



Bionano Genomics Announces First Publication Demonstrating OGM as an Alternative to Karyotyping for Product of Conception Sample Analysis

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The newly proposed workflow has 93% success rate compared to 9.6% success rate of traditional methods by eliminating cell culture, replacing karyotyping analysis with OGM for comprehensive SV analysis of fetal tissue and adding chromosomal microarray analysis of formalin-fixed, paraffin-embedded POC tissue to recover samples contaminated with maternal cells.

SAN DIEGO, Feb. 11, 2022 (GLOBE NEWSWIRE) -- Bionano Genomics, Inc. (BNGO), pioneer of optical genome mapping (OGM) solutions on the Saphyr® system and provider of NxClinical™, the leading software solution for visualization, interpretation and reporting of genomic data, today announced the first publication demonstrating OGM as an alternative to karyotyping (KT) for products of conception (POC) sample analysis.

Chromosomal abnormalities are the most common cause of early pregnancy loss and at least 5% of women trying to conceive face recurrent pregnancy loss with two or more consecutive miscarriages. According to current medical guidelines, KT and chromosomal microarray (CMA) can be performed on POC to determine the etiology of a loss and identify potential inherited causes. However, KT requires cultured cells, which are difficult to obtain with POC samples, and as a result, KT test failures are frequent. In addition to failing to culture, POC samples are highly heterogeneous and frequently contaminated with maternal cells, making any cytogenetic or molecular analysis challenging.

In this preliminary study, published as a preprint in *medRxiv*, researchers devised a novel workflow that eliminated the need for tissue culture by using OGM as an alternative to KT for comprehensive SV analysis, thereby circumventing the most common failure mode of POC analysis. Previous studies have demonstrated that OGM is highly concordant with KT, and because of its higher resolution, OGM often identifies additional genetic aberrations missed by other methods. The study workflow also describes a way to rescue samples that are contaminated with maternal cells through a combination of microdissection of formalin-fixed, paraffin-embedded (FFPE) POC samples followed by microarray analysis. OGM was not tested on the microdissected FFPE samples.

Overall, the preliminary study results showed that the new workflow using both OGM and CMA provided results in 93% of cases vs. 9.6% for workflows using KT and CMA, and identified genetic aberrations in 45.1% of samples compared to only 6.4% of samples with KT and CMA.

"POC samples are some of the most challenging samples I have ever dealt with in the lab. It's frustrating and emotionally draining not to be able to get results to families asking why they had a pregnancy loss," remarked Alka Chaubey, PhD, FACMG, Chief Medical Officer of Bionano. "It fills me with hope when I see indications of how OGM and other advanced molecular methods can significantly improve test success rates, and I am very proud to have worked on this approach with Dr. Kolhe and his team at Augusta University."

Erik Holmlin, PhD, president and chief executive officer of Bionano commented, "This study shows early-stage work in an area that we believe may prove to be very helpful to hopeful parents struggling with pregnancy loss. There is more work to do, but Dr. Kolhe and his team have brought a pioneering spirit to devising and testing this new method and the data show it may have a dramatic impact on analytical success rates as compared to standard workflows. We are eagerly awaiting their results as they extend this work to include more subjects and different iterations of the workflow."

This publication is available at: <https://www.medrxiv.org/content/10.1101/2022.02.03.22269494v1>

About Bionano Genomics

Bionano Genomics is a provider of genome analysis solutions that can enable researchers and clinicians to reveal answers to challenging questions in biology and medicine. The Company's mission is to transform the way the world sees the genome through OGM solutions, diagnostic services and software. The Company offers OGM solutions for applications across basic, translational and clinical research. Through its Lineagen business, the Company also provides diagnostic testing for patients with clinical presentations consistent with autism spectrum disorder and other neurodevelopmental disabilities. Through its BioDiscovery business, the Company also offers an industry-leading, platform-agnostic software solution, which integrates next-generation sequencing and microarray data designed to provide analysis, visualization, interpretation and reporting of copy number variants, single-nucleotide variants and absence of heterozygosity across the genome in one consolidated view.

For more information, visit bionanogenomics.com, lineagen.com or biodiscovery.com

Forward-Looking Statements of Bionano Genomics

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: how the application of OGM can significantly improve test success rates, including for POC analysis; and the ability of OGM to outperform KT in POC analysis workflows. Each of these forward-looking statements involves risks and uncertainties. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. Factors that may cause such a difference include the risks and uncertainties associated with: additional data from additional studies may contradict or fail to support the findings reported in this preliminary study and this press release, including with respect to the potential impact of OGM in POC analysis; the impact of the COVID-19 pandemic on our business and the global economy; changes in the competitive landscape, including the introduction of competitive technologies or improvements in existing

technologies; changes in our strategic and commercial plans; our ability to obtain sufficient financing to fund our strategic plans and commercialization efforts; whether medical and research institutions will adopt and/or continue to use our technologies, including as a result of their funding and the results of studies evaluating the utility and effectiveness of OGM; and the risks and uncertainties associated with our business and financial condition in general, including the risks and uncertainties described in our filings with the Securities and Exchange Commission, including, without limitation, our Annual Report on Form 10-K for the year ended December 31, 2020 and in other filings subsequently made by us with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. We do not undertake any obligation to publicly update any forward-looking statements, whether as a result of the receipt of new information, the occurrence of future events or otherwise.

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