



Biodesix Publishes Extended Analyses of the Nodify XL2® Lung Nodule Test

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Assessment Confirms Test Performance After Two Years of Surveillance

BOULDER, Colo.--(BUSINESS WIRE)--Dec. 1, 2020-- [Biodesix, Inc.](#) (Nasdaq: BDSX) a leading data-driven diagnostic solutions company with a focus in lung disease, today announced publication of an analysis of the company's Nodify XL2® lung nodule test. The test supports clinical decision-making for suspicious nodules by more accurately identifying patients with a very low risk of malignancy and shifting those patients into surveillance, thereby minimizing invasive procedures on those with benign nodules.

In [previously published findings](#) from the Pulmonary Nodule Plasma Proteomic Classifier (PANOPTIC) Trial, the Nodify XL2 test was shown to accurately identify patients with lung nodules who have a pre-test risk of malignancy less than 50% as "likely benign." After one year of follow-up, the test demonstrated a sensitivity of 97%, specificity of 44%, and negative predictive value of 98%, which is more accurate than other commonly used lung nodule risk assessment calculators.

The new paper, [published in the American College of Chest Physicians \(CHEST\) Journal](#), presents findings that all nodules in the study group that were established as benign after one year remained benign after two years of follow-up. This data confirms the performance of the Nodify XL2 test over the guideline-recommended two-year surveillance period to radiologically confirm a benign diagnosis. Additionally, a new analysis suggests that the classifier performs similarly regardless of the whether the nodule of concern was solitary or there were other nodules present.

"This assessment demonstrates our commitment to providing long-term follow-up for patients and to continuously study the performance of our tests," said Scott Hutton, CEO of Biodesix. "Central to our mission is the drive to improve patient outcomes while reducing ineffective and unnecessary treatments and procedures. Nodify XL2 exemplifies this. With this test, part of our Nodify Lung™ testing strategy, physicians are equipped with vital and time-sensitive information to help efficiently determine the appropriate course of treatment for each patient."

About Nodify XL2® Lung Nodule Test

The Nodify XL2 blood-based proteomic test helps identify patients who have a suspicious lung nodule that is likely benign or at a reduced risk of being cancerous. Results help physicians to identify patients who may be better candidates for routine CT surveillance to monitor for growth or shrinkage of the nodule over time instead of an invasive diagnostic procedure. The Nodify XL2 test is used for patients who are 40 years or older, have nodules between 8mm and 30mm, and have a pre-test risk of lung cancer of less than or equal to 50%.

The test is performed in Biodesix's COLA-accredited laboratory in De Soto, Kansas.

About Biodesix

Biodesix is a leading diagnostic company with a focus in lung disease. The Company develops diagnostic tests addressing important clinical questions by combining multi-omics through the power of artificial intelligence. Biodesix is the first company to offer six non-invasive tests for patients with diseases of the lung. Biodesix launched the SARS-CoV-2 ddPCR™ test and the Platelia SARS-CoV-2 Total Ab in response to the global pandemic and virus that impacts the lung and causes COVID-19. The blood-based Biodesix Lung Reflex® strategy for lung cancer patients integrates the GeneStrat® and VeriStrat® tests to support treatment decisions with results in 72 hours, expediting time to treatment. The blood-based Nodify Lung™ nodule risk assessment testing strategy, consisting of the Nodify XL2® and the Nodify CDT™ tests, evaluates the risk of malignancy in incidental pulmonary nodules, enabling physicians to better triage patients to the most appropriate course of action. Biodesix also collaborates with many of the world's leading biotechnology and pharmaceutical companies to solve complex diagnostic challenges in lung disease. For more information about Biodesix, visit [biodesix.com](#).

Note Regarding Forward-Looking Statements

This press release may contain forward-looking statements that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements contained in this press release other than statements of historical fact, are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "plan," "expect," "predict," "potential," "opportunity," "goals," or "should," and similar expressions are intended to identify forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors. Biodesix has based these forward-looking statements largely on its current expectations and projections about future events and trends. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, Biodesix operates in a competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for its management to predict all risks, nor can it assess the impact of all factors on its business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements it may make. Biodesix undertakes no obligation to revise or publicly release the results of any revision to such forward-looking statements, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements. All forward-looking statements are qualified in their entirety by this cautionary statement.

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