xT Validation

NEW YORK STATE

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).

xT assay (v4)† covers 648 genes spanning ~3.6 Mb of genomic space. Using DNA sequencing, somatic single nucleotide variants (SNVs), insertions and deletions (indels), copy number amplifications of 8 or more are reported in ERBB2 (HER2), and rearrangements in 22 genes are detected, along with one promoter region (TERT) and 239 sites to determine microsatellite instability status. Tumor mutational burden (TMB) and Microsatellite Instability (MSI) status are also reported for solid tumors. For tumor normal matched samples, potential germline variants may be reported in a subset of genes.

CAP/CLIA validation of the Tempus xT panel focused on actionable oncologic variants. The assay requires specimens with a tumor content of 20% post macrodissection. 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 (v4) 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.

xT PERFORMANCE SPECIFICATIONS

Variant Class	Limit of Detection	Sensitivity	Specificity
Single Nucleotide Variants	5% VAF	99.3%	>99.9%
Insertions and Deletions	10% VAF	90.8%	>99.9%
Copy Number Gains	30% tumor purity; gain—8 copies	98.4%	>99.9%
Microsatellite Instability Status	30% tumor purity	93.8%	>99.9%

† v4: fourth assay version

- The positive predictive agreement for chromosomal rearrangements in ABL1, ALK, BCR, EGFR, PML, RARA, RET, ROS1, TMPRSS2, when tested at a minimum of 30% tumor purity, exceeds 99.9%.
- The aggregate positive predictive value for chromosomal rearrangements in BRAF, ETV6, EWSR1, FGFR2, FGFR3, MYB, NRG1, NTRK1, NTRK2, NTRK3, PAX8, PDGFRA, TFE3, when tested at a minimum of 30% tumor purity, is 89%.