Why Use CyPath Lung? When to Use the CyPath™ Lung Test How Do I Order CyPath Lung? Clinical Results

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**Why Use CyPath™ Lung?**

CyPath™ Lung testing helps identify patients who are **likely or very likely to have lung cancer and** supports clinical decision-making so physicians can more confidently identify patients who may benefit from timely intervention.

When CyPath™ Lung sample analysis determines a patient is **unlikely or very unlikely to have lung cancer,** the result supports clinical decision-making so physicians can more confidently continue with **screening recommendations** for individuals at high risk for lung cancer.

Picture of Physician or of Patient – Have the “screening recommendations” jump to the box below that also includes a link to the US Preventative Service site

RESULTS

**When to Use the CyPath™ Lung Test**

Consider invasive testing including PET/CT or biopsy

Likely or Very Likely

**CyPath™ Lung**

Lung Cancer Screening Results Reveal Indeterminant Lung Nodule / Suspicion of Lung Cancer

Unlikely or Very Unlikely

Continue screening in accordance with screening guidelines

Patient management should be based on clinical judgment. Other clinical information (health status, medical history, family history of cancer, etc.), along with the CyPatn™ Lung Test result, should be considered in the shared decision making process.

CyPath™ Lung is a non-invasive test for the early detection of lung cancer that reveals the lung micro-environment by automated analysis of sputum using flow cytometry.

CyPath™ Lung is intended for use by **patients who are at high risk for lung cancer** following **recommended screening (see below for the jump that should be on this page)** that results in suspicion of lung cancer and the need for follow-up diagnostic procedures and testing.

Physicians will receive test results within 3 days after the laboratory receives the patient sputum sample. You can **view a Physician Report here**. (the physician report is attached as a power point slide and should be linked on its own page)

**How Do I Order CyPath™ Lung?**

Contact Precision Pathology Services

210-646-0890 (phone)

210- ??? (FAX)

Sales Representative

Maya Thukral, MSHA, MBA

[mthukral@precisionpath.us](mailto:mthukral@precisionpath.us)

[info@precisionpath.us](mailto:info@precisionpath.us)

**Need a Requisition Form?** Click here (include link to pdf that can be downloaded)

CyPath™ Lung is a flow cytometric test for the detection of a solid tumor. CPT codes covering its use are listed on the Requisition Form. For Patient Billing, click here [Billing Questions - Precision Pathology](https://www.precisionpath.us/billing-questions/)

**How Do My Patients Use CyPath™ Lung**

Physicians ordering CyPath™ Lung fill out a simple requisition form (provide link) contained in the Sample Collection Kit and fax or email it to **Precision Pathology Services**. (link to address and phone numbers)

CyPath™ Lung is patient-friendly, with patients collecting their sputum sample in the privacy of their own home for 3 days and shipping the sample to Precision Pathology laboratories using a pre-addressed FedEx Pak contained in the Sample Collection Kit.

An office visit is necessary to provide the patient with the Sample Collection Kit and to review **instructions for collection** that are provided by Precision Pathology to physicians. (Link to the flip chart for physicians reviewing instructions for collection.)

In addition to **the kit’s step-by-step instructions**, (link here – this is different than the physician’s flip chart), an **instructional video** (link here) and a live **Patient Coach** is available by calling **855-MYLUNGS** (prompt #1) to help patients with sample collection. When ordering CyPath™ Lung, physicians will be asked if they want the Patient Coach to proactively call or text patients to offer assistance.

**Clinical Results**

CyPath™ lung’s clinical trial delivered accurate results with high sensitivity and specificity while providing convenient and seamless testing. For a summary of research and clinical studies and list of publications, click here.

**Sensitivity**

**Specificity**

**92%**

**87%**

\*\*Test validation trial participants (n = 132) with **nodules less than 20 mm**

\*\*

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Precision Pathology Services licensed the Intellectual Property of bioAffinity Technologies, Inc. to develop CyPath™ Lung as a Laboratory Developed Test (LDT). A multi-site test validation trial was conducted by bioAffinity Technologies, resulting in 82% Sensitivity and 88% Specificity overall in 150-patient test validation trial of high-risk and Stages I-IV lung cancer patients. A majority of cancer patients had early Stages I-II lung cancer. **In individuals with nodules less than 20 mm, CyPath™ Lung performed with 92% Sensitivity and 87% Specificity**.

**How CyPath™ Lung Works**

CyPath™ Lung testing is performed on sputum processed into a single-cell suspension labeled with the fluorescent porphyrin TCPP that preferentially binds to cancer cells and cancer-related cells. Cells are also stained with fluorescently labeled antibodies that identify hematopoietic and epithelial cells within the sputum sample. A viability dye is used to eliminate dead cells. After the sputum sample is acquired through the flow cytometer and the sample data is acquired, software searches for the presence of pre-defined features that distinguish individuals at high risk who have a high likelihood of lung cancer from those who do not.

This Flow Cytometric assay was developed, and its performance characteristics of Accuracy, Precision, Specificity, and Sensitivity, determined by Precision Pathology Services Laboratory. This assay detects cell types that are indicative of the presence of lung cancer. The analysis is based on the following features: (1) proportion of cells with high TCPP fluorescence intensity, (2) proportion of cells with intermediate fluorescence intensity caused by the viability dye, and (3) proportion of cells that is CD206 negative but positive for one or more of the following markers: CD66b (granulocytes), CD3 (T cells) and CD19 (B cells) and (4) patient age.

**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 or approved 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.

Precision Pathology Services Laboratory is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as certified to perform high complexity clinical laboratory testing.

Who Should Be Screened for Lung Cancer?

The U.S. Preventive Services Task Force (USPSTF) [recommends](https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/lung-cancer-screening) yearly lung cancer screening with LDCT for people who—

* Have a 20 pack-year or more smoking history, ***and***
* Smoke now or have quit within the past 15 years, ***and***
* Are between 50 and 80 years old.

A *pack-year* is smoking an average of one pack of cigarettes per day for one year. For example, a person could have a 20 pack-year history by smoking one pack a day for 20 years or two packs a day for 10 years.

**Jump Pages**

**bioAffinity Publications List with links for CyPath Lung Physician webpage**

M.H. Grayson, S Lai, L.H. Bederka, P. Araujo, J.R. Samchez, X.T. Reveles, V.I. Rebel, J. Rebeles, ***Quality-Controlled Flow Cytometry for Lung Cancer Detection,*** JoVE, July 28, 2021 (see pdf)

D. J. Elzi, W. E. Bauta, J. R. Sanchez, S. Mogare, T. Das, P. Zannes-Fatland, V. I. Rebel, ***Meso-tetra (4-carboxyphenyl) porphyrin (TCPP) is incorporated into cancer cells by the CD320 receptor,*** International Conference on Porphyrins & Phthalocyannines (ICPP-11) June 28 – July 2, 2021 [S32-P-003 (bioaffinitytech.com)](https://www.bioaffinitytech.com/wp-content/uploads/2021/06/Elzi-ICPP-2021-FINAL.pdf)

D.J. Elzi, W.E. Bauta, J.R. Sanchez, T.D. Das, S. Mogare, P.Z. Fatland, M. Iza, A Pertsemlidis, V.I. Rebel, ***Identification of a novel mechanism for meso‐tetra (4‐carboxyphenyl) porphyrin (TCPP) uptake in cancer cells***, Journal of the Federation of Societies for the Study of Experimental Biology (FASEB Journal), Feb. 25, 2021 [Identification of a novel mechanism for meso‐tetra (4‐carboxyphenyl) porphyrin (TCPP) uptake in cancer cells (bioaffinitytech.com)](https://www.bioaffinitytech.com/wp-content/uploads/2021/04/Elzi_FASEB_2021.pdf)

L.H. Bederka, P. Araujo, J.R. Sanchez, M.H. Grayson, M.E. Lemieux, J. Rebeles, S Lai, X.T. Reveles, V.I. Rebel, ***Automated Flow Cytometry Test Distinguishes Cancer from Non-Cancer in Sputum with High Sensitivity and Specificity***, [International Association for the Study of Lung Cancer](https://www.iaslc.org/) (IASLC) 2020 World Conference on Lung Cancer, Jan. 2021 [PowerPoint Presentation (bioaffinitytech.com)](https://www.bioaffinitytech.com/wp-content/uploads/2021/02/WCLC2020-VRebel-Poster-Presentation.pdf)

L.H. Bederka, S Lai, J. Rebeles, M.H. Grayson, X.T. Reveles, V.I. Rebel, ***Sputum-Derived Cellular Profiles Produced by Flow Cytometric Analysis***, International Society for Advancement of Cytometry CYTO 2020, August 4, 2020 <https://www.bioaffinitytech.com/wp-content/uploads/2020/07/Bederka_CYTO_2020.pdf>

D. J. Elzi, W. E. Bauta, J. R. Sanchez, S. Mogare, T. Das, P. Zannes-Fatland, V. I. Rebel, ***Meso-tetra (4-carboxyphenyl) porphyrin (TCPP) is incorporated into cancer cells by the CD320 receptor and clathrin mediated endocytosis***, American Society of Cell Biology (ASCB) Cell Bio 2020, Dec. 14, [Meso-tetra (4-carboxyphenyl) porphyrin (TCPP) is incorporated into cancer cells by the CD320 receptor and clathrin mediated endocytosis, Poster Presentation, American Society of Cell Biology’s Cell Bio Virtual 2020; Cancer Therapy: Defining Therapeutic Targets and New Therapeutics, December 2-16, 2020. : BioAffinity Technologies](https://www.bioaffinitytech.com/dr-david-elzi-presents-poster-at-cell-bio-virtual-2020/)

D.J. Elzi, P. Fatland, B. Karia, M. Iza, A Pertsemlidis, V.I. Rebel ***Porphyrin uptake in lung cancer cells by dynamin-mediated endocytosis: a novel marker of dysregulated endocytosis in cancer***, American Society of Cell Biology Annual Meeting, December 2015 [Slide 1 (bioaffinitytech.com)](http://www.bioaffinitytech.com/wp-content/uploads/2019/05/ELZI_ASCB_2015_poster_VR_MZ_PDF.pdf)

L. Patriquin, D. Merrick, D. Hill, MD, R. Holcomb, V. Rebel, B. Karia, G. Bennett, T. Bauer II, ***Early Detection of Lung Cancer with Meso Tetra (4-Carboxyphenyl) Porphine (TCPP)-Labeled Sputum***, Journal of Thoracic Oncology, September, 2015[Early Detection of Lung Cancer with Meso Tetra (4-Carboxyphenyl) Porphyrin-Labeled Sputum - PubMed (nih.gov)](https://pubmed.ncbi.nlm.nih.gov/26200451/)

**SUMMARY OF CYPATH™ LUNG RESEARCH AND CLINICAL STUDIES**

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| --- | --- |
| **Study Description** | **Results** |
| *Porphyrin’s localization and evaluation of cancer cell uptake of 4 different porphyrins* | TCPP porphyrin localizes more than other porphyrins in cancer cells; higher uptake of TCPP in cancer cells than normal cells |
| *Blinded study to diagnose lung cancer by labeling sputum with TCPP and identifying Red Fluorescing Cells under a microscope* | Study of uranium miners (cancer N=8 / healthy N=4) labeling sputum with TCPP resulted in 100% sensitivity and 100% specificity; one patient entering study in the healthy cohort is correctly diagnosed with cancer by the test |
| *Internal validation study with microscopy based assay completed to optimize TCPP labeling of sputum containing cancer and cancer related cells in lung cancer samples* | By measuring florescence intensity of TCPP-labeled cells in sputum under a microscope, researchers correctly identified samples from lung cancer patients (cancer N= 15 / healthy N=12) resulting in 100% sensitivity and 100% specificity |
| *Early detection of lung cancer with Meso-Tetra (4-Carboxypheyl) Porphyrin-Labeled Sputum (Patriquin, et al, Journal of Thoracic Oncology, 2015)* | Clinical trial of high risk smokers and cancer patients used microscopy-based assay to identify TCPP-labeled cells in sputum (cancer N=26 / high risk N =102) that resulted in 81% accuracy; 77.9% sensitivity, 65.7% specificity |
| *Quality-controlled sputum analysis by flow cytometry (Bederka, et al, 2021, in draft)* | Research confirms that bioAffinity has developed and tested a novel flow cytometry assay including quality controls that analyzes sputum in a high-throughput manner for diagnosis of lung cancer and other lung diseases (N=140) |
| *Automated Flow Cytometry Test Distinguishes Cancer from Non-Cancer in Sputum with High Sensitivity and Specificity (Rebel, et al, 2021 in draft)* | Test validation trial using bioAffinity’s automated flow cytometry platform (cancer N=28 / high risk N=122) results in 82% sensitivity and 88% specificity; CyPath® Lung sensitivity is 92% and specificity is 87% for patients with nodules smaller than 2 cm |