CASE STUDY CAROL: Positive Test Result Helped Direct Next Steps in Care

PATIENT INFORMATION AND INITIAL WORKUP

- **Age:** 80 years old
- **Sex:** Female
- **Smoking status:** Tobacco abuse; quit in 2010
- **Medical history:** COPD; CAD with MI and cardiac stents
- **Breast cancer:** Diagnosed in 2019
- Patient chose to stop chronic breast cancer hormonal therapy
- Yearly LDCT screening for high-risk lung cancer

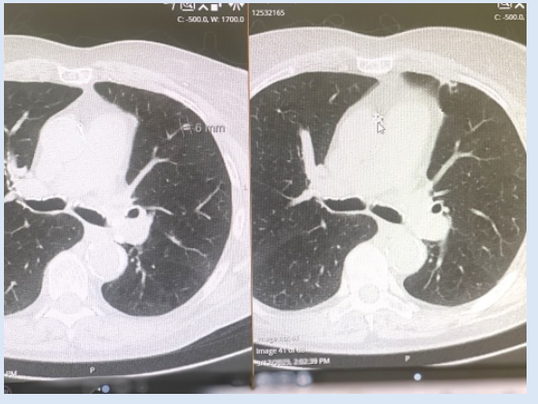
Actual patient case, but name has been changed to ensure privacy.

CAD=coronary artery disease; COPD=chronic obstructive pulmonary disease; CT=computed tomography; DDx=differential diagnosis; LDCT=low-dose computed tomography; LUL=left upper lobe; PET=positron emission tomography; RUL=right upper lobe.

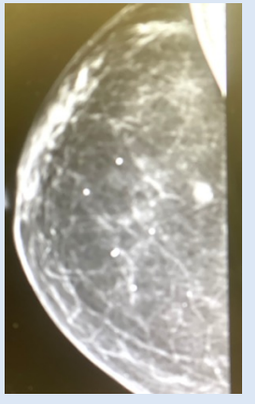
IMAGING RESULTS

Initial LDCT: 9/23 scan was negative. 10/24 scan revealed new noncalcified sub 8 mm nodules in LUL and RUL, as well as others.

12/24 mammogram: Revealed new suspicious areas in the right breast.

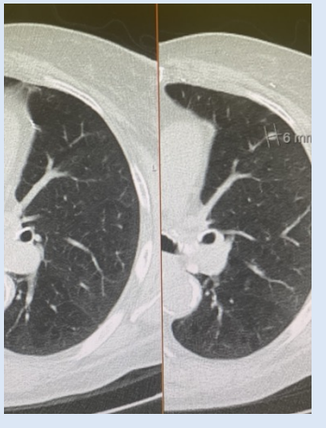


9/23 no nodule **10/24 6 mm nodule**



12/24 mammogram

Follow-up LDCT: 2/25 scan shows resolution of LUL nodule vs 10/24 scan.



2/25 scan **10/24 scan**

ADDITIONAL FINDINGS/ NEXT STEPS

- **Brock model risk:** 4.3%
- **PET scan:** Not recommended for nodules <8 mm because of low sensitivity
- **Serum markers:** Contraindicated given breast cancer within 5-year period
- **Follow-up testing options:** Bronchoscopy is high risk and poor yield without robotic augmentation

OUTCOME WITH CYPATH® LUNG

- **CyPath® Lung:** 11/24 test result: 0.72, likely lung cancer
- 12/24 mammogram to recheck patient's status revealed new suspicious areas in the breast
- Breast biopsy was positive for recurrent breast cancer; hormonal therapy was restarted
- 2/25 LDCT showed resolution of LUL nodule
- Patient is at high risk for lung cancer and will continue close CT surveillance
- DDx remains metastatic breast cancer to the lung now suppressed vs inflammatory process resolved
- **CyPath® Lung played a key role in next steps in care**

CASE STUDY CAROL: Summary

CyPath® Lung helped direct next step care for a patient with breast cancer who had discontinued her treatment. The "likely lung cancer" result prompted a mammogram and a breast biopsy to check for recurrence. Breast cancer treatment was restarted after the results came back positive.

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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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