DELFI-Tumor Fraction

Technical Specifications

DELFI-TF Intended Use:

DELFI-TF is a research service that has been developed to provide early evidence of treatment efficacy in early (phase I-II) oncology drug development trials

DELFI-TF has been applied by multiple pharmaceutical and biotechnology companies as a tool for early clinical decision-making in phase I-II development trials for diverse New Molecular Entities (NME).

DELFI-TF is a cost-effective alternative to current Mutant Allele Frequency (MAF) monitoring tests

DELFI-TF Assay Performance Characteristics:

Below is a summary of the performance metrics tested for the DELFI-TF assay*:

Performance Metric	DELFI-TF Performance
Sample Requirement	**800 uL plasma or 1 ng cfDNA**
Success Rate**	**99%**
Limit of Blank***	**0.3%**
Reproducibility: Coefficient of Variation In samples between LOB and 2x LOD, median (25%ile. 75%ile)	**13.6%** **(6.4%, 21.0%)**
Correlation with MAF (validation cohort)	**0.94%**
Concordance with RECIST (mNSCLC)	**77%**

*The DELFI-TF Assay and related services are for Research Purposes Only and are not intended for diagnostic procedures or applications.
**The success rate for this study is defined as the percentage of plasma samples able to be processed through the DELFI assay pipeline (WGS using 1ng of cfDNA).
***The limit of blank was previously defined as the maximum of 95th percentile of DELFI-TF among multiple non-cancer cohorts.