TEMPUS xE Validation

The Tempus xE assay sequences the entire coding region (exome) of the human genome. It is optimized for formalin fixed paraffin embedded (FFPE) tumor tissue samples. The FFPE tumor tissue is matched to a normal blood or saliva sample to ensure fidelity of somatic variant calling. The xE assay identifies actionable oncologic variants as well as neoantigens across the exome thus enabling immuno-oncology applications. The xE bioinformatics pipeline calls both somatic and germline single nucleotide polymorphisms (SNPs), insertions and deletions (indels), and copy number alterations.

CAP/CLIA validation of the Tempus xE panel focused on oncologically actionable variants. The assigned limit of detection is a variant allele fraction (VAF) of 10%. The xE validation set had a 98.8% sensitivity and 99.9% specificity for SNP's and indels at 10% VAF, as well as 87% sensitivity and 99% specificity for copy number alterations. These results establish high sensitivity and specificity for the Tempus xE assay.