TEMPUS xF Assay Description

The Tempus xF assay is a next-generation sequencing (NGS) liquid biopsy tumor profiling assay for identifying genomic alterations derived from solid tumors but circulating in the blood. The 77 gene panel includes single nucleotide variants (SNVs), insertions and deletions (indels), copy number variants (CNVs) and chromosomal rearrangements (translocations) detected by hybrid capture NGS. Please see the Tempus website for a complete gene list (hyperlink). The limit of detection for the assay is 0.5% variant allele fraction (VAF) with a technical sensitivity of 99% for SNVs, indels and CNVs. The limit of detection is 1% VAF with a technical sensitivity of 99% for translocations.

"Alterations Detected" is the total number of alterations detected in the plasma sample. "Potentially Actionable" are variants with an associated therapy. "Biologically Relevant" are variants that may have functional significance or have been observed in the medical literature, but are not associated with a specific therapy. "Unknown Significance" are variants exhibiting an unclear effect on function and/or not identified in the literature. The clinical summary of the report shows pathogenic and actionable variants with the highest levels of evidence when they are present in the patient's sequencing results.

TEMPUS DISCLAIMER

The analysis of DNA by next-generation sequencing (NGS) can be affected by multiple factors, including low circulating tumor DNA content limiting sensitivity. Additionally, the chance of detecting genetic alterations may be reduced in regions of the genome which are structurally difficult to sequence, in homologous genes, or due to sequencing errors.

Genetic alterations are defined as clinically significant based on peer-reviewed published literature and other authoritative sources such as NCCN guidelines. These references are not comprehensive, therefore clinically unknown findings may occur.

These test results and Information contained within the report are current as of the report date. Tempus will not update reports or send notification regarding reclassification of genomic alterations. The Tempus xF assay uses the Roche Avenio ctDNA Expanded Kit (cat# 8061076001). The assay was validated and its performance characteristics determined by Tempus. It has not been cleared or approved by the FDA. The laboratory is CLIA certified to perform high-complexity testing. Any decisions related to patient care and treatment choices should be based on the independent judgment of the treating physician and should take into account all information related to the patient, including without limitation, the patient and family history, direct physical examination and other tests. Tempus is not liable for medical judgment with regards to diagnosis, prognosis or treatment in connection with the test results.