EXENT®

The EXENT® System* – Transforming M-protein Measurement

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IMWG mass spectrometry committee endorses MALDI-ToF MS as an alternative to electrophoretic methods for routine clinical practice and clinical trials.[1]

Re-defining the approach to M-protein measurement

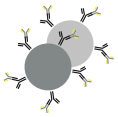
The EXENT System integrates an immunoassay with MALDI-ToF mass spectrometry to provide a sensitive and specific tool for the measurement of M-proteins.

Plasma cell clone

Each plasma cell produces a unique immunoglobulin

Unique immunoglobulins

Immunoglobulin molecules consist of two identical heavy chains and two identical light chains (Kappa or Lambda)

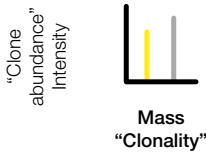


Isotype specific beads

Immunoglobulins are isolated by immuno-purification with isotype specific paramagnetic beads

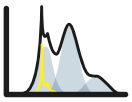
Unique heavy & light chain

Immunoglobulin molecules are dissociated into their constituent heavy and light chains. The low molecular weight of the light chains makes them ideal for analysis by MALDI-ToF mass spectrometry



The resulting mass spectra reflects the plot of mass vs intensity of the isolated and reduced immunoglobulins

In a patient without a monoclonal gammopathy (left), mass spectrometry resolves three peaks that are representative of the polyclonal Lambda, Kappa, and heavy Kappa light chains. In a patient with a monoclonal gammopathy (right), presence of a sharp peak (yellow) within the polyclonal background indicates the presence of a monoclonal immunoglobulin



Review and report

Data review software can be used to view and analyze patient results for reporting

The EXENT GAM Assay** is used to aid in the diagnosis and monitoring of monoclonal gammopathies.[2]

Entering a new era of analytical performance for M-proteins

The EXENT GAM Assay is designed to replace serum-based electrophoretic measurements throughout the patient pathway, providing enhanced analytical and clinical value.

Sensitive

Detect IgG, IgA, and IgM M-proteins down to 0.015g/L (in a 0.2g/L polyclonal background).[2] This enhanced sensitivity aids in the detection of M-proteins in patients below the levels of conventional methods.[3-5]

Specific

Monitor M-proteins by their unique molecular mass with a precision of ±4 m/z.[2] Increased specificity helps resolve interpretation challenges from oligoclonal banding and therapeutic antibody interference.[6–9]

Precise

Total precision is <8 CV% at <2g/L (all isotypes), providing enhanced analytical performance at concentrations where conventional methods are not typically able to report quantitative results.[2,3]

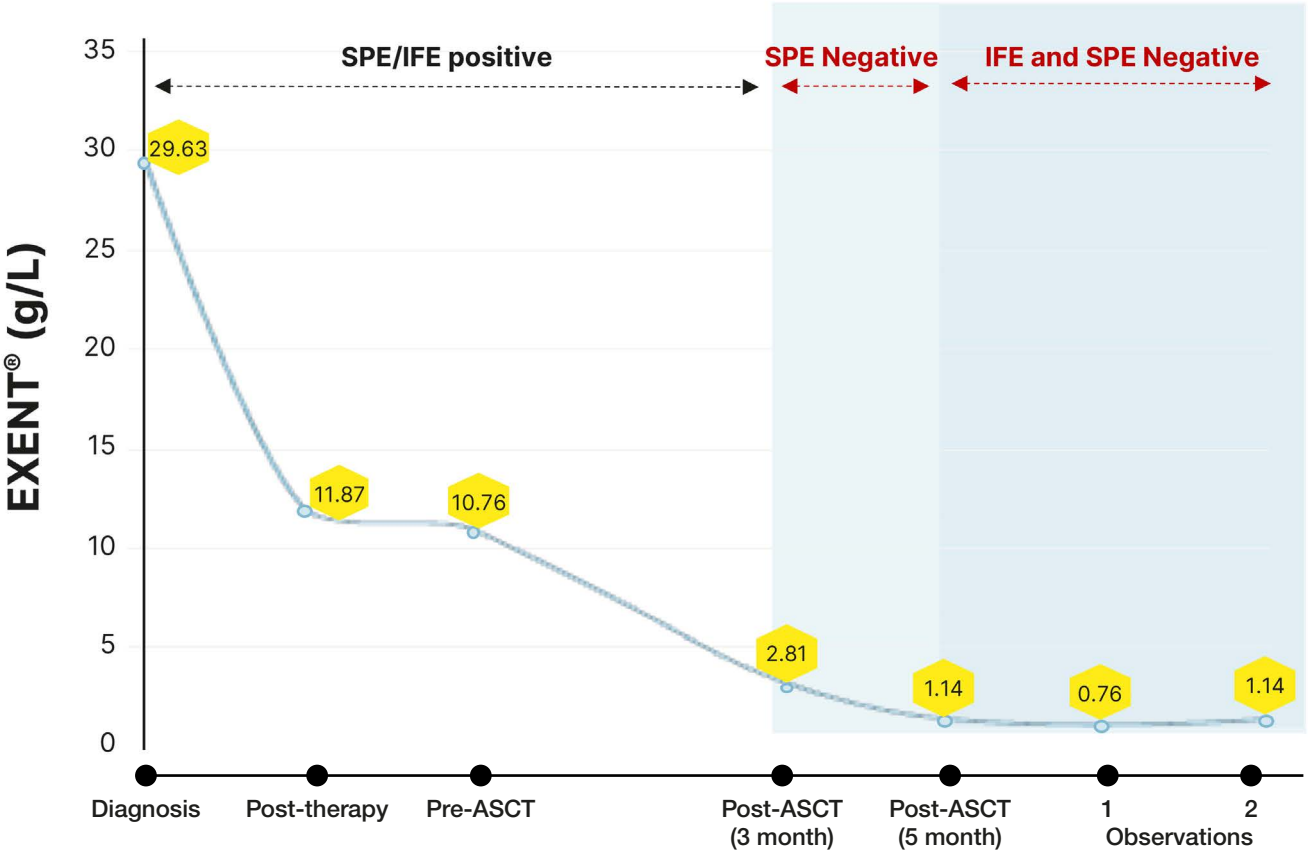
Measuring Range

A broad analytical measuring range enables M-protein measurement from high concentrations at diagnosis, to low levels in line with treatment response using a single assay.[2]

Measuring Range:
IgG - 0.015 – 88.9 (g/L)
IgA – 0.015 – 65.9 (g/L)
IgM – 0.015 – 74.2 (g/L)

The EXENT GAM Assay in action

Sequential EXENT GAM Assay results from an individual patient, demonstrating how the assay can detect M-proteins to levels below conventional methods.



The analyzer can process up to 150 patient samples within an 8 hour day

The EXENT Analyser – a sample to result solution

The EXENT Analyser streamlines laboratory workflows, enhances data interpretation and result reporting

The EXENT Analyser is comprised of three integrated steps:

Prepare

Primary serum sample to mass spectrometry ready

Automated immunoassay isolates immunoglobulins using isotype-specific paramagnetic reagents

Analyze

Rapidly analyze samples using MALDI-ToF mass spectrometry, with load and click technology

Integrated calibration and control routines are combined with automated sample measurement to remove the need for mass spectrometry expertise

Review

Easily review and release results using an intuitive data analysis software

The ability to specifically track M-proteins using their molecular mass reduces complexity and subjectivity when reviewing results

Optilite® Analyser

The EXENT System is used in conjunction with the Optilite Analyser allowing quantitative measurement of IgG, IgA and IgM immunoglobulins and qualitative measurement of IgG, IgA, IgM, total κ and total λ through an ASTM interface to a LIS/middleware.

The Optilite Analyser is not part of the EXENT System

Learn more online ›

References

1. Murray DL, et al. Blood Cancer J 2021; 11:24; 2. Immunoglobulin Isotypes (GAM) for the EXENT Analyser Instructions for Use; 3. Giles HV, et al. Blood 2022; 139:946-950; 4. Puig N, et al. Blood / Presented at ASH 2022; 140:866a; 5. Puig N, et al. J Clin Oncol 2020; 38:8512a; 6. Berlanga O, et al. Presented at AACC 2023; B371a; 7. Puig N, et al. Presented at AACC 2020; B-341a; 8. Derman BD, et al. Presented at AACC 2020; B-351a; 9. Lajko M, et al. Presented at AACC 2018; A-328a

*The EXENT® System combines EXENT® Analyser with the Immunoglobulin Isotypes (GAM) for the EXENT® Analyser
**EXENT GAM Assay refers to Immunoglobulin Isotypes (GAM) for the EXENT® Analyser

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