Defining a new standard of excellence in Serum Free Light (sFLC) Chain testing

Sebia FLC assay has better clinical specificity than the FreeLite® assay in a cohort of patients with signs and symptoms suggestive of Multiple Myeloma

Summary

The study compared the Sebia sFLC ratios to the FreeLite assay FLC ratios in 176 patients with conditions that were non-Plasma Cell Dyscrasias (PCD – the group of diseases including multiple myeloma) but who had clinical presentation similar to PCD. The Sebia FLC assay demonstrated better specificity (87.5%) compared to FreeLite (68.7%), correctly discerning that the patients did not have PCD more often and producing fewer false positive results. The study emphasizes the importance of assay-specific reference intervals (RI) and clinical specificity studies in interpreting FLC assay results accurately in patients with suspected MM or related conditions.

Clinical specificity of two assays for immunoglobulin kappa and lambda free light chains*

Authors: Christopher W. **Farnsworth**, Brittany **Roemmich**, Grant M. **Spears**, David L. **Murray**, Angela **Dispenzieri** and Maria Alice V. **Willrich**

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Key Takeaways*

Specificity of Sebia FLC vs. FreeLite Assays:

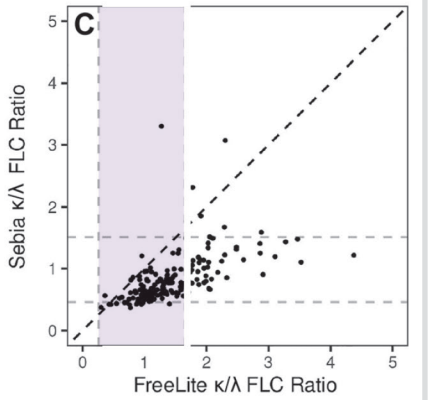
Sebia FLC assay demonstrated higher clinical specificity compared to the FreeLite assay. Specifically, 87.5% of specimens analyzed using Sebia assay were within the reference intervals (RI), while only 68.7% of FreeLite specimens were within the RI.

Impact of Kidney Disease on Assays:

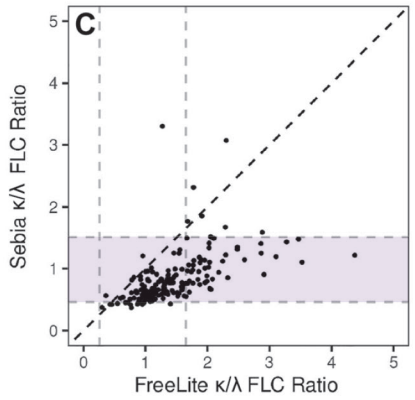
Black patients and those with impaired renal function are more likely to exhibit higher FLC κ/λ ratios, influenced at least in part by higher rates of chronic kidney disease. When renal-specific reference intervals were applied, fewer patients had results outside the RI: 13.6% with FreeLite and 4.5% with Sebia FLC. This suggests there could be reactivity differences for Sebia FLC and FreeLite assays towards dimers and monomers.

Analytical Comparisons and Correlations:

The graphs† show the correlation of κ/λ ratios between the two assays. The lower correlation coefficient demonstrates discordance between the two assays, with FreeLite tending to give higher κ/λ ratios than Sebia. For the κ/λ ratio, 31.3% (55/176) were outside RI with FreeLite assay, all of which were above RI. In contrast FLC κ/λ ratio measured with Sebia FLC, 12.5% (22/176) of results were outside RI, of which 14 were below and 8 were above.



Sebia FLC normal RI highlighted
Spearman r = 0.71
Slope = 0.507 (0.499-0.534)
Intercept = 0.067 (0.032-0.080



FreeLite normal RI highlighted
Spearman r = 0.71
Slope = 0.507 (0.499-0.534)
Intercept = 0.067 (0.032-0.080

Table 2: Proportion of results outside of the reference interval for each assay.

	Kappa	Lambda	κ/λ ratio
n	176	176	176
Below RI for FreeLite assay	3 (1.7 %)	2 (1.1 %)	0 (0.0 %)
Above RI for FreeLite assay	117 (66.5 %)	64 (36.4 %)	55 (31.3 %)
Total outside RI FreeLite	120 (68.2 %)	66 (37.5 %)	55 (31.3 %)
Below RI for Sebia assay	2 (1.1 %)	2 (2.1 %)	14 (8.0 %)
Above RI for Sebia assay	125 (71.0 %)	146 (83.0 %)	8 (4.5 %)
Total outside RI Sebia	127 (72.2 %)	148 (84.1 %)	22 (12.5 %)
p-Value[a]	0.12	<0.0001	<0.0001

[a]Bowker's symmetry test. RI, reference interval as n of samples outside RI using the κ/λ ratio. FreeLite kappa light chains, 3.3 and 19.4 mg/L|FreeLite lambda light chains, 5.7 and 26.3 mg/L kappa/lambda ratio, 0.26 and 1.65. Sebia kappa free light chains, 6.4 and 17.4 mg/L|Sebia lambda free light chains, 8.4 and 21.8 mg/L. Kappa/lambda ratio, 0.46 and 1.51.

Data outside of shaded region represents false positive result.

† *Study samples include patients with no previous diagnosis of multiple myeloma, but with other unrelated conditions. Values outside of the reference interval are not diagnostic for multiple myeloma and are likely secondary to other clinical conditions in these cohort of patients.*

Sebia | 1705 Corporate Dr # 400 | Norcross, GA 30093 | 1.800.835.6497 | info@sebia-usa.com | www.sebia-usa.com

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