TEMPUS xO Validation

The Tempus xO assay interrogates alterations in 1,711 genes using DNA sequencing in combination with whole transcriptome RNA sequencing of a patient's FFPE tumor tissue and matched normal saliva or blood.

The assay is designed to identify actionable oncologic variants in a wide array of solid tumor types and is capable of detecting both germline and somatic single nucleotide polymorphisms (SNPs), indels less than 100 bp, copy number variants, chromosomal rearrangements containing one or more RNA coding sequences and gene expression. Following the completion of testing, the xO assay report provides therapeutic indications for all detected somatic or gene expression alterations, as well as tumor mutational burden (TMB) metric, and linking them to associated evidence ranging from FDA approval to preclinical studies in the patient's cancer type, or in another cancer, as well as alterations associated with a known or suspected contraindication to a given therapy. The clinical trials section matches a patient to eligible biomarker-based clinical trials.

The CAP/CLIA validation of the Tempus xO panel was carried out using multiple, well characterized cell lines and reference standards, as well as retrospective FFPE clinical specimens and included concordance evaluation of xO assay results with academic and commercial reference laboratories. The validation focused on actionable genes, defined as variants known in the literature to be linked with response or resistance to targeted therapies, resistance to standard of care, or toxicities associated with treatment. Those variants were detected down to a variant allele fraction (VAF) of 5% with 98.3% sensitivity, over 99.9% specificity and 100% positive predictive value in FFPE tissue specimens of at least 20% tumor purity. High sensitivity and specificity was noted in detection of copy number change as well. There was 100% concordance between positive and negative HER2 amplification calls between the Tempus xO assay and a FISH assay performed in an academic medical center. Fusions in general were detected at 92% sensitivity, while clinically-actionable fusions were detected at 100% sensitivity. Of note, the high accuracy of Tempus xO assay was corroborated by high agreement between the xO test results and the orthogonal validated tests.

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