# Specimen Guidelines for Providers

To ensure accurate molecular profiling and optimal specimen processing, please follow the specimen guidelines below when submitting tumor samples. Use a Tempus collection kit to collect and ship specimens.

Tempus strongly suggests providing a matched normal specimen for solid tumor and lymphoma testing. We do not perform a normal match for leukemias. For solid tumors, saliva is accepted but blood is preferred. For lymphomas, only saliva is accepted.

# **Tissue Requirements**

- Per CAP guidelines, patient material must be labeled with two identifiers §§
- ✓ Tumor samples should be from the most recent procedure, if adequate for testing ¶
- FFPE Fixation Requirements:
  - 10% formalin fixation (neutral buffered) for 6–72 hours, paraffin embedded
  - EDTA is the only accepted method of decalcification
- ✓ Tumor required to be at least 20% of the sample by ratio of tumor cell nuclei to normal cell nuclei<sup>‡§</sup>
- Optimal tumor size = 25 mm², minimum = 5 mm²

# Circulating Hematologic Malignancy Requirements

Please send CBC with differential, flow cytometry results, and/or bone marrow pathology report.

- Confirm sample contains at least 20% tumor content
- Specimen must ship to Tempus via FedEx Overnight on the same day it is collected
- No freezing of the samples is preferred

#### Bone marrow:

Minimum 1 mL bone marrow aspirate in an EDTA tube (lavender top)

# Peripheral blood:

Minimum 8 mL peripheral blood in an EDTA tube (lavender top)

## SENDING SAMPLES

Send via priority overnight shipping using the prepaid shipping labels and Clinical Packs provided in the Tempus kits.

To order Tempus tissue collection kits, contact your Tempus representative or contact us at support@tempus.com or 800.739.4137

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**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 up to 3 blocks with a return address provided



**Slides**\*(5µm sections on positively charged, unbaked slides)

#### 10 FFPE unstained slides for NGS

Submit 10 additional slides if tissue size is <25 mm<sup>2</sup>

- 1 Terminal H&E stained slide
- **6** Additional FFPE unstained slides when DNA mismatch repair (MMR) protein panel IHC is ordered\*
- ${\bf 3}\;$  Additional FFPE unstained slides per clone when PD-L1 IHC is ordered  $^{\rm \#**}$

#### IHCs powered by NeoGenomics ††

CLDN18 3-4 unstained slides cut at 4 microns preferred,

5 microns acceptable

FOLR1 (FRa) 3-4 Unstained slides cut at 4 microns preferred,

5 microns acceptable

microns acceptable

HER2 6-7 unstained slides cut at 4 microns preferred, 5

Available for all solid tumor types, with reflex testing to ERBB2 FISH in cases of equivocal results (IHC score of 2+)

#### Neuro-oncology testing powered by NeoGenomics<sup>††</sup>

1p/19q 4 unstained slides cut at 4 microns is preferred,

co-deletion 5 microns acceptable.

MGMT promoter 6-11 unstained slides cut a  $t \ge 5$  microns.

methylation

While FISH reflex will occur for equivocal IHC results in any solid tumor, it is currently only guideline-supported for select tumor types. <sup>1,2,3</sup>

Allogeneic stem cell and solid organ transplants may interfere with molecular testing. Please call or email our Support team for guidance on testing for patients with a history of transplant.

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>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.

<sup>†</sup>If providing a non-preferred sample type or if you have questions regarding normal-matched sequencing for hematological malignancies or leukemias, please contact our support team before shipping samples.

§§Specimens received with only 1 identifier may incur delays in report delivery.

Specimens older than 5-6 years or smaller than 5 mm2 are more likely to be insufficient for testing and/or require longer processing times.

<sup>‡</sup>When feasible and warranted, Tempus may enrich tumor percentage via macrodissection.

§Required to be at least 40% for xE panel.

\*FFPE slides and blocks are stable at 10°C to 27°C indefinitely

\*Given the lack of PD-L1 interpretation guidelines for hematologic processes and the challenges with distinguishing neoplastic cells from non-neoplastic cells in various hematologicand thymic neoplasms, IHC testing (PD-L1 & MMR) for samples with hematologic or thymic neoplasia diagnoses will not be reported.

"View the number of clones applied to your order by visiting tempus.com/testing-resources/.

<sup>††</sup>NeoGenomics test offerings are not clinically indicated for hematologic and thymic neoplasms.

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