

Importance of FLC

**in clinical
decision for
Myeloma
patient**



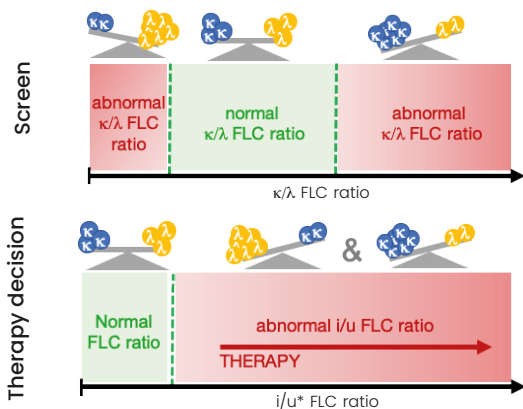
sebia 

The new language of life

WHY IS FLC MEASUREMENT IMPORTANT TO YOUR PATIENT?

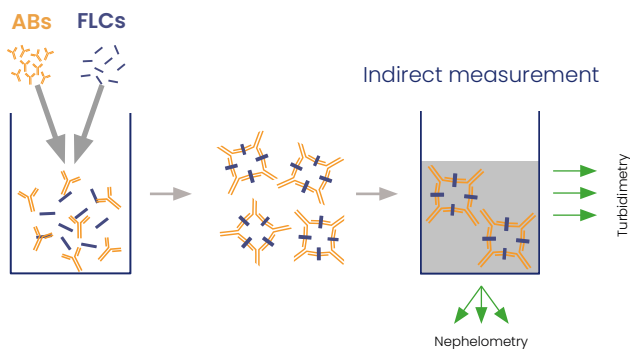
- The sFLC test is an important parameter in the diagnosis and management of patients with monoclonal gammopathies.
- sFLCs are highly heterogeneous molecules, however, the antibodies from each FLC assay react differently from one patient to another.
- Nephelometric and turbidimetric based assays have been shown to overestimate the sFLC levels that are not always consistent with Serum Protein Electrophoresis/Immunofixation and other clinical parameters.
- The Sebia sFLC ELISA assay is the only assay that reports sFLC concentrations close to those obtained by SPE when an FLC peak is present.
- No standardization is currently available for the sFLC assay unlike other laboratory tests, so there is a requirement for improving analytical accuracy in this important test.

Reference intervals and cut-off for screening and therapy



* iFLC: involved Free Light Chains
uFLC: uninvolved Free Light Chains

WHAT ARE THE LIMITATIONS OF THE CURRENT METHOD?



**Reaction
start**

**Complexes
formation**

Measurement

LIMITATIONS AND CONSEQUENCES

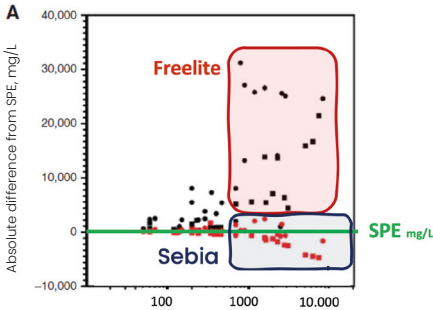
**Nephelometry/Turbidimetry
limitations**

**Possible consequences
for patients**

1. Polymerization: overestimation of FLC values¹ → Therapy too early?
2. Antigen excess: underestimation of FLC values⁶ → Therapy too late?
3. No linearity^{1, 4, 7} → Difficult to follow-up, "jumping" values
4. Variation between different systems⁵ → A comparison of FLC values between labs is not possible
5. Reference intervals exist only for one system (BNTMII)^{1, 8} → Partially incorrect interpretation of FLC values
6. Cut-off i/u* FLC ratio exists only for two tests^{1, 9} → Incorrect clinical interpretation

ADDED VALUES OF SEBIA FLC TEST

1. No overestimation by polymerization and consistency with SPE¹

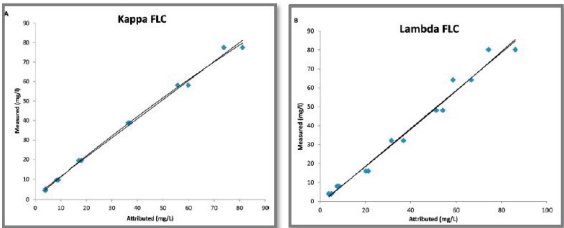


2. No underestimation by antigen excess effect⁶

Patient 1			Sebia (mg/L)
Dilutions	Lambda Freelite (mg/L)	Lambda Sebia FLC (mg/L)	
1/10	131 **	...	a Sebia (mg/L)
1/1000	>16 800	>90	
1/10 000	29 238	>900	
1/100 000	...	1791	

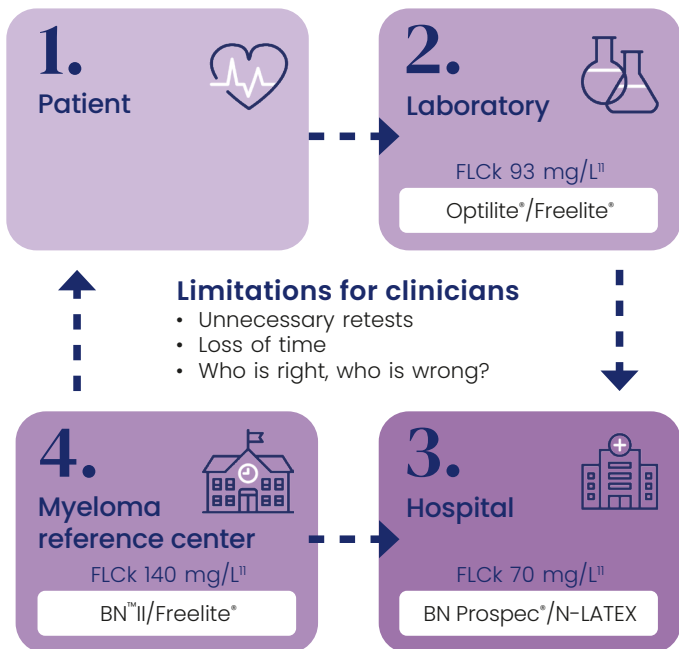
** False result leading to a wrong clinical interpretation

3. Good linearity^{1, 4, 7}



4. Currently no comparable FLC values between laboratories

Patient Journey



ONE SEBIA TEST ADAPTED TO MULTIPLE ELISA INSTRUMENTS

Sebia FLC: Reference intervals & cut-off

Normal reference ranges	Kappa - mg/L	4.9 - 13.7
	Lambda - mg/L	7.6 - 19.5
	κ/λ ratio	0.27 - 1.67
CKD reference ranges ²	κ/λ ratio	0.46 - 2.23
Myeloma defined event (SLiM criteria) ¹²	i/u s-FLC ratio	≥ 100
HR SMM CUT-OFF ¹²	i/u FLC	≥ 20

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Reference publication

¹ Jacobs JFM. et al., 2018

² Lutteri L. and Jacobs JFM., 2018

³ Caillon et al., 2019

⁴ Schieferdecker et al., 2020

⁵ Caponi et al., 2019

⁶ Pekar et al., 2019

⁷ Lutteri L. et al., 2018

⁸ Katzmann et al., 2002

⁹ Larsen et al., 2013

¹⁰ Rajkumar S.V. et al., 2014

¹¹ UK NEQAS Report, 2017, Sample 171-1/Kappa

¹² Willrich M. et al, Blood Cancer Journal, 2022

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