

NODIFY XL2™ INCIDENTAL LUNG NODULE TEST BACKGROUNDER

The Need for Diagnostic Tools

Under current medical practices, 95% of lung nodules are discovered incidentally through chest imaging for other health conditions.¹ Common examples include angiograms or chest x-rays following physical trauma where a nodule is discovered in the process. High and very low risk nodules have clear guideline-recommended management strategies; however, most nodules (75%) fall into the low to moderate risk categories.² For these patients, guidelines are less specific, and utilization of diagnostic tools such as PET, biopsy, surgery, and/or CT surveillance is largely determined by the physician.

Identifying which patients are candidates for diagnostic procedures can be difficult from a CT scan. Physicians can sometimes be uncertain about making the decision to monitor low to moderate risk patients with CT surveillance, which can lead to patients undergoing invasive, risky, and expensive procedures that may be unnecessary. As a result, many nodules are often confirmed as benign using a tissue biopsy instead of using surveillance monitoring.

To address this challenge, recent technological advances have led to the development of a simple, non-invasive blood-based test to help identify likely benign lung nodules. The test provides quick results that help expedite decision making and prevent delayed diagnosis. In addition, they help reduce unnecessary procedures and support a more clear and consistent management pathway.

Nodify XL2™ Incidental Lung Nodule Test

The Nodify XL2™ incidental lung nodule test helps physicians quickly and accurately rule out malignancy prior to bronchoscopy using information from a simple blood draw. The test integrates clinical risk assessment with proteomic insights to instill clinical decision-making confidence in effectively managing low to moderate risk incidental nodule patients.

Nodify XL2 testing is covered by Medicare with \$0 out of pocket expense for covered Medicare and Medicaid beneficiaries. The test is performed in a CAP accredited Washington state medical test site (WA MTS) clinical laboratory in Seattle, WA.

¹ Pham et al, "Lung cancer screening rates: Data from the lung cancer screening registry." ASCO Annual Meeting, Chicago, 2018.

² Silvestri G et al. "Assessment of plasma proteomics biomarkers ability to distinguish benign from malignant lung nodules." CHEST. 2018 Sept. 154(3):491-500. (PANOPTIC)