Hevylite®

A novel test for measurement of Myeloma monoclonal immunoglobulins

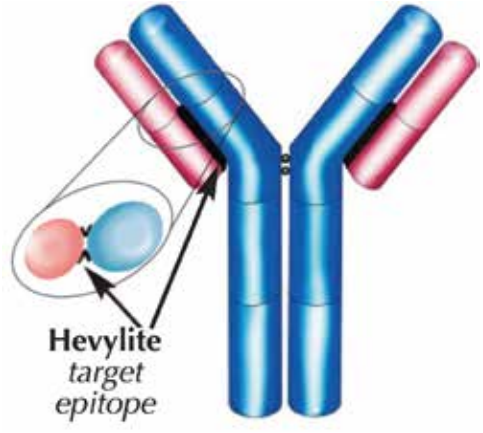
Hevylite quantifies immunoglobulin heavy chain/light chain pairs.

- Easy to interpret
- Detects monoclonal immunoglobulins masked by traditional methods
- Greater sensitivity than traditional methods
- Fully automated immunoassay

The Specialist Protein Company

Binding Site

Novel Hevylite Reagents Utilize Trusted, Proven Technology



Building on decades of experience in developing and manufacturing innovative assays such as **Freelite®**, Binding Site has developed novel assays to quantify intact immunoglobulin kappa and lambda isotypes, giving laboratorians and clinicans additional information to provide exceptionally sensitive tools to identify immunoglobulins. Intact immunoglobulin molecules contain unique junctional epitopes between the heavy chain and the light chain constant regions. These are the targets of the **Hevylite** assay. Because of the recognized epitopes, IgAκ can be measured independently of IgAλ, and IgMκ from IgMλ; this has not been previously possible. The immunoglobulin isotypes are quantified separately, and the results are used to calculate a ratio.

Hevylite—A specific, fully automated test that provides unprecedented insights into Myeloma pathology

Serum protein electrophoresis (SPE) / capillary zone electrophoresis (CZE), and immunofixation electrophoresis (IFE) have limitations for managing Myeloma patients.
Hevylite offers significant advantages over these traditional methods when managing patients with monoclonal gammopathies:

SPE/CZE/IFE versus Hevylite		
	Electrophoretic methods (SPE/CZE/IFE)	**Hevylite**
Detection	SPE/CZE—Semi-quantitative IFE—Qualitative	Quantitative
Interpretation	Can be difficult due to co-migration of proteins and less sensitive at low concentrations	Straightforward numerical results, making it easy to interpret, even at low concentrations
Throughput	Manual and labor intensive	Automated and fast

"Monoclonal proteins that migrate as broad bands can be difficult to distinguish, and quantitative assessment of immunoglobulin HLC pairs provides a measure of clonal synthesis." Donato, et al. Clin Chem 2011; 57:1645-1648

Hevylite Can Measure Myeloma Proteins When SPE is Unclear

Heavy/light chain analysis provides a sensitive method of quantifying monoclonal IgA proteins that are difficult to measure by electrophoresis

Figure 1

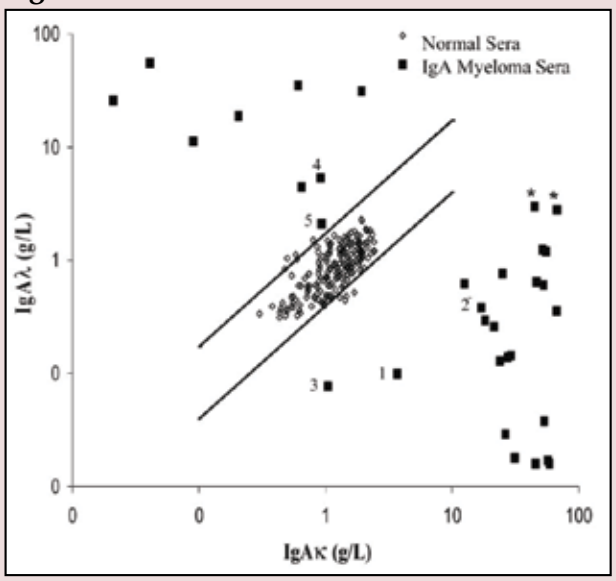
SPE of normal human serum (NHS) and 5 IgA Multiple Myeloma (MM) samples, in which SPE measurements were unreliable

Figure 2

Sample number	NHS	1	2	3	4	5
SPE appearance	normal	weak γ-band	β- and γ-bands	A_2-band	weak β-band	multiple bands
IgA (g/L)	2.29	4.37	17.0	1.71	8.7	2.47
IgAκ (g/L)	1.20	3.68	17.0	1.04	0.91	0.93
IgAλ (g/L)	0.84	0.01	0.38	0.07	5.35	2.1
IgA κ/λ ratio	1.49	37.2	44.4	13.5	0.17	0.44

Total IgA measurements plus **Hevylite** concentrations and ratios for samples from **Figure 1**

Figure 3



Samples from **Figure 1** clearly positive by **Hevylite**

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Approximately 50% of IgA MM patients and 5% of IgG MM patients* cannot be accurately monitored with SPE due to co-migration limitations.[2]

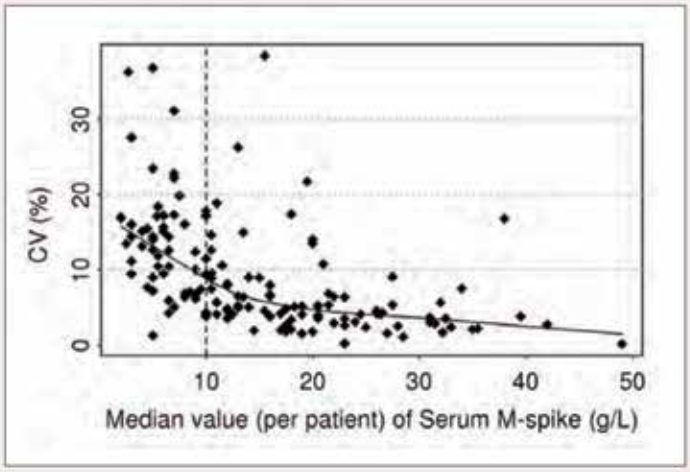
*Hevylite IgG pending FDA clearance

Remove the subjectivity of SPE/CZE/IFE.

Request Hevylite.

Traditional Methods of Measuring Low Levels of Monoclonal Proteins May be Inaccurate

SPE is inaccurate below 10g/L



This figure shows the limited sensitivity of SPE. SPE is inaccurate at concentrations below 10g/L. The lower the concentration, the greater the variability, making quantification of monoclonal protein inaccurate at low levels.[3]

CV - coefficient of variation

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Measure low level monoclonal proteins with confidence. Request Hevylite.

Hevylite FDA-cleared Intended Use

For the in vitro quantification of IgA kappa/lambda (combined α-heavy chain and κ/λ-light chain) concentration in human serum. The result is to be used with previously diagnosed IgA multiple myeloma, in conjunction with other clinical and laboratory findings.

Warning: This assay has not been established for the diagnosis, monitoring and prognosis of IgA myeloma.

For the in vitro quantification of IgM kappa/lambda (combined μ-heavy and κ/λ-light chain) concentration in human serum. The test result is to be used with previously diagnosed Waldenström's macroglobulinaemia, in conjunction with other clinical and laboratory findings.

This assay has not been established for the diagnosis, monitoring and prognosis of Waldenström's macroglobulinaemia.

References

1. Bradwell, *et al. Clin Chem* 2009; 55:1646-1655
2. Ludwig H, *et al. Leuk* 2012, 27:213-219
3. Katzmann J, *et. al. Clin Chem* 2011, 57: 1687-1692

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11/2013