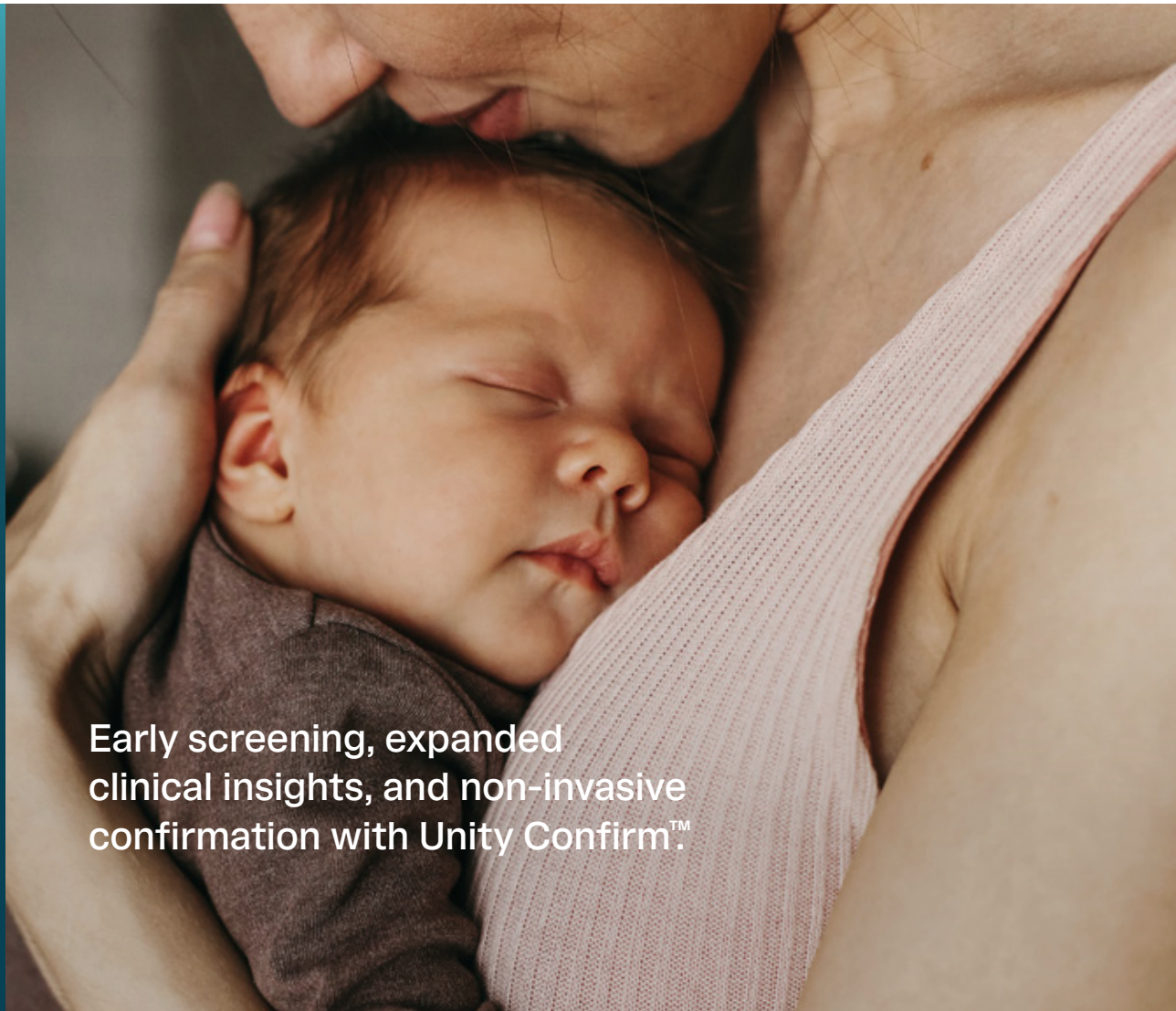
UNITY

by BILLIONTOONE

Unity Aneuploidy™ NIPT

Built for more. More patients. More results. More confidence.



Unity Aneuploidy™ NIPT is designed not only to identify high-risk pregnancies, but also to support next steps through access to non-invasive confirmatory testing.

cfDNA Testing | Circulating Fetal Cell Testing

Unity Aneuploidy™ NIPT

- Trisomy 21*
- Trisomy 18*
- Trisomy 13*
- Sex Chromosome Aneuploidies: XO, XXY, XYY, XXX
- Zygosity included for twins
- 22q11.2 Microdeletion Syndrome* optional
- Fetal Sex* optional

Unity Confirm™**

Non-invasive confirmatory testing for high-risk Unity Aneuploidy NIPT results,** powered by Fetal Cell Capture™ technology. Available exclusively when Unity Aneuploidy NIPT is ordered first-line.

Not available for high-risk monosomy X

Unity Fetal Antigen™ Tests

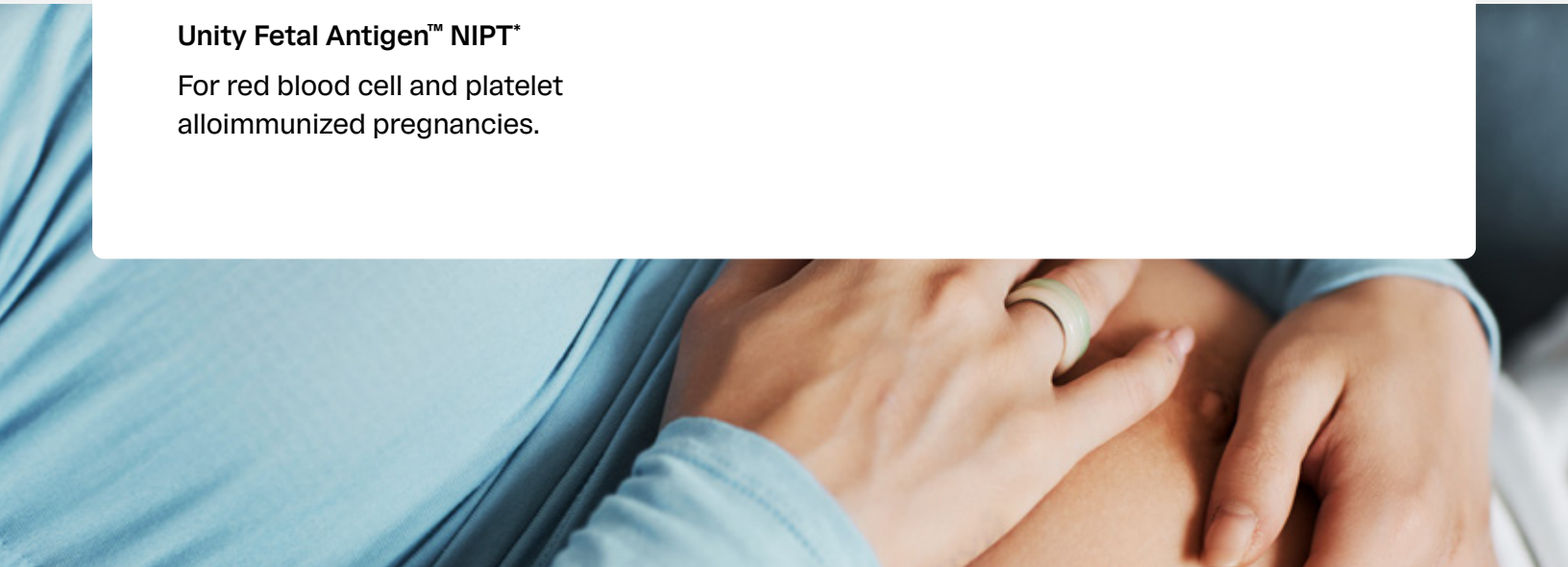
Add-On

Unity Fetal RhD™ NIPT*

For non-alloimmunized RhD-negative pregnancies.

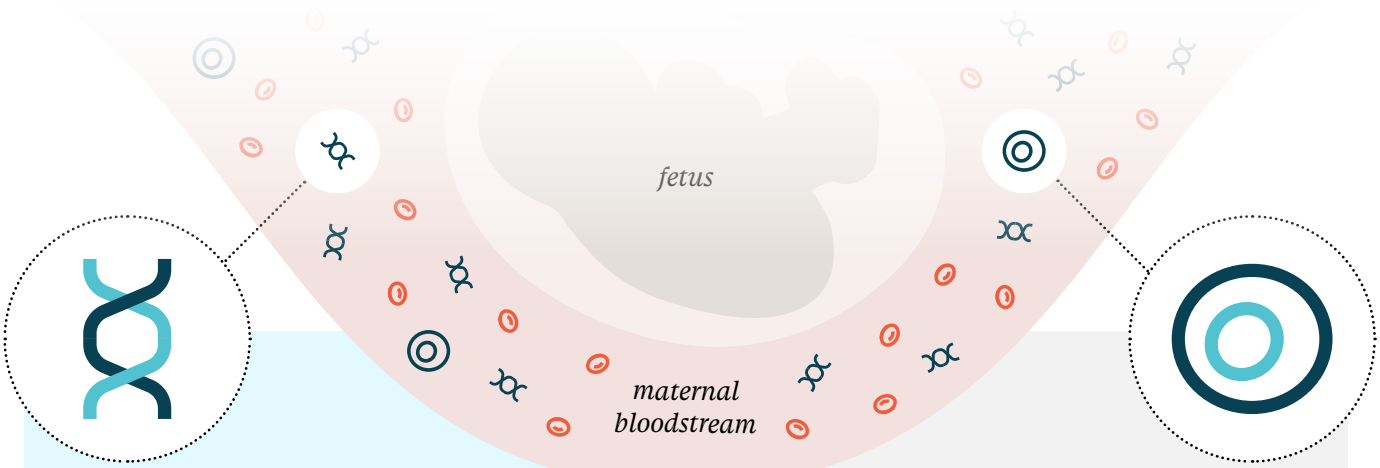
Unity Fetal Antigen™ NIPT*

For red blood cell and platelet alloimmunized pregnancies.



From cfDNA screening to confirmatory testing with circulating fetal cells.

Cell-free DNA (cfDNA) and circulating fetal cells are complementary biological signals that, when used sequentially, can provide additional insight into fetal risk and help guide pregnancy management.



cfDNA testing

What's measured
DNA fragments of placental origin.

Clinical use
Screening for common aneuploidies, recessive single-gene conditions, fetal antigen status.

Timing
As early as 9 weeks through gestation.

Circulating fetal cell testing

What's measured
Rare, intact fetal cells of placental origin.

Clinical use
Confirmation of high-risk Unity Aneuploidy NIPT cfDNA results,** non-invasively.

Timing
Available following a high-risk Unity Aneuploidy NIPT result** through 15 weeks 6 days gestation.

* Available for mono- and di-zygotic twins. ** Unity Confirm is not available for high-risk monosomy X pregnancies, twin or higher multiple pregnancies, vanishing twins, gestational carriers or egg donors, or for pregnancies >15 weeks 6 days gestation. Only available in the US.

Unity Aneuploidy™ NIPT

The only prenatal test with non-invasive confirmation for high-risk Unity Aneuploidy NIPT results.*

Unity Aneuploidy NIPT combines counting, SNPs, QCTs, and machine learning to reduce no-calls and maintain high accuracy — providing more results for more patients.

Counting

Measures relative chromosome quantity to detect deviations

SNPs

Calculates fetal fraction and determines zygosity

QCTs™ Proprietary

Enables accurate calls at low fetal fractions

Machine Learning

Filters noise from chromosomal correlations

- Available as early as 9 weeks into pregnancy[1]
- Aligns to current ACOG recommendations[2]
- Standard panel includes T21, T18, T13, XO, XXY, XYY, and XXX
- Available for twin pregnancies
- Validated in a general OB population[1]
- Demonstrated performance in fetal fractions as low as 1.5%[1]
- Exclusive access to Unity Confirm for eligible high-risk Unity Aneuploidy results*

* Unity Confirm is not available for high-risk monosomy X pregnancies, twin or higher multiple pregnancies, vanishing twins, gestational carriers or egg donors, or for pregnancies >15 weeks 6 days gestation. Only available in the US

>99%
demonstrated combined sensitivity for trisomies (T21, T18, T13)[1]

99.9%
demonstrated accuracy for fetal sex determination[3]

75%
demonstrated PPV for 22q11.2 microdeletion[4]

Explore the performance data behind our multi-technology approach.

Unity Fetal Antigen™ Tests

Comprehensive fetal antigen testing for when clinical needs arise. Exclusively through Unity Aneuploidy NIPT.

Developed to streamline care by delivering early, accurate fetal antigen status, Unity Fetal Antigen™ Tests can be ordered at any time during pregnancy.*

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

Unity Fetal RhD™ NIPT

For non-alloimmunized RhD-negative pregnancies

Designed to detect the presence or absence of the *RHD* gene deletion, *RHD-CE-D* hybrid gene and *RHDΨ* - variants common in Black and Asian populations.[5,6]

Unity Fetal Antigen™ NIPT

For alloimmunized pregnancies at-risk for HDFN and FNAIT

Designed to detect the presence or absence of up to 16 red blood cell and common platelet fetal antigens, including HPA-1a.

HDFN: hemolytic disease of the fetus and newborn.
FNAIT: fetal/neonatal thrombocytopenia.

>99.9%
demonstrated sensitivity[7,8,9]

>99.9%
demonstrated specificity[7,8,9]

100%
demonstrated concordance with neonatal outcomes across study populations[7,8,9]

<0.1%
demonstrated no-call rate[7,9]

Learn more about Unity Fetal Antigen Tests.

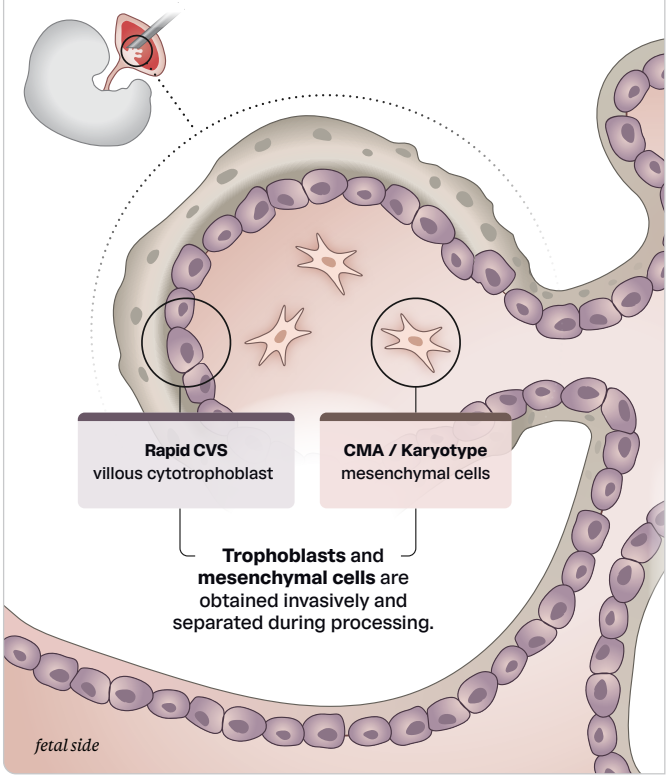
Unity Confirm™

Unity Confirm starts with first-line ordering of Unity Aneuploidy NIPT.

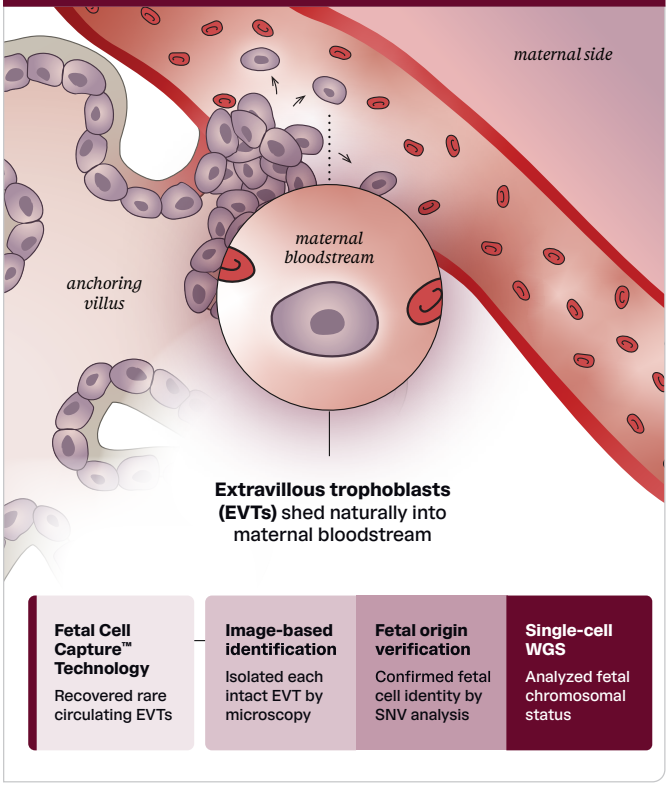
Powered by Fetal Cell Capture™ technology, Unity Confirm delivers confirmation of high-risk Unity Aneuploidy NIPT results* — without the procedural risks.[10]

- Available through 15 weeks 6 days gestation
- Imaging and sequencing-based fetal cell confirmation allowing for high accuracy
- Effectively provides 100% fetal fraction[11]
- Delivers rapid CVS-like insights, non-invasively[10]

Invasive — Chorionic Villus Sampling (CVS)



Non-Invasive — Circulating Fetal Cell (CFC) Test



Unity Confirm has demonstrated 100% concordance with known fetal outcomes.†

16/16 samples

† Unity Confirm results were compared with diagnostic testing via karyotype or microarray analysis of chorionic villus, amniocytes, products of conception, or with clinical diagnosis via fetal anatomy scan or physical exam of the resulting neonate if no genetic testing was performed.

Now enrolling in the largest prospective study of circulating fetal cell-based testing with invasive, diagnostic outcomes.

Target enrollment of 1,000 patients with concordance to invasive diagnostic testing.[12]

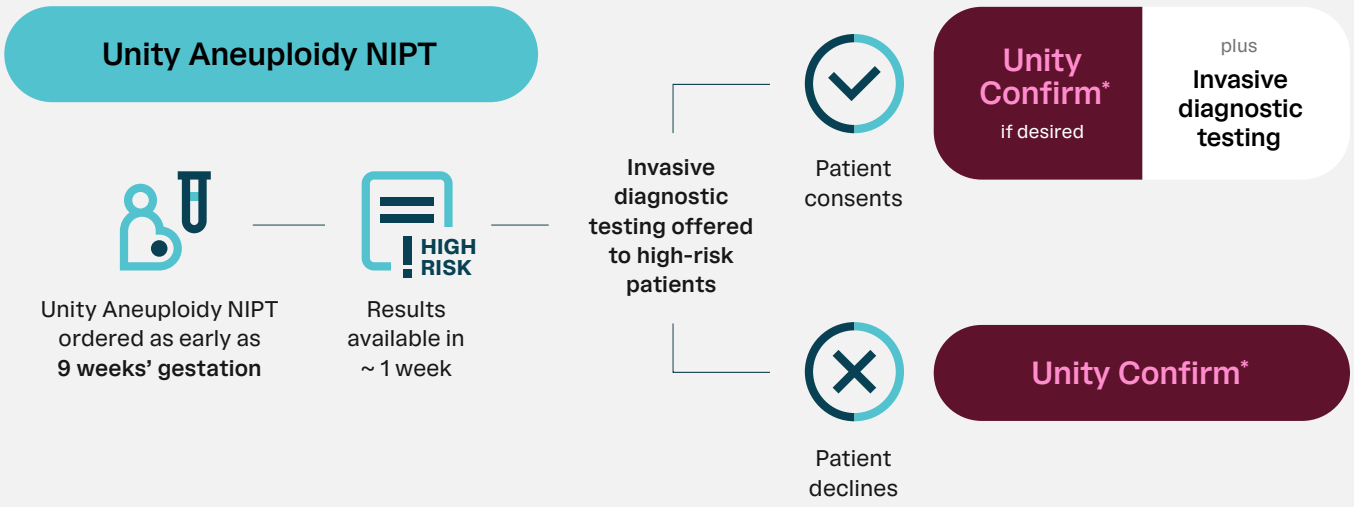
Bringing Unity Confirm into your practice.

Although amniocentesis remains the gold standard,[13,14] many patients either cannot, choose not to, or are still considering whether to pursue invasive diagnostic testing.[15] Unity Confirm helps bridge this gap.

Broadens access to testing regardless of resource barriers

Supports patients who decline invasive testing but still want more information

Empowers patients and providers with additional data for informed clinical decisions



* Unity Confirm is not available for high-risk monosomy X pregnancies, twin or higher multiple pregnancies, vanishing twins, gestational carriers or egg donors, or for pregnancies >15 weeks 6 days gestation. Only available in the US.

Unity Confirm is available following a high-risk Unity Aneuploidy NIPT result through 15 weeks 6 days gestation. For best performance, Unity Confirm should be ordered as early as possible, as intact circulating fetal cells can decrease with gestational age.

Read the white paper and stay up to date with the ongoing evidence supporting Unity Confirm.

More than a test. A partner in prenatal care.

When providers choose Unity, they are not simply adopting a test for what it is today – they are partnering with a company committed to advancing prenatal care and redefining how patients and providers navigate prenatal testing.

Streamlined provider workflow

- Order as early as 9 weeks gestation via EMR, provider portal or paper — with results delivered in about 1 week.
- High-risk Unity Aneuploidy patients eligible for Unity Confirm are clearly flagged in reports - order Unity Confirm directly through the provider portal.

Convenient blood draws

- Phlebotomy services, including mobile phlebotomy, phlebotomy staffing solutions, supply procurement, and more are available for your clinic and patients.

Wide insurance coverage

- Contracted with all major insurance plans, covering over 300 million lives.[16]
- Our US-based team contacts patients about balances before billing. One bill, one copay — no surprises.
- 4.9/5 patient billing satisfaction.[17]

Support when you need it

- Complimentary sessions with BillionToOne's genetic counselors are available to patients and providers.

1. Wynn, J., et al. "Performance Characteristics of a Next Generation Sequencing-Based cfDNA Assay for Common Aneuploidies in a General Risk Population." Ann Gynecol Obstetr Res. 2024; 7 (1) 1027. **2.** American College of Obstetricians and Gynecologists, and Society for Maternal-Fetal Medicine. "Screening for fetal chromosomal abnormalities: ACOG practice bulletin, number 226." Obstetrics & Gynecology 136.4 (2020): e48-e69. **3.** Internal ANP validation March 2024. **4.** Unity Aneuploidy NIPT clinical outcomes analysis. Data on file. May 2026. **5.** Singleton, B. (2000). The presence of an RHD pseudogene containing a 37 base pair duplication and a nonsense mutation in Africans with the Rh D-negative blood group phenotype. Blood, 95(1), 12–18. https://doi.org/10.1182. **6.** Zhang J, et al. RHD Genotypes in a Chinese Cohort of Pregnant Women. Front Genet. 2021 Dec 14;12:752485. doi: 10.3389/fgene.2021.752485. PMID: 34970297; PMCID: PMC8712876. **7.** Alford, B. et al. Validation of a non-invasive prenatal test for fetal RhD, C, c, E, K and Fya antigens. Sci Rep 13, 12786 (2023). https:// doi.org/10.1038/s41598-02339283-3. **8.** Mateus Nino, Julio F., et al. "Clinical performance of cell-free DNA for fetal RhD detection in RhD-negative pregnant individuals in the United States." Obstetrics & Gynecology 145.4 (2025): 402-408. **9.** Rego, Shannon et al. "Cell-Free DNA Analysis for the Determination of Fetal Red Blood Cell Antigen Genotype in Individuals With Alloimmunized Pregnancies." Obstetrics and gynecology vol. 144,4 (2024): 436-443. doi:10.1097/ AOG.0000000000005692. **10.** Unity Confirm and rapid CVS both analyze fetal-derived trophoblast cells. Unity Confirm isolates individual cells via whole genome sequencing, which is performed on each cell separately, whereas rapid CVS is often performed via FISH. While rapid CVS may analyze more cells, WGS generates more data per cell. In both rapid CVS and fetal cell capture, mosaicism cannot be excluded. No medical decisions should be made based on Unity Confirm alone. Clinical correlation is necessary. **11.** In rare instances, results may rely on a single cell that is co-sequenced with 1-2 maternal cells, which may reduce fetal fraction to 33% or 50%. When this occurs, the report clearly indicates this limitation. **12.** ADVANCE (Assay Development and Validation for Pre-Natal and Obstetric Conditions)." ClinicalTrials.gov, U.S. National Library of Medicine, NCT07643896, https://clinicaltrials.gov/study/NCT07643896 **13.** Okoror, Collins Ejakhianghe Maximilian, and Suruchi Arora. "Prenatal diagnosis after high chance non-invasive prenatal testing for trisomies 21, 18 and 13, chorionic villus sampling or amniocentesis?–Experience at a district general hospital in the United Kingdom." European Journal of Obstetrics & Gynecology and Reproductive Biology: X 19 (2023): 100211. **14.** Mokhtar, Rifat, et al. "Comparing noninvasive prenatal testing with invasive testing for the detection of trisomy 21." Cureus 14.11 (2022). **15.** Chetty, Shilpa, Matthew J. Garabedian, and Mary E. Norton. "Uptake of noninvasive prenatal testing (NIPT) in women following positive aneuploidy screening." Prenatal Diagnosis 33.6 (2013): 542-546. **16.** Number of individuals covered under contracts with payors in the US as of April 1, 2026. **17.** Patient satisfaction scores. Internal data on file. June 2026.

Contact Us

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UN-FB-044

Unity tests can produce false-positive and false-negative results. Results are not a guarantee. Amniocentesis should always be considered with high risk results. Important medical decisions should not rely on Unity test results alone. Clinical correlation is necessary, including but not limited to the results of prior and further prenatal testing. Unity tests are laboratory-developed tests performed in a CLIA-certified and CAP-accredited laboratory. They are not FDA-approved or FDA-cleared diagnostic tests. Test performance may vary based on gestational age and other factors.