VIXEN BIO

From Buffer to Patients: Native affinity assay Predicting therapeutic behaviour in patients

APPNOTE

Measuring affinity of mAb therapeutics in the patients native plasma as an early indicator for clinical efficacy and safety.

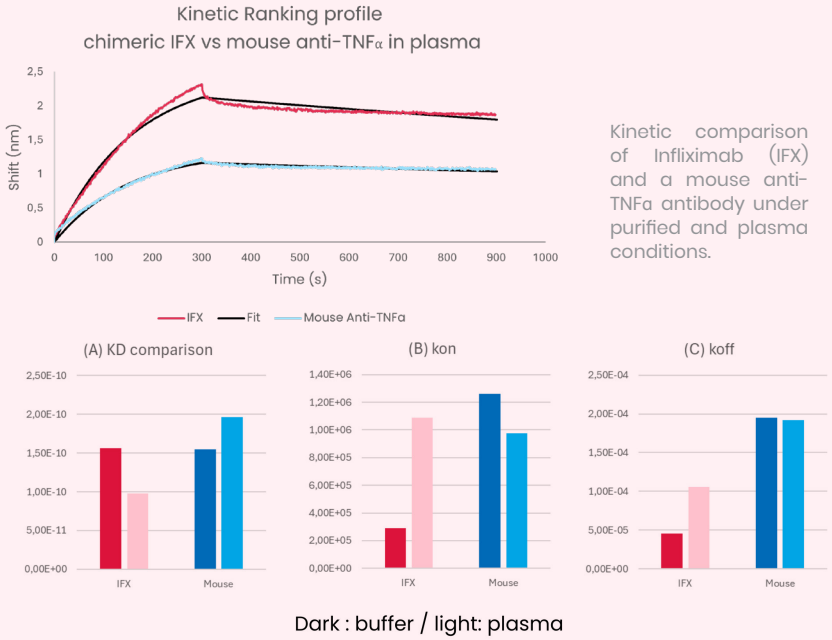
Monoclonal antibodies (mAbs) remain key therapeutics for immune and inflammatory diseases, as well as targeted cancer treatments. Affinity characterisation is a critical step in their development, helping to identify both the specificity of target recognition and the most potent candidates in terms of binding strength. While traditional affinity assays in purified systems reveal fundamental binding properties, they often overlook the complexity of real biological environments like plasma.

Our study case reveals that while all the right physicochemical data can be present, the therapeutics' behaviour can still be very different in the patient. A critical insight, especially for Biosimilars that rely on comparability filing, where our unique capability to measure in physiological conditions can identify unexpected efficacy or safety gaps that may arise without clinical validation.

While KD values appear **similar in purified assays, plasma measurements** reveal enhanced binding kinetics for IFX and reduced affinity for the mouse antibody, indicating superior **in-patient efficacy** for IFX.

Highlights

- **Better candidate selection** by engineering mAb's **Fab and Fc affinity in native conditions.**
- Provides significant data for regulatory filing by deep insights in **MoA, clearance pathways and dosing.**
- Strengthen therapeutic drug monitoring and **immunogenicity assessments** by linking personalised kinetics to functional outcomes
- **Reduce trial risk** by ensuring therapeutic performance holds beyond simplified assay conditions



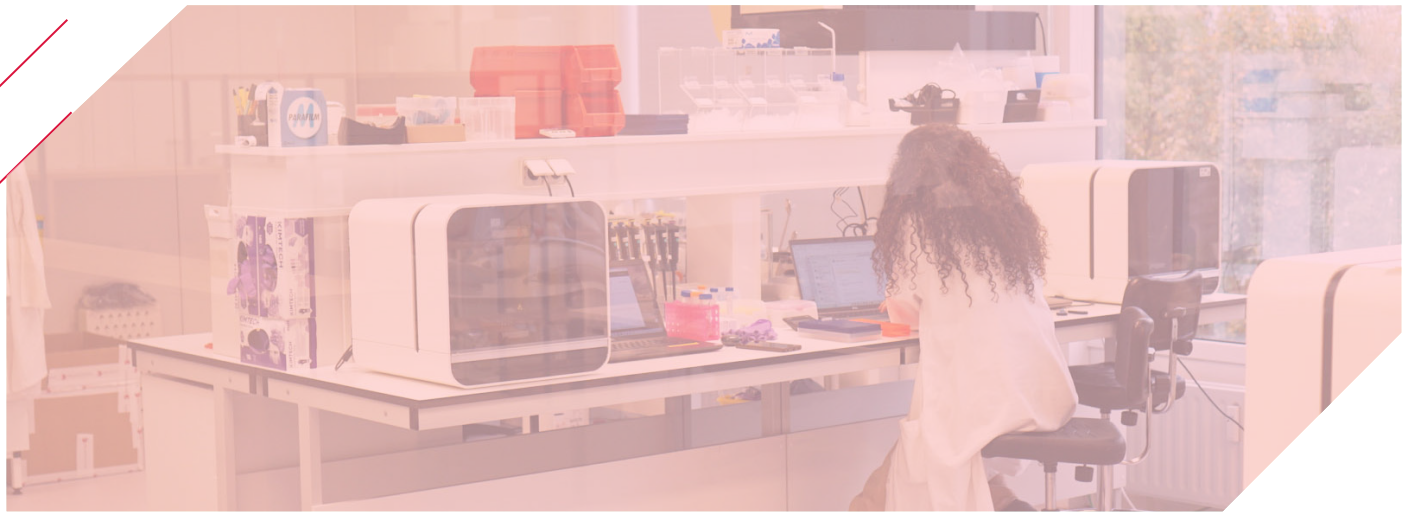
Kinetic comparison of Infliximab (IFX) and a mouse anti-TNFa antibody under purified and plasma conditions.

Dark : buffer / light: plasma

Conclusion

Advanced real-time immunoassays under native conditions provides a full image of true antibody functionality in patient samples. Vixen can help de-risk potential candidates and accelerate the path to commercialisation by kinetic characterization of both the target recognition as functional potency in native conditions.

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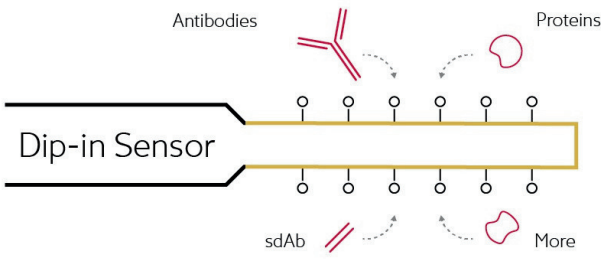


Supporting faster, smarter and safer drug diagnostic development.

Vixen Bio empowers biopharma and CROs with deeper immunological insights through precise quantitation and kinetic analysis using our unique WHITE FOx platform.
Our smart dip-in probe technology makes it possible to analyze complex -even clinical- samples with ease and accuracy, at every stage of drug development.
Turn early immuno-insights into faster, smarter, and safer clinical success.

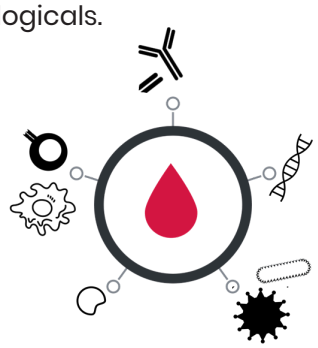
The advantages of WHITE FOx by Vixen Bio:

- **Label-free direct single interactions** (epitope, Fc, anti-hIgG, proA/G,...)
- **High accuracy and precision**
- **Fast: sample to result in as little as 10 minutes**
- **No fluidics** - No cleaning
  - Minimal sample processing
  - No cross-contamination



Services by Vixen Bio:

- **Real-time kinetics & concentration from any target in any sample**
- **Fast, Sensitive & To industry standards**: highly comparable results with ELISA & other real-time technologies.
- **Flexible:**
  - Samples measured **@ Vixen Bio labs**
  - WHITE FOX **@ your lab**
  - Fully **developed** assays for a variety of biologicals.



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