

Tailored Testing Solutions

Tempus offers a comprehensive range of tailored testing solutions to address the unique needs of each cancer patient. Our offerings include immunohistochemistry (IHC), fluorescence in situ hybridization (FISH), algorithmic tests, and more—delivering actionable insights for personalized cancer care.

IHC TESTING

CANCER TYPE	IHC/CLONE	DESCRIPTION	SCORING METHOD	COMPATIBLE ASSAYS
All solid tumors	MMR Panel (MSH6, MSH2, MLH1, PMS2)	Evaluates for deficiencies in the mismatch repair (MMR) pathway by identifying the presence or absence of MMR proteins.	Protein expression presence/absence.	xT CDx xR xT xE
All solid tumors	HER2 [†] With reflex to <i>ERBB2</i> FISH for equivocal results (IHC score of 2+). <i>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}</i>	Determines HER2 protein expression levels, providing crucial information on HER2 amplification status that may guide the use of anti-HER2 targeted therapies for patients.	IHC scoring on 0-3+ scale with or without FISH reflex based on applicable ASCO/CAP scoring guidelines for all solid tumors. ^{1,2} Breast scoring will apply to breast neoplasms while all other sample types will receive gastric scoring based on the DESTINY-PanTumor02 trial data and subsequent drug approval. ³	xT CDx xR xT
All solid tumors	PD-L1 22C3 PD-L1 28-8 PD-L1 SP142 PD-L1 SP263	PD-L1 expression has been observed in various cancer types, present on both tumor and immune cells. Patients with PD-L1 expression may be eligible for immune checkpoint inhibitor therapy, which enhances the immune system's ability to target and eliminate cancer cells.	Tumor Proportion Score (TPS)%; Combined Positive Score (CPS); Tumor Cell Staining (TC)%; Tumor-Infiltrating Immune Cell Staining (IC)% PD-L1 protein expression scoring is specific to each clone. For details on individual PD-L1 clones and scoring, visit www.tempus.com/testing-resources/	xT CDx xR xT xE
Ovarian	FOLR1 (FRα) [†]	Detects folate receptor alpha (FRα) protein expression, which is commonly overexpressed in ovarian and certain other gynecological cancers.	Expression percentage (2+/3+ staining).	xT CDx xR xT
Gastric/GEJ	CLDN18 [†]	Detects CLDN18.2 expression, often elevated in gastric and gastroesophageal adenocarcinomas.	Expression percentage (2+/3+ staining).	xT CDx xR xT
NSCLC	c-MET [†]	Detects c-Met expression, often elevated in non-squamous non-small cell lung cancer (NSCLC).	Expression percentage (3+ staining).	xT CDx xR xT

[†] Powered by NeoGenomics

xT CDx is only available as a tumor + normal assay; xT is only available as a tumor-only assay.

NEURO-ONCOLOGY TESTING

CANCER TYPE	TEST	DESCRIPTION	COMPATIBLE ASSAYS
Glioma	MGMT promoter methylation [†]	MGMT promoter methylation leads to gene silencing and serves as a prognostic and predictive biomarker for glioma response to alkylating agents.	xT CDx xR xT
Glioma	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.	xT CDx xR xT

AI-DRIVEN ALGORITHMIC TESTING

CANCER TYPE <i>(Most relevant)</i>	TEST	DESCRIPTION	COMPATIBLE ASSAYS <i>(No additional tissue required)</i>
All solid tumors	Immune Profile Score (IPS)	Multimodal biomarker that can be used as a prognostic indicator for adult patients with advanced pan-solid tumor disease who are already considered candidates for immune checkpoint inhibitor (ICI) based therapy.	xT CDx with xR OR, xT with xR <i>Both DNA and RNA seq are required for processing.</i>
Breast and Ovarian Cancer <i>(DNA-based methods)</i> All other cancers <i>(RNA-based methods)</i>	Homologous Recombination Deficiency (HRD)	Predicts the likelihood of a cancer exhibiting homologous recombination deficiency (HRD), indicating impaired DNA repair through the HRR pathway. For ovarian and breast cancer, this includes genome-wide loss of heterozygosity or biallelic BRCA1/2 loss; for other cancers, it provides an HRD score based on whole transcriptome RNA expression.	xT CDx with xR OR, xT with xR OR, xR only <i>The matched normal sample for xT CDx is required for breast and ovarian cancer.</i>
Breast, Colorectal, Pancreatic, and other GI cancers	DPYD	Identifies patients who may be at elevated risk for toxicity from 5-FU and/or capecitabine treatment by analyzing the DPYD gene, which encodes the enzyme involved in drug metabolism.	xT CDx only OR, xT CDx with xR <i>The matched normal sample is required for processing.</i>
Breast, Colorectal, Pancreatic, and Urothelial cancers	UGT1A1	Identifies patients at elevated risk for toxicity from irinotecan, sacituzumab govitecan, and/or belinostat treatment by analyzing the UGT1A1 gene, which encodes the enzyme involved in drug metabolism.	xT CDx only OR, xT CDx with xR <i>The matched normal sample is required for processing.</i>
Cancers of unknown primary and cases with uncertain diagnosis	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.	xT CDx with xR OR, xT with xR OR, xR only <i>RNA seq is required for processing.</i>
Unresectable stage III or IV Pancreatic Ductal Adenocarcinoma (PDAC)	PurIST SM	Classifies PDAC into basal or classical subtypes using RNA sequencing information, which may help guide clinical management. These subtypes are associated with prognosis and survival outcomes. ^{4,5}	xT CDx with xR OR, xT with xR OR, xR only <i>RNA seq is required for processing.</i>

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.

4 Rashid NU, et al. Purity independent subtyping of tumors (PurIST), a clinically robust, single-sample classifier for tumor subtyping in pancreatic cancer. *Clin Cancer Res.* 2020;26(1):82-92.

5 Wenric S, Davison JM, Guittar J, et al. Real-world data validation of the purist pancreatic ductal adenocarcinoma gene expression classifier and its prognostic implications. *medRxiv.* Published online February 24, 2023.

[†] Powered by NeoGenomics

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 AI, Inc., Chicago, IL. For the complete xT CDx label, including companion diagnostic indications and important risk information, please visit tempus.com/xt-cdx-label/