

NODIFY LUNG™ NODULE RISK ASSESSMENT BACKGROUNDER

The Need for Diagnostic Tools

Under current medical practices, approximately 95% of lung nodules are discovered incidentally through chest imaging for other health conditions.¹ Common examples of such chest imaging procedures include angiograms or chest x-rays following physical trauma. Guidelines inform physicians how to manage lung nodules based on risk classification. High and very low risk nodules have clear guideline-recommended management strategies; however, most nodules (75%) fall into the middle group, referred to as the low to moderate risk category.² For these patients, guidelines are less specific, and utilization of diagnostic tools such as positron emission tomography (PET), biopsy, surgery, and/or computed tomography (CT) surveillance is largely determined by the physicians clinical judgement.

Identifying which patients are candidates for diagnostic procedures can be difficult using only information from an image such as a CT scan. Physicians are sometimes reticent about making the decision to only monitor low to moderate risk patients with CT surveillance despite the evidence that a significant proportion of these nodules are benign. This reticence often leads to patients undergoing invasive, risky, and expensive procedures on more benign nodules than is necessary. As a result, many nodules are often confirmed as benign using a tissue biopsy instead of by imaging. Additionally, some patients have nodules that appear lower risk by imaging and are sent for surveillance when their nodule is malignant and experience a delay in diagnosis. It is clear that risk profiling based only on imaging features is challenging and may lead to a misdiagnosis in a subgroup of patients.

To address these challenges, supplementing imaging features with objective blood based immune and cancer markers have led to the development of clinical tests to help physicians quickly and more accurately decipher the risk of malignancy of a lung nodule from a single blood draw. More precise risk profiling of patients with lung nodules helps physicians identify lung cancer earlier and reduce unnecessary procedures on benign nodules, which supports a clearer and more consistent patient management pathway.

Nodify Lung Nodule Risk Assessment

The Nodify Lung™ nodule risk assessment testing strategy incorporates both the Nodify XL2™ and Nodify CDT™ proteomic tests from a single blood draw to help physicians reclassify the risk of malignancy of incidental lung nodules. The Nodify XL2™ proteomic test helps physicians identify patients with a very low risk lung nodule who may benefit from CT surveillance and the Nodify CDT™ proteomic test helps physicians identify patients with a high risk lung nodule who may benefit from timely intervention.

Nodify Lung testing shifts 26% of patients with low to moderate risk nodules into the very low risk group³. With a potential 43% reduction in biopsies on benign nodules and a 29% reduction in surgeries on benign nodules², enacting a Nodify Lung testing strategy could potentially result in a gross reduction of 16% of biopsies and 6% of surgeries*, alleviating high demand healthcare resources. Additionally, 9% of patients with low to moderate risk nodules may be reclassified as high risk and should be prioritized for diagnostic intervention to avoid the risk delayed diagnosis of lung cancer.

There is no out of pocket expense for Medicaid and covered Medicare patients for Nodify Lung testing. Testing is performed in a COLA certified clinical laboratory in De Soto, Kansas.

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)

³ Biodesix, "Data on File - Subgroup Analysis of PANOPTIC," 2019.

*A majority of procedures that are not completed are on benign nodules. Calculated by multiplying the percent of biopsies or surgeries on benign nodules by the percent reduction in biopsies or surgeries on benign nodules.