BillionToOne Launches Unity Confirm™: A category-defining test that bridges the gap between screening and invasive diagnostics

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A breakthrough in prenatal care, Unity Confirm enables non-invasive confirmation for high-risk screening results through the capture of intact circulating fetal cells using BillionToOne's Fetal Cell Capture™ Technology

MENLO PARK, Calif., May 1, 2026 /PRNewswire/ -- For more than two decades, the ultimate quest for scientists and clinicians studying prenatal genetics was the capture of an intact fetal cell non-invasively so that its fetal DNA could be directly analyzed. While cell-free DNA has revolutionized prenatal genetics, it left an uncertainty—a gap between screening and invasive diagnostics, for patients who cannot, or choose not to, access invasive diagnostics. Today, BillionToOne, Inc. (Nasdaq: BLLN), a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, announced the launch of Unity Confirm™, a circulating fetal cell-based, non-invasive confirmation test, designed to address this need from a simple maternal blood draw.

Since its introduction in the early 2010s, non-invasive prenatal testing (NIPT) has become the standard of care for screening for fetal aneuploidies. However, when screening returns a high-risk result, clinical guidelines recommend diagnostic confirmation via chorionic villus sampling (CVS) or amniocentesis. These invasive procedures carry a small but real risk of pregnancy loss, and are increasingly difficult to access. The majority of patients decline, leaving clinicians and families without the information needed to guide next steps, and widening gaps in inequitable care.

While cell-based prenatal genetics has been studied since before the advent of cell-free DNA tests, the scientific barrier has long been the rarity and fragility of fetal cells in maternal circulation. Presenting at fewer than one cell per milliliter of blood and nearly indistinguishable from millions of surrounding maternal cells, intact circulating fetal cells have been too difficult to isolate in an accessible way for clinical use. The cell-based approaches were previously studied across multiple independent publications[1] in more than 1,500 patients, consistently demonstrating that when a fetal cell is captured and sequenced, it provides an accurate result that has extremely high concordance with invasive diagnostic testing. However, these methodologies have stayed too academic, expensive, and inaccessible.

Unity Confirm addresses this directly. Available for all patients who use UNITY Aneuploidy for their front-line screen*, BillionToOne's Fetal Cell Capture™ technology, a multi-step immunological enrichment and single cell isolation process, isolates intact circulating fetal cells, effectively providing 100% fetal fraction[2], and performs whole genome sequencing on each individual cell. By analyzing the direct fetal cells rather than fragmentary cfDNA, similar to invasive procedures, Unity Confirm delivers rapid CVS-like insights[3] non-invasively, from a single blood draw.

"For years, the idea of capturing whole fetal cells non-invasively was largely viewed as an elusive holy grail, something theoretically possible but practically out of reach," said Oguzhan Atay, PhD, Co-founder and CEO of BillionToOne. "Unity Confirm is proof that it does not have to be. For the first time, a clinician can confirm a high-risk prenatal result non-invasively, with a level of accuracy the field has never before seen outside of an invasive procedure. For the first time, this technology is broadly accessible."

"A high-risk NIPT result does not give you a diagnosis. It gives you a decision to make under enormous stress, often without enough information," said Haywood Brown, MD, Chief Medical Officer, Prenatal, BillionToOne. "For too long, the options were limited: forgo confirmation, or undergo an invasive procedure with a small but real risk. What makes Unity Confirm truly different is not just the science; it is that this capability is now clinically accessible. That's not an incremental improvement. That is a fundamentally different standard of care."

In BillionToOne's own clinical validation, Unity Confirm demonstrated 100% concordance with known fetal outcomes and invasive diagnostic results across 16 of 16 samples, including affected fetuses for common aneuploidies and 22q11.2 microdeletion. The clinical data supporting Unity Confirm will be presented at ACOG 2026 in Washington, D.C., presenting the science behind the technology to the broader OB/GYN community for the first time. Beginning on May 28, providers using Unity Aneuploidy™ Screen will have access to Unity Confirm following a high-risk result. To further validate performance at scale, BillionToOne is now enrolling in the largest prospective study of a fetal cell-based confirmation assay with invasive diagnostic outcomes, targeting enrollment of 1,000 patients and measuring concordance to invasive diagnostic testing.

**Unity Confirm is intended for patients who cannot, or choose not to, pursue invasive diagnostic testing following a high-risk Unity Aneuploidy Screen result before 16 weeks of gestation. Available for Trisomy 21 (Down syndrome), Trisomy 18, Trisomy 13, 22q11.2 microdeletion, XXY, XYY, and XXX aneuploidies. Requires Unity Aneuploidy Screen as the frontline screen for the pregnancy.*

Sources

[1]Hatt, Lotte, et al. "A new marker set that identifies fetal cells in maternal circulation with high specificity." Prenatal Diagnosis 34.11 (2014): 1066-1072.; Stampalija, T., et al. "Single-cell-based non-invasive screening for fetal pathogenic microimbalances using maternal blood: comparison with invasive prenatal diagnosis." Ultrasound in Obstetrics & Gynecology (2026).; Weymaere, Jana, et al. "Enrichment of circulating trophoblasts from maternal blood using filtration-based Metacell® technology." Plos one 17.7 (2022):e0271226.; Jeppesen, Line Dahl, et al. "Screening for Fetal Aneuploidy and Sex Chromosomal Anomalies in a Pregnant Woman with Mosaicism for Turner Syndrome—Applications and Advantages of Cell-Based NIPT." Frontiers in Genetics 12 (2021): 741752.; Bellair, Michelle, et al. "Noninvasive single-cell-based prenatal genetic testing: A proof of concept clinical study." Prenatal Diagnosis 44.3 (2024):304-316.; Chakchouk, Imen, and Ignatia B. Van den Veyver. "Whole-Genome Amplification on Single Circulating Trophoblast Cell." Whole Genome Amplification: Methods and Protocols. New York, NY: Springer US, 2026. 11-23.; Zhuo, Xinming, et al. "Use of amplicon-based sequencing for testing fetal identity and monogenic traits with Single Circulating Trophoblast (SCT) as one form of cell-based NIPT." PLoSOne 16.4 (2021): e0249695.

[2]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 50% or 33%. When this occurs, the report clearly indicates this limitation.

[3]Unity Confirm and rapid CVS both analyze fetal-derived trophoblast cells. Unity Confirm isolates individual cells via whole genome sequencing

(WGS), 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. Unity Confirm may have false-positive and false-negative results. Results are not a guaranty. Important medical decisions should not rely on UnityConfirm test results alone. Clinical correlation is necessary. Unity Confirm is a laboratory-developed test performed in a CLIA-certified and CAP-accredited laboratory. It is not an FDA-approved or FDA-cleared diagnostic test. Test performance may vary based on gestational age and other factors.

Forward-Looking Statements
This press release contains certain forward-looking statements within the meaning of federal securities laws. These forward-looking statements generally are identified by the words "believe," "project," "expect," "anticipate," "estimate," "intend," "strategy," "future," "opportunity," "plan," "may," "should," "will," "would," "will be," "will continue," "will likely result," and similar expressions. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Forward-looking statements in this press release include, but are not limited to, statements regarding the clinical effectiveness of Unity Confirm. These statements are based on management's current expectations, forecasts and assumptions, and actual outcomes and results could differ materially from these statements due to a number of factors, some of which are beyond BillionToOne's control. These and additional risks and uncertainties could affect BillionToOne's financial and operating results and cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. These risks and uncertainties include, but are not limited to, the risk that Unity Confirm is not clinically effective and not adopted by healthcare professionals and those discussed under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operation" and elsewhere in BillionToOne's most recently filed Annual Report on Form 10-K, and other filings we make with the Securities and Exchange Commission from time to time. The forward-looking statements in this press release are based on information available to BillionToOne as of the date hereof, and BillionToOne disclaims any obligation to update any forward-looking statements provided to reflect any change in its expectations or any change in events, conditions, or circumstances on which any such statement is based, except as required by law. These forward-looking statements should not be relied upon as representing BillionToOne's views as of any date subsequent to the date of this press release.

About BillionToOne
Headquartered in Menlo Park, California, BillionToOne is a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all. The company's patented Quantitative Counting Templates™ (QCT™) molecular counting platform is the only multiplex technology that can accurately count DNA molecules at the single-molecule level. For more information, visit www.billiontoone.com.

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