Case Study Helen: Positive CyPath® Lung for patient with sub-solid ground-glass nodules results in earlier cancer diagnosis

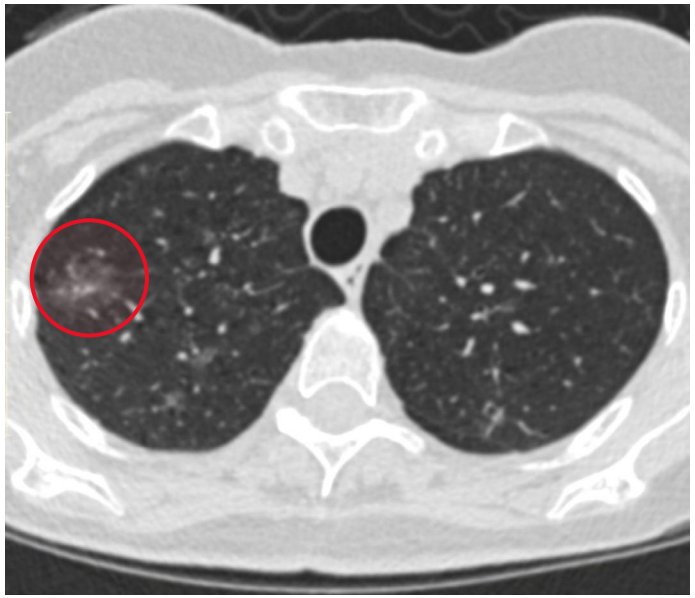
Patient Information and Initial Workup

- **Age:** 66 years old
- **Sex:** Female
- **Smoking status:** Former smoker; quit 5 years ago
- **Medical history:** CT scan ordered to diagnose pain in abdomen incidentally captured ground-glass nodule in lung

NOTE: Actual patient case, but name has been changed to ensure privacy.

Imaging Results

Dedicated CT of chest revealed multiple ground-glass nodules with largest approx. 13 mm; no suspicious nodule characteristics but patient referred to lung clinic due to smoking history



Additional Findings/Next Steps

- **PET scan:** PET not expected to be informative re ground-glass nodules
- **Follow-up testing options:** Society recommendation is serial 6-month CTs and watchful waiting up to 3-5 years to monitor changes to nodule(s)
- Patient was uncomfortable with watchful waiting
- Physician ordered CyPath® Lung for more definitive risk stratification

Outcome with CyPath® Lung

- **CyPath® Lung:** CyPath® Lung result "Likely Malignant" with score of 7
- **Biopsy** of nodules using robotic bronchoscopy
- Pathology reported **positive for cancer**
- **Patient referred for surgery**
- Tumor Board review

Dx= diagnosis; LDCT=low-dose computed tomography.

CASE STUDY HELEN: Summary

CyPath® Lung identified lung cancer early in a patient with an incidental finding of ground-glass nodules which are often difficult to diagnose and are generally subject to “watchful waiting” and serial CT scans.

Why CyPath® Lung?

CyPath® Lung fills an important need for a noninvasive test to improve the early detection of lung cancer in high-risk patients. CyPath® Lung can be used alone or in combination with other diagnostic tools.

ACTIONABLE RESULTS

92% sensitivity, 87% specificity, and 88% accuracy in detecting lung cancer in high-risk patients with pulmonary nodules less than 20 mm.[1]*

CONVENIENT SAMPLE COLLECTION

Pre-paid overnight packaging makes it easy for your patients to collect and return their samples to the laboratory.

FAST TURNAROUND

Physicians receive results 3 days after the lab receives the sample. Medicare and private insurance accepted.

FLOW CYTOMETRY ENHANCED BY AI

Flow cytometry identifies cell populations indicating malignancy. Automated data analysis developed using artificial intelligence aids in determining if cancer is present or the patient is cancer-free.

Order CyPath® Lung

Precision Pathology Laboratory Services
A bioAffinity Technologies Company
Phone: (210) 646-0890 • Fax: (210) 646-9191
info@precisionpath.us

cypathlung.com

Physicians will receive results within 3 days after sample is received by Precision Pathology Laboratory Services.

*Nodules detected by low-dose computed tomography. Test performance reflects 95% Area Under the Curve; 95% Confidence Interval; 99% Negative Predictive Value, 44% Positive Predictive Value. This test is a Laboratory Developed Test and has not been cleared by the US Food and Drug Administration (FDA).[1]

DISCLAIMER: Failure of individual assays may occur due to problems with specimen quality or technical issues. Negative findings do not rule out the presence of an abnormality, and not all positive findings are indicative of an abnormality. All findings should be correlated with patients’ clinical history and imaging. This test has not been cleared by the US Food and Drug Administration (FDA). The FDA has determined that such clearance or approval is not necessary. This test is for diagnostic purposes. It should not be regarded as investigational or for research.

Reference: 1. Lemieux ME, Reveles XT, Rebeles J, et al. Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning. Respir Res. 2023;24(1):23. doi:10.1186/s12931-023-02327-3

CyPath® Lung