The Tempus xT next generation sequencing assay is designed to detect actionable oncologic targets by sequencing tumor samples with matched normal saliva or blood samples, when available. The second version of the xT assay (v2) covers 596 genes spanning ~3.1 Mb of genomic space. From DNA sequencing, somatic and incidentally detected germline single nucleotide variants (SNVs), insertions and deletions (indels), copy number variants (CNVs) and translocations in 21 genes are detected, along with 43 sites to determine microsatellite instability status. Tumor mutational burden (TMB) is also reported. From RNA sequencing, gene fusions (translocations) are detected in an unbiased and comprehensive manner, which allows association with fusion targeting FDA-approved therapies and investigational therapies in clinical trials.

CAP/CLIA validation of the Tempus xT panel focused on actionable oncogenic variants. The assay requires specimen with a tumor content of 20% post macrodissection (minimum 30% for MSI status). For solid tumors, an FFPE tumor sample is sequenced along with a matched normal blood or saliva sample (when available). For circulating hematologic malignancies, a blood or bone marrow sample is sequenced. Clinical sequencing is performed to 500x depth of coverage for tumor specimens and 150x for normal specimens. Performance specifications are listed in Table 1 below. These results establish high sensitivity and specificity for the Tempus xT (v2) assay.

The xT assay is used across a diverse set of clinical settings including leading academic centers, NCI designated cancer centers, hospital networks and community hospitals.

TABLE 1: PERFORMANCE SPECIFICATIONS

Variant Class	Limit of Detection	Sensitivity (%)	Specificity (%)
Single Nucleotide Variants	5% VAF	99.1	>99.9
Insertions and Deletions	10% VAF	98.1	>99.9
Copy Number Alterations	30% tumor purity; loss—0 copies; gain—8 copies	98.4	99.8
Rearrangements/Fusions*	10% tumor purity	>99.9	>99.9
Microsatellite Instability Status	30% tumor purity	>99.9	>99.9

** Utilizing both DNA and RNA sequencing*

REFERENCES

1. Beaubier, et al. 2019. *Oncotarget*. Clinical validation of the Tempus xT next-generation targeted oncology sequencing assay.
2. Beaubier, et al. 2019. *Nature Biotechnology*. Integrated genomic profiling expands clinical options for patients with cancer.