1035 O'Brien Drive
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F 833.915.0146
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| PATIENT | | SAMPLE | | PROVIDER | |
|---|---|---|---|---|---|
| **First Name** | Jane | **Sample Type** | Blood | **Provider** | John Smith |
| **Last Name** | Doe | **Date Collected** | 08/11/2022 | **Clinic Address** | 1035 O'Brien Drive<br>Menlo Park, CA 94025 |
| **DOB** | 01/01/2000 | **Date Received** | 08/12/2022 | **Phone Number** | 650-460-2551 |
| **Ethnicity** | Northern European | **Accession ID** | 1234567X0000 | **Fax Number** | 833-915-0146 |
| **Gender** | Female | **Requisition ID** | 1234567X0000-1 | | |
| **Gestational Age** | 10w2d | **Date Reported** | 08/18/2022 | | |
| **Medical Record #** | 123456789 | | | | |

# UNITY Fetal Antigen NIPT: **Kell (K) Antigen**

Singleton Gestation

## SUMMARY OF RESULTS

### Kell (K) Antigen: Detected

The clinic reports the patient has anti-Kell (K) alloimmunization. NIPT was performed to determine the presence or absence of the Kell (K) antigen. The Kell (K) antigen was DETECTED in the cell-free DNA. Patients with anti-Kell (K) alloimmunization carrying a fetus positive for the Kell (K) antigen have a pregnancy at increased risk for hemolytic disease of the fetus and newborn (HDFN). Appropriate clinical surveillance is recommended based on the patient's clinical history.

The fetal fraction was 9.9%.

## METHODS AND LIMITATIONS

### UNITY Fetal Antigen NIPT

Cell-free DNA (cfDNA) was isolated from 2-4mL of plasma from whole blood collected in a Streck cell-free DNA tube. The resulting DNA was subjected to a Custom Amplicon Panel PCR with proprietary Quantitative Counting Template molecules. The amplified DNA was sequenced by synthesis on an Illumina sequencer. Results were aligned and examined on a custom bioinformatics pipeline and compared to the published human genome build GRCh37/hg19 reference sequence. A modified fetal fraction calculation is performed for twin pregnancies and pregnancies conceived with a gestational carrier.

Paternal alleles present in common single nucleotide variants (SNVs) were used to measure the fraction of cell-free DNA of fetal origin. Quantitative Counting Templates were used to quantify the presence or absence of a custom panel of immunogenic gene(s) or allelic variant(s) in the cell-free DNA. Results are reported only for the specific antigen(s) as requested by the provider.

Test Limitations: Fetal antigen NIPT is only performed for pregnant patients alloimmunized against the specific antigen screened. Results may not be reported when the amount of cell-free fetal DNA in the blood sample is too low. Results from this test are highly accurate; however, discordant results may occur. Potential causes of discordant results include rare mutations or fusion genes, vanishing twin, maternal organ or bone marrow transplant, recent blood transfusion, and patient misidentification/sample handling errors.

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This NIPT was developed and its performance characteristics determined by the BillionToOne laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The BillionToOne laboratory is regulated under CLIA. This test is used for clinical purposes. It should not be regarded as investigational or for research.

| | | | | | |
|---|---|---|---|---|---|
| **BillionToOne Laboratory** | | **Laboratory Director** | Joseph Michael Anderson, MD | **Phone** | (650) 460-2551 |
| 1035 O'Brien Drive | | **CLIA ID** | 05D2167800 | **Fax** | (833) 915-0146 |
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BILLIONTOONE

| PATIENT | | SAMPLE | | PROVIDER | |
|---|---|---|---|---|---|
| **First Name** | Jane | **Sample Type** | Blood | **Provider** | John Smith |
| **Last Name** | Doe | **Date Collected** | 08/11/2022 | **Clinic Address** | 1035 O'Brien Drive<br>Menlo Park, CA 94025 |
| **DOB** | 01/01/2000 | **Date Received** | 08/12/2022 | **Phone Number** | 650-460-2551 |
| **Ethnicity** | Northern European | **Accession ID** | 1234567X0000 | **Fax Number** | 833-915-0146 |
| **Gender** | Female | **Requisition ID** | 1234567X0000-1 | | |
| **Gestational Age** | 10w2d | **Date Reported** | 08/18/2022 | | |
| **Medical Record #** | 123456789 | | | | |

# UNITY™ Complete: **Aneuploidy Screen**

Singleton Gestation

## SUMMARY OF RESULTS

**LOW RISK** FETUS | **MALE** FETAL SEX | **9.9%** FETAL FRACTION

| CONDITIONS SCREENED | FETAL RISK *by* NIPT | RISK *Before* NIPT | RISK *After* NIPT |
|---|---|---|---|
| **Trisomy 21** | **Low Risk** | **1 in 675** | **<1 in 10,000** |
| **Trisomy 18** | **Low Risk** | **1 in 2126** | **<1 in 10,000** |
| **Trisomy 13** | **Low Risk** | **1 in 5936** | **<1 in 10,000** |
| **Monosomy X** | **Low Risk** | **1 in 250** | **<1 in 10,000** |
| **Sex Chromosome Aneuploidy** (XXX / XXY / XYY) | **Not Detected** | | |

## RECOMMENDED FOLLOW-UP

Genetic counseling is available to review the implications of this result.

The patient may contact BillionToOne at (650) 460-2551 to schedule an appointment for a complimentary telephone genetic consultation to review these results.
A genetic counselor can also be found at www.nsgc.org.

**Interpretation** *next page* ›

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| Patient Name Jane Doe | DOB 01/01/2000 | Gestational Age 10w2d | Medical Record # 123456789 |
|---|---|---|---|

# INTERPRETATION

## UNITY™ Complete: **Aneuploidy Screen**
## Singleton Gestation

**The fetus is LOW RISK to be affected with aneuploidy of chromosomes 13, 18, 21, X, & Y.**
**The estimated fetal fraction was 9.9%**

NIPT was performed to evaluate for fetal copy number of chromosomes 13, 18, 21, X, & Y.

This NIPT result is valid only for a singleton gestation.

A low risk NIPT result significantly reduces the risk of the screened aneuploidies; it does not eliminate the risk. NIPT does not exclude abnormalities of other chromosomes not evaluated by the screen, microdeletions, triploidy, other genetic syndromes, or birth defects. A low risk NIPT result does not guarantee a normal pregnancy outcome.

Genetic counseling is available for this patient to review the implications of this result. The patient may contact BillionToOne at (650) 460-2551 to schedule an appointment for a complimentary telephone genetic consultation to review these results. Comprehensive genetic counseling is recommended for a patient with a family history of a chromosome abnormality or other genetic disorder so that risks can be accurately discussed, as well as additional testing options that may be available. A genetic counselor can also be found at www.nsgc.org.

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# METHODS AND LIMITATIONS

## UNITY™ Complete: **Aneuploidy Screen**

Cell-free DNA (cfDNA) was isolated from 2-4 mL of plasma from whole blood collected in a Streck cell-free DNA tube. A paternal inheritance NIPT was performed as a multiplex PCR on common single nucleotide variants (SNVs) to measure the fraction of cell-free DNA of fetal origin. A modified fetal fraction calculation is performed for twin pregnancies and pregnancies conceived with a gestational carrier. The fetal risk for aneuploidy of chromosomes 13, 18, 21, X, & Y for singleton pregnancies or chromosomes 13, 18, & 21 for twin pregnancies, was determined by a separate multiplex PCR on cfDNA using no more than 99 amplicons per chromosome to perform relative chromosomal dosage analysis. When multiple blood tubes are analyzed for NIPT (e.g. for redraws), we report the combined reported fetal fraction by taking the arithmetic mean of fetal fractions across different tubes. Due to the tube-to-tube assay variability, the reported fetal fraction for the same patient can differ between single-gene NIPT and aneuploidy NIPT. Pre-test risks for aneuploidy ('Risk Before NIPT') are based on maternal age and gestational age. Post-test residual risks ('Risk After NIPT') for high-risk results are personalized and calculated based on the test sensitivity, test specificity, and prior risks, as determined by maternal age and gestational age. Post-test residual risks for low-risk results are not personalized and calculated based on the test sensitivity, test specificity, and prior-risk in the general population.

Test Limitations: Results may not be reported when the amount of cell-free fetal DNA in the blood sample is too low. Results from this test are highly accurate; however, discordant results may occur. Potential causes of discordant results include: maternal, fetal, or placental mosaicism, low fetal fraction, vanishing twin, maternal malignancy, maternal organ or bone marrow transplant, or other reasons. Findings of unknown significance will not be reported. UNITY™ does not screen for neural tube defects or abdominal wall defects. This test does not screen for microdeletions. UNITY™ NIPT is not diagnostic. No irreversible decisions regarding the pregnancy should be made without confirmatory invasive prenatal testing.

| CONDITIONS SCREENED | SENSITIVITY | SPECIFICITY | POSITIVE PREDICTIVE VALUE | NEGATIVE PREDICTIVE VALUE |
|---|---|---|---|---|
| **Trisomy 21** | 99.8%<br>[98.9% - 100%] | 99.9%<br>[99.8% - 99.9%] | 84.2% | > 99.9% |
| **Trisomy 18** | 99.9%<br>[99.0% - 100%] | > 99.9%<br>[99.9% - 100%] | 94.2% | > 99.9% |
| **Trisomy 13** | 99.1%<br>[97.4% - 100%] | > 99.9%<br>[99.9% - 100%] | 52.5% | > 99.9% |
| **Monosomy X** | 97.7%<br>[93.7% - 100%] | > 99.9%<br>[99.9% - 100%] | 85.5% | > 99.9% |
| **Sex Chromosome Aneuploidy**<br>(XXX / XXY / XYY) | Reported when identified | > 99.9% | n/a | > 99.9% |
| **Presence of Y Chromosome** | > 99.9% | > 99.9% | n/a | > 99.9% |

** Internal analytical validation data for singleton pregnancies. Performance metrics are estimated based on analytical data from contrived aneuploidy samples at 9% fetal fraction. Representative coefficients of variance from human plasma samples were applied to this analytical data to perform Monte Carlo simulations to calculate these metrics, assuming prior risks for a patient population of advanced maternal age. Mosaicism is not reflected in the validation.*

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