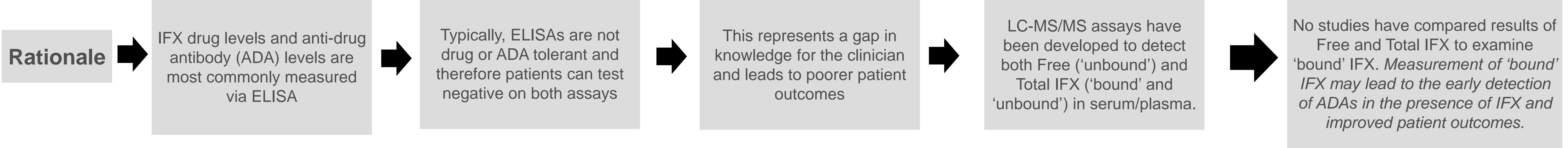


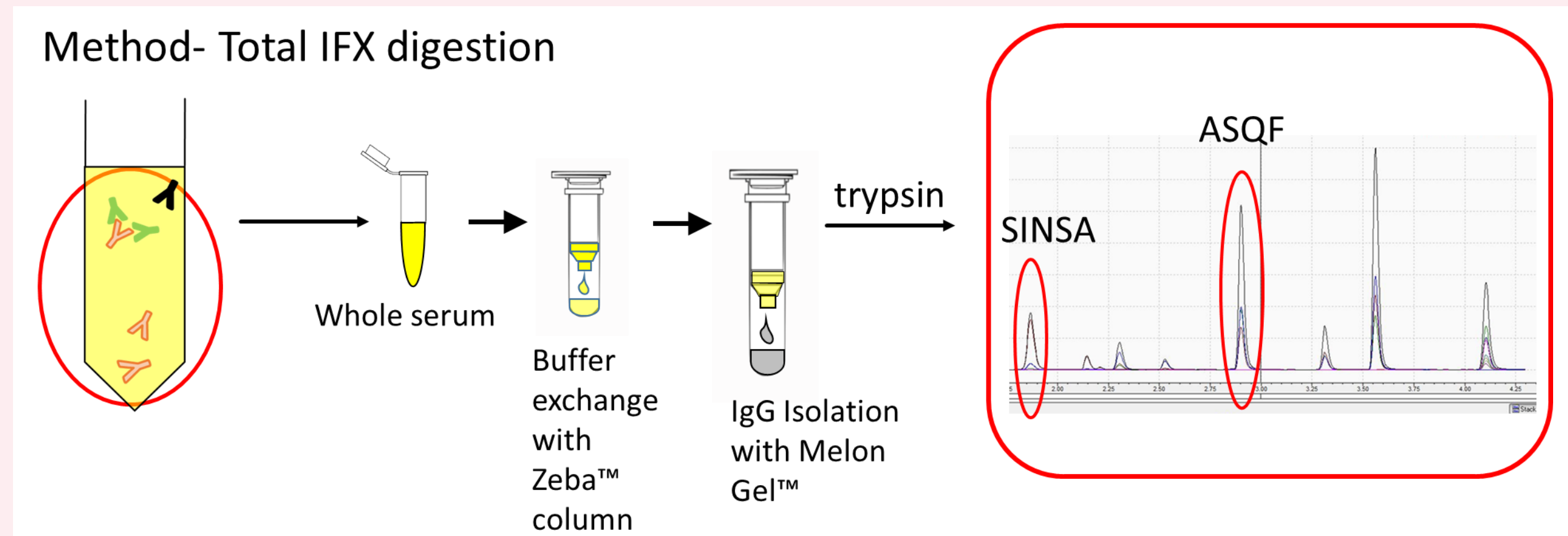
# Development and Evaluation of an LC-MS/MS Method for Therapeutic Drug Monitoring of Infliximab for Use in the Routine Clinical Laboratory

Melissa Sam (1,2,3), Catherine Toong (1,2,3,5), David G. Harman (4), William A. Donald (2)

(1.) NSW Health Pathology (2.) University of New South Wales (3.) The Ingham Institute of Applied Medical Research (4.) Western Sydney University (5.) Liverpool Hospital, South-Western Sydney Local Health District

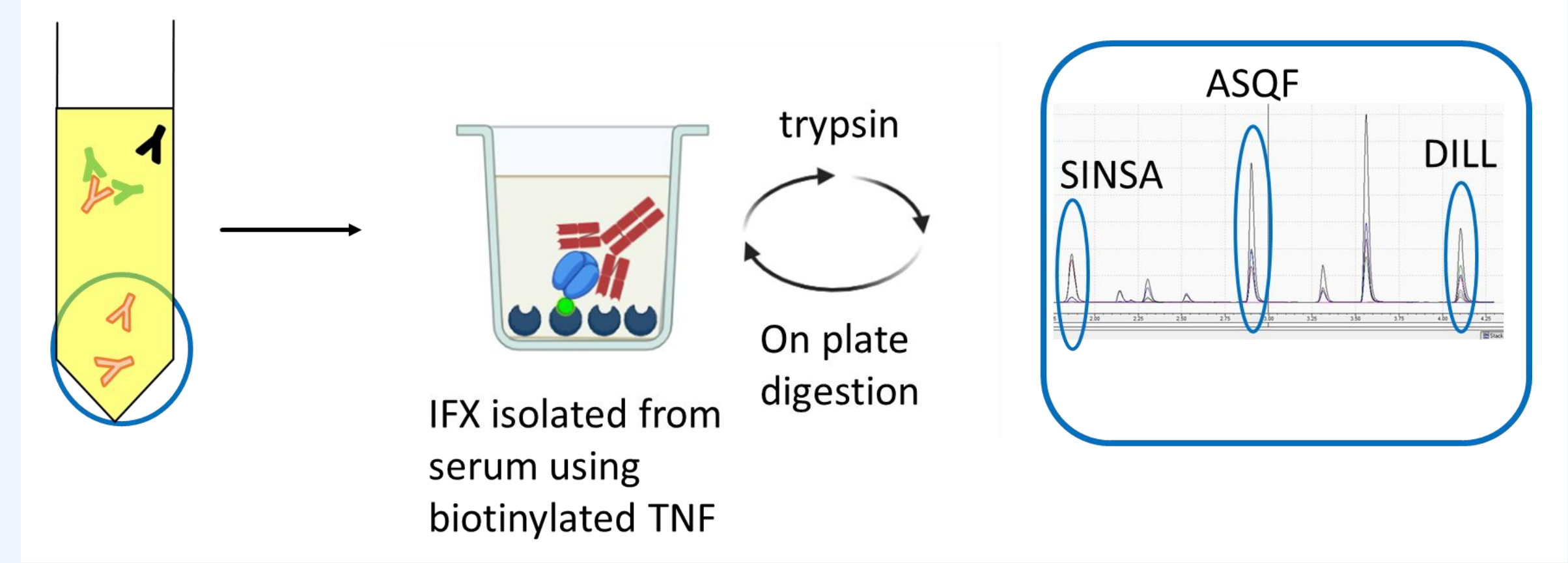


## TOTAL IFX MEASUREMENT



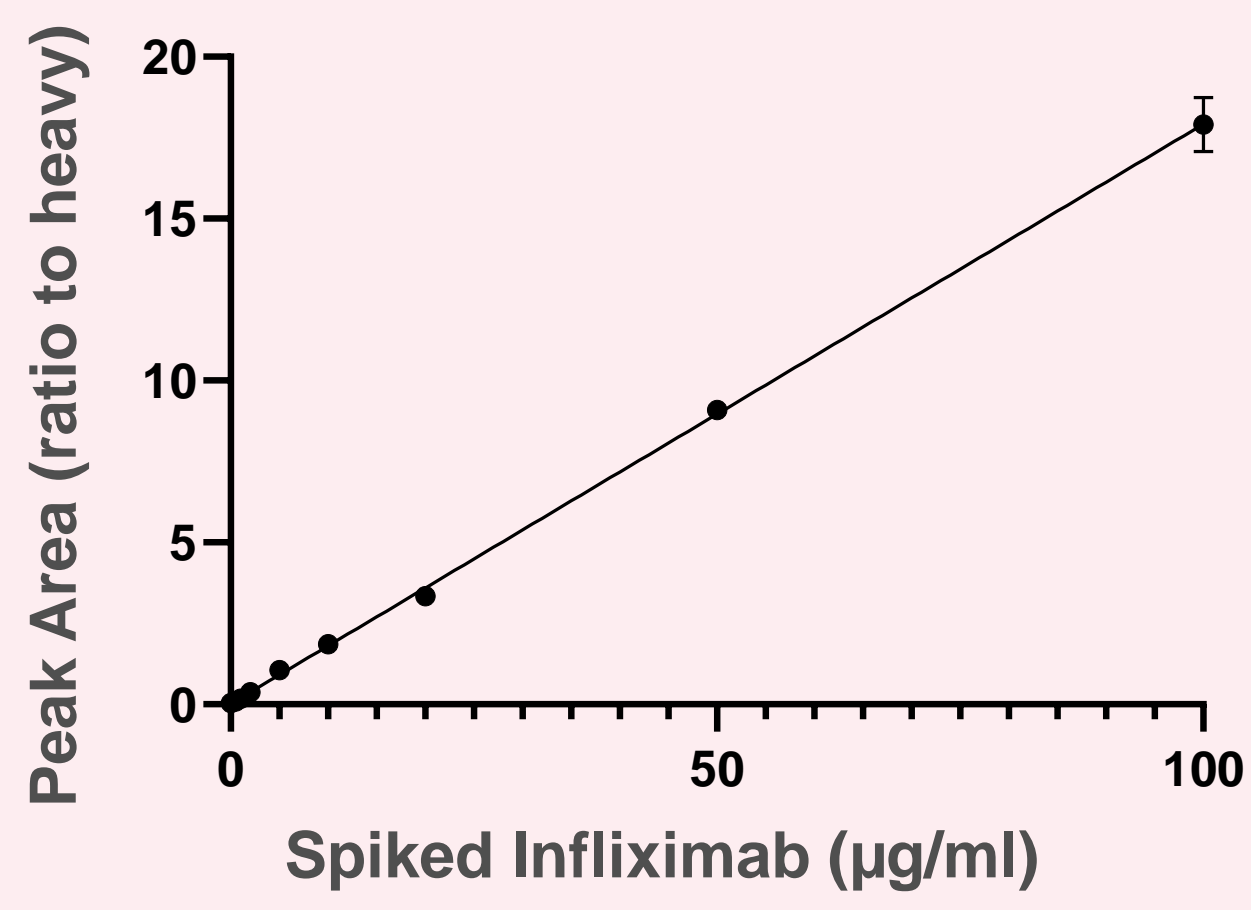
Methods in summary

## FREE IFX MEASUREMENT



## Results

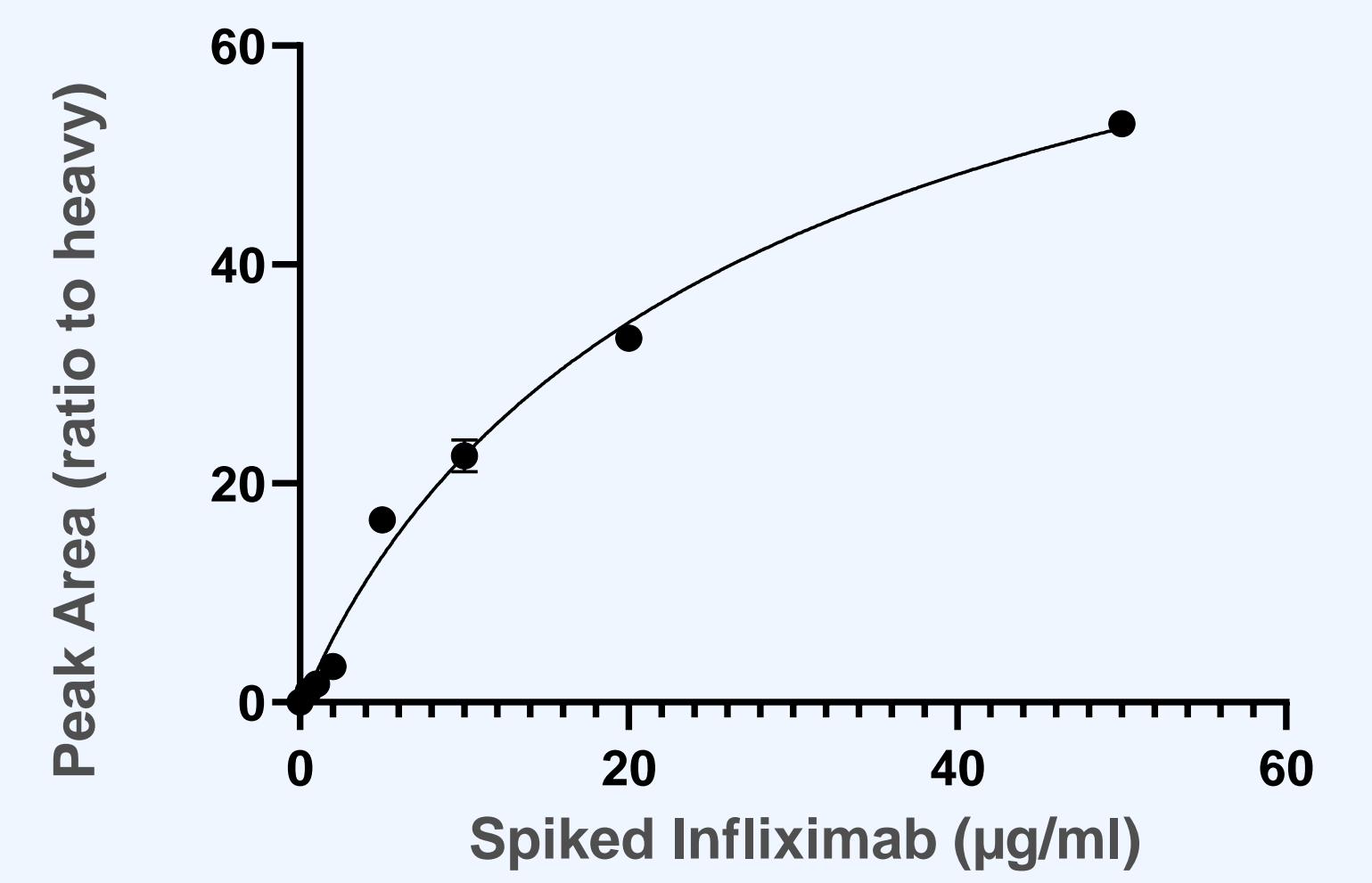
Standard curve for total IFX measured in serum



Linear regression analysis  $R^2 = 0.998$   
Range 0.5-100 µg/ml  
Inter-assay CV= 12%  
Intra-assay CV < 4%

## Results

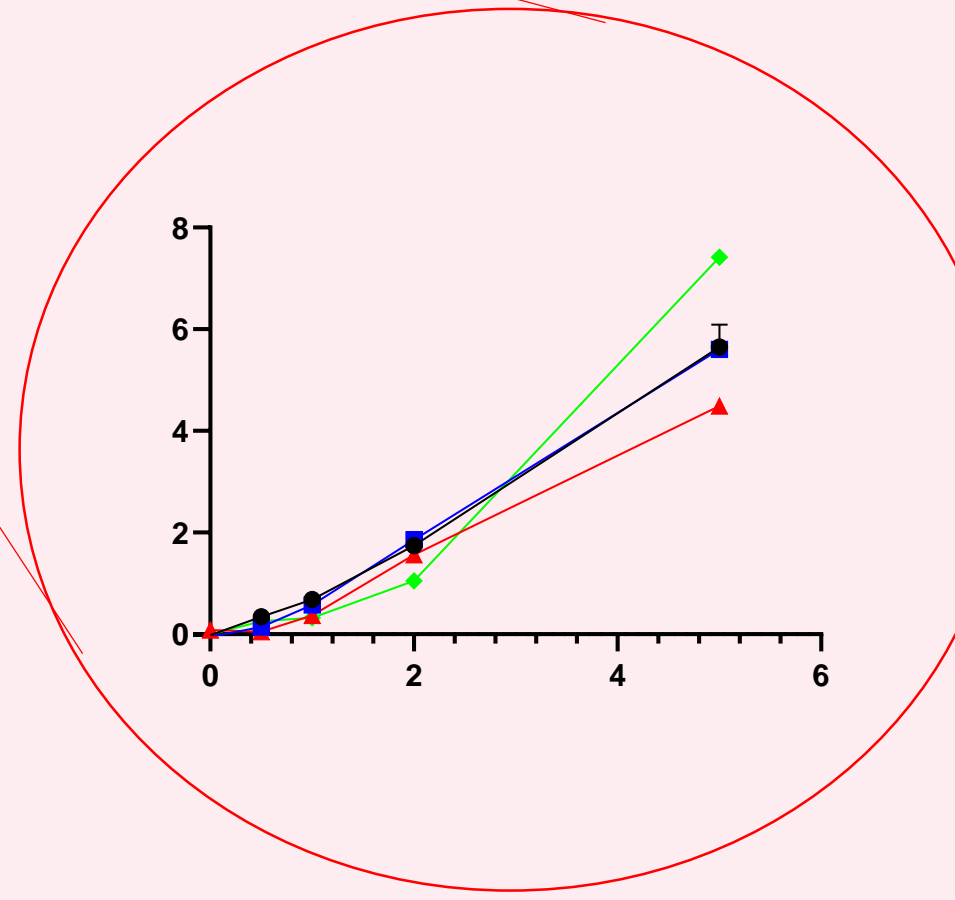
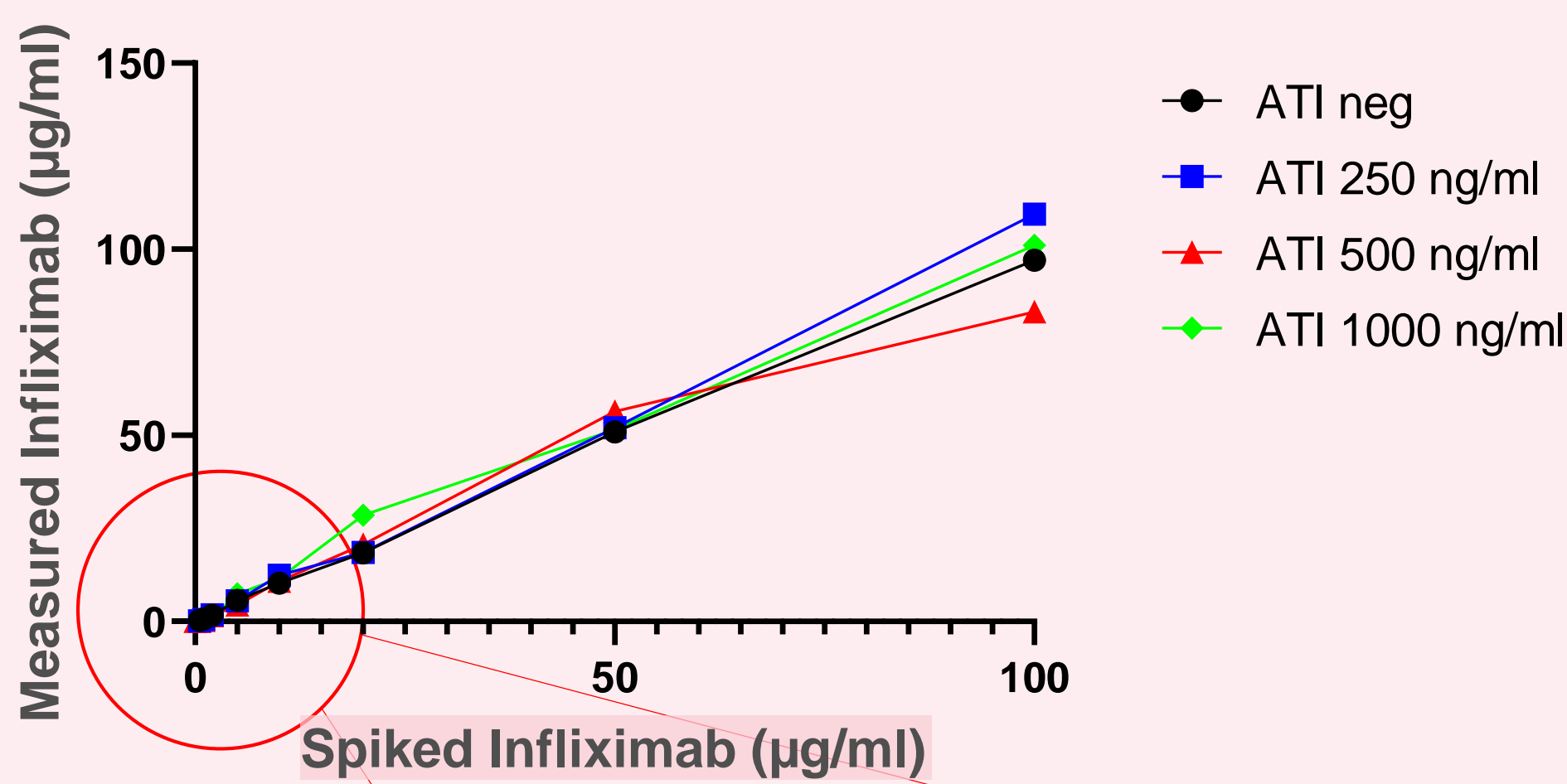
Standard curve for total IFX measured in serum



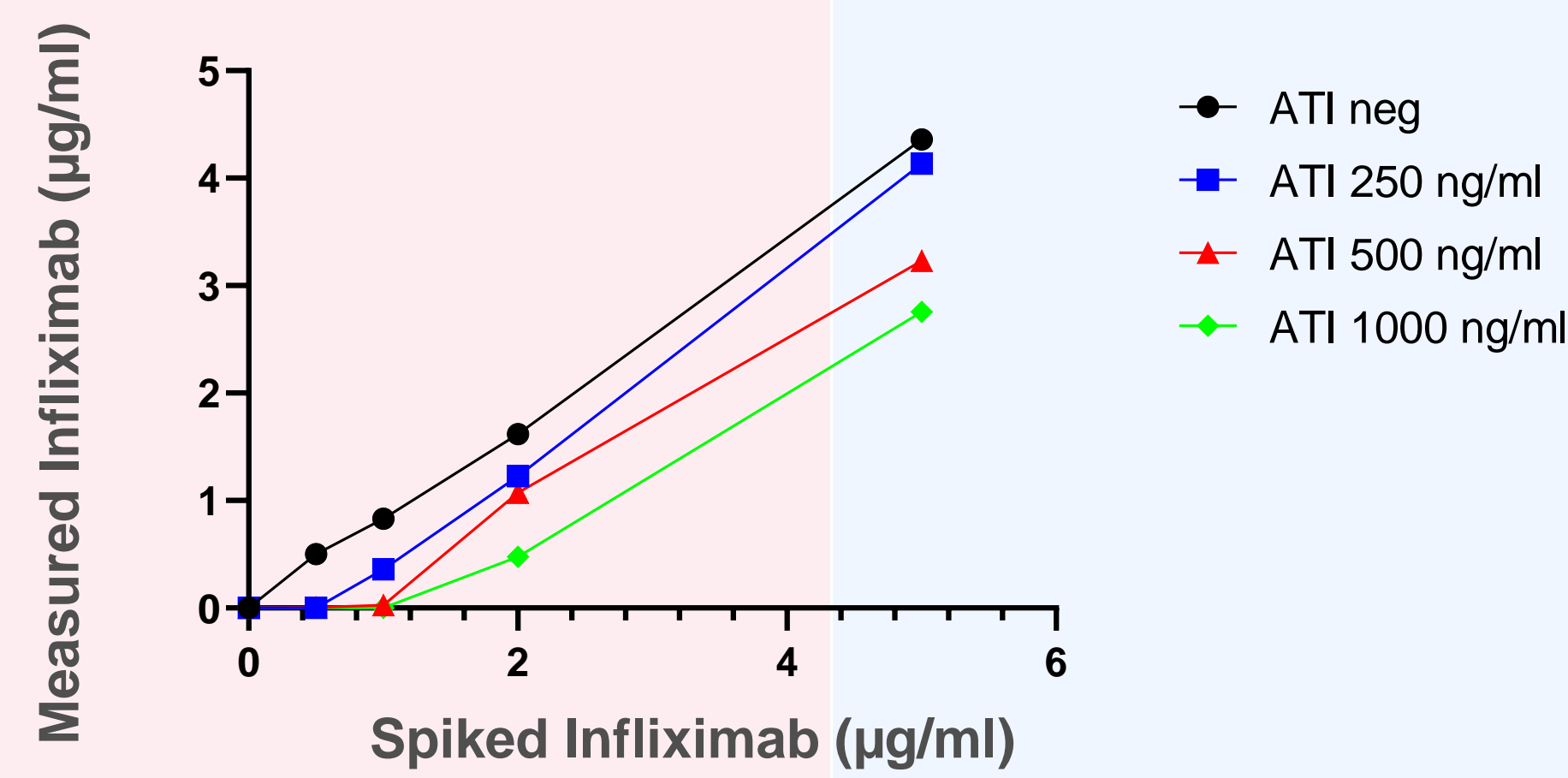
4PL regression analysis  $R^2 = 0.98$   
Range 0.5-50 µg/ml  
Inter-assay CV= 12%  
Intra-assay CV < 8%

Bound IFX can be detected using a comparison of Free and Total IFX measured by LC-MS/MS. This paves the way for indirect detection of ADAs and thus improved outcome for patients on IFX therapy.

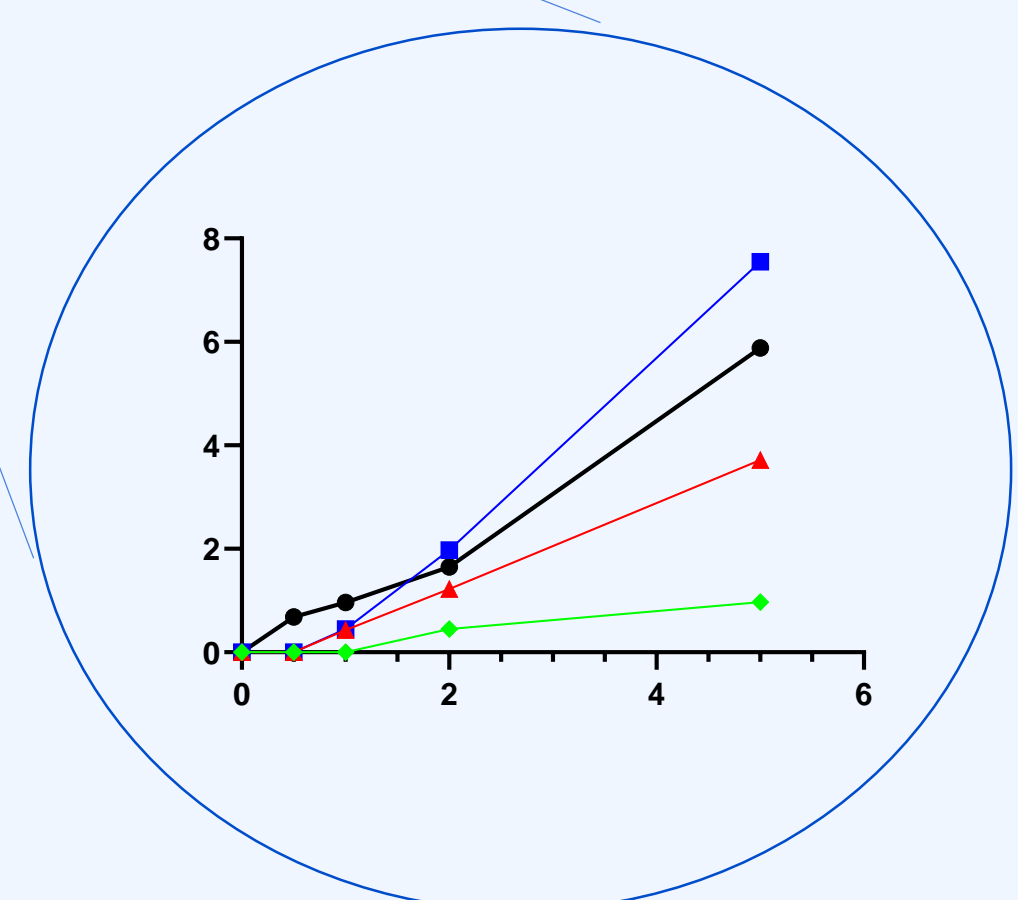
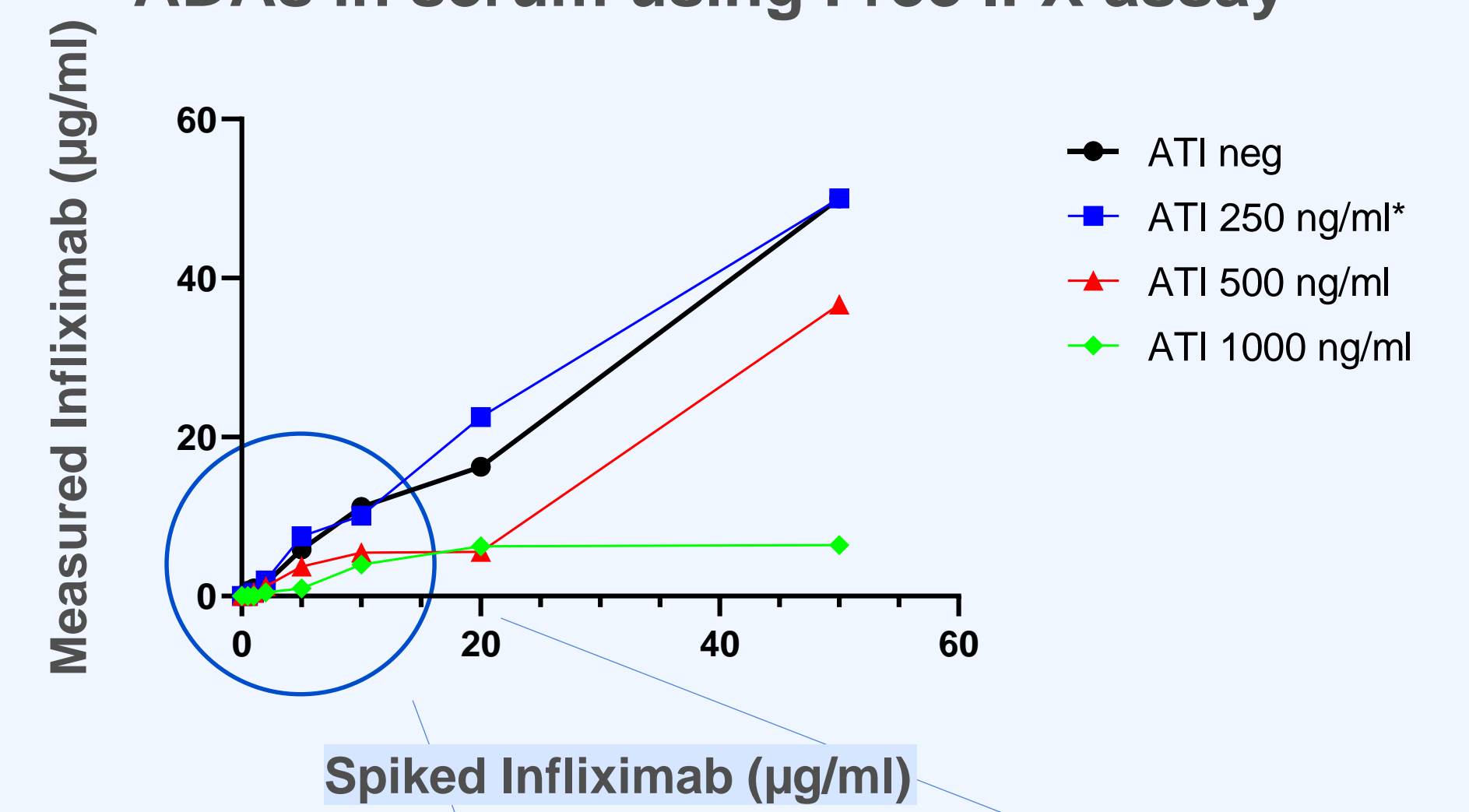
Comparison of measured IFX in the presence of ADAs in serum using Total IFX assay



Effect of ADAs on Infliximab measurement in ELISAs



Comparison of measured IFX in the presence of ADAs in serum using Free IFX assay



Next steps- comparison of patient samples testing negative on both IFX and ADA Immunoassays