TEMPUS xT Validation

The Tempus xT assay combines a 596 gene somatic and germline DNA sequencing panel with RNA-sequencing. For solid tumors, it uses an FFPE tumor sample with a matched normal saliva or blood sample. For circulating hematologic malignancies, a blood or bone marrow sample is used. The assay is designed to identify actionable oncologic variants and is capable of detecting both somatic and germline single nucleotide polymorphisms (SNPs), indels less than 100 bp, copy number variants, and rearrangements in a targeted subset of clinically actionable genes via a single DNA sample. When RNA-seq is done, there is additional clinically validated unbiased gene fusion detection.

"This panel sets a new standard for broad panel genomic testing, since it allows physicians to test solid tumors and hematologic malignancies in one test and uses a normal sample for reference when feasible, thus improving the accuracy of the test for patients," said Gary Palmer, Chief Medical Officer at Tempus. "Most importantly, it utilizes clinical outcome data to inform possible treatment decisions, allowing patients to receive the best evidence-based treatment available."

CAP/CLIA validation of the Tempus xT panel focused on oncologically actionable variants that were assayed with a limit of detection of 5% variant allele fraction (VAF) for SNP's and 10% for indels. The validation set for Tempus xT showed a 98.1% sensitivity and 100% specificity for DNA-derived variants. These results establish high sensitivity and specificity for the Tempus xT 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.