TEMPUS | ONCOLOGY

# Tempus Comprehensive Therapy Selection

A streamlined ordering solution that ensures no critical tests are missed.

## SIMPLIFIED CANCER TESTING

With a single checkbox on the paper requisition form, Tempus' Comprehensive Therapy Selection (CTS) allows you to effortlessly order a suite of tests tailored to your patient's cancer type.

Each Comprehensive Therapy Selection order for solid tumor cancers includes xT CDx (DNA), xR (RNA), and a curated selection of biomarker tests based on your patient's cancer type (see table below). For hematologic malignancies, a Comprehensive Therapy Selection order will include xT Heme (DNA) and xR (RNA). Additional add-on options are available for liquid biopsy, hereditary testing, minimal residual disease, or monitoring assays to further personalize patient care.

## CURATED TESTING BY CANCER TYPE

Tempus uses the diagnosis information you provide on the requisition form to determine tests ordered by cancer type. Please ensure this information is accurate when submitting an order. Only select one diagnosis checkbox per requisition form. If you would like to send multiple specimens for different primary cancers, please send separate requisition forms to ensure the appropriate tests are run on each specimen.

| Cancer Type | IHCs / Clincal Biomarker Tests | Algorithmic Tests |
|---|---|---|
| Bladder | HER2, PD-L1 (22C3) | DPYD, Immune Profile Score (IPS), UGT1A1 |
| Breast | HER2, PD-L1 (22C3) | HRD, DPYD, IPS, UGT1A1 |
| Cancer of unknown primary (CUP) | HER2, MMR, PD-L1 (22c3) | DPYD, TO, UGT1A1 |
| Colorectal (CRC) | HER2, MMR | DPYD, IPS, UGT1A1 |
| Esophageal | CLDN18, HER2, MMR, PD-L1 (22C3) | DPYD, IPS, UGT1A1 |
| Head & Neck | HER2, PDL1 (22C3) | DPYD, IPS |
| Melanoma | HER2, PD-L1 (22C3) | IPS |
| Non-small cell lung (NSCLC) | HER2, PD-L1 (22C3), PD-L1 (SP142), PD-L1 (SP263), PD-L1 (28-8) | IPS |
| Ovarian | FOLR1, HER2 | DPYD, HRD, UGT1A1 |
| Pancreatic | HER2 | DPYD, PurIST℠, UGT1A1 |
| Prostate | HER2, MMR | |
| Others | HER2 | |

*Specimen guidelines and tissue requirements for testing remain the same. To ensure optimal specimen processing, please follow the guidelines outlined at tempus.com/resources/document-library/tempus-onco_specimen-guidelines/. Note: Algorithmic tests are laboratory developed tests and do not require any additional tissue. IPS is indicated for patients already considered candidates for ICI-based therapy. If you do not wish to order IPS, you may order single tests individually.*

## Questions?

For more information regarding test selections, please contact support@tempus.com.

## TEST DESCRIPTIONS

| | | |
|---|---|---|
| **Therapy Selection**<br>*Included in every Comprehensive Therapy Selection order for solid tumor cancers* | **xT CDx (DNA)** | FDA- approved 648-gene tissue-based tumor + normal matched NGS test for molecular profiling of all malignant solid tumors, that includes assessment of MSI status, and companion diagnostic (CDx) claims for colorectal cancer (CRC) patients. |
| | **xT LDT (DNA)** | Solid tumor testing if a matched normal specimen is unavailable or if the normal specimen cannot be successfully sequenced. |
| | **xR (RNA)** | Whole transcriptome RNA sequencing test. |
| **IHC Testing** | **CLDN18**† | Detects Claudin-18 (CLDN18) expression, often elevated in gastric and gastroesophageal adenocarcinomas. |
| | **FOLR1**† | Detects folate receptor alpha (FRα) protein expression, which is commonly overexpressed in ovarian and certain other gynecological cancers. |
| | **HER2**† | With reflex to *ERBB2* FISH for equivocal results (IHC score of 2+).*<br>Determines HER2 protein expression levels, providing crucial information on HER2 amplification status that may guide the use of anti-HER2 targeted therapies for patients. |
| | **MMR Panel (MSH6, MSH2, MLH1, PMS2)** | Evaluates for deficiencies in the mismatch repair (MMR) pathway to identify the loss of MMR proteins. |
| | **PD-L1** | PD-L1 protein expression testing via IHC (available clones: 22C3, 28-8, SP142, SP263). |
| **Neuro-Oncology Testing** | **MGMT promoter methylation**† | MGMT promoter methylation leads to gene silencing and serves as a prognostic and predictive biomarker for glioma response to alkylating agents. |
| | **1p/19q co-deletion**† | 1p/19q co-deletion via FISH testing is a diagnostic marker for oligodendrogliomas, offering prognostic and predictive value for treatment strategies. |
| **Algorithmic Testing** | **DPYD** | Identifies patients who may be at elevated risk for toxicity from 5-FU and/or capecitabine treatment by analyzing the DPYD gene. |
| | **Homologous Recombination Deficiency (HRD)** | Predicts the probability for a phenotype characterized by the inability to repair DNA breaks via the homologous recombination repair (HRR) pathway. |
| | **Immune Profile Score (IPS)** | Multimodal biomarker that can be used as a prognostic indicator for adult patients with stage IV or metastatic pan-solid tumor disease who are already considered candidates for immune checkpoint inhibitor (ICI) based therapy. |
| | **PurIST**℠ | Algorithm-based test leveraging RNA seq data to classify pancreatic ductal adenocarcinoma (PDAC) into one of two subtypes (basal-like or classical). |
| | **Tumor Origin (TO)** | Uses tumor RNA expression to predict the most likely cancer type(s) from 68 possible types, aiding in diagnosis and informing patient care and clinical trial eligibility. |
| | **UGT1A1** | Identifies patients who may be at elevated risk for toxicity from irinotecan, sacituzumab govitecan, and/or belinostat treatment by analyzing the UGT1A1 gene. |

*† Powered by NeoGenomics*

** While FISH reflex will occur for equivocal IHC results in any solid tumor, it is currently only guideline-supported for select tumor types.*[1,2,3]

*xT CDx is a qualitative Next Generation Sequencing (NGS)-based in vitro diagnostic device intended for use in the detection of substitutions (single nucleotide variants (SNVs) and multi-nucleotide variants (MNVs)) and insertion and deletion alterations (INDELs) in 648 genes, as well as microsatellite instability (MSI) status, using DNA isolated from Formalin-Fixed Paraffin Embedded (FFPE) tumor tissue specimens, and DNA isolated from matched normal blood or saliva specimens, from previously diagnosed cancer patients with solid malignant neoplasms.The test is intended as a companion diagnostic (CDx) to identify patients who may benefit from treatment with the targeted therapies listed in the Companion Diagnostic Indications table in accordance with the approved therapeutic product labeling. Additionally, xT CDx is intended to provide tumor mutation profiling to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with previously diagnosed solid malignant neoplasms. Genomic findings other than those listed in the Companion Diagnostic Indications table are not prescriptive or conclusive for labeled use of any specific therapeutic product. xT CDx is a single-site assay performed at Tempus Labs, Inc., Chicago, IL. For the complete xT CDx label, including companion diagnostic indications and important risk information, please visit tempus.com/xt-cdx-label/*


1 *Wolff AC, Somerfield MR, Dowsett M, et al. Human epidermal growth factor receptor 2 testing in breast cancer: ASCO-College of American Pathologists guideline update. J Clin Oncol. 2023;41(22):3867-3872.*

2 *Bartley AN, Washington MK, Ventura CB, et al. Her2 testing and clinical decision making in gastroesophageal adenocarcinoma: guideline from the College of American Pathologists, American Society for Clinical Pathology, and American Society of Clinical Oncology. Arch Pathol Lab Med. 2016;140(12):1345-1363.*

3 *Meric-Bernstam F, Makker V, Oaknin A, et al. Efficacy and Safety of Trastuzumab Deruxtecan in Patients With HER2-Expressing Solid Tumors: Primary Results From the DESTINY-PanTumor02 Phase II Trial. J Clin Oncol. 2024;42(1):47-58.*