



SAMPLE

GENESYS BIOLABS

Detecting Cancer – In the Beginning

Genesys BioLabs

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Patient Information

Patient ID#: _____
Medical Record #: _____
Name: _____
DOB: _____
Sex: _____
Date Sample Collected: _____
Date Sample Received: _____
Report Date: _____

Ordering Physician

Name: _____
Address: _____
City/State/Zip: _____
Phone: _____
FAX: _____

PAULA’s Test Results

Test date: _____
Test ID#: _____
PAULA’s Test Score: _____
Risk Category: _____

PAULA’s test is a multiplex immunoassay that determines the risk of the presence of lung cancer in asymptomatic individuals who are greater than 50 years of age and current or former smokers with greater than or equal to a twenty pack-year smoking history (less than or equal to 15 years since last use of tobacco for former smokers). The test analyzes six biomarkers that give a composite score that categorizes patients into lung cancer risk categories based on empiric data from retrospective clinical studies. It is intended that results of this test are to be used in conjunction with other clinical data to determine the appropriate diagnostic follow up.

PAULA’s Test Score	Risk Category	Increased Likelihood of Having Lung Cancer at Time of Test
>20	Highest Risk	13.4x
15-20	Intermediate-High Risk	5.0x
10-14	Intermediate Risk	2.1x
7-9	Intermediate-Low Risk	0.7x
≤6	Low Risk	0.4x

Dr. Stephen Keith, MD
Laboratory Director

Date

Disclaimer: PAULA’s test is not for the diagnosis of disease. It is intended for use as an aid in the determination of appropriate diagnostic follow-up for patients at high-risk for lung cancer, including asymptomatic individuals ≥50 years of age with a history of tobacco use of ≥20 pack-years and who are either current or former smokers. This test is not indicated for individuals who have had a previous diagnosis of cancer, or who currently have symptoms indicative of lung cancer. PAULA’s Test is a laboratory developed test that is performed in a certified laboratory in accordance with the Clinical Laboratory Improvement Act (CLIA) of 1988.
CLIA LIC# 21D2037411