xF Validation

The non-invasive Tempus xF liquid biopsy assay detects cell-free DNA (cfDNA) in blood specimens of advanced solid tumor patients. The assay is capable of detecting mutations in two variant classes in ~105 genes, including: Single Nucleotide Variants (SNVs) and insertions and deletions (indels), as well as Copy Number Amplifications (CNAs) in 5 genes, and gene rearrangements (translocations) in 5 genes spanning ~0.3 Mb of genomic space. The assay spans clinically relevant coding exons for 24 genes and covers recurrent hotspot mutations in 70 genes. Insertions and deletions will be reported down to the lower limit of detection (LLOD) in clinically relevant regions in 97 genes (list available upon request). The panel is designed to provide clinically relevant information for patients with solid tumors and is focused on the identification of oncologic, including resistance, mutations.

CAP/CLIA validation of the Tempus xF panel focused on the detection of actionable oncologic and resistance variants in blood plasma. The assay requires two 8.5 mL Streck tubes of peripheral blood. Clinical sequencing is performed to ~20,000x coverage (at least 5,000x deduplicated reads). Performance specifications are listed in Table 1 below. These results establish, as shown in the table, high sensitivity and specificity for the Tempus xF assay.

Not intended for:

- Hematologic malignancies
- Early stage (stage I/II) cancers
- Primary CNS malignancies

TABLE 1: PERFORMANCE SPECIFICATIONS

Variant Class	Variant Allele Fraction (VAF)	Sensitivity	Specificity
Single Nucleotide Variants (SNVs)	>0.50%	>99.9%	>99.9%
	0.50%	>99.9%	>99.9%
	0.25%	97.0%	>99.9%
Insertions and Deletions	>0.50%	98.8%	>99.9%
	0.50%	96.0%	>99.9%
Copy Number Amplifications (CNAs)*	>0.50%	>99.9%	96.2%
	0.50%	>99.9%	96.2%
Rearrangements/Fusions*	>0.50%	97.4%	>99.9%
	0.50%	70.8%	>99.9%

** Variant Allele Fraction (VAF) is based on limit of detection dilution studies.*