PRECISION PATHOLOGY LABORATORY

CyPath Lung

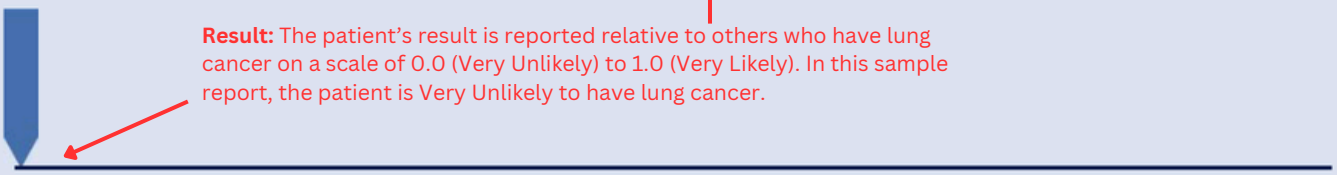
Identifying Information: Patient identifiers, sample collection and receipt dates, report date, CPT codes, physician information

Patient: TEST, PATIENT	**Collection Date:** 07/13/2024	**Facility:** Pulmonary Client Office
DOB / Age / Sex: 10/28/1953 , 70 , Male	**Received Date:** 07/16/2024	**Client ID Number:** CP00267
Accession Number:	**Report Date:** 07/17/2024 05:40	**Ordering Physician:** Pulmonologist, M.D.
Result ID: CY24-000324	**ICD 10 Codes:**	**Copies To:**
	CPT Codes: 0406U X 1	

Results Interpretation: VERY UNLIKELY malignancy in the lung

Note: This test does not differentiate between primary or metastatic cancer in the lung.

Result: The patient's result is reported relative to others who have lung cancer on a scale of 0.0 (Very Unlikely) to 1.0 (Very Likely). In this sample report, the patient is Very Unlikely to have lung cancer.



Patient Sample Result Value is 0.00

Reference Range:
≥0.00 and <0.10 Very unlikely
≥0.10 and <0.50 Unlikely
≥0.50 and <0.90 Likely
≥0.90 and =1.00 Very likely

Reference Range for interpreting numerical result

Sample Adequacy: Measuring the number of cells and alveolar macrophages confirms that the sputum sample is adequate.

Sample Adequate: YES

Number of Alveolar Macrophages per 10,000: 12.54

Absolute Number of Cells for Analysis: 173006

Signed By: Jim Humphreys, M.D.06/28/2024 05:40

Test Description and Disclaimer

CyPath® Lung Flow Cytometry disclaimer

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 Laboratory Services. 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. 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. Sample data was acquired on the Navios EX Flow Cytometer (Beckman Coulter, Indianapolis, IN.). 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.

Precision Pathology Laboratory Services,
3300 Nacogdoches Rd., Suite 110, San Antonio, TX // CLIA # 45D1064267 / CAP # 7221111/
Medical Director: Dr. Roby P. Joyce.