic DNA is amplified and sequenced using the same protocol. Sequencing data is analyzed using the NATUS algorithm to determine the fetal copy number for chromosomes 13, 18, 21, X and Y, thereby identifying any whole chromosome abnormalities at those chromosomes. If a sample fails to meet the quality threshold, no result will be reported for that chromosome and a redraw may be requested. Limitations: This test has been validated on women with a singleton pregnancy, and of at least nine weeks gestational age. Tests run prior to 9 weeks have an increased no result rate. This test will not return results on pregnancies conceived with an egg donor or those which used a surrogate and cannot be performed on women who have received a bone marrow transplant. If a paternal sample is submitted and non-paternity is identified, it will not be reported and the paternal sample will not be used in the analysis. Samples are analyzed for aneuploidy of chromosomes 13, 18, 21, X and Y only. Abnormalities on other chromosomes or those involving only a portion of the chromosomes tested cannot be excluded. This test may not be able to identify abnormalities or may report a positive result in the presence of mosaicism (which may be confined to the placenta). Fetal sex will be reported as male or female based on presence or absence of a Y chromosome and does not confirm presence or absence of SRY. Gender will not be reported in cases consistent with triploidy/vanishing twins. Pregnancies involving multiples or abnormal ultrasound findings may be better served by other screening or testing options. There is a chance of detecting maternal sex chromosome abnormalities during this testing process (either in full or mosaic form), which, if present, may interfere with the accuracy of the results on the fetal sex chromosomes. Although this test has a high accuracy, the results are not diagnostic. These results should always be interpreted by a clinician in the context of clinical and familial data.


If the ordering provider has questions or wishes to discuss the results, please contact us at 650-249-9092 and ask for the genetic counselor on call.

APPROVED BY: Greg M. Enns MB, CHB, FAAP
APPROVED BY: Susan Znaimer, Ph.D., FACMG, Laboratory Director

Natera, Inc., 1-855-866-NIPT (6478)
201 Industrial Road Suite 410, San Carlos, CA 94070
Unable to report due to uninformative DNA pattern. Redraw is not recommended.

Reasons for uninformative DNA pattern can include: higher than expected levels of homozygosity (i.e. haploblocks) that affect the test bioinformatics, multiple gestations, vanishing twins, triploidy, clarity of maternal SNP profile, or use of egg donors and/or surrogates.

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**SEX OF FETUS: Male**

**Fetal fraction:** xx%

**Patient Name:** A Patient
**Date of Birth:** 01/01/1970
**Maternal Age at EDD:** 20
**Gestational Age:** 18 weeks/6 days

**Ordering Physician:** Dr. Pepper, MD
**Clinic Information:** IVF, Inc.

**Samples Collected:** 1/1/2013
**Samples Received:** x Mother Blood

**Report date:** 4/4/2013
**Case file ID:** 20

**APPROVED BY:** Greg M. Enns MB, CHB, FAAP
**APPROVED BY:** Susan Znaimer, Ph.D., FACMG, Laboratory Director

**References:**


This test was developed and its performance characteristics determined by Natera, Inc as required by the CLIA ‘88 regulations. It has not been cleared or approved by the U.S. Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. These results are provided for informational purposes only

**IF THE ORDERING PROVIDER HAS QUESTIONS OR WISHES TO DISCUSS THE RESULTS, PLEASE CONTACT US AT 450-249-9092 AND ASK FOR THE GENETIC COUNSELOR ON CALL.**
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**APPROVED BY:**

### SEX OF FETUS: N/A

**Fetal fraction:** N/A

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**Natera, Inc., 1-855-866-NIP T (6478)**

201 Industrial Road Suite 410, San Carlos, CA 94070

Report ID Customer CLIA ID 05D1082992

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