VIXEN BIO

Streamline Commercialisation through Structural Analysis and Functional Affinity

APPNOTE

Accelerated Trastuzumab clone selection by all-in-one analysis of yield & functional Fab/Fc affinity, confirmed by structural data

The journey from hit discovery to lead and final antibody candidate selection is often a demanding and iterative process -a continuous waltz of production, purification, and characterization. Each refinement cycle depends on analytical and computational data to ensure no hidden pitfalls remain before downstream development.

RIC and Vixen close this critical gap in this combined study by offering **an integrated solution that connects titer and affinity with structural integrity.** This enables confident candidate validation, while **early Fc-functionality insights** provide assurance of functional stability and therapeutic potential.

Streamlined workflow

Vixen Assay	Direct quantification in cell culture supernatant	Insight in production yield	**Select the best mAb candidates**
	Rapid kinetic profiling (kon, koff, KD) in the same medium	Revealing the true strong affine binders among similar KD's	
	Integrated isolation of mAb's from the crude medium	Integrated purification for downstream analysis with MS	
RIC	Structural analysis with MS	Identify post-translational modifications and how they correlate with affinity/titer	

Highlights

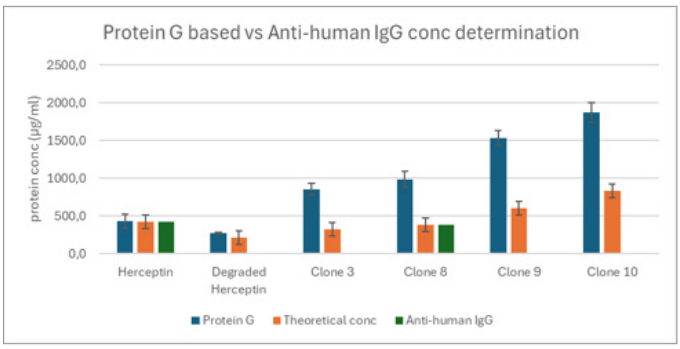
- Streamlined mAb development workflow: **at-line titration with direct affinity check** that allows direct cell culture, stability and purification optimisation.
- Efficiently get structural data and link it to mAb functionality by **affinity insights in FcRn binding region - as early as during purification.**
- **All-in-one solution** omitting the need for costly intermediate purification steps and lenghty ELISA solutions.
- **Select the best candidates early-on.** Combining structural and performance data provides validation of candidates in terms of potency, functionality and stability. Paving the road for a secured NDA submission.

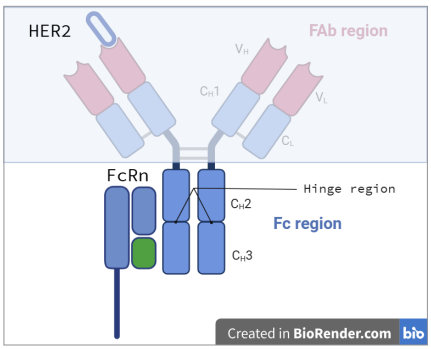
Study Insights

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1

Quantitation from medium and direct functional feedback **on changes in Fc structure that impact FcRn receptor binding.**

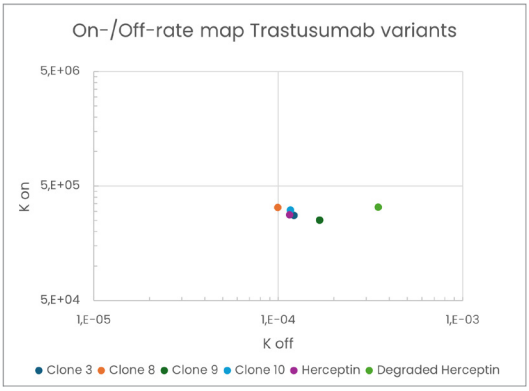


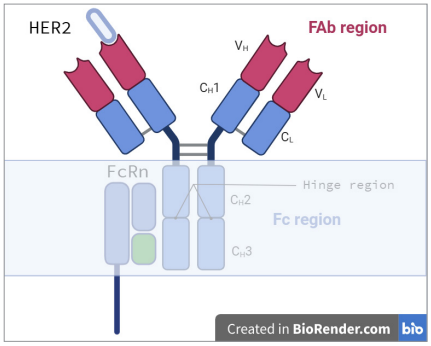


Antibody capture not only measures titer, but also shows effect of PTM's at Ch2-Ch3 and the binding site of the chosen purification method (proG) compared to anti-Hu IgG measured concentrations.

2

Integrated confirmation **Fab affinity** and specificity by real-time kinetic analysis directly from crude medium.

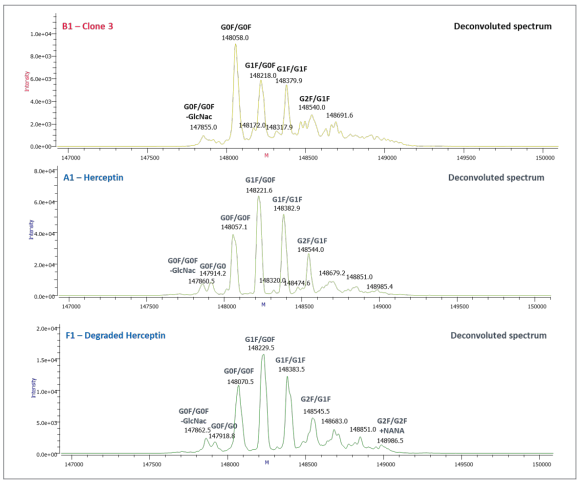


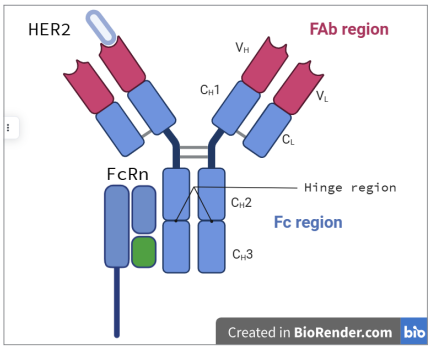


Kinetic profiling of mAb's Fab binding to HER2. Study samples had similar kon, koff and KD values as commercial trastuzumab (Herceptin). Degraded Herceptin exhibited reduced affinity by significantly higher koff, reflecting impact of the stability study.

3

Mass spectrometry on isolated fraction by White FOx confirms **structural integrity** on glycosylation pattern and PTM's that translate in affinity shifts on Fc-region





Differences in Fc glycosylation were confirmed between Herceptin and the study samples. Degraded Herceptin could not be differentiated by MS at intact mAb level but by additional peptide mapping. However , affinity analyis omits this additional need.

Supporting faster, smarter and safer drug diagnostic development.

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