TEMPUS xF Validation

The Tempus xF test is a targeted hybrid capture next generation sequencing (NGS) liquid biopsy assay, which interrogates sequences of 77-genes, including genes captured in the Comprehensive Cancer Network (NCCN) Guidelines and additional emerging cancer biomarkers. It employs the CAPP-Seq (CAncer Personalized Profiling by deep Sequencing) technology [1,2], an ultrasensitive method for quantifying circulating tumor DNA, to detect key oncogenic DNA alterations in four variant classes: single nucleotide variants (SNVs), insertions and deletions (indels), copy number variants (CNVs), and chromosomal rearrangements (translocations) using circulating cell-free DNA (cfDNA) isolated from plasma derived from peripheral whole blood (10mL).

In the validation study performed by Tempus CAP/CLIA laboratory, the xF panel demonstrated high technical sensitivity of 99% for all 4 classes of alterations, with a limit of detection of 0.5% for SNVs, indels, CNVs, and 1%. for translocations. Tempus xF liquid biopsy testing was shown to accurately detect gene alterations previously called by an orthogonal reference testing of matched tumor tissue (Tempus xO), with over 90% positive predictive value (PPV) across SNVs and CNVs.

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 Tempus laboratory is CLIA certified to perform high-complexity testing.

[1] Newman AM, Bratman SV, To J, et al. An ultrasensitive method for quantitating circulating tumor DNA with broad patient coverage. Nature Medicine. 2014;20(5):548–554.
[2] Bratman, Scott V. (2015). "Potential clinical utility of ultrasensitive circulating tumor DNA detection with CAPP-Seq". Expert Review of Molecular Diagnostics. 15 (6): 715–719.

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