Get to know your CyPath™ Report

PRECISION PATHOLOGY
"A Spirit of Excellence"

Identifying Information: Patient Identifiers, Sample Collection and Receipt Dates, Report Date, CPT Codes, Physician Information

CyPath™ Lung

Patient: SAMPLE, P ACCURACY
Patient DOB/Age/Sex: 11/02/1961, 59, M
Patient ID:
Accession Number: 10292692

Collection Date: 11/20/2020
Received Date: 11/03/2020
Report Date:
ICD 10 Codes:
CPT Codes: 88185 X 8, 88184 X 1, 88188 X1

Facility: Precision Pathology Services - Naco
Client ID Number: PPS
Ordering Physician: Roby Joyce, MD
Copies to:

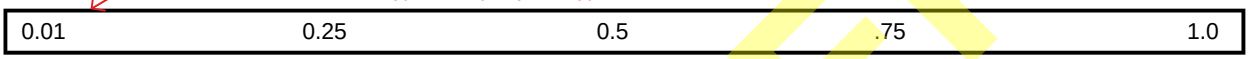
CyPath™ Lung Test Results

Patient Sample Result Value is 0.07

Assay Interpretation: **VERY UNLIKELY LUNG CANCER**

Quantitative Result: In this Report, the patient is **Very Unlikely** to have lung cancer

Quantitative Result: The patient's result relative to others who have lung cancer on a scale of 0.0 (Very Unlikely) to 1.0 (Very Likely)



Sample Adequate: yes
Number of Alveolar Macrophages per 10,000 - 139.68
Absolute Number of Cells for Analysis = 348515

Sample Adequacy: Sufficient alveolar macrophages are required to confirm sample came from the lung and sufficient number of cells are required for reliable analysis

Reference Range:

Very Unlikely:	0.0-0.10
Unlikely:	0.10-0.50
Likely:	0.50-0.90
Very Likely:	0.90-1.0

Reference Range for Interpreting Qualitative Result

Disclaimer including Description of CyPath® Lung Test

CyPath™ Lung Test 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 cytometry 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 Cytometry 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. 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 Services, 3300 Nacogdoches Rd., Suite 110, San Antonio, TX / 210-646-0890 / CLIA # 45D1064267 CAP #Medical Director: Dr. Roby P. Joyce.

Patient Name

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