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Abstract category: Laboratory Hematology

Evaluation of Sebia Free Light Chain ELISA Tests in a routine diagnostic laboratory

Mirlinda Dervisi[1] , Rachel Schoumacker[2] Denis Venet[2], Christian Kalberer[1], Giuseppe Colucci[1,3]

[1] Outer Corelab, Viollier AG, Allschwil
[2] SEBIA, Parc Technologique Léonard de Vinci, Lisses, France
[3] Department of Hematology, University of Basel, Basel

Background and Objective

Serum free light chain (FLC) Kappa/Lambda ratio is used for diagnosis and monitoring of clonal B-cell or plasma cell disorders. This study compares the concordance of FLC measured with Freelite on the Optilite (The Binding Site) and SEBIA FLC (Sebia) on the Dynex Agility platform.

Methods

Non-interventional study analyzing consecutive, unselected samples in routine diagnostic laboratory settings using both methods. Patients were classified as normal, high-risk smoldering multi-ple myeloma (HRSMM) or multiple myeloma (MM) based on FLC results obtained with Freelite and Sebia according to IMWG criteria, i.e. K/L ratio > 20 for HRSMM and K/L ratio > 100 for MM, respectively. Comparation and agreement were assessed with appropriate nonparametric tests.

Results

Between January 28, and June 3, 2025, a total of 2995 samples were analyzed; 36 (1.2%) samples were excluded and 2959 (98.2%) included in the statistical analysis. Concentration of FLC and the K/L ratio were significantly different between both methods ($p<0.0001$), especially for samples with high levels of FLC (> 150 mg/L; $p<0.0001$). Methods agreement was high (96.3%) for cohorts with normal K/L ratio but low for cohort with abnormal ratio (47.2%).

Overall, the agreement classification with IMWG criteria reached 77.8% [95% CI: 76.2% - 79.2%] for the total cohort, 57.4% [95%CI: 48.0% - 66.3%] for the HRSMM group and 45.5% [95% CI: 33.0% - 58.5%] for the MM group.

1609 samples out of 2959 (54% of the cohort) were negative for monoclonality at both protein electrophoresis and immunofixation. Of these, 294 samples (18.3%) fell outside the normal range (0.26 – 1.65) with the Freelite test, mostly just above the upper limit, while with Sebia they were within normal limits (0.27 – 1.67). 81% of these outliers had Freelite ratios between 1.65 and 2.14. Only 2.1% of samples with normal Freelite ratios exceeded the Sebia reference values.

Conclusion

Quantitative agreement between both methods was low, probably explained by Freelite limitations such as Kappa drift, as already known in the literature. Despite limited quantitative agreement, IMWG risk classification was good, supporting commutability of the “20” and “100” cut-offs with Sebia FLC assays. Because this study does not include clinical data, further studies are needed to confirm this observation.

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VIOLLIER