OncoLUNG Dx

Non-invasive blood test useful to suggest a possible diagnosis in patients with suspected malignancy in the lungs, reduce inappropriate diagnostic tests, days of hospitalization, as well as morbidity.
Global
Lung Cancer (both Small Cell and Non-Small Cell) is the second most common cancer in both men and women (not counting Skin Cancer). In men, Prostate Cancer is more common, while in women Breast Cancer is more common. About 14% of all new cancers are Lung Cancers.

Lung Cancer is by far the leading cause of cancer death among both men and women; about 1 out of 4 cancer deaths are from Lung Cancer. Each year, more people die of Lung Cancer than of Colon, Breast, and Prostate Cancers combined.

Lung Cancer mainly occurs in older people. About 2 out of 3 people diagnosed with Lung Cancer are 65 or older, while less than 2% are younger than 45. The average age at the time of diagnosis is about 70.

Number of New Cases and Deaths per 100,000
In United States, the number of new cases of Lung and Bronchus Cancer was 55.8 per 100,000 men and women per year. The number of deaths was 44.7 per 100,000 men and women per year. These rates are age-adjusted and based on 2010-2014 cases and deaths.

Percent Surviving 5 Years
Based on data from SEER 18 2007-2013, only the 18.1% of patients being diagnosed with Lung and Bronchus Cancer will survive 5 years or more. Gray figures represent those who have died from Lung and Bronchus Cancer. Green figures represent those who have survived 5 years or more.

Lifetime Risk of Developing Cancer
Approximately 6.4 percent of men and women will be diagnosed with Lung and Bronchus Cancer at some point during their lifetime, based on 2012-2014 data.

Prevalence of This Cancer
In 2014, there were an estimated 527,228 people living with Lung and Bronchus Cancer in the United States.
<table>
<thead>
<tr>
<th>RISK FACTORS</th>
<th>SYMPTOMS &amp; SIGNS</th>
</tr>
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<tbody>
<tr>
<td>Tobacco smoke</td>
<td>A cough that does not go away or gets worse</td>
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<tr>
<td>Exposure to second hand smoke</td>
<td>Chest pain that is often worse with deep breathing, coughing, or laughing</td>
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<tr>
<td>Exposure to radon gas</td>
<td>Hoarseness</td>
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<tr>
<td>Exposure to asbestos and other carcinogens</td>
<td>Weight loss and loss of appetite</td>
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<tr>
<td>Family history of Lung Cancer</td>
<td>Coughing up blood or rust-colored sputum (spit or phlegm)</td>
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<tr>
<td>Radioactive ores such as uranium</td>
<td>Shortness of breath</td>
</tr>
<tr>
<td>Inhaled chemicals or minerals such as arsenic, beryllium, cadmium, silica,</td>
<td>Feeling tired or weak</td>
</tr>
<tr>
<td>vinyl chloride, nickel compounds, chromium compounds, coal products,</td>
<td>Infections such as bronchitis and pneumonia that don’t go away or keep coming</td>
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<tr>
<td>mustard gas, and chloromethyl ethers</td>
<td>back</td>
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<tr>
<td>Air pollution</td>
<td>New onset of wheezing</td>
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<tr>
<td>Radiation therapy to the lungs</td>
<td>Horner syndrome</td>
</tr>
<tr>
<td>Arsenic in drinking water</td>
<td>Superior vena cava syndrome</td>
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<td></td>
<td>Paraneoplastic syndromes</td>
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Prognosis refers to the likely outcome, or forecast, of a disease. For cancer, it refers to the chance of recovery or recurrence. The prognosis for Lung Cancer is an estimate based on the course of the disease taken from studying hundreds or thousands of people who have been diagnosed.

SCLC grows quickly and has often already reached an advanced stage when it is diagnosed. NSCLC, on the other hand, is more slow growing and may be diagnosed at a stage when it can be surgically removed.

People presenting at early stages such as I or II — localized—, have the highest survival ratios at five years (55%).

Survival is lower for those diagnosed with advanced stages —regional—, is close to 29%.

However, survival for those people with metastasis —distant—, is the lower one (less than 5%).

In this way, as in most cancers, catching it early and being able to remove it surgically results in the best outcomes.

**STATE OF THE ART IN LUNG CANCER DIAGNOSIS**

Currently, doctors consider age and smoking habits of patients with symptoms such as the two main factors to model the risk of Lung Cancer.

If patients fall into this consideration, it is recommended a Computerized Tomography (CT) —a test with a high cost that sometimes detected benign nodules as potentially cancerous—.

Approximately 28 percent of high-risk individuals who are subjected to CT Scans obtained a positive finding, since the test often identifies all existing pulmonary nodules, resulting in unnecessary lung tissue biopsies that patients have to undergo when suspicious finding.
OncoLUNG is based on a simple blood test that can detect Lung Cancer with 93.5% of sensibility and 96.2% of specificity.

OncoLUNG reduces —in a very significant way—, the number of false positives (FP) and false negatives (FN) typical of other diagnosis procedures.

OncoLUNG reduces the number of unnecessary tissue biopsies that patients have to undergo when suspicious imaging finding.

OncoLUNG has been performed with data from 4,296 consecutive patients, then fine-tuned by other research.
WHY CHOOSE BIOPROGNOS’ TEST?

✔ Innovative
Based on the combined count of a panel consisting of 6 Serum Tumor Markers (CA 15.3, CEA, CYFRA 21-1, NSE, SCC and ProGRP).

✔ Non-invasive
First test based on a simple blood test.

✔ Accurate
Very high diagnostic capabilities: 93.5% Sensitivity and 96.2% Specificity.

✔ Cost-effective
Solution to help in Lung Cancer diagnosis as well as confirmatory diagnostic —reducing the number of unnecessary tissue biopsies that patients have to undergo—.

✔ More complete
If Cancer, it also determines Non-Small Cell Lung Cancer or Small Cell Lung Cancer, as well as Adenocarcinoma or Squamous Cell Carcinoma (if NSCLC).

✔ Already validated

FOR WHOM IS IT INTENDED?

✔ Smokers older than 55 years.

✔ Patients with previous image findings suspicious of Lung Cancer that should be biopsied to verify malignancy.
USES AND PURPOSES

✔ Aid in diagnostic assessments for high-risk patients.

✔ Confirm or discard malignancy from results obtained previously with other tests —such as Computed Tomography (CT) Scan—, to avoid invasive, costly and unnecessary biopsies —as well as days of hospitalization—, to low-risk patients.

✔ Therapy monitoring (how the cancer is responding to treatment) and predict or monitor for recurrence (detecting a recurrence sooner than current methods).

INTERPRETATION OF RESULTS

Once the blood is analyzed and the Tumor Marker values are calculated, a final report with the probability of finding Lung Cancer is generated.

This report includes all patient information previously collected, results, comments —if available—, as well as conclusions. It also includes a comprehensive 3 level color score bar to facilitate test interpretation in an easy way, which can result in Negative, Low Positive and High Positive as follows:

- **LOW**
- **MODERATE**
- **HIGH**

The meaning of these segments of the score bar is:

- **High:** There is a high risk of Lung Cancer.

- **Moderate:** There is a certain chance of Lung Cancer that does not allow to exclude malignancy, so it is recommended to repeat the test in 4 weeks to obtain a serial determination and determine the final risk. Of every three individuals with “Moderate” result, 1 will present Lung Cancer.

- **Low:** There is a low risk of Lung Cancer and it is recommended to repeat the test in one year due to low risk of malignancy.

Besides, for Positive High results, test can determine Non-Small Cell Lung Cancer or Small Cell Lung Cancer, as well as Adenocarcinoma or Squamous Cell Carcinoma (if NSCLC), helping doctors in final decisions.
Improving clinical outcomes and quality of life