A concordance study of the ArcherDx Reveal ctDNA 28 NGS panel and Biocept’s Target-Selector™ mutation assay using ctDNA collected in Biocept’s CEE-sure blood collection tube

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Poster # 762

Study Design

Table 1: circulating DNA from patient blood collected in the patented Biocept CEE-sure was extracted from plasma and used in Target-Selector™ assays specific for EGFR (Del19, L858R, T790M), KRAS or BRAF mutations. In certain cases, CTC enumeration and biomarker testing was also performed. Sequencing of the amplified Target-Selector™ product was used to confirm the presence of the mutation. The remnant DNA samples were de-identified and sent blinded to ArcherDx and processed through their Reveal ctDNA workflow. Each sample contained either a high or low mutational burden for one of the 5 clinically actionable markers listed along with two samples which tested negative for all five.

Table 2: Additional information on patients tested in the study from the Biocept Clinical Laboratory using the targeted tumor ctDNA platform. Cytosine-negative CTGs are indicated in red. Highlighted CTGs include the two where no other genetic alterations were found. Highlighted cells indicated signal was detected. Dash lines mean the test was not ordered.

Table 3: Concordance of the tests in 7 of 12 patients. The Biocept test outperformed on sensitivity for the most common markers, but the ArcherDx panel added important additional markers that could guide patient treatment in certain cases. Overall the tests complement each another. For instance one could test the most common markers from Biocept and if negative follow up with a larger panel to look for less common markers that may guide treatment toward therapeutics in clinical trials.

Conclusions

* In this pilot evaluation, the tumor status of 12 patients were tested using both the Biocept Target Selector Assay and the Archer DxD reveal 28 NGS panel.

* Archer was able to produce high quality libraries from the stored sample, indicating that little DNA damage occurred during preservation in the CEE-Sure tube.

* The two methods were shown to have good concordance and while the target selector tests excelled at finding low abundance markers, the Archer panel uncovered mutations untested in the Biocept profiling.

* This study demonstrates that both breadth of coverage and depth of analysis are important factors for today’s oncologist when considering which diagnostics to perform on their patient. The rise of the liquid biopsy provides an powerful, informative, non-invasive option when looking for actionable biomarkers.