Defining a new standard of excellence in sFLC testing

*Sebia's assay demonstrates clinical equivalence in a study performed at The Mayo Clinic**

Summary

The Serum Free Light Chain (sFLC) testing guidelines, established by the International Myeloma Working Group (IMWG), were conducted using the Freelite® Assay on the Siemens BNII analyzer. This clinical study, performed by the Mayo Clinic Department of Laboratory Medicine and Pathology, has demonstrated that Sebia's sFLC assay, when compared to The Binding Site's™ Freelite® assay, has clinical equivalence and commutability in regard to the ratio Free Light Chain (rFLC) of >100 and >20. These ratios are key diagnostic criteria when determining a patient's status of Multiple Myeloma.

Comparison of two free light chain assays:

Performance of the involved free light chain ratio and implications for diagnosis of multiple myeloma

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

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Key Takeaways

Sebia's FLC assay is clinically equivalent and commutable to The Binding Site's™ Freelite® assay

- The rFLC of >100 can be used with Sebia's sFLC assay
  - rFLC > 100 is one of the diagnostic criteria used to determine if a patient has Multiple Myeloma
- The rFLC > 20 can be used with Sebia's sFLC assay
  - FLC >20 is one of the risk criteria used to determine how likely the patient with Smoldering Multiple Myeloma (SMM) is to progress to Multiple Myeloma

Multiple sFLC assays on the market could improve the diagnosis and monitoring of Multiple Myeloma and SMM

- Enabling smaller labs to gain access to the sFLC assay
- Provide significant financial savings
- Allow more labs to be in alignment with CAP screening guidelines

Harmonization between assays

- Despite the analytical differences between Freelite® and Sebia's sFLC assay, the existing FLC criteria for Multiple Myeloma and SMM is applicable

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