Indications for use

The Tempus xT-RNA assay is a next generation sequencing-based in-vitro device intended for use in the detection of oncologically relevant fusions and altered splicing events using RNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens from previously diagnosed cancer patients. xT-RNA is intended to provide RNA fusions and altered splicing to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms. The Tempus xT-RNA assay is a single-site assay performed and Tempus Labs, Inc.

Limitations

The Tempus xT-RNA assay is intended to provide tumor gene RNA profiling, including fusions and altered splicing events, to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with solid malignant neoplasms, however such additional tumor profiling results are not prescriptive or conclusive for labeled use of any specific therapeutic product.

Contradictions

There are no known contraindications.

Warnings and Precautions

The test does not provide information about susceptibility to cancer. Biopsy may pose a risk to the patient when archival tissue is not available for use with the assay. The patient's physician should determine whether the patient is a candidate for biopsy.

Product Description

Tempus xT-RNA is a whole-transcriptome Next Generation Sequencing assay for detection of gene fusion and altered splicing events. Tempus works directly with oncologists and pathologists to obtain tumor samples. Once a physician and patient determine that Tempus testing is the right next step, the test can be ordered by the physician.

Our kits include everything needed for specimen collection, including easy-to follow instructions, specimen guidelines, and packaging for convenient and fast shipping to our lab. Ordering physicians receive a comprehensive report for each patient that highlights key findings, including actionable treatments, that can be immediately translated into cancer patient care.

Ordering a Test

Tempus xT-RNA assay can be ordered using the Tempus requisition found in the Tempus CE Clinical Trials Solid Tumor Collection Kit. The requisition should be fully completed, include at least two patient identifiers, and be signed by the ordering physicians or another authorized medical professional. The Tempus CE Clinical Trials Solid Tumor Collection Kit contains all necessary instructions to package and submit samples for testing.

Results/Reports

Tempus' xT-RNA assay is CE marked for the detection of fusions and altered splicing using RNA for solid tumors. RNA fusions and altered splicing events will be added to the clinical report as an addendum.

Procedure

The Tempus xT-RNA Assay employs TNA extraction methods for FFPE biopsy (tumor) from which total RNA is isolated through the digestion of DNA. xT-RNA library preparation is performed using IDT unique dual-index adapters, followed by hybrid capture with custom the IDT xGen Lockdown probes. The final libraries are sequenced using the Illumina NovaSeq 6000 Sequencer, a high throughput sequencing system. The clinical report provides doctors with diagnostic, prognostic, therapeutic evidence and clinical trial options based on the molecular results of the test.

xT-RNA Performance Characteristics

Validation Summary

The Tempus xT-RNA next generation sequencing assay is designed to detect actionable oncologic targets by sequencing tumor samples. RNA-Seq detects gene fusions (translocations) and altered splicing events. The assay requires specimens with a tumor content of 20% post macrodissection. Performance specifications are listed on Table 1 and Table 2 below. These results establish high sensitivity and specificity for the xT-RNA assay.

Table 1

Variant Class	Limit of Detection	Sensitivity (%)	Specificity (%)
Rearrangements	10% tumor purity	91.7	99.99

Table 2

Altered Splicing Event	Limit of Detection	Positive Percent Agreement (PPA)	Negative Percent Agreement (NPA)
NOTCH1-4	20% tumor purity	95%	98.2%
MET exon 14	20% tumor purity	100%	100%
EGFRvIII	20% tumor purity	95.5%	91.3%

TEMPUS SPECIMEN GUIDELINES

To ensure accurate molecular profiling, please follow the specimen guidelines below when submitting tumor samples.

TISSUE REQUIREMENTS

- Patient material, labeled with two identifiers
- Tumor samples should be from the most recent procedure, if adequate for testing, **should be less than 6 years old**
- FFPE Fixation Requirements
  - 10% formalin fixation (neutral buffered) for 6–72 hours, paraffin embedded
  - No decalcification of the samples is preferred (EDTA is accepted)
- Tumor required to be at least 20%* of the sample by ratio of tumor nuclei to benign nuclei
- Optimal tumor size = 25 mm^2, minimum = 5 mm^2

BLOCKS *Preferred collection method

1 **FFPE block with greatest tumor content**

1 **H&E stained slide, optional**

If you would like us to evaluate quality, please send multiple blocks with a return address.

OR

SLIDES

10 **FFPE unstained slides for NGS 5µm sections on positively charged, unbaked slides**

1 **Terminal H&E stained slide**

**Submit 10 additional slides if tissue size is <25 mm2

Tempus CE Clinical Trials Solid Tumor Collection Kit Components

FedEx shipping envelope

Biohazard bag

Sticker seal

2 Slide Cases

(each case can hold 10 slides)

Requisition form