/C O R R E C T I O N -- BillionToOne/

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In the news release, Largest Prospective Study in General-Risk Pregnancies Strengthens Evidence for cfDNA Fetal Risk Assessment as a Primary Screen for Recessive Conditions, issued 18-Aug-2026 by BillionToOne over PR Newswire, we are advised by the company that changes have been made. The complete, corrected release follows, with additional details at the end:

Largest Prospective Study in General-Risk Pregnancies Strengthens Evidence for cfDNA Fetal Risk Assessment as a Primary Screen for Recessive Conditions

Study of more than 2,200 pregnant carriers demonstrates strong clinical performance in the intended-use, general-risk population, with outcomes available for more than 98% of eligible cfDNA results

MENLO PARK, Calif., Aug. 18, 2026 /PRNewswire/ -- BillionToOne, Inc. (Nasdaq: BLLN), a next-generation molecular diagnostics company with a mission to create powerful and accurate tests that are accessible to all, today announced publication of *A Prospective, Multi-Site Study of Performance of Cell-Free DNA Testing for Recessive Conditions in a Large, General-Risk Pregnancy Population* in *The Green Journal*. This is the first prospective NIPT study conducted in an intended-use screening population with near-complete pregnancy outcome ascertainment, providing important new evidence supporting routine use of cfDNA fetal risk assessment in general-risk pregnancies.

Conducted across nine U.S. institutions, the prospective study evaluated 2,212 pregnant carriers in which partner carrier status was unknown at the time of testing. Unlike studies enriched with known high-risk couples or pregnancies with other indications of increased fetal risk, this design reflects how cfDNA fetal risk assessment is used as a primary screen in routine prenatal care. Investigators assessed these carriers with cfDNA fetal risk results for cystic fibrosis, spinal muscular atrophy, and alpha- and beta-hemoglobinopathies, collecting outcomes for 98.6% of pregnancies completing care at participating sites.

Traditional carrier screening depends on partner testing to determine fetal risk, but partner follow-up is often incomplete, delayed, or unavailable due to logistical, financial, and access barriers[1]. Unity Fetal Risk Screen demonstrated 94.4% sensitivity, confirming that this approach identifies more affected pregnancies than traditional carrier screening alone, which classifies fewer than 50% of affected pregnancies as high-risk, mainly due to incomplete partner screening. This advantage holds even in the ideal scenario in which every partner completes testing: carrier screening detects approximately 90% of spinal muscular atrophy carriers, 95% of alpha-thalassemia cases, and up to 99% of cystic fibrosis carriers, and the tested partner may not always be the biological father. Unity Fetal Risk Screen overcomes both limitations by assessing fetal risk directly rather than inferring it from parental genotypes.

In addition to excellent sensitivity, the assay demonstrated 99.5% specificity and >99.9% negative predictive value. Unity Fetal Risk Screen provides a personalized, quantitative fetal risk as high as 9-in-10 — compared to the maximum 1-in-4 risk offered by traditional screening when both partners are confirmed carriers — and as low as 1 in 10,000, giving patients added reassurance.

"Multi-center studies with this level of outcome completeness are rare in prenatal screening," said Eliza McElwee, MD, Assistant Professor College of Medicine Department Obstetrics Gynecology at Medical University of South Carolina. "These results provide clinicians with a much stronger evidence base for incorporating cfDNA fetal risk assessment into routine carrier screening, with data that are directly relevant to everyday clinical practice."

The study also demonstrated consistent performance across a racially and ethnically diverse population, supporting equitable access to prenatal genetic screening without the need for partner testing. Researchers point to the growing urgency of early detection, as new therapies show that earlier diagnosis can meaningfully change outcomes for affected children.

"This publication shows that carrier screening with cfDNA fetal risk assessment performs reliably in the general-risk population, not just in a research setting," said Haywood Brown, MD, Chief Medical Officer, Prenatal at BillionToOne. "For patients, that means a high-risk pregnancy is far less likely to be missed simply because a partner sample was never collected."

Unity Fetal Risk Screen is part of BillionToOne's Unity Complete® prenatal screening portfolio, combining carrier screening, cfDNA-based fetal risk assessment, and aneuploidy screening to deliver prenatal genetic information from a single maternal blood draw via the company's proprietary Quantitative Counting Template™ (QCT™) technology. The publication follows BillionToOne's recent announcement that it is expanding its fetal risk screen portfolio to include a new 130-gene panel, reflecting the company's continued investment in advancing comprehensive prenatal screening and fetal risk assessment.

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 proprietary single-molecule next-generation sequencing (smNGS) platform is the only multiplex technology that can detect and precisely quantify genetic targets at the physical limit of detection, down to the single DNA molecule. Enabled by Quantitative Counting Templates™ (QCTs™), the platform quantifies disease-related DNA fragments with single base-pair resolution, providing absolute quantification. For more information, visit www.billiontoone.com.

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 incorporation of cfDNA fetal risk assessment into routine carrier screening. 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, 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 Annual Report on Form 10-K, BillionToOne's most recently filed Quarterly Report on Form 10-Q, 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.

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[1] Giles Choates M, Stevens BK, Wagner C, Murphy L, Singletary CN, Wittman AT. It takes two: uptake of carrier screening among male reproductive partners. Prenat Diagn. 2020 Feb;40(3):311-316. doi: 10.1002/pd.5588. Epub 2019 Dec 2. PMID: 31793013.

Correction: A hyperlink has been added in the 1st paragraph.

View original content to download multimedia:https://www.prnewswire.com/news-releases/largest-prospective-study-in-general-risk-pregnancies-strengthens-evidence-for-cfdna-fetal-risk-assessment-as-a-primary-screen-for-recessive-conditions-302854319.html

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