TO Validation

The Tempus Tumor Origin (TO) test uses information from analysis of nucleic acids by next-generation sequencing (NGS) performed as part of a separately-ordered Tempus|xT test. The TO test uses tumor mRNA expression results to predict the highest probability primary and other potentially likely cancer types from 68 possible diagnostic cancer types. The Tempus TO test can be reported only for samples with ≥20% tumor purity.

Validation of the Tempus TO test was performed in a CLIA-certified, CAP-accredited lab. An analytical validation cohort consisting of 9,210 tumor samples of known origin and 1,708 cancers of unknown primary (CUPs) was created from the Tempus database. The validation cohort consisted of 25% of the labeled samples, which were selected via stratified random sampling, from within the Tempus database. All CUPs were used for the biomarker concordance analysis. All samples with an mRNA expression profile passing the quality control checks were eligible for the study. These samples were assigned one of 68 diagnostic labels or designated as CUPs based on the diagnosis assigned to the sample by Tempus pathologists at the time of sample accessioning and histologic review. Samples included formalin-fixed, paraffin-embedded (FFPE) slides, FFPE tissue blocks, blood, bone marrow aspirates, and fresh frozen tissue.

Labeled samples (n= 9,210) were used to characterize the performance of the TO test. The samples contained a broad range of tumor purities as determined by manual pathologist review, ranging from <20% to 100% tumor purity. Performance metrics of the assay were stratified by type and subtype; the overall accuracy was 91%.

Samples labeled as a CUPs (n= 1,708) were not used in determining performance specifications of the classifier, but were utilized in other studies to characterize reportable range and interassay reproducibility.

The sixty eight (68) possible diagnostic types of the TO test are:

- Acute lymphoblastic leukemia
- Acute myeloid leukemia
- Adenoid cystic carcinoma
- Adrenal cortical carcinoma
- Anogenital squamous cell carcinoma
- B cell lymphoma
- Breast carcinoma
- Carcinosarcoma
- Cervical carcinoma
- Cholangiocarcinoma
- Chondrosarcoma
- Chronic lymphocytic leukemia
- Chronic myeloid leukemia
- Colorectal adenocarcinoma
- Endometrial serous carcinoma
- Endometrial stromal sarcoma
- Endometrioid carcinoma
- Ependymoma
- Ewing sarcoma
- Fibrous sarcoma
- Gastroesophageal adenocarcinoma
- Gastroesophageal squamous cell carcinoma
- Gastrointestinal neuroendocrine carcinoma
- Gastrointestinal stromal tumor
- Goblet cell adenocarcinoma
- Gynecological clear cell carcinoma
- Head and neck squamous cell carcinoma
- Hepatocellular carcinoma
- High grade glioma
- Leiomyosarcoma
- Liposarcoma
- Low grade glioma
- Lung adenocarcinoma
- Lung squamous cell carcinoma
- Medulloblastoma
- Melanoma
- Meningioma
- Mesothelioma
- Metaplastic breast carcinoma
- Multiple myeloma
- Neuroendocrine lung tumor
- Oligodendroglioma
- Osteosarcoma
- Ovarian mucinous adenocarcinoma
- Ovarian serous carcinoma
- Pancreatic adenocarcinoma
- Pancreatic neuroendocrine tumor
- Peripheral nerve sheath tumor
- Prostate neuroendocrine carcinoma
- Prostatic adenocarcinoma
- Renal chromophobe carcinoma
- Renal clear cell carcinoma
- Renal papillary carcinoma
- Rhabdomyosarcoma
- Salivary carcinoma
- Schwannoma
- Skin neuroendocrine carcinoma
- Skin squamous and basal cell carcinoma
- Small bowel adenocarcinoma
- Small cell lung carcinoma
- Synovial sarcoma
- T cell lymphoma
- Thymic squamous cell carcinoma
- Thyroid cancers
- Urothelial carcinoma
- Urothelial neuroendocrine carcinoma
- Vascular sarcoma
- Well differentiated gastrointestinal neuroendocrine tumor

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