



**Freelite™**  
Serum Free  
Light Chain Assay

# AL Amyloidosis

**Freelite serum free light chains can be identified in 98% of AL amyloidosis patients**

*Freelite provides specific free light chain identification from a single analysis.*

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### Accuracy of different diagnostic approaches for monoclonal proteins

Using data currently available<sup>1-4</sup>, Table 1 shows the “pick up” rate for all Multiple Myelomas, AL amyloidosis, Light Chain Multiple Myelomas and Nonsecretory Multiple Myelomas using different combinations of screening tests.

Although the maximum number of AL amyloidosis patients were detected by **Freelite** alone, it can be seen that the optimal pick up rate for all paraproteins can be achieved using simply SPE or CZE and **Freelite**.

### This screening strategy replaces the need for urine testing

Protocols	% of Paraproteins detected			
	*Myeloma	AL	LCMM	NSMM
SPE/CZE alone	90	50	45	0
SPE/CZE, serum IFE	95	70	75	0
SPE/CZE and UPE	95	75	90	0
SPE/CZE, UPE, serum and urine IFE	97	90	95	0
FLC alone	96	98	100	82
SPE/CZE and FLC	99	98	100	82
SPE/CZE, FLC and serum IFE	99	98	100	82

Table 1.

**SPE: Serum Protein Electrophoresis, CZE: Capillary Zone Electrophoresis, IFE: Immunofixation Electrophoresis, FLC: Free Light Chains, LCMM: Light Chain Multiple Myeloma, NSMM: Nonsecretory Multiple Myeloma, AL: AL amyloidosis**

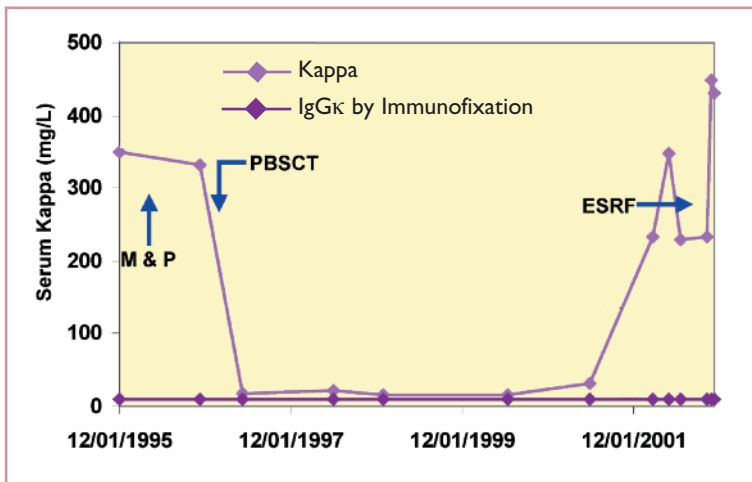
\*Myeloma is inclusive of samples from patients identified with Intact Immunoglobulin Multiple Myeloma, Light Chain Multiple Myeloma and Nonsecretory Multiple Myeloma.

### Confidence

In a retrospective analysis of stored serum, 98% of patients had abnormal free light chain concentrations. Monoclonal immunoglobulin could not be detected by electrophoresis or immunofixation in either serum or urine in 55 (21%) of this patient group.<sup>2</sup>

- Serum free light chains provide a more sensitive marker than electrophoresis and immunofixation in serum. This enables detection of most amyloidosis from a serum sample.
- Use of the serum kappa/lambda ratio ensures confidence in results, irrespective of renal impairment.
- **Freelite** eliminates the problems of patient compliance with 24-hour urine sample collections.
- **Freelite** can help you evaluate the effectiveness of chemotherapy rapidly.

## Freelite can provide effective monitoring of AL amyloidosis



*Changes in serum monoclonal proteins during the disease course of a patient with AL amyloidosis.*

*M&P: melphalan & prednisolone; PBSCT: peripheral blood stem cell autograft; ESRF: end stage renal failure*

Subsequently, symptoms progressed (loss of weight, worsening renal function, aspiration pneumonia, syncopal episodes) in parallel with rising serum free kappa levels but the monoclonal IgG kappa (detectable by IFE) remained unchanged. Progressive renal and cardiac failure indicated the terminal phase of the illness and the patient became too ill to be treated with chemotherapy.

The availability of free light chain assay results, prompting earlier chemotherapy, may have produced a more favourable outcome.<sup>1</sup>

### Clinical case history

Throughout this patient's illness, there was a low level of monoclonal IgG kappa in the serum which was detectable by immunofixation electrophoresis.

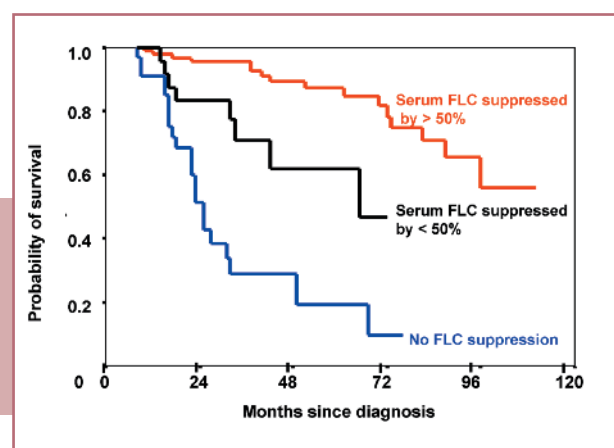
However, changes in its concentration were not sufficient to act as a useful clinical marker.

**Retrospective** analysis of serum samples showed a monoclonal free kappa protein had been present at various stages of the patient's disease. It was high at presentation, fell following the stem-cell autograft and was undetectable for several years. It then recurred in August 2000 as minor symptoms developed.

## Peace of mind

- The high sensitivity of the **Freelite** assay allows accurate identification of patient plateau status.
- Reduction of amyloidogenic serum free light chain concentration can suppress accumulation of AL amyloid deposits.
- Serum free light chains have a circulation life of several hours compared to several weeks for intact immunoglobulin, and so can be a much earlier indicator of response to therapy.
- **Freelite** can help minimise patients exposure to unnecessary chemotherapy.
- Guidelines state that treatment should be continued until clonal disease has been substantially suppressed by at least 50-70% or until plateau, and should be monitored by serum free light chain assay.<sup>5</sup>

*Kaplan-Meier estimate of survival in 137 patients with AL showing that a reduction of free light chain concentrations by greater than 50% following chemotherapy was associated with increased survival.<sup>1</sup>*



## Freelite Analysis

**Freelite** assay time is less than 20 minutes, facilitating rapid clinical decisions.

All kits are FDA cleared for *in vitro* diagnostic use to aid in the diagnosis and monitoring of Multiple Myeloma, Lymphocytic neoplasms, Waldenstrom's macroglobulinaemia, AL amyloidosis, Light Chain Deposition Disease and connective tissue diseases such as Systemic Lupus Erythematosus.

**Freelite** is CE marked for many European countries, please contact us for the latest information.

Assays are available on a wide range of automated platforms, ensuring accuracy and reduced hands on time.

## Ordering information

Analyser	Description	Pack	Code
Dade Behring BN™II	Freelite Kappa Kit	2 x 50 test	LK016.T
	Freelite Lambda Kit	2 x 50 test	LK018.T
Dade Behring BN ProSpec®	Freelite Kappa Kit	2 x 50 test	LK016.P
	Freelite Lambda Kit	2 x 50 test	LK018.P
Beckman Coulter IMMAGE®	Freelite Kappa Kit	2 x 50 test	LK016.IM
	Freelite Lambda Kit	2 x 50 test	LK018.IM
Roche Hitachi 911/912/917/P module	Freelite Kappa Kit	2 x 50 test	LK016.H
	Freelite Lambda Kit	2 x 50 test	LK018.H
Olympus AU400/640/2700/5400	Freelite Kappa Kit	2 x 50 test	LK016.AU
	Freelite Lambda Kit	2 x 50 test	LK018.AU

Protocols for other instruments are being developed so please contact us for the latest information.

## References

1. Serum Free Light Chain Analysis. A.R. Bradwell 2004
2. Lachmann *et al.* Outcome in systemic AL amyloidosis in relation to changes in concentration of circulating free immunoglobulin light chains following chemotherapy. *British Journal of Haematology* 2003; **122**: 78-84
3. Bradwell *et al.* Serum test for assessment of patients with Bence Jones myeloma. *Lancet* 2003; **361**:489-491
4. Drayson *et al.* Serum free light-chain measurements for identifying and monitoring with nonsecretory multiple myeloma. *Blood* 2001; **97**: 2900-2902
5. United Kingdom Myeloma Forum. Guidelines on the diagnosis and management of AL amyloidosis. *British Journal of Haematology* 2004; **125**: 681-700

## Additional References

Roshini *et al.* Quantitative Analysis of Serum Free Light Chains, A New Marker for the Diagnostic Evaluation of Primary Systemic Amyloidosis. *American Journal of Clinical Pathology* 2003; **119**:274-278

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