NATIONAL CANCER INSTITUTE
Technology Transfer Center

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

Summary

NCI scientists developed a method that uses urine samples to detect early-stage cancers and that could supplement low-dose computed tomography (LD-CT) for early-stage cancer detection, and significantly decrease expensive false negative/false positive results. 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.

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Description of Technology

In the United States alone, one of four cancer deaths occur from lung cancer and there are over 8 million individuals considered to be at high-risk due to cigarette smoking and other behaviors. It's well known that early detection of cancer 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 and provides indication of potentially cancerous nodules above a certain size, however it suffers from low sensitivity and specificity (55 and 81%, respectively), can miss occult cancer (10% false negative rate), or incorrectly diagnose cancer when it is not there, with up to 90% false positive results. False negatives can lead to detection only at later-stages when treatment options are limited, while false positives can lead to additional, expensive

testing, invasive biopsies, and patient anxiety. In addition, the compliance rate for LD-CT screening is less than 5% of the eligible population due to access to infrastructure and other chalenges.

Scientists in the NCI's Laboratory of Human Carcinogenesis have proven a unique, non-invasive screening tool and diagnostic that detects lung cancer at an early stage utilizing liquid chromatography-mass spectrometry of urine samples. Urine samples minimize patient discomfort, unlike current early detection methods that are invasive, such as a blood or tissue biopsy or bronchoscopy, could be done easily during a routine exam, and could supplement existing LD-CT that cannot detect such early-stage nodules.

The NCI scientists validated a unique metabolite profile by profiling of urine samples obtained from smokers and non-smokers in three independent cohorts.The four componenets of the profile have shown high correlation to lung cancer ($p < 0.00001$). Patient data indicate the methdology can also provide prognostic data on patient survival and have led to an understanding of the mechanism of action that creates the metabolic profile.

The NCI seeks research collaborations to discover additional aspects of this methdology in patient samples, or licensing to commercialize the technology through CLIA or LDT.

Potential Commercial Applications

- Diagnostic test for early-stage lung cancer to supplement or supplant current LD-CT-based methods
- Prognostic test for patient survival, and a method to help physicians make informed treatment decisions

Competitive Advantages

- Greatly improves early stage cancer screening with significantly lower false positive/false negative results than LD-CT (standard of care)
- Ease of sample collection and low cost of analysis could supplement regular patient exams

Inventor(s)

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Development Stage

- Clinical

Publications

Mathé EA, et al. Noninvasive urinary metabolomic profiling identifies diagnostic and prognostic markers in lung cancer. [PMID 24736543]

Patent Status

- **U.S. Patent Issued:** U.S. Patent Number 10,393,745, Filed 11 Jul 2013, Issued 27 Aug 2019
- **Foreign Issued:** EP - Patent Number 1039745, Filed 11 Jul 2014, Issued 27 Aug 2019

Related Technologies
- E-248-2002

Therapeutic Area
- Cancer/Neoplasm

Updated
Thursday, April 13, 2023

Source URL:https://techtransfer.cancer.gov/availabletechnologies/e-121-2013