

# TEMPUS

## Tempus Receives U.S. FDA 510(k) Clearance for Tempus xR IVD, its RNA NGS In Vitro Diagnostic Device

September 22, 2025

CHICAGO--(BUSINESS WIRE)--Sep. 22, 2025-- Tempus AI, Inc. (NASDAQ: TEM), a technology company leading the adoption of AI to advance precision medicine and patient care, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its RNA-based Tempus xR IVD device. xR IVD will be offered as a life sciences tool to support drug development programs.

RNA sequencing captures a large array of biological information and offers deeper insights into the mechanisms of diseases, including enhanced fusion detection. RNA analysis is increasingly an important tool in research and development because it can identify molecular pathways and networks that are directly involved in disease progression.

"We have long known that RNA sequencing offers additional insights beyond DNA alone, but only now are we beginning to unlock its full value in supporting therapeutic development. This FDA clearance further demonstrates the promise of RNA sequencing and opens up new opportunities for us with our biopharma customers," said Kate Sasser, PhD, Chief Scientific Officer at Tempus. "Now, our life science partners can leverage our RNA assay to more precisely identify which patients are most likely to respond to specific therapies and to design more efficient clinical trials. As new therapeutics tied to RNA biomarkers enter the market, we believe that this assay will become even more critical for personalized treatments for patients with cancer."

The Tempus xR IVD assay is a qualitative next generation sequencing-based in vitro diagnostic device that uses targeted high throughput hybridization-based capture technology for detection of rearrangements in two genes, using RNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens from patients with solid malignant neoplasms. Information provided by xR IVD is intended to be used by qualified health care professionals in accordance with professional guidelines in oncology for patients with previously diagnosed solid malignant neoplasms. Results from xR IVD are not intended to be prescriptive or conclusive for labeled use of any specific therapeutic product.

The FDA authorization further solidifies Tempus as a one-stop-shop for precision medicine solutions. Collaborators can leverage Tempus' comprehensive collection of intelligent diagnostics and growing multimodal dataset that supports therapeutic innovation. xR IVD is one of the many solutions Tempus is applying to advance oncology therapeutic research and development.

### About Tempus

Tempus is a technology company advancing precision medicine through the practical application of artificial intelligence in healthcare. With one of the world's largest libraries of multimodal data, and an operating system to make that data accessible and useful, Tempus provides AI-enabled precision medicine solutions to physicians to deliver personalized patient care and in parallel facilitates discovery, development and delivery of optimal therapeutics. The goal is for each patient to benefit from the treatment of others who came before by providing physicians with tools that learn as the company gathers more data. For more information, visit [tempus.com](https://tempus.com).

### Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended, about Tempus and Tempus' industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release are forward-looking statements, including, but not limited to, statements regarding the potential for Tempus' xR assay to support therapeutic research as well as forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "going to," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Tempus cautions you that the foregoing may not include all of the forward-looking statements made in this press release.

You should not rely on forward-looking statements as predictions of future events. Tempus has based the forward-looking statements contained in this press release primarily on its current expectations and projections about future events and trends that it believes may affect Tempus' business, financial condition, results of operations and prospects. These forward-looking statements are subject to risks and uncertainties related to: Tempus' financial performance; the ability to attract and retain customers and partners; managing Tempus' growth and future expenses; competition and new market entrants; compliance with new laws, regulations and executive actions, including any evolving regulations in the artificial intelligence space; the ability to maintain, protect and enhance Tempus' intellectual property; the ability to attract and retain qualified team members and key personnel; the ability to repay or refinance outstanding debt, or to access additional financing; future acquisitions, divestitures or investments; the potential adverse impact of climate change, natural disasters, health epidemics, macroeconomic conditions, and war or other armed conflict, as well as risks, uncertainties, and other factors described in the section titled "Risk Factors" in Tempus' Quarterly Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the Securities and Exchange Commission ("SEC") as well as in other filings Tempus may make with the SEC in the future. In addition, any forward-looking statements contained in this press release are based on assumptions that Tempus believes to be reasonable as of this date. Tempus undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of this press release or to reflect new information or the occurrence of unanticipated events, except as required by law.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20250922109511/en/): <https://www.businesswire.com/news/home/20250922109511/en/>

Erin Carron  
[media@tempus.com](mailto:media@tempus.com)

Source: Tempus AI, Inc.