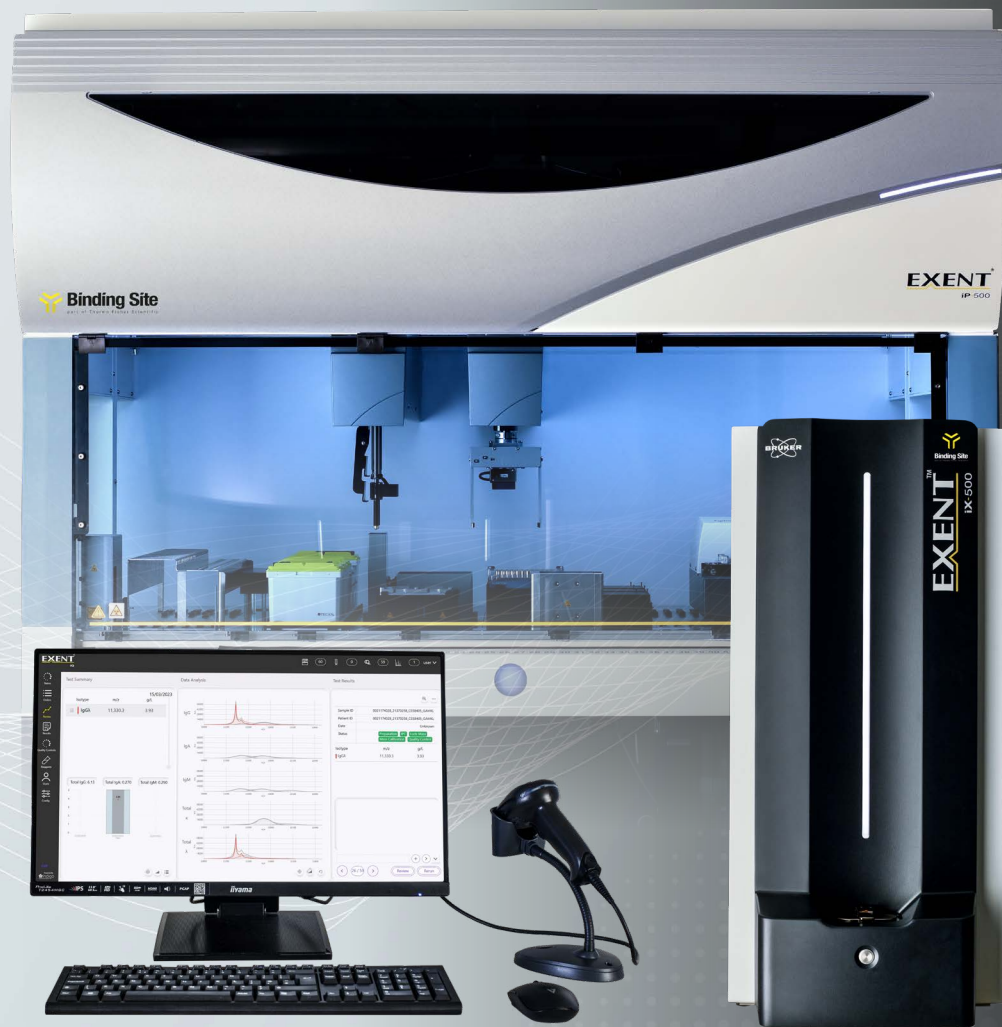


# EXENT<sup>®</sup>

The EXENT<sup>®</sup> System\* – Transforming  
M-protein Measurement





IMWG mass spectrometry committee endorses MALDI-ToF MS as an alternative to electrophoretic methods for routine clinical practice and clinical trials.<sup>1</sup>

## 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.



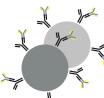
Plasma cell clone

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)



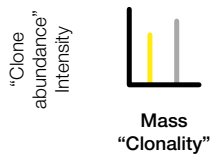
Isotype specific beads

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

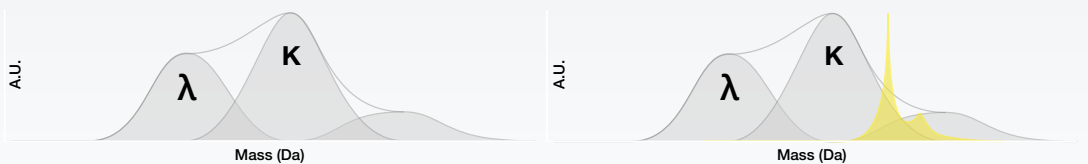


Unique heavy & light chain

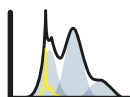
Immunoglobulin molecules are dissociated into their constituent heavy and light chains. The low molecular weight of the light chains makes them ideal for analysis by MALDI-ToF mass spectrometry



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 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.<sup>2</sup>

# 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).<sup>2</sup> This enhanced sensitivity aids in the detection of M-proteins in patients below the levels of conventional methods.<sup>3-5</sup>

## Specific

Monitor M-proteins by their unique molecular mass with a precision of  $\pm 4$  m/z.<sup>2</sup> Increased specificity helps resolve interpretation challenges from oligoclonal banding and therapeutic antibody interference.<sup>6-9</sup>

## Precise

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

## Measuring Range

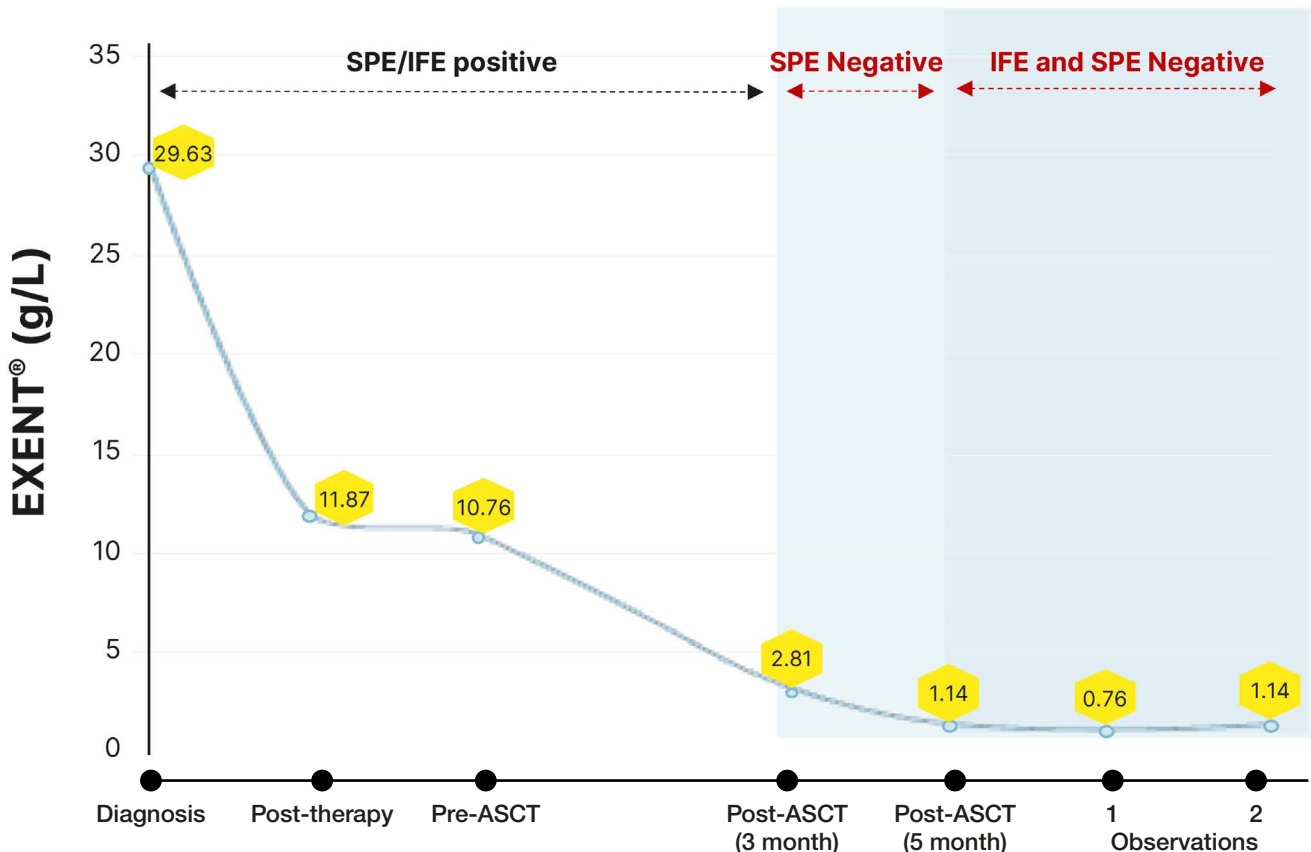
A broad analytical measuring range enables M-protein measurement from high concentrations at diagnosis, to low levels in line with treatment response using a single assay.<sup>2</sup>

### 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<sup>®</sup> 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  $\kappa$  and total  $\lambda$  through an ASTM interface to a LIS/middleware.

The Optilite Analyser is not part of the EXENT System

## 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<sup>®</sup> System combines EXENT<sup>®</sup> Analyser with the Immunoglobulin Isotypes (GAM) for the EXENT<sup>®</sup> Analyser

\*\*EXENT GAM Assay refers to Immunoglobulin Isotypes (GAM) for the EXENT<sup>®</sup> Analyser

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