



GENESYS BIOLABS

Detecting Cancer – In the Beginning

# PAULA's Test Laboratory Report

Genesys BioLabs

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www.genesysbiolabs.com

Patient Information		Clinician Information	
Patient ID:	Patient Name:	Provider Name:	
DOB:	Gender:	Provider Street Address:	Provider City, State, Zip:
Collection Date:	Medical Record #:	Provider Phone:	Provider FAX:

Laboratory Analysis	
<b>PAULA's Test</b>	
TEST SCORE:	RISK CATEGORY:
TEST ID:	TEST DATE:

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Stephen N. Keith, M.D. MSPH  
Laboratory Director

\_\_\_\_\_  
Date

**PAULA's Test** is a multiplex immunoassay that determines the risk of the presence of lung cancer in the high risk population (asymptomatic individuals who are greater than or equal to 50 years of age and current or former smokers with greater than or equal to a twenty pack-year smoking history). This risk was determined based on empirical data from retrospective clinical studies in a cohort of similar high risk patients.

The test analyzes four biomarkers that give a composite score. When these four biomarkers are combined and analyzed the overall sensitivity of the test is 74% and the specificity is 80%. Upon risk stratification the PPV (Positive Predictive Value) is 6.7% and the NPV (Negative Predictive Value) is 99.3%.

Risk Stratification Information (per 1000 Individuals Tested)		
Test Score	Risk Category	# of True Cancers Found
>6.4	High	15 of 20
≤6.4	Low	5 of 20

NOTE: A low risk score on PAULA's test is a strong indicator that the patient **does not** have cancer (99.3 percent of patients with a score 6.4 or below **do not** have cancer). Based on the prevalence of lung cancer (2% in the high risk population, 20 individuals would likely be found to have lung cancer among a population of 1000 individuals. If all of these individuals receive PAULA's test, about 215 will score in high risk category. If all of them are referred to low-dose CT, one can expect 15 out of 20 cancers to be detected. For more information on positive predictive value and negative predictive value go to [www.genesysbiolabs.com](http://www.genesysbiolabs.com)

**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.