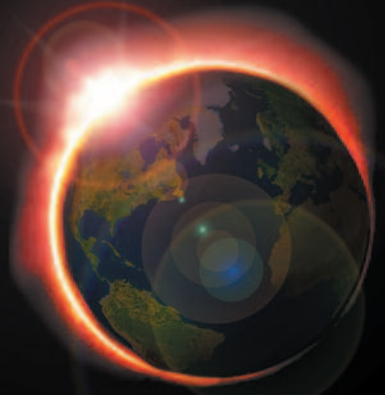


Freelite™
Serum Free
Light Chain Assay

Monoclonal Gammopathy of Undetermined Significance

Identify your low risk MGUS patients

The serum free light chain ratio is an independent risk factor for progression to myeloma or related malignancies.

THE BINDING SITE

Identify your low risk MGUS patients.

The serum free light chain ratio is an independent risk factor for progression to myeloma or related malignancies.

Monoclonal gammopathy of undetermined significance (MGUS) affects some 3% of persons aged 50 years or older.[1] The majority of MGUS patients will not develop multiple myeloma or a related disorder in their lifetime.
However, as approximately 1% of MGUS patients will progress to disease each year, the management of MGUS patients presents a significant challenge to healthcare professionals.

For the first time, simple serum analysis will enable you to risk stratify your MGUS patients. The risk stratification uses several independent markers, of which the kappa and lambda free light chain ratio (κ/λ) is a major new factor.

Freelite is a sensitive, specific marker of kappa and lambda free light chains in serum.

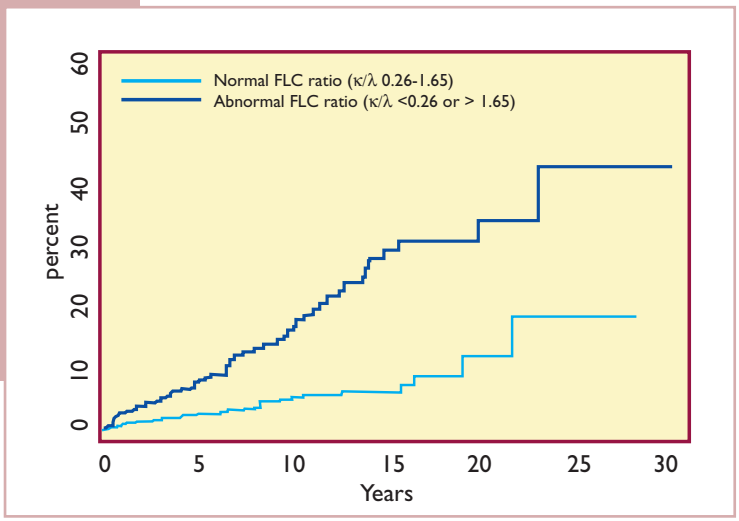
Risk stratification

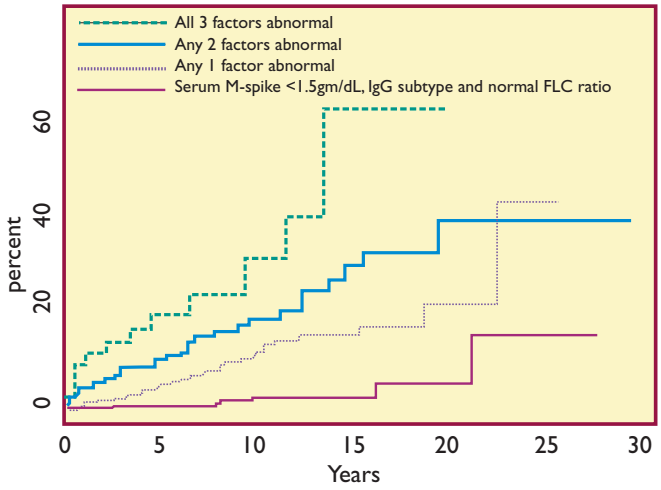
In a recent study of 1148 MGUS patients seen at the Mayo Clinic between 1960 and 1994, an abnormal serum kappa/lambda free light chain ratio was identified as a major independent risk factor for progression of MGUS to myeloma or a related malignancy.[2]
This risk stratification identified a low risk subset (40%) with a remarkably small life-time risk of progression, only 2% over 20 years.

	Risk Factors	Number of Patients	Absolute Risk of Progression at 20 Years	Absolute Risk of Progression at 20 Years*
Low-Risk	Normal FLC ratio (0.26 -1.65), serum M protein <1.5gm/dL, IgG subtype	**449**	**5%**	**2%**
Low-Intermediate Risk	Any 1 factor abnormal	**420**	**21%**	**10%**
High-Intermediate Risk	Any 2 factors abnormal	**226**	**37%**	**18%**
High-Risk	All 3 factors abnormal	**53**	**58%**	**27%**

*Accounting for death as a competing risk
FLC = Free Light Chain

The upper curve illustrates risk of progression of monoclonal gammopathy of undetermined significance in patients with an abnormal serum kappa/lambda free light chain ratio (<0.26 or >1.65). The lower curve illustrates the risk of progression in patients with a normal ratio.





Risk of progression of MGUS to myeloma or related disorder using a risk stratification model that incorporates the free light chain ratio and the size and type of the serum monoclonal protein.

Freelite and MGUS patient management

Freelite provides a sensitive quantitative measurement of serum free light chains, free kappa and free lambda. The ratio of these measurements is highly indicative of monoclonality.
The clinical application of serum free light chain measurement is already well characterised for the diagnosis and monitoring of AL amyloid[3], Nonsecretory Multiple Myeloma[4], Light Chain Multiple Myeloma[5] and Intact Immunoglobulin Multiple Myeloma[6] patients.

Now an abnormal serum free light chain ratio has been identified as an important, independent risk factor for progression of MGUS to myeloma or related malignancies.

Freelite can contribute to the management of your MGUS patients.

- Low risk patients may account for 40% of all MGUS patients.[2]
- **Freelite** enables you to provide reassurance to low risk MGUS patients.
- High risk patients may account for 5% of all MGUS patients.[2]
- **Freelite** enables you to identify high risk patients and monitor them more closely.
- Risk stratification of MGUS patients with **Freelite** will enable you to allocate resources appropriately.

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 for analysis.

Ordering information

Analyser	Description	Pack	Code
Dade Behring	Freelite Kappa Kit	2 x 50 test	LK016.T
BN™II	Freelite Lambda Kit	2 x 50 test	LK018.T
Dade Behring	Freelite Kappa Kit	2 x 50 test	LK016.P
BN ProSpec®	Freelite Lambda Kit	2 x 50 test	LK018.P
Beckman Coulter	Freelite Kappa Kit	2 x 50 test	LK016.IM
IMMAGE®/IMMAGE® 800	Freelite Lambda Kit	2 x 50 test	LK018.IM
Roche Hitachi	Freelite Kappa Kit	2 x 50 test	LK016.H
911/912/917/P module	Freelite Lambda Kit	2 x 50 test	LK018.H
Olympus	Freelite Kappa Kit	2 x 50 test	LK016.AU
AU400/640/2700/5400	Freelite Lambda Kit	2 x 50 test	LK018.AU
Bayer*	Freelite Kappa Kit	2 x 50 test	LK016.B
ADVIA®1650	Freelite Lambda Kit	2 x 50 test	LK018.B

*Please enquire regarding current FDA status

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

References

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2. S. Vincent Rajkumar *et al*. Serum free light chain ratio is an independent risk factor for progression in monoclonal gammopathy of undetermined significance (MGUS). *Blood* 2005;**106**:3:812-817
3. United Kingdom Myeloma Forum. Guidelines on the diagnosis and management of AL amyloidosis. *British Journal of Haematology* 2004;**125**:681-700
4. Drayson *et al*. Serum free light-chain measurements for identifying and monitoring patients with nonsecretory multiple myeloma. *Blood* 2001;**97**:2900-2902
5. Bradwell *et al*. Serum test for assessment of patients with Bence Jones myeloma. *Lancet* 2003;**361**:489-491
6. Mead *et al*. Serum free light chains for monitoring multiple myeloma. *British Journal of Haematology* 2004;**126**:348-354

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