CASE STUDY JAMES: Negative Test Result Prevented High-Risk Biopsy

PATIENT INFORMATION AND INITIAL WORKUP

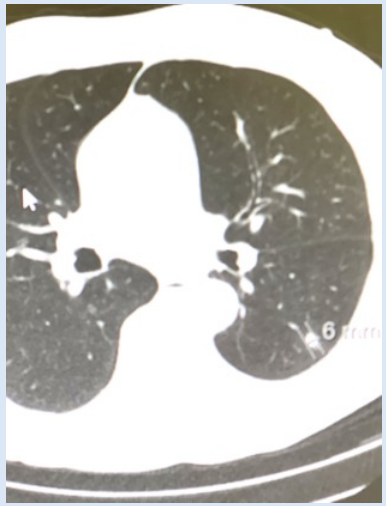
- **Age:** 85 years old
- **Sex:** Male
- **Smoking status:** Former smoker (>20 pack-years)
- **Medical history:** Asbestos exposure; COPD/OSA
- **Family history:** Unremarkable
- **Malignancy risk:** 99x risk vs nonsmoker without asbestos exposure
- Patient acutely aware of his high-risk status, requested LDCT for surveillance

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

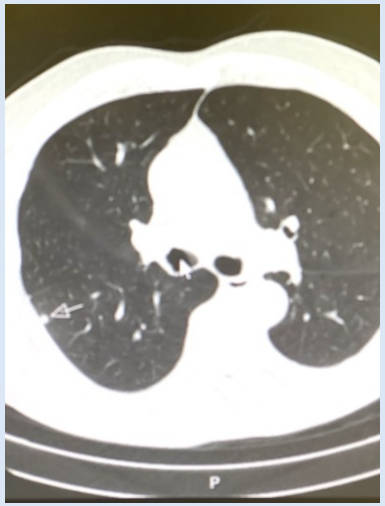
bx=biopsy; COPD=chronic obstructive pulmonary disease; CT=computed tomography; LDCT=low-dose computed tomography; LLL=left lower lobe; OSA=obstructive sleep apnea; PET=positron emission tomography; RLL=right lower lobe.

IMAGING RESULTS

Initial LDCT: 4/24 scan revealed several new subcentimeter (≤8 mm) noncalcified nodules. 6-mm LLL noncalcified nodule concerning for malignancy was in a difficult-to-reach location.

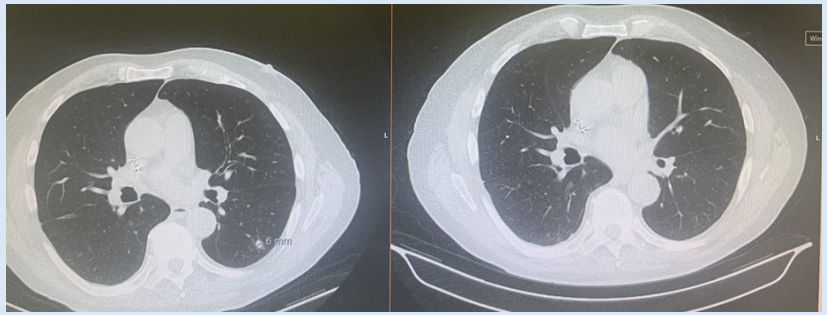


6 mm nodule LLL



4 mm nodule RLL

Follow-up chest CT scans: Complete resolution of nodules on 7/24 scan. 1/25 scan (not shown) revealed no new nodules.



ADDITIONAL FINDINGS/ NEXT STEPS

- **Brock model risk:** 1.5%
- **PET scan:** Not recommended for nodules <8 mm because of low sensitivity
- **Biodesix Nodify:** Not recommended for nodules <8 mm
- **Follow-up testing options:** Serial CT scans, robotic bronchoscopic bx, percutaneous bx
- Patient favored robotic biopsy despite low Brock risk score

OUTCOME WITH CYPATH® LUNG

- **CyPath® Lung:** 5/24 test result: 0.46; unlikely lung cancer
- Patient comfortable with serial CT scans instead of robotic bx or high-risk percutaneous bx
- Follow-up CT scans on 7/24 and 1/25 showed no nodules
- **CyPath® Lung prevented unnecessary biopsy**

CASE STUDY JAMES: Summary

CyPath® Lung helped resolve a common diagnostic dilemma by ruling out lung cancer to prevent the attempted biopsy of a difficult-to-reach nodule. The patient, who had originally favored biopsy, instead chose close CT surveillance because of the CyPath® Lung results.

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

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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