Background and Methods

Figure 1. NSCLC Continuum of Care. The schematic highlights Biodesix’s approach to the continuum of care for patients previously diagnosed with lung cancer. Tests currently performed in the Biodesix CLIA Laboratory are in blue, while development process concepts are in green.  – See Weber et al. AACR 2016: Abstract No. 4817.

Figure 2. Overview of the current GeneStrat CLIA Test Workflow. The test process is initiated when whole blood drawn into Blood Collection Tubes (BCT) arrives at the Laboratory. Patient samples are accessioned into the LIMS and processed through parallel workflows to isolate either circulating DNA or RNA. Following nucleic acid extraction and cDNA synthesis for RNA, sample DNA is amplified using the Bio-Rad iQ500 ddPCR system. Droplet count evaluation is conducted using QuantaSoft, and Test Result Reports are generated from the secure LIMS.

Results

Figure 3. Overview of GeneStrat Clinical Validation. A. Example of droplet distributions for positive donor samples for each of the variants evaluated in GeneStrat validation studies. B. GeneStrat performance as determined in clinical validation studies. For DNA tests, the total samples tested were 151 and 24 samples for the EML4-ALK RNA test.

Figure 4. Turnaround time around the 72 hour window. Data in A, and B. Excludes weekends/holidays and samples held due to incomplete clinical data on Test Request Form.

Figure 5. GeneStrat Orders by Site. GeneStrat is predominantly ordered by physicians identified as community site practitioners.

Figure 6. GeneStrat Lung Cancer orders by gene class. The percentage of test orders that contain each gene class is shown. Tests were ordered either as single variants, or grouped with test requests for additional gene class variants.

Figure 7. GeneStrat Mutation Detection Rates. The percentage of GeneStrat DNA variant tests that yielded either a ‘Detected’ or a ‘Not Detected’ result.

Conclusions

- Greater than 94% of the GeneStrat test results were generated within 72 hours of sample receipt
- Detected results for individual variants ranged from 1.2% - 15.8%
- 76% of EGFR T790M tests ordered also included EGFR sensitizing variants
- 2% of the EML4-ALK variant tests were Detected

In conclusion, GeneStrat is a highly sensitive, targeted liquid biopsy mutation test that identifies actionable mutations with proven clinical utility for diagnosis or therapy monitoring.

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References


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*Poster is updated to reflect current data on file and inclusion of a new assay for EML4-ALK

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