UNITY BY BILLIONTOONE T (650) 460-2551 F (833) 915-0146 E support@unityscreen.com unityscreen.com

Patient		Sample		Provider	
Name	**Jane Doe**	Sample Type	**N/A**	Provider	**N/A**
Date of Birth	**01/01/1901**	Date Collected	**07/25/2025**	Clinic Address	**N/A**
Sex Assigned at Birth	**N/A**	Date Received	**07/26/2025**	Phone Number	**N/A**
Gestational Age	**N/A**	Requisition ID	**N/A**	Fax Number	**N/A**
Medical Record #	**N/A**	Date Reported	**07/31/2025**		

SUMMARY OF RESULTS

LOW RISK FETUS | **Female** fetal sex | **9.6%** fetal fraction

UNITY **Aneuploidy**™ NIPT

Singleton Gestation

ANEUPLOIDIES SCREENED	FETAL RISK *by* NIPT	RISK *Before* NIPT	RISK *After* NIPT
Trisomy 21	**Low Risk**	**1 in 616**	**<1 in 10,000**
Trisomy 18	**Low Risk**	**1 in 1939**	**<1 in 10,000**
Trisomy 13	**Low Risk**	**1 in 5414**	**<1 in 10,000**
Monosomy X	**Low Risk**	**1 in 560**	**<1 in 10,000**
Sex Chromosome Aneuploidy (XXX / XXY / XYY)	**Not Detected**		

UNITY **Fetal RhD**™ NIPT

Singleton Gestation

RHD SUMMARY OF RESULTS
Rh+ **RhD: DETECTED**

Interpretation *next page* ›

Interpretation

UNITY **Aneuploidy**™ NIPT
Singleton Gestation

The fetus is LOW RISK to be affected with aneuploidy of chromosomes 13, 18, 21, X & Y.

A low risk NIPT result significantly reduces the risk of the screened aneuploidies; it does not eliminate the risk. This result does not guarantee a normal pregnancy outcome.

UNITY **Fetal RhD**™ NIPT
Singleton Gestation

The *RHD* gene was DETECTED in the cell-free DNA (RhD positive).

NIPT was performed to determine the presence or absence of the *RHD* gene. The *RHD* gene was DETECTED in the cell-free DNA (RhD positive).

If the pregnant patient's blood type is RhD negative: This result indicates fetal RhD positive blood type. Anti-D prophylaxis is indicated for RhD negative patients who are not alloimmunized and carrying an RhD positive fetus.

If the pregnant patient's blood type is RhD positive: This result is not clinically relevant and could reflect either maternal or fetal RhD positive blood type. Anti-D prophylaxis is not indicated.

In rare cases, a fetus with the *RHD* gene detected may have an RhD negative phenotype as the result of a mutation in the *RHD* gene this test is unable to identify. Additionally, fetuses with a weak D genotype will have an *RHD* gene detected NIPT result, however, they may present with an RhD negative phenotype at birth.

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 be found at www.nsgc.org. NIPT does not exclude abnormalities of other chromosomes and microdeletions not evaluated by the screen, triploidy, other genetic syndromes, or birth defects.

Methods and Limitations

UNITY **Aneuploidy**™ NIPT

Cell-free DNA (cfDNA) was isolated from 2-4 mL of plasma from whole blood collected in a 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. Twin zygosity is determined through a likelihood maximization algorithm based on the allele fractions at each SNV. 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, we report the combined reported fetal fraction by taking the arithmetic mean of fetal fractions across different tubes from the same draw. 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. Post-test risks are valid only for the specified fetal number (singleton or twin gestation). In addition, results are not valid for twin gestations achieved with egg donation or higher order multiples.

Test Limitations: Results may not be reported when the amount of cell-free fetal DNA in the blood sample is below the limit of detection. 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, laboratory error, or other reasons. Findings of unknown significance will not be reported. UNITY Aneuploidy NIPT does not screen for mosaicism, triploidy, neural tube defects or abdominal wall defects. This test does not screen for microdeletions. UNITY Aneuploidy 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
			(AVERAGE RISK POPULATION)	(HIGH RISK POPULATION)	
Trisomy 21	99.5%	> 99.9%	96%	99%	> 99.9%
Trisomy 18	99.9%	> 99.8%	52%	90%	> 99.9%
Trisomy 13	99.6%	> 99.9%	58%	92%	> 99.9%
Monosomy X	95.4%	> 99.7%	64%	64%	> 99.9%
Sex Chromosome Aneuploidy (XXX / XXY / XYY)	92.6%	> 99.9%	97%	97%	> 99.9%
Presence of Y Chromosome	> 99.9%	> 99.9%	N/A	N/A	> 99.9%

** Performance metrics are estimated by combining the data from 7,864 clinical samples from pregnant patients and the fetal fraction distribution characteristics obtained from 11,610 clinically ordered samples. The PPV and NPV were calculated based on the sensitivity, specificity, and expected prevalence at 9-14 weeks of gestation for average risk (30 year old) and high risk (40 year old) pregnant patients.*

Methods and Limitations

UNITY **Fetal RhD**™ NIPT

Cell-free DNA (cfDNA) was isolated from 2-4mL of plasma from whole blood collected in a 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 next generation sequencing (NGS). Results were aligned and examined on a custom bioinformatics pipeline and compared to the published human genome build GRCh37/hg19 reference sequence along with the sequence of *RHD-psi*. 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 determine the presence or absence of molecules of the *RHD* gene, as well as the common non-antigenic RhD variants, *RhD-psi* and *RhD-CE(4-7)-D* in the cell-free DNA.

Test Limitations: UNITY Fetal RhD NIPT may not be reported when the amount of cell-free fetal DNA in the blood sample is below the limit of detection. Results from this test are highly accurate; however, discordant results may occur. Potential causes of discordant results include: rare fetal or maternal genotype, low fetal fraction, vanishing twin, laboratory error, or other reasons. In twin gestations, individual fetal RhD statuses are not provided. RhD pseudogenes not mentioned above may not be able to be differentiated from RhD and may be reported as *RHD* detected. Pregnant patients with an RhD positive blood type will receive an *RHD* detected result, due to the presence of maternal RhD in the cell-free DNA.

Maternal RhD Status	UNITY Fetal RhD NIPT Result	Predicted Fetal RhD status	Clinical Implications for Rh Incompatibility
Rh negative	Not Detected	Rh(D) negative*	N/A
	Detected	Rh(D) positive+	Anti-D prophylaxis may be indicated; monitor for Rh incompatibility as clinically warranted.
Rh positive	Detected	Rh(D) positive or negative#	N/A#
Rh weak D	Detected	Rh(D) positive or negative#	Anti-D prophylaxis administration in weak D patients is considered standard of care, although risk of alloimmunization is minimal.^

* Possible fetal genotypes include *RHD* gene deletion, *RHD-psi*, or *RHD-CE(4-7)-D* hybrid. Genotype does not impact clinical recommendations.
\+ Possible fetal genotypes include *RHD* gene present, weak D type 1, 2, 3, etc. or the presence of a rare *RHD* mutation.
\# Fetal genotype is not clinically significant in Rh positive or Rh weak D pregnant patients.
^ ACOG Practice Bulletin 181: Prevention of RhD Alloimmunization

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. This test was performed using BillionToOne's patented technology (www.billiontoone.com/patents).

BillionToOne Inc.
3200 Whipple Road
Union City, CA 94587

Phone **(650) 460-2551**
Fax **(833) 915-0146**
Email support@unityscreen.com

John ten Bosch
New York Lab Director
New York License: TENBJ1

Joseph Michael Anderson, MD
CLIA Lab Director
California License:
A 98379

Low Risk

UNITY Aneuploidy™ NIPT

Non-invasive prenatal testing (NIPT) through UNITY Screen™ looks for specific chromosome changes. A person with a different amount of genetic information may have health problems, birth defects, and/or developmental delays. The symptoms and severity vary depending on which genetic material is extra or missing. Any pregnancy can have a chromosome change, regardless of age, ethnicity, or family history.

Your UNITY Result: Low Risk

The testing performed by UNITY shows your baby's chance of having the conditions screened is very low. Please note, if you are pregnant with twins, both babies are considered low risk.

Because UNITY is a screen, and not diagnostic, a low risk result significantly reduces but does not completely eliminate the chance of your baby having a chromosome change. UNITY cannot guarantee a healthy baby. Additional screening and testing remain available, should you desire more information, such as ultrasound or prenatal diagnostic testing (such as chorionic villus sampling or amniocentesis).

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

Resources

- National Society of Genetic Counselors - https://www.nsgc.org/
- American College of Obstetricians and Gynecologists Guide to Prenatal Diagnosis - https://www.acog.org/womens-health/faqs/prenatal-genetic-diagnostic-tests

RHD

UNITY Fetal RhD™ NIPT

UNITY's non-invasive prenatal testing (NIPT) for Fetal RhD screening detects DNA that makes the RhD red-blood-cell protein during pregnancy. This test helps Rh-negative pregnant patients and their providers make informed decisions about their prenatal care.

What Is The Rh Factor?

The Rh factor refers to proteins found on red blood cells that determine whether your blood type is positive or negative. If a pregnant person and their baby have different RhD types, there can be a risk for complications in future pregnancies.

Knowing your Rh type and your baby's Rh type can help you and your provider understand if there is a risk for an immune system response called sensitization or alloimmunization. This happens when the immune system creates protective cells called antibodies as a result of finding a different type of Rh factor coming from a pregnancy. While these antibodies don't usually cause complications in a first pregnancy, they can attack fetal red blood cells in future pregnancies if the baby is RhD positive.

Providers use a pregnant person's Rh status to determine if they need a medication called anti-D prophylaxis during their pregnancy to prevent this immune system response. If you are Rh negative, finding out your baby's Rh status can help you and your provider make the best decisions about your pregnancy care.

UNITY Fetal RhD™ Results

The two most common types of RhD results from the UNITY screen are either RhD Detected or RhD Not Detected. How these results affect your pregnancy care depends on your own RhD type. You should discuss your results and implications with your healthcare provider.

If you are RhD positive

RhD positive pregnant patients are not at risk for RhD sensitization. UNITY Fetal RhD™ NIPT results should not impact pregnancy care.

If you are RhD negative and your UNITY Fetal RhD™ results say:

"RhD Detected": This usually means that you are Rh negative and your baby is Rh positive. You may be at risk for RhD sensitization and your provider may discuss the use of anti-D prophylaxis or additional monitoring.

"RhD Not Detected": This usually means that you and your baby are both Rh negative and the risk for sensitization is extremely small.

Resources

- ACOG The Rh Factor: How it can affect your pregnancy - https://www.acog.org/womens-health/faqs/the-rh-factor-how-it-can-affect-your-pregnancy#:~:text=When%20the%20blood%20of%20an,attack%20the%20fetus's%20blood%20cells
- Rh-Factor Blood Type and Pregnancy - https://americanpregnancy.org/healthy-pregnancy/pregnancy-complications/rh-factor/