

Full Title	A Study to Evaluate a Panel of Blood Biomarkers for Use in Patients Undergoing Evaluation for Lung Cancer
Principal Investigator	Uday Dasika, MD
Sub-Investigators	Wassim Abi Jaoude, MD
Study Objectives	<p>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</p> <p>To investigate relationships among biomarker levels and tumor burden</p> <p>To investigate relationships among biomarker levels and tumor grade and stage</p>
Inclusion Criteria	<ul style="list-style-type: none">• 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:<ol style="list-style-type: none">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 LDCTIn 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