xR Validation

The Tempus xR test is a whole-transcriptome genomic sequence analysis panel for solid tumor and hematologic malignancy samples that reports clinically relevant fusions[1] arising from genetic rearrangement for more than 100 targeted genes,[2] as well as altered splicing for MET Exon 14 and EGFRvIII, in an unbiased and comprehensive manner. Test results are intended to provide tumor molecular information that can be used by clinicians to help inform clinical management when patients are seeking further cancer treatment.

CAP/CLIA validation of the Tempus xR test in its Chicago, Illinois and Durham, North Carolina laboratories focused on actionable oncologic variants. The assay requires specimens with a tumor content of 20% post macrodissection. Clinical sequencing is optimized to generate at least 50,000,000 unique reads for tumor specimens. Performance specifications are listed in Tables 1 and 2 below. These results establish high sensitivity and specificity for the Tempus xR assay.

The Tempus xR assay may be 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—CHICAGO LAB[3]

Variant Class	Limit of Detection	Positive Percentage Agreement	Negative Percentage Agreement
Rearrangements/Fusions	20% Tumor Purity	100.0% PPA (targeted) 97.0% PPA (untargeted)	99.9% NPA (targeted) 99.9% NPA (untargeted)
Altered Splicing (MET Exon 14)	20% Tumor Purity	100.0% PPA	100.0% NPA
Altered Splicing (EGFRvIII)	20% Tumor Purity	95.5% PPA	91.3% NPA

TABLE 2: PERFORMANCE SPECIFICATIONS—DURHAM LAB

Variant Class	Limit of Detection	Positive Percentage Agreement	Negative Percentage Agreement
Rearrangements/Fusions	20% Tumor Purity	96.8% PPA (targeted) 100.0% PPA (untargeted)	99.9% NPA (targeted) 99.9% NPA (untargeted)
Altered Splicing (MET Exon 14)	20% Tumor Purity	100.0% PPA	100.0% NPA
Altered Splicing (EGFRvIII)	20% Tumor Purity	100.0% PPA	100.0% NPA

1 Clinically relevant fusions are defined as alterations that are associated with available therapeutic options, prognostic implications, diagnostic relevance, or clinical trial enrollment opportunities for a specific variant identified in a patient's tumor or hematologic malignancy

2 Examples of targeted genes include but are not limited to: ALK, RET, ROS1, NTRK1/2/3, FGFR1/2/3, NRG1, BRAF, EWSR1, ESR1-CCDC170, MYB-NFIB, PML-RARA, BCR-ABL

3 Comparison with the first version of Tempus' RNA sequencing assay