

Thermo Fisher Scientific Announces the Launch of the EXENT® Solution with IVDR Certification

Transforming monoclonal gammopathy management to address an unmet clinical need through an innovative mass spectrometry solution

BIRMINGHAM, UK, August 24, 2023 /EINPresswire.com/ -- Thermo Fisher Scientific, the world leader in serving science, today announced the commercial launch of the EXENT® Solution, after receiving IVDR certification*. The EXENT solution is a fully integrated and automated mass spectrometry system designed to transform diagnosis and assessment for patients with monoclonal gammopathies, including multiple myeloma which, according to the World Health Organization in 2020, is the second most prevalent blood cancer worldwide[1]. The EXENT Solution is now commercially available in the following countries: Belgium, France, Germany, Italy, the Netherlands, Spain and United Kingdom.

The EXENT Solution enables clinical laboratories to measure, quantify and track specific endogenous M-proteins and exogenous therapeutic monoclonal antibodies with enhanced analytical sensitivity and specificity in serum. The EXENT Solution is easy to implement in routine laboratory use and features three integrated modules: EXENT-iP®500, an automated sample preparation instrument; EXENT-iX®500, a Matrix Assisted Laser Desorption Ionization - Time of Flight Mass Spectrometer (MALDI-ToF MS); and EXENT-iQ®, an intelligent and intuitive workflow software, including data review. The analyser is combined with the EXENT® Immunoglobulin Isotypes (GAM) immunoassay, a highly sensitive and specific immunoassay for measuring and quantifying IgG, IgA, and IgM.

“The EXENT Solution represents a significant breakthrough in innovation for the detection and monitoring of monoclonal immunoglobulins,” said Dr. Stephen Harding, Chief Scientific Officer, Protein Diagnostics, Thermo Fisher.

Traditionally, treatment for monoclonal gammopathies is determined by monitoring M-protein levels, which can indicate tumor size. With remarkable treatment successes in recent years, many patients are achieving M-protein concentrations below detectable limits using standard techniques. However, differences in disease progression persist within this group. The EXENT Solution addresses this unmet clinical need for more sensitive analytical methods that can differentiate between subsets, without initiating invasive bone marrow biopsy techniques too early.

The EXENT Solution was developed with Mayo Clinic intellectual property, combining industry leadership in innovation with Mayo's expertise in monoclonal gammopathy research. The EXENT Solution is intended to aid diagnosis of monoclonal gammopathies and monitoring of multiple myeloma and Waldenström's macroglobulinemia patients.

Key features and innovations of the EXENT Solution include:

- **Enhanced Analytical Sensitivity:** By pushing the boundaries of sensitivity, empowers clinicians and laboratories to monitor patients to a deeper level of response with just a serum sample.
- **Dynamic Monitoring of Unique M-proteins:** Tracking specific M-proteins over time, enabling the identification of additional M-proteins produced by emerging clones.
- **Advanced Visualization:** Presents M-proteins in a visually intuitive manner, supporting clinicians and laboratories to make informed decisions regarding endogenous M-proteins.
- **Simplified and Less Invasive Serum Testing:** Prioritizes patient comfort and convenience by requiring a simple and minimally invasive serum test.
- **Smart Software with Automated Algorithm Data Processing:** Supported by intelligent software equipped with automated algorithm data processing that minimizes manual labor, enhances data accuracy, and expedites analysis.
- **Quantification with the Optilite[®] Analyser:** In combination with the Optilite Analyser, provides precise quantification of M-proteins for comprehensive and accurate results.

Earlier this year, Thermo Fisher Scientific completed the acquisition of The Binding Site, adding protein diagnostics solutions, including diagnosis and monitoring for monoclonal gammopathies, to its specialty diagnostics portfolio.

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue over \$40 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, increasing productivity in their laboratories, improving patient health through diagnostics or the development and manufacture of life-changing therapies, we are here to support them. Our global team delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, Patheon and PPD. For more information, please visit www.thermofisher.com.

The EXENT Solution is not commercially available in the USA or China, future commercial availability cannot be guaranteed. Product availability is subject to country specific regulatory requirements. Contact your local representative for availability in your country.

EXENT, EXENT Immunoglobulin Isotypes (GAM) immunoassay, EXENT-iP, EXENT-iQ, EXENT-iX, and

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* The EXENT Solution consists of the following CE marked products: EXENT Analyser, IE800 (IVDR Class A, nonsterile), Immunoglobulin isotypes (GAM) for the EXENT Analyser - MSR801.M (IVDR Class C),

EXENT Immunoglobulin Isotypes (GAM) Control Pack - MSQ801.M (IVDR Class C).

[1] [International Agency for Research on Cancer, World Health Organization 2020](#), (Viewed on 27/07/2023)

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