

PAULA's Test

Is lung cancer testing right for you?

A DISCUSSION GUIDE FOR YOU AND YOUR DOCTOR

PAULA's Test is a biomarker test persons with moderate to high risk for lung cancer and who may be ineligible or do get screening with CT scans. You and your doctor should discuss your health history and risk factors and whether screening or biomarker testing is appropriate for you. This guide can help frame the conversation about your options for lung cancer testing.

Are you at risk for lung cancer?

RISK FACTOR	YES	NO
Long term smoking history, even if you have already quit?		
Exposure to second hand smoke?		
Environmental exposure to asbestos, radon or other carcinogens?		
Family history of lung cancer (immediate family members)?		
Previously diagnosed with other cancers?		
Lung disease such as COPD or pulmonary fibrosis?		

An online lung cancer risk calculator can be found at www.shouldiscreen.com

Is lung cancer screening with CT available at a local hospital? ___Yes ___No

If yes, do you meet all of the eligibility requirements for screening with CT? ___Yes ___No

Have you evaluated the benefits and harms of screening with CT?

You should speak with your doctor about the risks and benefits associated with lung cancer screening with CT. Information about lung cancer screening can be found at:

If you don't qualify for screening with CT, are you considering other options?

While the use of biomarker testing for initial detection of lung cancer is not a standard recommended practice, it has been shown to be able to detect malignancy risk in patients with the disease.

How does PAULA's Test detect lung cancer?

PAULA's Test looks for tumor biomarkers associated with lung cancer in your blood. People with lung cancer often do not have symptoms until the disease reaches later stages when it spreads to other parts of the body. By finding out if you have lung cancer early, your survival odds are much higher and treatment options are better.

SCIENTIFIC INFORMATION FOR YOUR HEALTHCARE PROFESSIONAL

PAULA's Test can detect 74% of non small cell lung cancers (NSCLC) with dramatically lower false positives than LDCT screening.

Technical Performance:

- Sensitivity: 74%
- Specificity: 80%
- PPV: 7.14% (vs 2.4% with CT screening, 1 round)
Note: Max PPV is 9.1% with 80% specificity in a population with a 2% prevalence rate.
- NPV: 99%



Biomarkers Tested:

CEA, CA 125, CYFRA 21-1, NY-ESO1

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Rockville, MD 20850
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CLIA LIC# 21D2037411

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Who Should Get Tested?

PAULA's Test is for those who are at high risk for getting lung cancer. Numerous organizations have published guidelines which define the various risk levels for lung cancer but you and your doctor should discuss your own health history and risk factors when considering getting tested.

How do I get tested?

Getting a PAULA's Test is easy, just like getting other routine blood tests, except this test is sent to our specialty lab for testing. In fact, you can even have your specimen drawn at the same time as getting other routine blood tests. You will need to order the test and have a specimen kit sent to you, which you bring to your doctor. Your doctor will need to sign the test requisition form.

How are the results of PAULA's Test provided to my doctor?

After we receive your specimen, in about 7-10 business days, your doctor will receive a report by fax with the results of your test. You should contact your doctor to discuss the results of your test.

What are the next steps if my test comes back with a high score?

You and your doctor should discuss the results of your test and if additional testing is recommended. The most common next step for those with a high score is to get a CT scan which will show a detailed image of your lungs.

How much does it cost?

The test costs \$149.00 plus shipping. Shipping includes the cost to ship a specimen collection kit sent to you and the cost of returning your specimen back to us using overnight express delivery.

Can I use my insurance to pay for PAULA's Test?

We do not accept insurance. PAULA's test is an elective test and not part of a recommended screening regimen. Many insurance companies do not recognize the medical necessity of elective tests. If you have a medical savings account, you may be able use this account to pay for the test.

TO GET MORE INFORMATION ABOUT PAULA's TEST

Eligible Patients:

- Ages 50 and older.
- Current or former smokers with smoking history equivalent to 1 pack per day over 20 years or more. (20+ pack-years)
- If already quit, within past 15 years
- Asymptomatic and not being treated for lung cancer

Price:

- \$149.00 plus shipping
- **Not** covered by Medicare and commercial insurance plans
- Health Savings Accounts may be used.



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