Non-invasive diagnostic and prognostic assay for early stage lung cancer

Summary (1024-character limit)
NCI scientists developed a method that uses urine samples to detect early-stage cancers and that could supplement low-dose computed tomography (LD-CT) to significantly decrease its expensive false negative/false positive results, and the NCI seeks co-developers or licensees to commercialize this technology.

NIH Reference Number
E-121-2013

Product Type
- Diagnostics

Keywords
- Non-small Cell Lung Cancer, nsclc, liquid biopsy, urine
- LD-CT, LDCT, low-dose computed tomography

Collaboration Opportunity
This invention is available for licensing and co-development.

Contact
- John D. Hewes
  NCI - National Cancer Institute

  240-276-5515

  John.Hewes@nih.gov

Description of Technology
In the United States alone, one of four cancer deaths occur from lung cancer. There are now over 220,000 new cases of lung cancer and more than 155,000 deaths, and over 8 million high-risk individuals. Early detection significantly improves survival of this disease, however a lack of lung cancer screenings and analysis precludes fast results at a low cost. Low-dose computer tomography (LD-CT) is the current standard, however it suffers from low sensitivity and specificity (55 and 81%, respectively) and can miss occult cancer (false negative) or incorrectly diagnose cancer when it is not there (false positive). False negatives can lead to detection only at later-stages when treatment options are limited, while false positives can lead to additional, expensive testing or invasive biopsies.

Scientists from the NCI’s Laboratory of Human Carcinogenesis provides a unique, non-invasive diagnostic to detect early stage lung cancer and predict patient survival through a simple assay utilizing
liquid chromatography-mass spectrometry of urine samples. Urine samples minimize patient discomfort, unlike current early detection methods that are highly invasive, such as a blood or tissue biopsy or bronchoscopy, and could supplement existing LD-CT that cannot detect such early-stage nodules.

The method provides superior false-positive and false-negative rates compared to LD-CT, which suffers from low specificity and false positive rates of 80% or more. The NCI scientists developed and validated this unique metabolite profile using metabolic profiling of urine samples obtained from 1,005 people, that diagnoses early stage lung cancer and predicts patient survival with a high accuracy. Efforts are underway to find facilities with clinical LD-CT capabilities that wish to collaborate with NCI.

**Potential Commercial Applications**
- Diagnostic test for early-stage lung cancer that could supplement current LD-CT-based methods
- Prognostic test for patient survival, and a method to help physicians make informed treatment decisions

**Competitive Advantages**
- Urinary patient samples could supplement low-dose computed tomography (LD-CT) scans by improving on false positive/false negative results

**Inventor(s)**
Curtis Harris (NCI), Majda Haznadar (NCI), Frank Gonzalez (NCI), Ewy Mathe (NCI), Kristopher Krausz (NCI), Soumen Manna (NCI), Andrew Patterson (Pennsylvania State University)

**Development Stage**
- Clinical

**Publications**

**Patent Status**
- **U.S. Patent Filed:** U.S. Patent Application Number 61/845,055, Filed 11 Jul 2013
- **Foreign Filed:** Patent Application PCT/US14/46294, Filed 11 Jul 2014

**Related Technologies**
- E-248-2002

**Therapeutic Area**
- Cancer/Neoplasm