

Together with you. We are redefining what is possible.

BillionToOne creates products based on a simple principle: when clinical clarity is essential for patient management and existing tools fall short, data and better solutions should lead the way.

We don't build tests to match what already exists. We build them to close gaps in care, support confident clinical decision-making, and move clinical practice forward — together with you.

Launched Unity Fetal Risk™ Screen

2019

First commercially available NIPT to assess fetal risk for recessive conditions without relying on partner testing.

Launched Unity Fetal Antigen™ NIPT

2022

First-and-only NIPT to determine red blood cell (RBC) fetal antigen status in alloimmunized pregnancies at-risk for HDFN.

Unity Fetal Risk Screen Leads the Way for sgNIPT

2023

Awarded Top 10 Clinical Advancement of 2023 by AJHG.

Expanded Unity Fetal Antigen NIPT

2026

Launch of Unity's expanded RBC Fetal Antigen NIPT and the first-and-only Platelet Fetal Antigen NIPT available in the US, enabling fetal risk assessment in pregnancies at-risk for FNAIT.

Launched Unity Aneuploidy™ Screen and Unity Fetal RhD™ NIPT

2020

Introduced a unified prenatal testing platform, including the first widely available non-invasive test to determine fetal RhD status in RhD-negative pregnancies.

Clinical Guidelines Recognized cfDNA-Based Fetal Antigen Testing

2024

Two ACOG guideline updates supporting the use of cfDNA to determine fetal RhD and fetal antigen status, citing Unity clinical data as supporting evidence.

Unity Platform Milestones & Expansions

2025

- Unity surpasses 1,000,000 tests ordered⁶
- Launch of Unity Fetal Risk Screen 14-gene panel
- JAMA Network Open guideline recommends cfDNA for fetal antigen testing, citing Unity data³



Contact Us

650.460.2551
support@unityscreen.com

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1. Ashimi Balogun, Olaide, et al. "High frequency of critical and rising titers in alloimmunized pregnancies with antigen-negative fetuses." Pregnancy 1.6 (2025): e70113. 2. Moise, Kenneth J., Jr., et al. "A Clinical Practice Guideline for the Management of Pregnancy Alloimmunized to Red Blood Cell Antigens." JAMA Network Open, vol. 8, no. 11, 24 Nov. 2025, e2544649. doi:10.1001/jamanetworkopen.2025.44649 3. Rego, Shannon, et al. "Cell-free DNA analysis for the determination of fetal red blood cell antigen genotype in individuals with alloimmunized pregnancies." 4. Alford, Brian, et al. "Validation of a non-invasive prenatal test for fetal RhD, C, c, E, K and Fya antigens." Scientific Reports 13.1 (2023): 12786. 5. BillionToOne Announces Global Collaboration to Provide Its Unity Fetal Antigen™ Clinical Trial Assay in Johnson & Johnson Phase 3 Clinical Trial of Nipocalimab in Hemolytic Disease of the Fetus and Newborn - BillionToOne." Billiontoone.com, 2023, www.billiontoone.com/news-media/billiontoone-announces-global-collaboration-to-provide-its-unity-fetal-antigen-clinical-trial-assay-in-johnson-johnson-phase-3-clinical-trial-of-nipocalimab-in-hemolytic-disease-of-the. Accessed 5 Jan. 2026. 6. Internal data on file. August 2025.

Unity Fetal Antigen NIPT is a screening test, not a diagnostic test. False positive and false negative results may occur. Testing is physician-ordered and results should be interpreted by a qualified healthcare provider in the context of the patient's clinical history. Unity Fetal Antigen NIPT is a laboratory-developed test performed in a CLIA-certified and CAP-accredited laboratory. It is not an FDA-approved test. Test performance may vary based on fetal fraction, maternal age, zygosity, and other clinical factors.

UNITY

by BILLIONTO ONE

Unity Fetal Antigen™ Tests The new standard in prenatal care.



First-and-only fetal antigen
testing from cell-free DNA.

Innovation driven by clinical need.

Alloimmunized pregnancies have historically been managed with indirect tools, incomplete information, and prolonged uncertainty. Serial titers, partner testing, and invasive procedures often guide care, not because they are ideal, but because other options have not existed.

We've set the new standard in care for alloimmunized pregnancies. This is only the beginning.

Clinical evidence has demonstrated that traditional monitoring strategies may lead to unnecessary surveillance in alloimmunized pregnancies when the fetus is antigen-negative, highlighting the importance of **early, accurate fetal antigen determination** to guide appropriate care.

NEW Clinical Study

PREGNANCY

High Frequency of Critical and Rising Titers in Alloimmunized Pregnancies with Antigen-negative Fetuses¹

~70% of pregnancies reached critical titers regardless of fetal RBC antigen status, showing that titers increased even when there was no fetal risk.

Published clinical practice guidance now recommends early fetal antigen assessment via cfDNA.

NEW Clinical Guidance



A Clinical Practice Guideline for the Management of Pregnancy Alloimmunized to Red Blood Cell Antigens²

Published guidance recommends **“the use of cell-free fetal DNA (cffDNA) to accurately determine fetal red blood cell antigen status”** and “if cffDNA testing reveals an antigen negative fetus, no further surveillance including repeat titers or middle cerebral artery Doppler measurements are indicated for the remainder of the pregnancy.”

Moving the field forward. Again.

New

Expanded RBC Fetal Antigen NIPT plus the first-and-only Platelet Fetal Antigen NIPT available in the US for pregnancies at-risk for HDFN and FNAIT.

Alloimmune conditions such as hemolytic disease of the fetus and newborn (HDFN) and fetal/neonatal alloimmune thrombocytopenia (FNAIT) can lead to severe fetal and neonatal complications. Unity Fetal Antigen NIPT is the **first-and-only** non-invasive test to determine both red blood cell (RBC) and platelet fetal antigen status via cell-free DNA available in the US.

Closing gaps in RBC alloimmunization

RBC Fetal Antigen NIPT

Designed to determine fetal antigen status for up to 16 fetal antigens based on clinical prevalence for pregnancies at-risk for HDFN.

i HDFN affects ~1% of pregnancies, with clinical outcomes ranging from mild anemia to hydrops and stillbirth.

D C c E K Fya

Newly Added:

e⁺ k⁺ Fyb⁺ Jka⁺ Jkb⁺

M⁺ N⁺ S⁺ s⁺ U⁺

Covers 99% of antigens associated with HDFN.

* M and N antigens must be selected at ordering and cannot be added after the test is submitted.

Creating a new path for FNAIT

Platelet Fetal Antigen NIPT

Designed to determine platelet fetal antigen status for pregnancies at-risk or with a history of FNAIT.

i FNAIT may lead to catastrophic fetal consequences such as thrombocytopenia, intracranial hemorrhage, or fetal loss.

Available Exclusively Through

Unity Aneuploidy™ Screen

Unity Fetal Antigen Tests can be added to Unity Aneuploidy Screen as early as 9 weeks gestation or at any point during pregnancy. No additional order or blood draw needed.*

Unity Fetal Antigen Tests were developed to streamline care by delivering early, accurate fetal antigen status, enabling appropriate monitoring of at-risk pregnancies and providing peace of mind to those not at-risk.

Unity's role in advancing care.

Unity Fetal Antigen Tests have helped advance the management of alloimmunized pregnancies, with three clinical guideline updates incorporating evidence from Unity's peer-reviewed studies to support earlier, more precise care.

>99.9%
sensitivity^{3,4}

>99.9%
specificity^{3,4}

100%
concordance with neonatal outcomes across study populations^{3,4}

Outcomes Study

OBSTETRICS & GYNECOLOGY

Cell-free DNA analysis for the determination of fetal red blood cell antigen genotype in alloimmunized pregnancies⁴

July 2024

- 465 neonatal outcomes collected
- 100% concordance

Clinical Validation

nature scientific reports

Validation of a non-invasive prenatal test for fetal RhD, C, c, E, K, Fy^a antigens³

August 2023

- >99.9% sensitivity, specificity, and reproducibility
- 100% concordance

Press Release

PRNewswire

BillionToOne Announces Global Collaboration to Provide its Unity Fetal Antigen™ Clinical Trial Assay in Johnson & Johnson Phase 3 Clinical Trial⁷...

December 2023

- Global collaboration with Johnson & Johnson



Learn More About Unity Fetal Antigen

