



Tempus xM

RESEARCH USE ONLY (RUO)

Tumor-naïve MRD assay for ctDNA detection
in stage II–III colorectal cancer



Tempus xM

xM is a liquid-only approach to MRD assessment that detects trace amounts of residual ctDNA, leveraging both methylation and genomic variant MRD classifiers while applying algorithms that support filtering of artifacts, like CHIP and germline variants, to deliver a binary MRD call.

As a tumor-naïve assay with dual workflows, Tempus xM offers several advantages to biopharma, including accelerated turnaround times as well as the availability of variant-level information.

Tumor-naïve

Accelerated TAT
Solely blood-based assay
Increased operational efficiency

Tumor-informed

Slower TAT
Require tumor baseline sample
Add'l. operational complexities

Harnessing the power of a dual workflow

xM leverages both variant and methylation workflows to call MRD+/-, bringing forward variant-level data about your patient cohort with every blood draw.

SAMPLE INPUT

~17 mL blood ~8 mL plasma ~30–50 ng cfDNA
1 kit, 2 Streck tubes

20 ng methylated cfDNA

10–30 ng cfDNA

WET LAB

Methylation panel
6 Mb panel; coverage of 1000s of differentially methylated loci

DNA/variant panel*
0.3 Mb panel; coverage of informative regions in >100 genes

BIOINFORMATICS

Epigenetic signals
Signal processing

Genomic alterations
Corrected for known confounders (i.e., CHIP and Germline)

DATA PRODUCT*

MRD +/- call

Positive call if either workflow detects related ctDNA based on prespecified threshold

Comprehensive value for MRD assessment

✓ Faster TAT

As a tumor-naïve assay, xM reduces operational research delays due to tissue procurement.

✓ Data-informed model

The xM algorithmic model was developed using Tempus' robust multimodal database, leveraging known tumor profiles and clinical outcomes to correct for CHIP and germline confounders.

✓ Binary MRD call

xM utilizes both methylation and variant workflows to call MRD+/-, helping to bring forward variant level data on cohorts with every sample.

Specification and sample information¹

xM is available for research use only (RUO).

Sensitivity	53%
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Specificity	94%
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Sample requirement	2 Streck tubes (8.5 ml each)
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Sensitivity and specificity of stage II/III CRC patients at a landmark time point (LMT) defined as 4 weeks after curative surgery.

Learn more about xM and our RUO ctDNA assays.

Visit tempus.com/life-sciences/sequencing/ →



Broad ctDNA detection solutions for biopharma

RESIDUAL DISEASE DETECTION (RUO)

Tempus xM

Tumor-naïve minimal residual disease (MRD) test for recurrence surveillance.

Utilizes both DNA variant and methylation workflows for a binary MRD call.

Available for research use only.

THERAPY SELECTION

Tempus xF

105 gene liquid biopsy panel

Solid tumors.

Clinical sequencing is performed to >5000x and >1500x unique coverage for enhanced and additional regions, respectively.

Identifies SNVs, insertions / deletions, CNVs, and fusions for select genes, MSI-H, bTMB.

Tempus xF+

523 gene liquid biopsy panel

114 gene enhanced region; solid tumors.

Clinical sequencing is performed to >5000x and >1500x unique coverage for enhanced and additional regions, respectively.

Identifies SNVs, insertions / deletions, CNVs, and fusions for select genes, MSI-H, bTMB.

Tempus is building a new version of the xF+ assay now under design controls.

TREATMENT RESPONSE MONITORING (RUO)

Tempus xF Monitor

ctDNA Tumor Fraction for ctDNA Quantification and Monitoring

A ctDNA assay which measures changes in ctDNA tumor fraction to determine early response to immunotherapy for patients with advanced cancers.

Currently available for research use only.

Research Use Only (RUO) Use Cases

The Tempus xM assay is RUO. The assay can be utilized for:

- 01 Retrospective analysis of clinical samples from an existing or previously closed clinical study and/or
- 02 Exploratory endpoint analysis within an existing clinical study or a clinical study still to be opened

For both of these use cases, xM can help support the following research, dependent on the study design:

01 Drug Development and Efficacy Monitoring:

Evaluate the effectiveness of experimental colorectal cancer therapies by determining in preclinical and clinical trials. Assess the impact of novel drugs on residual disease burden for early indications of treatment efficacy.

02 Inform MRD Based Patient Stratification for Future Clinical Trials:

Stratify patients more effectively for future clinical trials based on learnings of how MRD status has impacted your previous clinical trial results. Enhance the selection process for trial participants, leading to more targeted and successful trials.

03 Treatment Response Assessment:

Assess patient response to standard and experimental therapies by monitoring MRD levels over time. Facilitate the early identification of non-responders and support future adaptive treatment strategies to be incorporated in future trial designs.

04 Longitudinal Disease Surveillance:

Track MRD dynamics in patients post-treatment to understand the long-term impact of interventions. Provide valuable insights into disease recurrence and the need for continued surveillance or intervention.

05 Disease Progression Studies:

Investigate the natural progression of colorectal cancer by studying MRD at different stages. Contribute to the understanding of disease biology, enabling the identification of critical intervention points.

06 Exploration of Therapeutic Resistance Mechanisms:

Investigate MRD dynamics in cases of therapeutic resistance. Uncover molecular mechanisms associated with resistance, informing the development of strategies to overcome treatment challenges.

(cont.)

07 Pharmacodynamic Assessments:

Perform pharmacodynamic assessments of drug candidates by studying MRD changes in response to treatment. Support the optimization of dosing regimens and therapeutic strategies.

08 Early Intervention Opportunities:

Identify opportunities for future clinical trial designs for early intervention based on MRD trends. Enable the development of interventions aimed at preventing disease recurrence or progression.

09 Companion Diagnostics Development:

Facilitate the development of companion diagnostics by identifying MRD markers that can be used to guide treatment decisions. Support the integration of RUO MRD assays into future clinical trials with various therapies.

References

- 1 Nakamura, Y., et al. A tumor-uninformed ctDNA assay detecting MRD in patients with resected stage II or III colorectal cancer predicts recurrence: Subset analysis from the GALAXY study in CIRCULATE-Japan. Presented at ASCO GI 2024.

* Notes for *Harnessing the power of a dual workflow*:

DNA/Variant panel is run after the methylation panel passes quality control

Various genomic alterations can be provided from the panel (1 positive variant will meet the MRD + call threshold)

CHIP filtering algorithm is implemented on the genomic workflow with a high probability of success

