**Full Title**  
A Study to Evaluate a Panel of Blood Biomarkers for Use in Patients Undergoing Evaluation for Lung Cancer

**Principal Investigator**  
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**Sub-Investigators**  
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**Study Objectives**  
To develop a blood-based gene expression signature to be used in the detection of lung cancer in patients who underwent radiologic screening for lung cancer and had lung nodules detected  
To investigate relationships among biomarker levels and tumor burden  
To investigate relationships among biomarker levels and tumor grade and stage

**Inclusion Criteria**  
- Women or men age 21 years or older  
- History of smoking cigarettes, either current or past  
- Willing and able to comply with study-related procedure  
- Willing and able to donate up to 30 mL of blood  
- Underwent one of the following:  
  a. Recent LDCT with nodule 3 cm in largest diameter or smaller identified, leading to recommendation of ongoing management (may include further radiological screening, radiological surveillance at a later date, nodule biopsy and/or surgery)  
  b. Lung nodule 3 cm in largest diameter or smaller identified by other diagnostic modality (e.g., CT scan, PET scan) leading to recommendation of ongoing management (may include further radiological screening, radiological surveillance at a later date, nodule biopsy and/or surgery)  
  c. Received confirmed diagnosis of NSCLC and treatment-naïve (e.g., has not undergone surgical excision, chemotherapy or radiation therapy for this malignancy)  
  d. Underwent radiologic imaging at 1-2 years prior to enrollment with documented no growth and presumed benign 1-2 years post initial LDCT  
In the view of the investigator, would be a candidate for bronchoscopy, biopsy or surgical excision which would provide
a histopathology diagnosis OR for radiological surveillance for up to 2 years which would provide a presumed benign diagnosis

- Willing to provide LDCT, other CT or PET scan, radiology, bronchoscopy, biopsy/surgery and histopathology results to the sponsor

**Exclusion Criteria**

- In the view of the investigator, subject is unable to comply with study-related procedures
- In the view of the investigator, subject is not a candidate for:
  a. Bronchoscopy, biopsy or surgical excision due to co-morbidities or other findings (e.g., COPD, emphysema, infectious disease, indwelling electronic device) OR
  b. Ongoing radiological surveillance for up to 2 years due to co-morbidities, limited lifespan, or other findings
- Subject is known to have current ongoing or recurrent lung cancer (prior history of lung cancer with documented no evidence of disease is acceptable)
- Subject has history of any non-lung primary malignancy, with the exception of previously treated non-melanoma skin cancer or cervical cancer
- As a result of current screening with a diagnosis of lung cancer, subject has had curative lung cancer surgery or systemic therapy that removed the current lung cancer pathology

**Affiliations & Sponsors**
OncoCyte Corporation

**Status**
Open to enrollment

**Keywords**
lung, cancer, biomarkers, nodules, pulmonology