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 6 genes, Copy Number Deletions (CNDs) in 2 genes,* and gene rearrangements (translocations) in 7 genes spanning ~0.3 Mb of genomic space. Microsatellite Instability High (MSI-H) status is also reported when detected. The panel is designed to provide clinical decision support 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 Indicated For:

- Hematologic malignancies
- Early stage (stage I/II) cancers
- Brain cancers
- Sarcomas

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%	
	0.25%	97.0%	
	0.10%	70.4%	
Insertions and Deletions	>0.50%	98.8%	>99.9%
	0.50%	96.0%	
	0.25%	81.0%	
Copy Number Amplifications (CNAs)	>0.50%	>99.9%	96.2%
	0.50%	>99.9%	
Rearrangements/Fusions	>0.50%	97.4%	>99.9%
	0.50%	70.8%	
Microsatellite Instability High (MSI-H) Status	N/A	37.5%	>99.9%

** BRCA1 and BRCA2 copy number loss are reported when detected*