

Proteometer-CV Charge Variant Profile



The Novilytic Proteometer-CV Kit is for the analysis of biologics containing the human IgG Fc domain, including therapeutic monoclonal antibodies (mAbs), bi-specifics, antibody-drug conjugates, and Fc-fusion proteins. The kit is utilized with an HPLC-FLD system, allowing for the simultaneous determination of charge variant profile and the titer of the analyte directly from clarified fermentation broth (CFB) *without the need for Protein A purification*.

How It Works

Sample components, including mAb charge variants and host cell proteins, are fractionated using the Proteometer-CV Reactor. The specific detection of the mAb analyte proteoforms in the fractionated sample is achieved by utilizing a fluorescently labeled affinity selector, which binds with high specificity to the Fc domain of humanized IgGs. The fluorescently labeled low molecular weight affinity selector has greater selectivity for human IgG Fc than Protein A². Contaminants in the sample are either not detectable by the fluorescence detector or are separated, thus eliminating the need for a purified mAb sample.

- The amount of bound affinity selector:
 - Quantifies the mAb analyte, providing titer within the linear dynamic range
 - Verifies the amount and presence of a functional, humanized Fc domain in the mAb
 - Correlates with the expected recovery of Protein A purified mAb product

Results

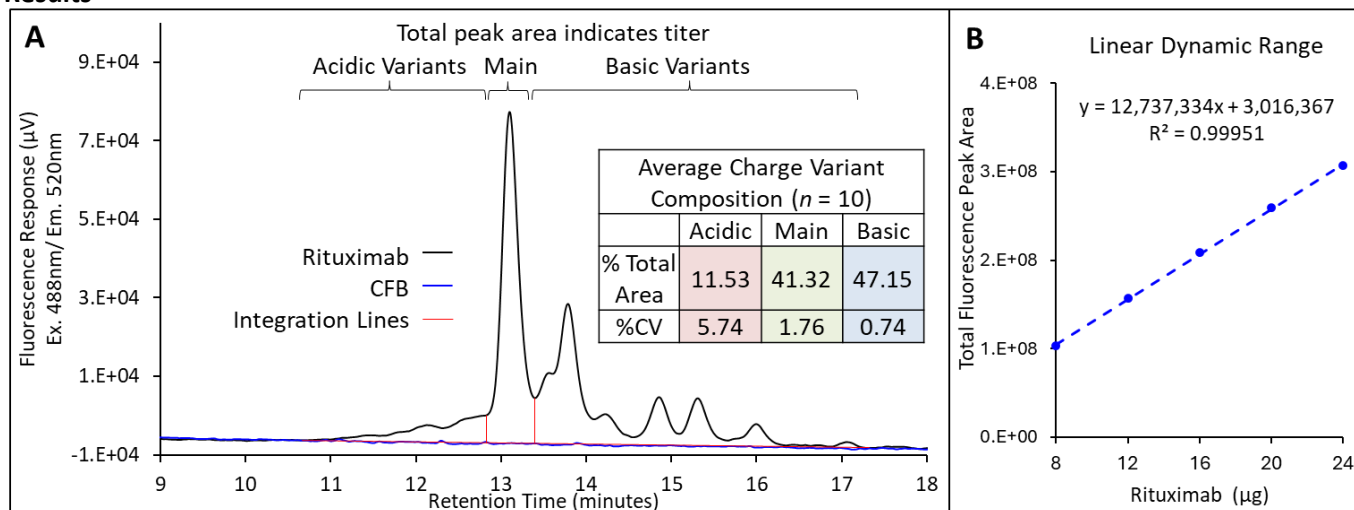


Figure 1. Proteometer-CV analysis of a Rituximab (IgG1, pI 9.3) biosimilar formulated in Clarified Fermentation Broth (CFB). **A.** Integrated chromatogram of the Rituximab biosimilar (8 μg) and CFB blank obtained with Proteometer-CV Kit (quaternary pump configuration¹). **B.** Linear dynamic range of Rituximab biosimilar.

Benefits

- Two critical quality attributes in the same assay: charge variant profile and titer
- Analysis directly from CFB eliminates the need for Protein A purification, providing results that are representative of mAb in the production environment
- Rapid 25-minute turnaround time allows for high throughput using serial analyses
- Excellent reproducibility³
- Verifies presence of a functional human Fc domain
- Early warning of critical quality deviations reduces the need for time-consuming structural analyses

REFERENCES

1. Proteometer-CV Kit for mAb Charge Variant Analysis Quaternary Pump Configuration Instructions for Use, v.1.03, dated 25September2025. Novilytic.com.
2. Narsimhan, M.L., Kim, J., Morris, N.A., Bower, M.A., Gunawardena, H.P., Bowen, E. and Regnier, F.E., 2023. Mobile Affinity Selection Chromatography Analysis of Therapeutic Monoclonal Antibodies. *Analytical Chemistry*, 95(44), pp.16115-16122.
3. Analysis of Rituximab Biosimilar with Proteometer-CV Kit v.1.00 October2025. Novilytic.com