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Thermo Fisher gains expanded FDA clearance for EXENT to help monitor two blood cancers

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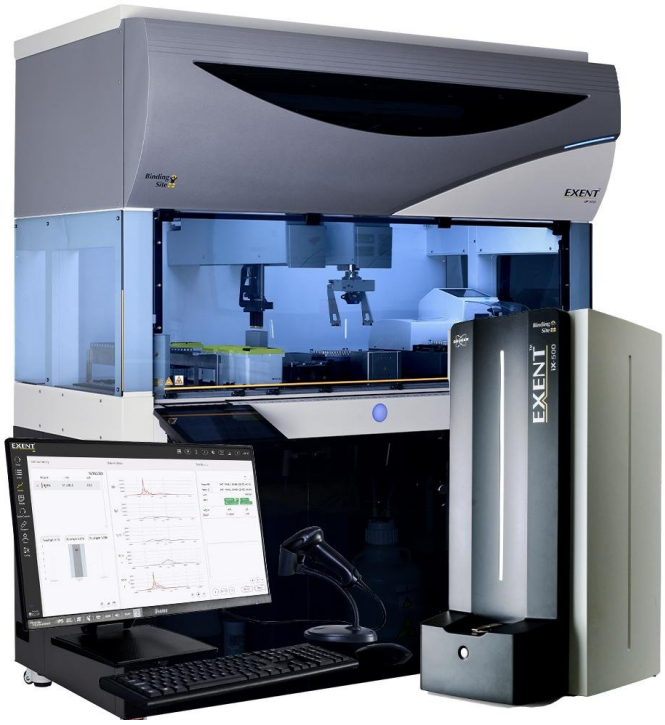
The EXENT Analyser and GAM Assay use mass spectrometry to track monoclonal proteins, helping clinicians assess disease status and treatment response in patients with multiple myeloma or WaldenstrÃ¶mâ??s macroglobulinaemia.



Thermo Fisher Scientific Inc. the world leader in serving science, announced that the U.S. Food and Drug Administration (FDA) has cleared an expanded intended use for its EXENT Analyser with the EXENT GAM Assay, enabling clinical laboratories to use mass spectrometry-based testing to aid in monitoring of disease status and treatment response in patients with multiple myeloma and Waldenström's macroglobulinemia. Building on the EXENT system previous clearance to aid in diagnosis, this milestone expands the system's clinical utility across the patient journey, helping clinicians detect and track monoclonal proteins over time, including at low concentrations, and distinguish disease-related proteins from certain known therapeutic antibodies.

Over the last three years, the EXENT system has been used to test thousands of patients in 13 countries, expanding access to innovative testing technology and helping clinicians gain deeper insights into their patients' disease. The expanded clearance addresses a critical challenge in managing these complex blood cancers: giving clinicians greater insight into how a patient's disease is changing and responding to treatment. By bringing sensitive, specific mass spectrometry-based testing directly into clinical laboratories, the EXENT system enables healthcare providers to monitor patients over time using a single platform, from initial diagnosis through ongoing disease management.

"For patients living with multiple myeloma or Waldenström's macroglobulinemia, understanding how their disease is responding to treatment is critical," said Stephen Harding, vice president and general manager, protein diagnostics, Thermo Fisher Scientific. "This expanded clearance brings the precision of mass spectrometry beyond diagnosis and into ongoing monitoring, giving clinicians greater insight into disease status and treatment response. It reflects our commitment to bringing innovative diagnostics into clinical practice to help physicians make more informed decisions and give patients greater confidence in their care."

Clinical Need and Technology

Multiple myeloma and Waldenström's macroglobulinemia are both monoclonal gammopathies that require frequent, sensitive monitoring of M-protein levels to assess disease status, treatment response and detect potential relapse. Patients are typically monitored for M-protein levels throughout their lifetime following diagnosis. According to the National Cancer Institute, an estimated 36,000 new cases of multiple myeloma occurred in the United States in 2026.

Conventional methods may present challenges when M-protein concentrations are low or when treatment-related antibodies interfere with interpretation. Within its cleared intended use, the EXENT system uses mass spectrometry-based detection to identify and track M-proteins, helping clinicians assess disease status and treatment response over time. It also allows clinicians to track a patient's disease as it evolves, including when the immune system is rebounding after therapy. Together, these limitations underscore an unmet clinical need for sensitive monitoring that can track M-proteins and help distinguish disease-related signals from known treatment-related interference.

The EXENT system is designed to address this need with mass spectrometry-based detection for routine use in clinical laboratories and requires no prior mass spectrometry expertise, allowing labs already using the EXENT system for diagnostic testing to extend the same workflow to ongoing patient monitoring. With enhanced sensitivity, objectivity and reproducibility, the technology helps provide clearer answers for clinicians to support better patient care.