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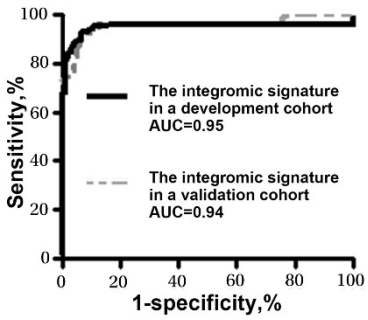
Liquid Biopsy Test for Early Detection of Lung Cancer

Overview

Low-dose computed tomography (LDCT) is recommended for annual screening by the US Preventive Services Task Force, and the test is reimbursed by Medicare (see below). LDCT is intended for early detection of cancer, but unfortunately has a high false-positive rate (i.e., it detects indeterminate pulmonary nodules (PNs), 96% of which are ultimately benign). Following a positive LDCT screen, patients are subjected to additional procedures, some of which are invasive and expensive (e.g., PET, MRI, transthoracic needle and/or transbronchial biopsies) to confirm the nature of the PNs. In an effort to address the inadequacies of LDCT screening, UMB researchers developed a new lung cancer diagnostic panel and algorithm, which incorporates key biomarkers and other patient data. Specific sncRNA biomarkers were identified from sequence analysis of early-stage lung tumors and matched controls, and an integromic signature combines different categories of biomarkers to further enhance the assay results. UMB's lung cancer diagnostic panel has been performed on hundreds of patient samples, and demonstrates the ability to precisely distinguish malignant from benign PNs with high sensivity and specificity. One feature that enhances the precision of UMB's method is the use of droplet digital PCR (ddPCR) for the quantification of nucleic acid. This analysis of lung tumor-associated molecular changes in plasma &/or sputum provides a liquid biopsy for safely and cost-effectively detecting early-stage lung cancer.



Investigator
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Field
Oncology
Diagnostics

Description
Lung cancer biomarkers and algorithm for early detection

Technology Status
Available for licensing & sponsored research

Patent Status
Patent pending (*please inquire*)

UMB Docket Reference
FJ-2016-076
FJ-2017-097

External Reference
Leng Q et al. (2018) Oncotarget. 9(37):24684-92.

Lin Y. et al. (2017) Int J Cancer. 141(6):1240-48.

Su Y, Guarnera MA, Fang H, Jiang F. Mol Cancer. 2016 May 12;15(1):36

Market & Applications

In the USA, more than 43.4 million smokers (ages 55-74 years) are eligible for LDCT lung cancer screening. Of these, more than 10.8 million (25%) will receive a positive LDCT diagnosis without a clear indication of lung cancer. The cost of LDCT is ~ $240/person/year and yearly screenings are now covered by Medicare (*Pyenson et al. 2014, Am Health Drug Benefits*). Other academic groups have developed predictive algorithms, which rely on multiple patient data for input variables, but these methods do not approach the high sensitivity and specificity of UMB's diagnostic panel.

Technology Advantages

- Robust method, using patient-specific data and liquid biopsy samples (plasma &/or sputum) to detect biomarkers in various categories (e.g., miRs, lncRNA, FUT)
- Higher sensitivity and specificity than current methods
- Promising as a complementary test to differentiate LDCT-positive patients and focus care on those who need it

Stage of Development

Translational research is underway to adapt UMB's lung cancer diagnostic panel to reliably perform as a Laboratory Developed Test in a CLIA setting.

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