Lung nodules, lung microenvironment, predictive models and clinician risk stratification using CyPath® Lung testing for early diagnosis of lung cancer

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CyPath® Lung testing has gained traction for both early lung cancer diagnosis and recurrence surveillance because of its reproducible ability to help clinicians stratify the risk of malignancy in newly discovered or changing pulmonary nodules. Clinicians who assess pulmonary nodules for possible malignant potential are facing a herculean task over the next five years as a confluence of factors dramatically complicates this process.[1] The burden of nodules needing assessment is exploding as AI mines medical records for any mention of nodules in imaging tests, our understanding of lung cancer risk factors expands, and screening/surveillance becomes more hardwired into primary and specialist patient care.[2, 3, 4]

Predictive models and tests to help risk stratification are beneficial but have limitations. As Mark Twain said, “Lies, damn lies and statistics.” Uneven understanding of the limitations inherent in predictive models and diagnostic test statistics can cause significant confusion and clinical misunderstandings.[5,6,7] AI augmentation of imaging and introduction of supplemental diagnostic tests that interrogate blood and other body fluids create a mixture of outcome benefits at best and a minefield of pitfalls at worst.[5, 6, 7]

Navigational guidance is different for primary care programs involved in lung cancer screening compared to pulmonary nodule programs with specialized clinicians and patient navigators. Additionally, guidance for an oncology specialist wanting robust surveillance during survivorship requires algorithms unique to these populations.

Relatively newer understanding shows that the lung harbors microenvironments that are distinct from blood phenotypes, giving insight into site- specific pathophysiology and treatment opportunities.[8, 9, 10] Additionally, lung microenvironments are affected by genome, genetic expression and alterations caused by exposures, severity of inflammation, and carcinogens, to name a few. Interrogating the lung micro- environment to better understand clinical expression and treatment response in asthma and COPD is well established with new insights being discovered every month.[8] Tumor lung microenvironments are also being recognized, and exploring this pathophysiology will lead to insights for better diagnosis and treatment of lung cancer.[8, 9, 10]

Taken together, the burden of disease, specialty-specific navigational requirements, and information to be gleaned from interrogating the lung microenvironment pose demanding questions and significant challenges but also offer avenues to explore and define these disease processes in ways that assist rather than confuse clinical champions at every level.

How we address and navigate the above challenges requires an understanding that there is no “magic bullet” diagnostic or screening regimen. Each circumstance will have unique patient/clinician stressors, obstacles and pathways. CyPath® Lung testing uses a chimera analysis for interrogating lung sputum, identifying evidence of cancer cells and tumor-associated lung microenvironment cells resulting in a powerful diagnostic test.[11, 12, 13] Addressing navigation in the context of each specialty’s needs, we expect to add pathways to interrogate the lung microenvironment and real-time cancer manifestation to diminish statistical confusion.

CyPath® Lung Testing in Primary Care Practices

Primary care practices, both Family Practice and Internal Medicine, may have a robust lung cancer screening program as part of their practice. Data

suggests 98% of primary care practices refer patients to proactive specialty programs, but less than 10% utilize internal comprehensive programs.[14] Up to 60% of these practices adopt internal screening programs for breast and colorectal cancers; however, the data are unclear for how many practices screen for lung cancer or perform survivorship surveillance.

Case Study Marge: Negative Test Result Prevents Biopsy of Benign Nodule

Patient Information

Age: 79 years old

Sex: Female

Smoking status: Former 30-pack-year social smoker

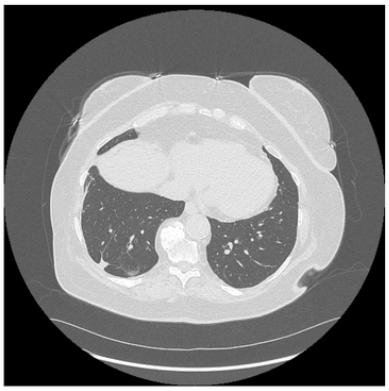
Medical History: High risk with COPD, CAD; empyema right pleura; initial CT 6/18/2025 and repeated 10/02/2025

Diagnostic Dilemma: Pulmonary nodule calculator 39%, MD gestalt benign

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

Imaging Results

Initial LDCT: 6/18/2025 CT scan reveals spiculated pleural parenchymal abnormality measuring 14.9mm at right lung base



Next Steps

CT Follow-Up Options without CyPath® Lung: Patient anxiety, pulmonary nodule calculator uncertainty and possible biopsy

CyPath® Lung: Negative test result, 0.25, unlikely malignancy in the lung

Follow-Up CT 10/2/2025 CT Scan: No discrete pulmonary nodule is seen; the previously noted partially loculated right pleura effusion resolved

Outcome with CyPath® Lung: Patient comfortable with serial annual CT scans as follow-up care

A negative CyPath® Lung result prevented invasive and potentially risky biopsy of benign nodule

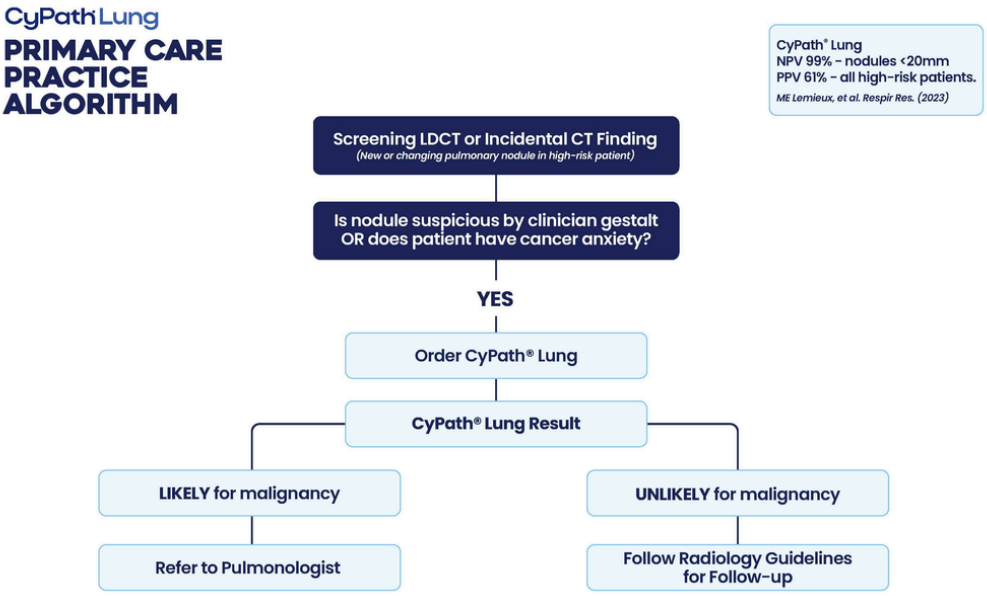
CAD=coronary artery disease; LDCT=low-dose computed tomography

CyPath Lung

The "Marge" case was referred to a pulmonary nodule program from Family Practice when nodules were incidentally reported on a calcium score CT scan to assess heart disease risk. This is a frequent occurrence, according to a recent discussion at a CHEST meeting in Chicago, March 2026, which suggested more lung cancers are diagnosed from incidental discovery than from screening programs. Data describing the poor penetration of low-dose CT (LDCT) screening for patients at high risk for lung cancer makes this source of nodule discovery less pertinent for primary care but increases the relevance of nodules found incidentally.[1] Would primary care practices be more likely to internally address a presentation like "Marge" rather than make a referral if there was a streamlined "go, no go" algorithm they could employ with confidence, as they do with colorectal screening and mammograms?

Most pulmonary nodules are small, measuring less than 10-15 mm.[15] CyPath® Lung testing offers a negative predictive value (NPV) of 99% for these nodules.[11, 12, 13] A reasonable primary care-centered nodule algorithm would be to order the CyPath® Lung noninvasive sputum test for patients with incidentally found or screened smaller nodules. If the CyPath® Lung result is unlikely for malignancy, the clinician would follow standard Fleischner or American College of Radiology (ACR) society guidelines rather than refer to a specialist. Nodules larger than 12-15 mm are more likely to be a malignancy than the smaller nodules, and referral to a specialty practice should be considered. The positive predictive value (PPV) of the CyPath® Lung test is between 40% and 61% depending on the size of the nodule, and if the test result is likely for malignancy, referral should also be considered.[11, 12, 13]

Empowering primary care practices with a simple straightforward "go, no go" algorithm with the CyPath® Lung test would address most imaged nodules that physicians are asked to evaluate in their practices. Additionally, many primary care practices could employ nurse or extender navigators to provide this service, improving patient communication, saving significant time, and reducing the number of expensive additional tests and referrals. Cost of pulmonary nodule assessment is an additional consideration. Employing expensive advanced robotic or navigational bronchoscopies to biopsy smaller nodules with low probability for malignancy is not a sustainable cost-effective strategy.



Morris, et al. demonstrated significant cost savings could be realized by employing CyPath® Lung testing rather than moving immediately to costly and often risky invasive procedures.[16] Additionally, combining CyPath® Lung with physician gestalt to stratify which patients should have their sputum interrogated versus watchful waiting with CT scan follow-up would further address cost concerns.

CyPath® Lung Testing in Pulmonary Nodule Programs

Pulmonary nodule programs, whether academic-centered or free-standing community-based, have specialist clinicians, navigators and support staff to address the accelerating burden of pulmonary nodules needing evaluation. New or changing nodules discovered in screening or incidentally arrive at these programs through colleague referral or auto-referral within systems that direct nodules for specialist assessment. The majority of patients referred to pulmonary nodule programs will be high risk for lung cancer or non-high-risk individuals with high-suspicion nodules. Additionally, survivors of lung cancer or other solid tissue cancers that are known to metastasize to the lung require surveillance for new or changing nodules. Each of these populations carries different prevalences for the nodule being a primary or metastatic cancer. Understanding the clinical nuances of screening and the strengths and weaknesses of diagnostic tests is extremely important in this arena to confidently determine which patients require watchful waiting versus invasive testing. Specialty physicians' clinical gestalt and experience give them the ability to assign an accurate malignancy probability based on patient history, symptoms, nodule appearance and location. Any additional input from added testing should help clarify complicated or contradictory nodule presentations and not lead to greater uncertainty.

All clinically available tests intended to assist in the evaluation of pulmonary nodules report validation statistics to help clinicians decide on the test's utility. Unfortunately, there are no tests that provide 100% sensitivity, specificity, NPV or PPV.[5, 6, 7] Often this can lead to an expert clinician's concern that additional testing may not alter their initial impression but only add expense and possible risk. A journal article authored by MD Anderson pulmonologist Dr. David Ost on the interpretation of likelihood ratios (LR) in thoracic oncology suggests that diagnostic tests that report results as non-binary (more than two categorial test results) may lead to falsely low estimates of the probability of cancer in some pulmonary

nodules.[5] Drs. Humberto K. Choi, Michael Ghobrial and Peter Mazzone of the Cleveland Clinic reviewed eight models that estimate probability of malignancy in patients with pulmonary nodules.[6] The paper discusses how each model's cohort cancer prevalence can significantly affect malignancy probabilities. For example, a high prevalence cohort model can overestimate the probability of cancer in benign nodules. Additionally, the paper points out that several studies suggest that expert opinion often is equal to or better than the models at predicting the malignant nature of nodules. This is an opinion voiced repeatedly at national meetings and is framed to suggest that supplemental testing which cannot reproducibly change their expert gestalt adds expensive and potential procedural side effects without significant patient benefit. Finally, the paper by Dr Li, et al. on the performance of lung cancer prediction models for nodules found through screening, incidentally or post biopsy performed differently depending on clinical situation, and none of the models were as accurate when applied to biopsied nodules.[7]

The CyPath® Lung test is designed to deliver a binary result and is completely independent of imaging models. The "likely" or "unlikely" test result is equally dependent on the unbiased AI/machine learning algorithm developed for the flow cytometry platform which identifies porphyrin-incubated tumor cells, tumor-related immune cells and apoptotic cells.[11]

Consequently, CyPath® Lung avoids many of the pitfalls associated with predictive imaging models or diagnostic tests that use predictive models in their algorithm. Additionally, it observes the real-time presence of tumor cells and tumor-associated cells and is therefore not excluded for use in patients with previous solid tissue cancer or lung cancers. Accordingly, CyPath® Lung testing is appropriate for surveillance of cancer survivors who present with new or changing pulmonary nodules. CyPath® Lung testing also interrogates in real time the lung's microenvironment which will have unique features and signature profiles depending on whether the observed pulmonary nodules are benign or malignant.[5, 6, 7]

The lung microenvironment is a complex, dynamic system comprising epithelial, stromal, and immune cells, alongside the extracellular matrix (ECM) and a specialized microbiome. It acts as a critical regulator of homeostasis, injury response, and disease, particularly in cancer progression (tumor microenvironment, or TME) and chronic obstructive pulmonary disease (COPD).[8, 9, 10] Therefore, a CyPath® Lung result of "likely malignancy" has at least two critical findings associated with active lung malignancy – porphyrin-stained tumor cells and tumor-associated cells and evidence of TME-related immune cells. The combination of reporting the presence of real-time cancer cells and evidence of TME-related cells gives the expert clinician confidence that CyPath® Lung testing can clarify contradictory statistics and imaging results.

Case Study Gloria: CyPath® Lung detects rare pulmonary mucinous adenocarcinoma at Stage 1A

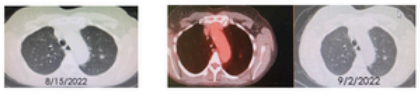
Patient Information and Initial Workup

- **Age:** 62 years old
- **Sex:** Female
- **Smoking status:** 100+ pack-year history
- **Medical history:** Stage 1 COPD (FEV1 109%)
- **Status:** High risk due to heavy smoking history and COPD
- **Presentation:** Chest X-ray with abnormal hyperinflation
- **Scans:** LDCT in August 2022, May 2023 and July 2024; PET in September 2022
- **Surveillance:** Patient missed recommended follow-up appointments

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

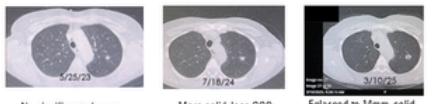
Imaging Results

LDCT on 08/15/22 revealed 12mm LUL mixed solid nodule with GGO features, lung cancer probability of 16%. PET scan SUV was 1.19, lung cancer probability 3.5% under Herder model.



12 mm GGO LUL — PET SUV 1.19

Missed 2 follow-up appointments; next LDCT scans were 5/25/23 and 10/18/2023 without significant changes. But 7/18/24 LDCT showed growth and less GGO characteristics. By 3/10/25 LDCT nodule had grown to 14mm with cystic changes.



No significant change — More solid, less GGO — Enlarged to 14mm, solid with cystic changes

Additional Findings/Next Steps

- **Brock model risk:** 16%/3.5% (Herder model with PET)
- **Nodify:** first blood serum marker test returned "reduced risk" result; second Nodify test came back as "indeterminate" with no circulating antibodies
- Patient refused invasive bronchoscopic biopsy
- **Follow-up PET:** denied by insurance in July 2024

Outcome with CyPath® Lung

- **CyPath® Lung:** 3/7/25 test result: 0.56, likely malignancy
- **Wedge resection:** Successful surgery on 6/11/25 with good margins, negative nodes
- **Diagnosis:** Stage 1A lung mucinous adenocarcinoma
- Patient quit smoking March 2025 and has returned to baseline pulmonary function
- **CyPath® Lung:** detected pulmonary mucinous adenocarcinoma in a high-risk individual whose previous tests and follow-up scans suggested a low probability of cancer

COPD=chronic obstructive pulmonary disease; LDCT=low-dose computed tomography; PET=positron emission tomography; LUL=left lower lobe; GGO=ground-glass opacity.

CyPath Lung

Case Study Peggy: Negative CyPath® Lung Result Leads to Additional CT Showing Resolution of Large Nodule and Avoiding Scheduled Biopsy

Patient Information

Age: 70 years old

Sex: Female

Smoking status: 50 pack-year history, current smoker

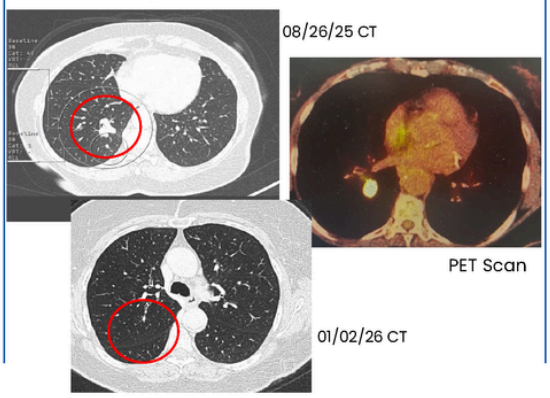
Medical history: High-risk with centrilobular emphysema, increased symptoms of cough, sputum and dyspnea

Diagnostic Dilemma: High-risk patient with suspicious CT/PET scans and elevated predicted risk while clinical acumen indicated low risk

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

Imaging Results

LDCT: Concerning RLL 3 cm infrahilar process with adenopathy and PET with very high-risk parameters; pulmonary nodule calculators: Mayo 91.3, Herder 91.3, Brock 49.7



Additional Findings/Next Steps

CT follow-up options without CyPath® Lung: Invasive biopsy was scheduled; clinician remained uncertain despite calculators and PET and ordered CyPath® Lung

Outcome with CyPath® Lung

CyPath® Lung: Test result was negative, 0.25, unlikely malignancy in the lung, leading to follow-up CT prior to scheduled invasive procedure

Follow-up 01/02/2026 CT scan: RLL 3 cm nodule resolved

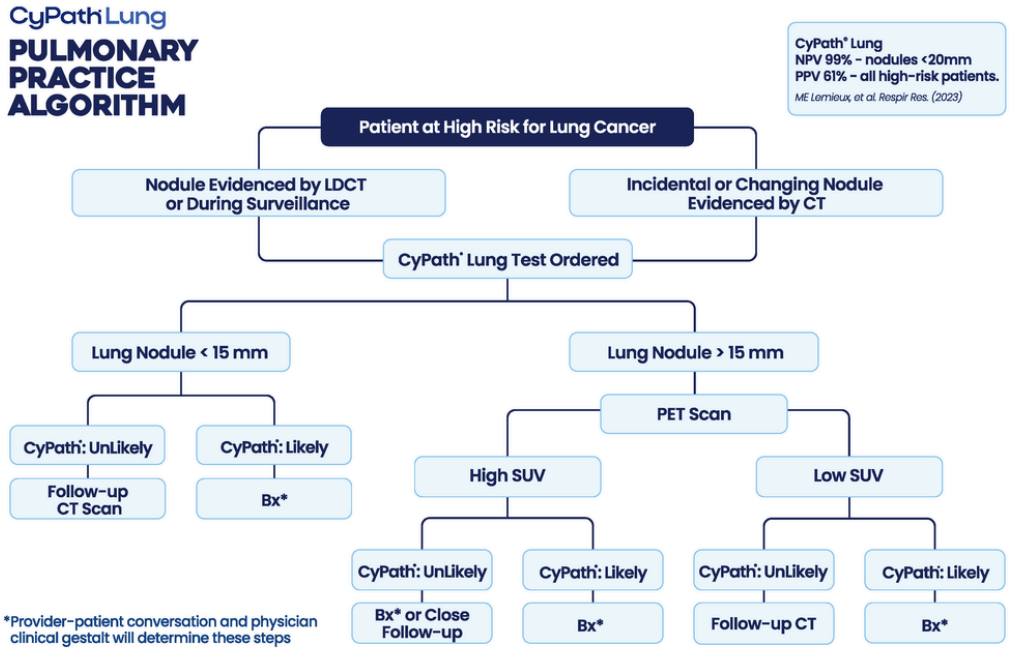
CyPath® Lung result led to CT follow-up prior to biopsy which revealed reversible inflammatory process

PET=positron emission tomography; LDCT=low-dose computed tomography; RLL=right lower lobe.

CyPath Lung

Both the “Gloria” and “Peggy” cases demonstrate how contradictory clinical data can complicate a patient’s presentation. In the “Gloria” case, imaging data pointed toward a benign process, and society recommendations would have been watchful waiting. CyPath® Lung testing returned a result of “likely malignancy,” and surgical resection was recommended. Stage 1A lung cancer was successfully removed in a timely manner. In the “Peggy” case, predictive modeling and imaging test results strongly suggested malignancy, and the Mayo Clinic and Brock predictive models were 91.3 and 49.7% respectively. Additionally, the right lower lobe (RLL) nodule had a standardized uptake value (SUV) of 14.2 on PET scanning, but the clinician’s gestalt was that the process may be inflammatory rather than malignant. The CyPath® Lung result was “unlikely malignancy” which led to a repeat CT scan prior to invasive biopsy. The follow-up CT scan demonstrated complete resolution of the RLL nodule.

The algorithm we propose for specialty clinicians emphasizes clinician gestalt as the final arbiter for testing decisions but gives the clinician a high-confidence data point to help clarify complex presentations, particularly when test results are contradictory.



CyPath® Lung Testing in Interventional Pulmonology Practices

Technological advances in interventional pulmonology (IP) have exploded over the last five years. There are currently 40 accredited IP fellowships in the United States and 300-400 active IP physicians.[17] Most regions will have access to both IP specialists as well as these advanced technologies. The impact is that most newly found or changing pulmonary nodules discovered via lung cancer screening or incidentally will have a biopsy option. The question is not can nodules be biopsied, but should they be biopsied? This discussion involves the sustainability of cost, side effect profile for debilitated patients, issues of overdiagnosis, and availability of malignancy risk stratification testing to assist in decision-making.[18]

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

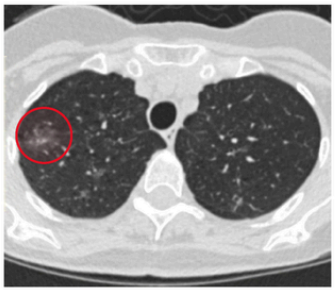
Patient Information and Initial Workup

- **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.

CyPath Lung

There are sound arguments to support a low threshold for conducting a biopsy on low-risk nodules and equally compelling arguments to further risk stratify the nodules prior to biopsy. CyPath® Lung testing has a documented 99% NPV in these nodules with low- probability for malignancy.[11] The test has been commercially available for three years and is covered by Medicare and most commercial insurance. More than 2200 tests have been performed, and in-house analysis suggests that our clinical trial's statistical parameters of NPV and PPV are valid in the regions serviced with their unique regional lung cancer prevalences. It is reasonable to employ a practice algorithm that continues serial imaging of patients with low-risk nodules when the CyPath® Lung testing result is "unlikely malignancy." Physician gestalt again is the final arbiter in discussions with the patient about course of action. In follow-up discussions with physicians using CyPath® Lung, clinicians have reported increased confidence when discussing follow-up care with their patients. The "Helen" case demonstrates CyPath® Lung's ability to identify as "likely malignancy" a non-suspicious 13 mm ground glass opacity (GGO) with a solid component. The patient was subsequently referred to IP for a robotic biopsy which revealed a stage IA adenocarcinoma.

Case Study James: Negative Test Result Prevented High-risk Biopsy

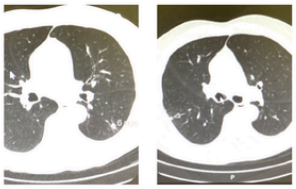
Patient Information and Initial Workup

- **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

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

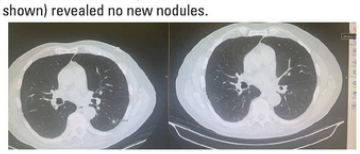
Imaging Results

Initial LDCT: 4/24 scan revealed several new sub centimeter (≤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**

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.

CyPath Lung

The "James" case demonstrates the other side of the coin, an older male with very high-risk parameters was found to have a 6 mm solid nodule. The CyPath® Lung test result was "unlikely malignancy." The tumor board discussed robotic biopsy versus close CT scan follow-up. Based on the CyPath® Lung result, the physician and patient opted for the follow-up CT scan option. Follow-up CT revealed a resolution of the nodule. In both cases, CyPath® Lung testing was instrumental in the physician-patient discussion opting for courses of action that benefited the patient.

CyPath® Lung Testing in Oncology Specialty Practices

The American Cancer Society (ACS) at its annual roundtable meeting in November 2025 placed an emphasis on management of survivorship post-cancer treatment as well as on the expansion of screening for lung cancer. Off-ramping cancer survivors into resumption of normal life does not mean ignoring surveillance for these patients in the two-to-five years following diagnosis and treatment.

Because CyPath® Lung testing is not contra-indicated for patients with previous lung cancer or other solid tissue cancers and can reveal the real-time presence of cancer cells, it can be an effective tool for surveillance.[13] CyPath® Lung testing can be used in patients with a history of lung cancer or solid tumors that may metastasize to the lung who are found to have a new or changing pulmonary nodule on CT scan.

The physician and patient can be confident in the NPV for an "unlikely malignancy" result; likewise, if the test result is "likely malignancy," the PPV can be used to direct possible invasive testing or at least close follow-up CT scanning.

Case Study Lisa: Positive Test Result Convinces Radiation Oncologist to Start Treatment in Patient with Prior Lung Cancer

Patient Information and Initial Workup

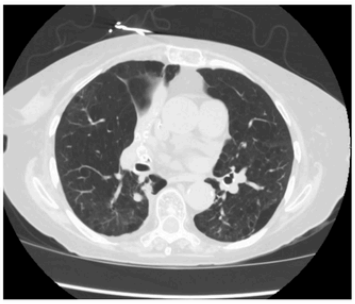
- **Age:** 78 years old
- **Sex:** Female
- **Smoking status:** Prior 40-pack-year smoker quit 2015
- **Medical history:** Known end-stage COPD and prior lung cancer (LUL) in 2018; new lesion found 2024

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

Imaging Results

Initial LDCT: Incidental lesion found in RLL

PET Scan: 1.4 cm in lower lobe lesion; SUV 4.6



Additional Findings/Next Steps

- **Follow-up testing options:** Monitor for interval repeat imaging versus high-risk biopsy

Outcome with CyPath® Lung

- **CyPath® Lung:** 11/13/24 test result was positive, likely lung cancer
- Radiation oncologist proceeded with treatment without biopsy
- Lesion stable at 1-year follow-up
- **High Risk patient did not need to undergo invasive procedure prior to treating recurrence of lung cancer**

LDCT=low-dose computed tomography; RLL=right lower lobe.

CyPath Lung

The “Lisa” case involved a 78-year-old female with previous left upper lobe (LUL) lung cancer diagnosed in 2018 who was found to have a new 14 mm nodule in the right lower lobe (RLL) in 2024. The patient’s performance status would not support an invasive procedure, but based on the CyPath® Lung result Radiation Oncology proceeded with radiation therapy for the patient which resulted in an excellent tolerated clinical response.

Case Study Carol: Positive Test Result Helped Direct Next Step Care

Patient Information and Initial Workup

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

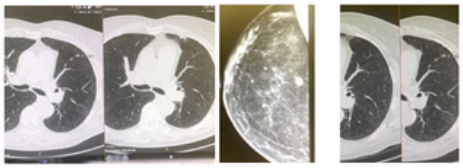
NOTE: Actual patient case, but name has been changed to ensure privacy.

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.

Follow-up chest LDCT: 2/19/25 scan shows resolution of LUL nodule vs 10/21/24 scan.



9/23 no nodule | 10/24 6 mm nodule | 12/24 mammogram | 2/19/25 scan | 10/21/24 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 high-risk and poor-yield without robotic augmentation

Outcome with CyPath® Lung

- **CyPath® Lung:** 11/13/24 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
- 2/19/25 CT showed resolution of LUL nodule
- Patient is at high risk for lung cancer and will continue close CT surveillance
- DDx remains metastatic breast to the lung now suppressed vs inflammatory process resolved
- **CyPath® Lung played a key role in next step care**

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

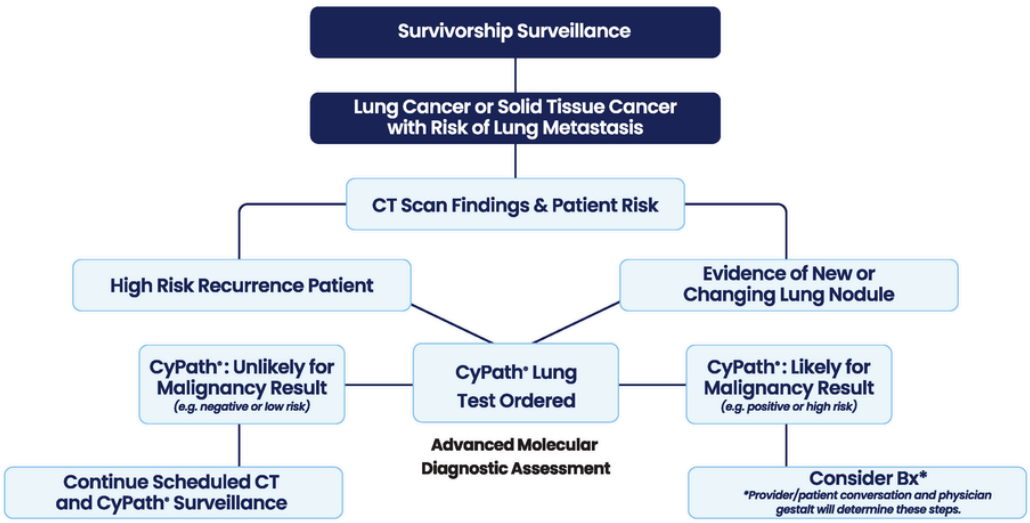
CyPath Lung

In the “Carol” case, a patient who had breast cancer five years earlier was at risk for a new lung cancer. CyPath® Lung identified a metastatic breast cancer to the right upper lobe (RUL). Both cases demonstrate the utility of CyPath® Lung for survivorship surveillance of oncology patients. The algorithm we propose for oncology emphasizes clinician gestalt as the final arbiter for testing decisions but gives the clinician actionable data for patient care.

CyPath Lung

ONCOLOGY PRACTICE ALGORITHM

CyPath® Lung
NPV 99% – nodules <20mm
PPV 61% – all high-risk patients.
ME Lemieux, et al. Respir Res. (2023)



Conclusion

CyPath® Lung testing can be a powerful tool for the clinician involved with both screening for cancer in the lung and during survivorship surveillance. CyPath® Lung testing demonstrates robust statistical performance with the confidence that these statistics are generated from unenhanced interrogation of sputum representing real-time cancer cells in a microenvironment consistent with TME. Three years of commercial use have reinforced our initial clinical trial results and given clinicians greater confidence in the recommended course of action for their patients.

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