CASE STUDY JOAN: Positive Test Result Led to Diagnosis of 2nd Primary Cancer

PATIENT INFORMATION AND INITIAL WORKUP

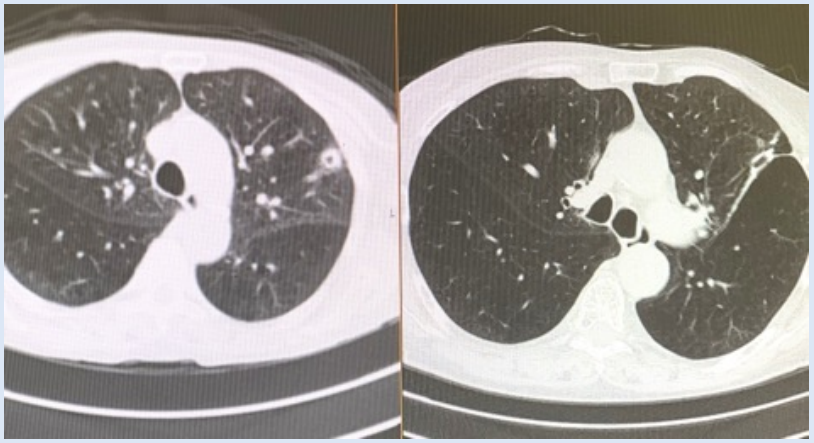
- **Age:** 72 years old
- **Sex:** Female
- **Smoking status:** 50 pack-year smoker; quit 2021; using vape pen
- **Medical history:** COPD/OSA with chronic respiratory failure on O_2
- **Cancer history:** 10/4/23 LUL wedge resection for clinical Stage IA NSCCA of the lung
- Patient with Stage IA NSCCA of the lung requires close follow-up

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

COPD=chronic obstructive pulmonary disease; CT=computed tomography; ES-SCLC=extensive-stage small cell lung cancer; LUL=left upper lobe; NSCCA=non-small cell carcinoma; OSA=obstructive sleep apnea; PET=positron emission tomography.

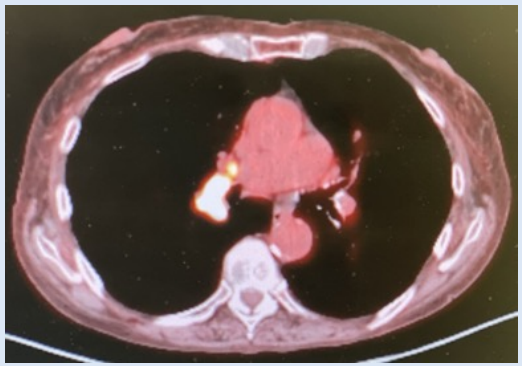
IMAGING RESULTS

Initial CT: 4/15/24 scan revealed subtle changes to LUL post-op resection site.



Pre- and post-op wedge resection, post-op increased nodularity from 10/4/23 to 4/14/24

Follow-up PET: 7/19/24 scan showed post-op scar without avidity, but right hilum and mediastinum grossly positive. Unusual presentation for metastatic NSCCA from LUL lesion.



ADDITIONAL FINDINGS/ NEXT STEPS

- **Serum markers:** Contraindicated given cancer within 5-year period
- Subtle post-op changes common and present a diagnostic dilemma

OUTCOME WITH CYPATH® LUNG

- **CyPath® Lung:** 5/5/21/24 test result: 0.83, likely lung cancer
- Because this represents a real-time possible recurrence, follow-up PET ordered 7/19/24
- PET showed right lung, right mediastinal and liver uptake
- Liver biopsy confirmed new small cell lung cancer as second primary
- Patient is currently being treated for ES-SCLC
- **CyPath® Lung positive result led to PET scan and diagnosis of a second primary cancer**

CASE STUDY JOAN: Summary

CyPath® Lung provided real-time information that a patient's suspicious findings were likely due to recurrence of prior Stage 1 NSCCA or a second primary cancer. The patient was subsequently diagnosed with ES-SCLC.

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