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Control/Tracking Number: 18-A-4263-AACR
Activity: Abstract Submission
Current Date/Time: 12/1/2017 12:22:30 PM

CTC and ctDNA profiling to detect 6 NCCN-guideline recommended classes of alterations for immunotherapy and targeted therapy selection using sample from a single blood draw

Short Title:
Liquid biopsy using CTC & ctDNA

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Abstract:
Introduction The availability of targeted and immunotherapies has provided NSCLC patients with more effective treatment options. However, this has resulted in an increase in the number and modality of tests required for treatment selection. Given 30-50% of advanced lung cancer patients have insufficient or unavailable tissue for comprehensive genomic profiling, there is a need for a non-invasive assay that can accurately detect all guideline-recommended markers for NSCLC treatment selection. To meet this need, we have developed a blood test that detects six classes of alterations (SNV, Indels, Rearrangements, CNA, Microsatellite Instability and PD-L1 expression) for therapy selection. **Methods & Results** Three tubes of blood from a routine blood draw were sent to our CLIA-certified and/or CAP accredited lab for analysis. PD-L1 expression was evaluated in circulating tumor cells (CTCs) utilizing two different assays; (i) Immunofluorescence (IF) antibody staining, (ii) mRNA qPCR. CTCs were captured on the CMx^{TM} CTC Platform coated with lipid bilayer and antibodies to EpCAM. PD-L1 expression results were highly correlated between IF and qPCR assays in ten solid tumor cell lines (lung, breast, prostate and colorectal cancer) spiked into whole blood to mimic the actual patient CTC capture process. In an ongoing study on clinical samples from NSCLC patients (N=20), we observed greater than 90% concordance between tissue (IHC by 22C3 PD-L1 clone) and blood (CTC IF and mRNA assays). A proprietary Single Molecule Sequencing (SMSEQ^{TM}) NGS assay was performed on plasma in order to detect 5 classes of genomic alterations (SNV, Indels, Rearrangements, CNA, MSI) from ctDNA. This assay was validated in accordance with the latest ACMG and AMP guidelines to accurately detect variants at low mutant allele fraction (.1% for SNVs and Indels, 1% for rearrangements and 5 copies for CNA) with high sensitivity and specificity. MSI status was determined by assessing nucleotide repeat sequences in five standard markers (BAT-25, BAT-26, MONO-27, NR-21, NR-24), and was detectable down to a MAF of 1%. In an ongoing study on clinical samples from NSCLC patients (N=20), we observed high concordance of MSI status between tissue (immunohistochemistry for dMMR/MSI status) and blood (ctDNA SMSEQ assay). **Conclusion** Tissue insufficiency and procurement challenges are the primary reasons why ~90% of patients diagnosed with advanced NSCLC are not comprehensively tested per NCCN-guidelines in the community setting where most cancer is treated, leading to suboptimal treatment selection. An accurate blood test that detects all 6 NCCN-recommended markers for immunotherapy and targeted therapy selection has the potential to significantly improve adherence to NCCN testing guidelines and enable optimal treatment selection.
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Author Disclosure Information:

H.B. Hsieh: ; CellMax Life. **J. Wu:** ; CellMax Life. **F. Lin:** ; CellMax Life. **J. Lucas:** ; CellMax Life. **A. Atkins:** ; CellMax Life. **P. Gupta:** ; CellMax Life. **H. Shao:** ; CellMax Life. **Y. Chen:** None. **W. Huang:** None. **C. Hsieh:** None. **R. Hsieh:** None. **K. Chen:** None. **M. Yen:** None. **M. Javey:** ; CellMax Life. **S. Chang:** ; CellMax Life. **T. Marfatia:** ; CellMax Life. **D. Watson:** None. **M. Amin:** None. **A. Nimgaonkar:** None. **O. Segurado:** ; CellMax Life. **R. Mei:** ; CellMax Life.
Sponsor (Complete):
Category and Subclass (Complete): CL06-02 Immune checkpoints
Research Type (Complete): Clinical research
Keywords/Indexing (Complete): NSCLC ; Targeted therapy ; Immunotherapy ; Circulating tumor cells
Organ Site/Structures (Complete):
*__Primary Organ Site:__ Lung cancer: non-small cell
*__Choose Chemical Structure Disclosure Option:__
NOT APPLICABLE. No compounds with defined chemical structures were used.
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*__Reference or patent application number__ : N/A

Financial Support for Attendance (Complete):
Submission Fee (Complete): Your credit card order has been processed on Wednesday 29 November 2017 at 6:08 PM.
Status: Complete

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