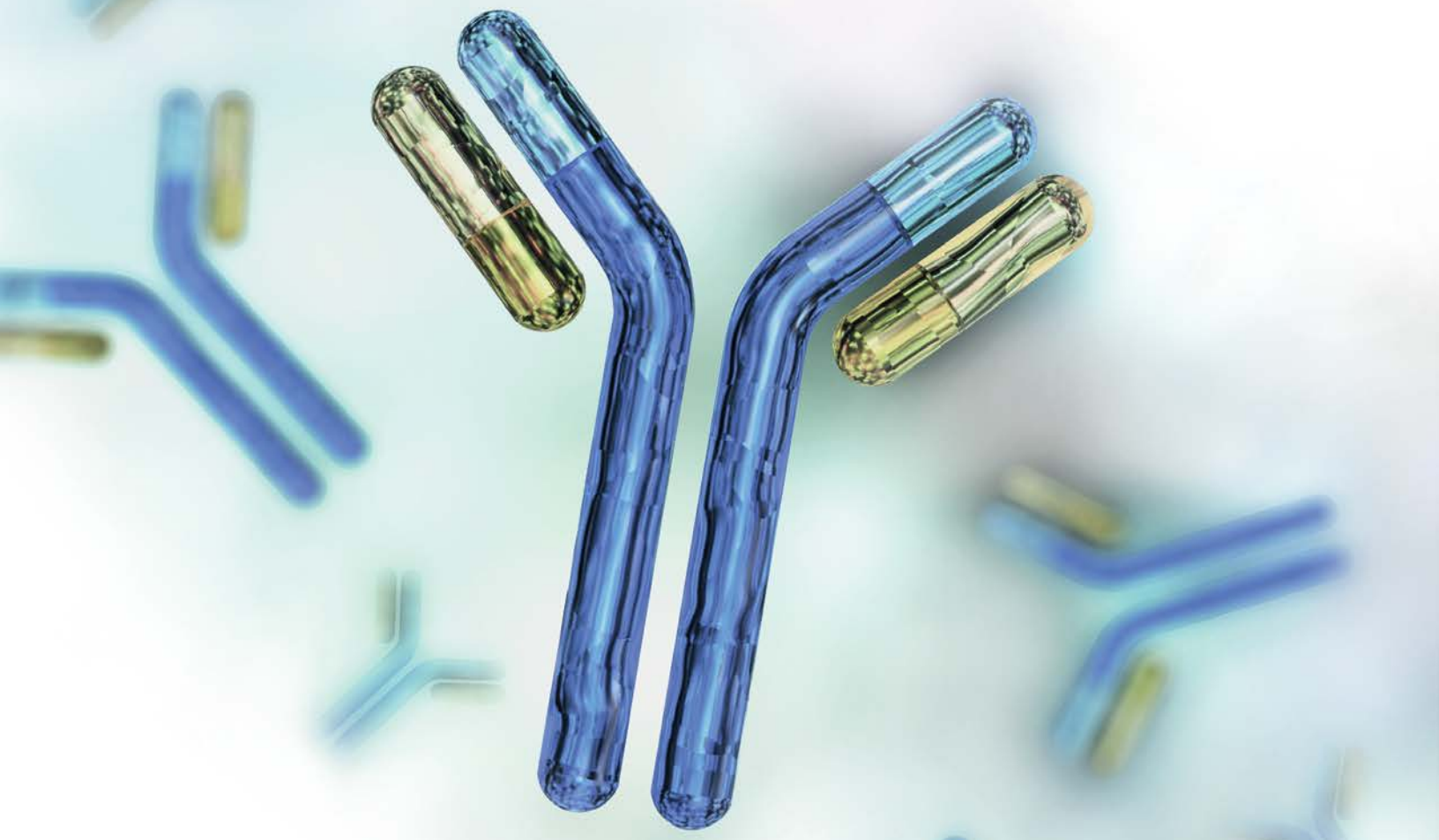
FLC Kappa

FLC Lambda

Defining a New Standard of Excellence *in Serum Free Light Chain Testing*

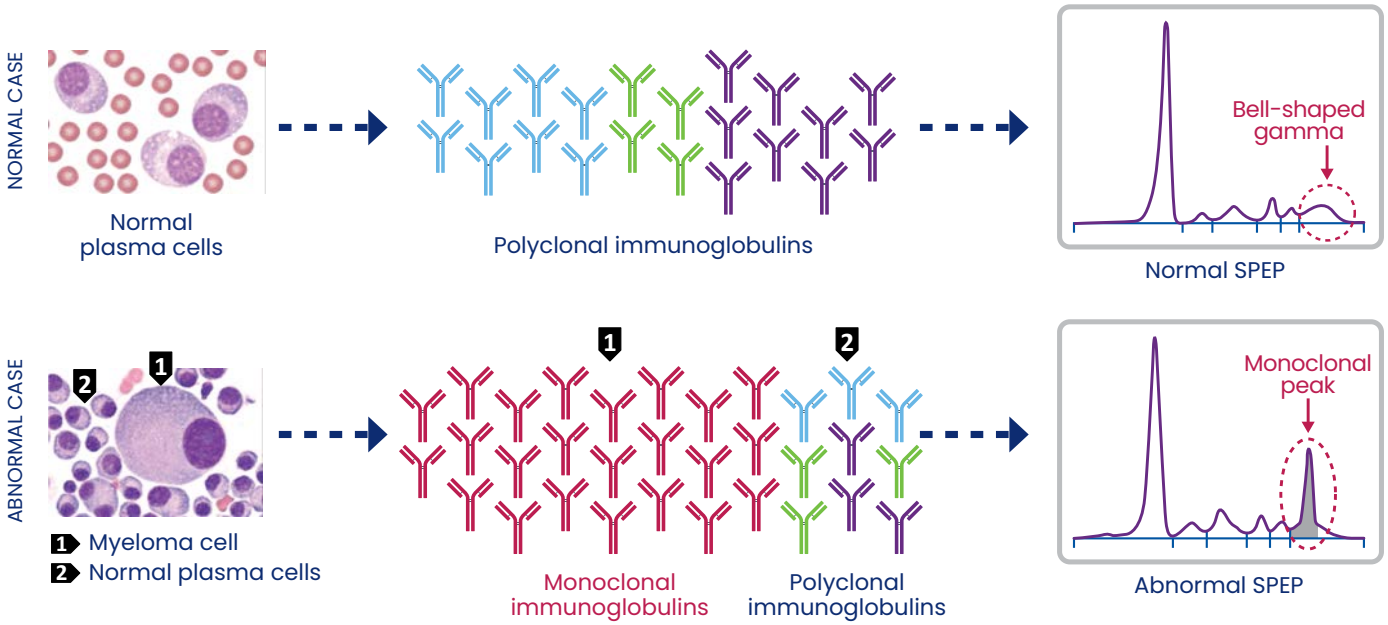


sebia

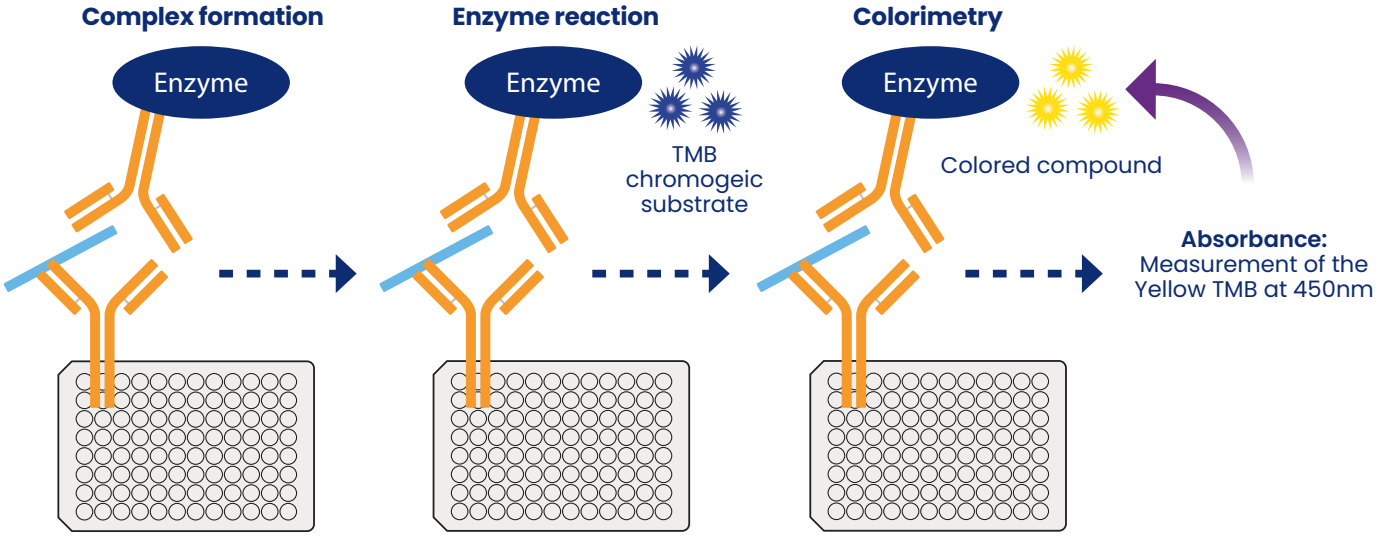
The new language of life

Why is FLC an *important biomarker?*

Free Light Chains are a **very sensitive biomarker reflecting the status of monoclonal gammopathies.**



ELISA *Principle*



Introducing a new analyte on a well-established methodology, compatible with a wide range of platforms

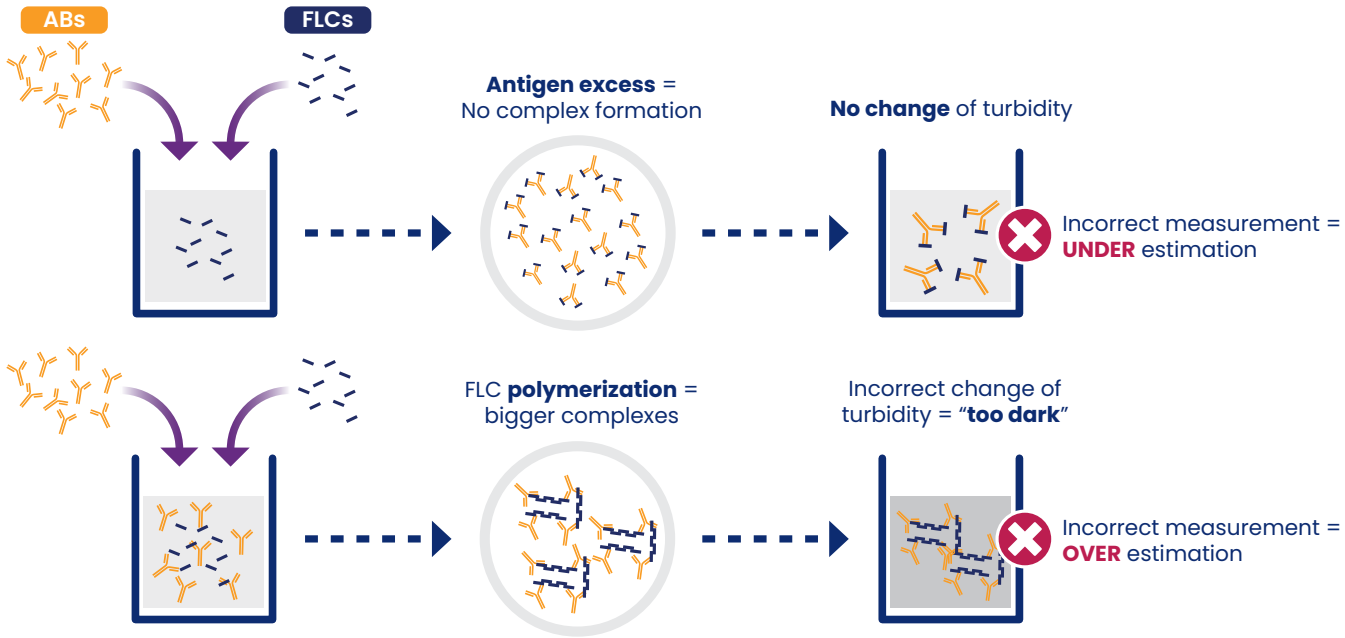
Limitations and Challenges *of Existing Methods*

Analytical & Clinical Limitations

- Antigen excess[1]
  - Potential to underestimate high sFLC concentrations, leading to false negatives
- Polymerization[2]
  - Multi-reactivity can lead to complex formation, resulting in potential overestimation of sFLC results
- Potential overestimation by up to 7x, resulting in potentially incorrect clinical interpretations[5]
- Lack of agreement with SPE[3]
  - Resulting in potential overestimation of sFLC results

Impact to Laboratory & Clinicians

- Unnecessary retests
- Potential inaccuracy of results due to lack of linearity



1. Bosmann M, Kossler J, Stolz H, Walter U, Knop S, Steigerwald U. Detection of serum free light chains: the problem with antigen excess. Clin Chem Lab Med 2010;48:1419—22.

2. Vercammen M, Meirlaen P, Broodtaerts L, Broek IV, Bossuyt X. Effects od sample dilution on serum free light chain concentration by immunonephelometric assay. Clin Chim Acta 2011;412:1798—804.

3. Vavrova J, Maisnar V, Tichy M, Friedecky B, Cermakova Z, Dastych M, et al. Interlaboratory study of free monoclonal immunoglobulin light chain quantification. Clin Chem Lab Med 2011;49:89—92.

Advantages and Opportunities *of sFLC by Sebia*

Analytical & Clinical Performance

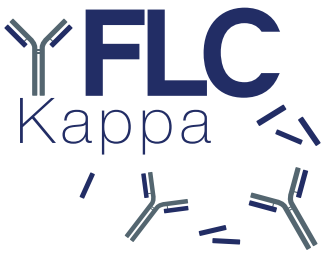
- Clinical equivalence and commutability in regard to the ratio Free Light Chain (rFLC) of >100 and >20
  - >20 and >100 sFLC ratios are key diagnostic criteria when determining a patient's status of Smoldering Multiple Myeloma (SMM) and Multiple Myeloma[4]
  - The existing FLC criteria for Multiple Myeloma and SMM is commutable when using Sebia's sFLC assay[4]
- Agreement with SPE[5]
  - Minimizes risk of overestimation of sFLC
- Reduced Impact from Antigen Excess
  - Minimizes risk of underestimation of high sFLC concentrations
  - Reduces potential discrepancies in results

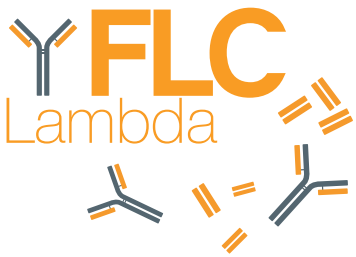
Impact to Laboratory & Clinician

- Reduced repeat rate[5]
  - Up to 4x times fewer repeats compared to current methods, resulting in potential significant cost savings
- Accessibility
  - Affordable reagents and accessible methodologies allow sFLC by Sebia to be run in any laboratory

Flexible ELISA Compatibility

- Dynex DS2®
- Dynex DSX®
- Dynex Agility®
- Gold Standard ThunderBolt®
- Gold Standard The Bolt®





4. Willrich MAV, Murray DL, Rajkumar SV, Bryant SC, Larson D, Pazdernik V, Snyder MR, Kyle RA, Dispenzieri A. Comparison of two free light chain assays: performance of the involved free light chain ratio and implications for diagnosis of multiple myeloma. Blood Cancer J. 2022 Sep 2;12(9):127.

5. Jacobs JFM, de Kat Angelino CM, Brouwers HMLM, Croockewit SA, Joosten I, van der Molen RG. Evaluation of a new free light chain ELISA assay: bringing coherence with electrophoretic methods. Clin Chem Lab Med. 2018 Jan 26;56(2):312-322.

Sebia *sFLC Assay*

Product Information

PN 5102
Sebia FLC Kappa Kit

PN 5103
Sebia FLC Lambda Kit

PN 5112
Sebia FLC Control Level 1

PN 5113
Sebia FLC Control Level 2

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