TEMPUS | ONCOLOGY

Clinical Overview of the Tempus xF Liquid Biopsy Assay

There is emerging evidence for the clinical validity of cfDNA testing in the identification of genomic alterations predictive of response and resistance to targeted therapies and evaluation of genomic heterogeneity.

Potential uses for Tempus xF to support clinical decision making

01 WHEN LIMITED TISSUE IS AVAILABLE FOR SEQUENCING

When tumor tissue is insufficient for sequencing, the Tempus xF liquid biopsy assay may be used to assess cfDNA from a peripheral blood draw, providing a genomic result.

- For use in patients with tumors that have limited tissue available for sequencing.
- Also useful for patients unable to undergo additional tissue collection procedures.

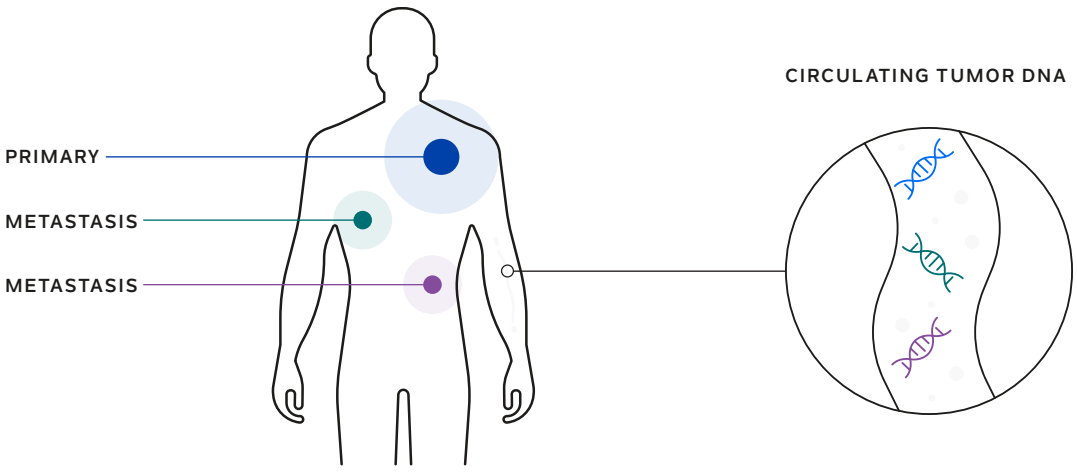
02 TO MONITOR MECHANISMS OF RESISTANCE

Recently published data has identified multiple resistance mechanisms that arise from frontline targeted therapies in patients with advanced cancer such as:

- EGFR T790M/L789I/C797S & ALK L1196M in lung cancer [1,2]
- BRCA1/2 reversion in ovarian and breast cancer [4]
- ESR1 Y537/D538 mutations in breast cancer [3]
- BRAF V600E mutations & FGFR3 fusion events in colorectal cancer [5,6]

03 TO GAIN A COMPREHENSIVE VIEW OF A PATIENT'S METASTATIC DISEASE

Inter- and intra-tumor heterogeneity may lead to detection of non-overlapping, potentially actionable findings when concurrent solid tissue and cfDNA liquid biopsy testing are utilized. This approach may provide a more comprehensive evaluation of the genomic heterogeneity across all tumor sites. [7,8,9]



Tempus xF

The Tempus xF assay is a non-invasive, liquid biopsy panel of 105 genes focused on oncogenic and resistance mutations in cell-free DNA (cfDNA). It is designed to support clinical decision making for solid tumors.

- SNVs (single nucleotide variants) and insertions and deletions (indels) are detected in 105 genes
- Copy number variants (CNVs) and chromosomal rearrangements (translocations) are detected in a subset of genes
- DNA Sequencing Depth: average 20,000x (raw reads)/5,000x (unique reads)
- Specimen Requirements: Two Streck tubes of peripheral blood (8.5mL each)

The report includes genomic alterations in select genes, microsatellite instability-high status when present,* median variant allele fraction (mVAF), therapy options and clinical trials matched to the patient's genomic profile, as well as available clinical history.

Tempus Financial Assistance Program **

We help provide access to our tests for patients in financial need. Patients can complete the application online at **access.tempus.com** or call 800-739-4137 to speak to a member of our team.

* MSI status will be reported when the specimen is determined to be MSI-High.

**Tempus testing is conducted based on medical necessity as determined by the ordering physician.

REFERENCES

1 Chabon, J., Simmons, A., Lovejoy, A. et al. (2016). doi:10.1038/ncomms11815
2 Ihuegbu, N., Banks, K., Fairclough, S. et al. (2016). doi:10.1200/JCO.2016.34.15_suppl.e20643
3 Fribbens, C., O'Leary, B., Kilburn, L. et al. (2016). doi:10.1200/JCO.2016.67.3061
4 Weigelt, B., Comino-Méndez, I., de Bruijn, I. et al. (2017). doi:10.1158/1078-0432.CCR-17-0544
5 Parikh, A.R., Leshchiner, I., Elagina, L. et al. (2019). doi:10.1038/s41591-019-0561-9
6 Clifton, K., Rich, T., Parseghian, C. et al. (2019). doi:10.1200/PO.19.00141
7 Aggarwal, C., Thompson, J., Black, T., et al. (2019). doi:10.1001/jamaoncol.2018.4305
8 Schwaederle, M., Patel, S., Husain, H. et al. (2017). doi:10.1158/1078-0432.CCR-16-2497
9 Maxwell, K., Soucier-Ernst, D., Tahirovic, E. et al. (2017). doi:10.1007/s10549-017-4257-x