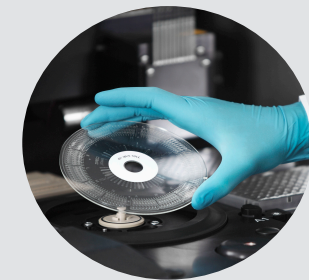


# THE EFFICIENT GENERATION OF PHARMACOKINETICS DATA USING AFFINITY FLOW-THROUGH NANOLITER FORMAT IMMUNOASSAYS

Gyros Protein Technologies AB

Chris Fox (They/Them)



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**GYROS PROTEIN**  
Technologies

# GYROS PROTEIN TECHNOLOGIES – OUR FOUNDATION AND HOW WE OPERATE

A DIVISION OF MESA LABS

## IMMUNOASSAY SOLUTIONS



### Expertise

Immunoassay solutions:  
Microfluidics, system development  
& immunoassay expertise

Peptide Synthesis Solutions:  
Precision machining and assembly  
of peptide synthesizers



### Customer base

Biopharma, Pharma, CRO, CMO,  
Academic, Government institutions,  
Diagnostics

1/3 of customers worldwide have multiple  
Gyrolab platforms



### Two Centers of Excellence

Tucson, AZ & Uppsala, Sweden  
(ISO 9001:2015 certified)

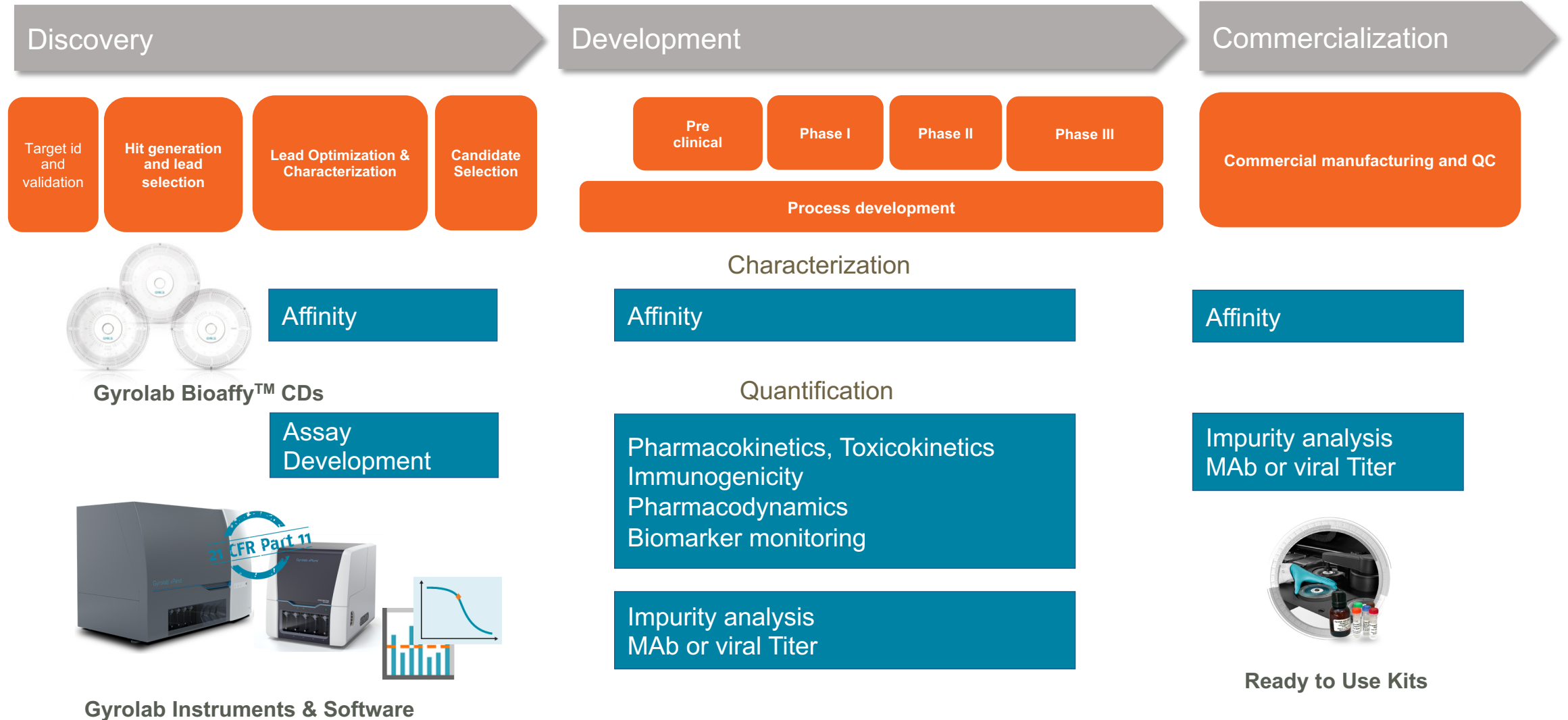


### Global service and support

Online and In-lab Technical Support,  
Instrument and Software Support

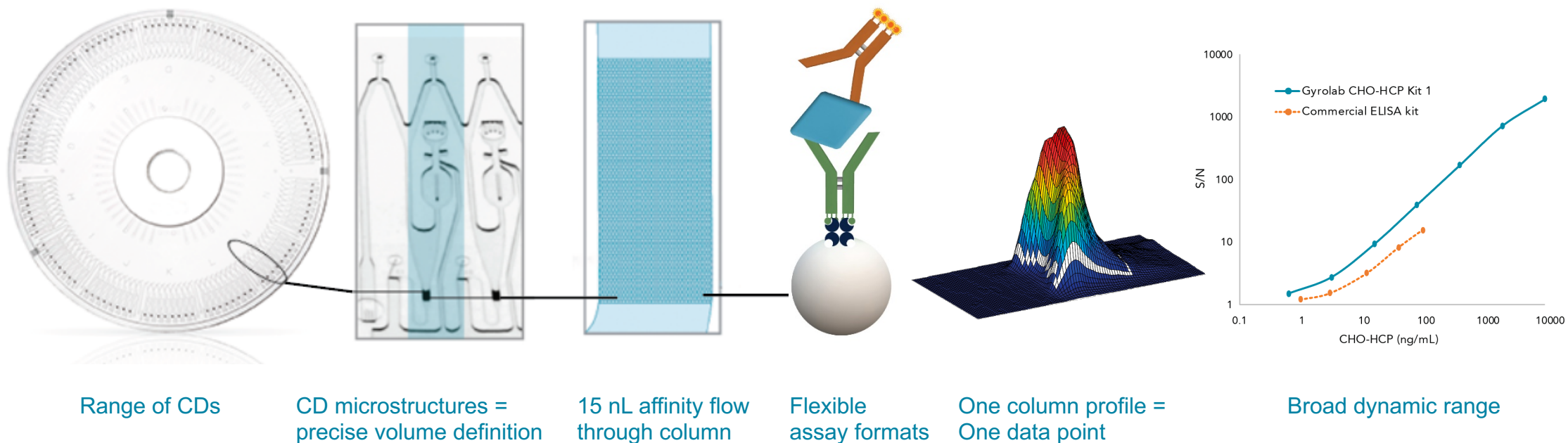


# GYROLAB® SYSTEMS IN APPLICATIONS FROM DISCOVERY TO QC



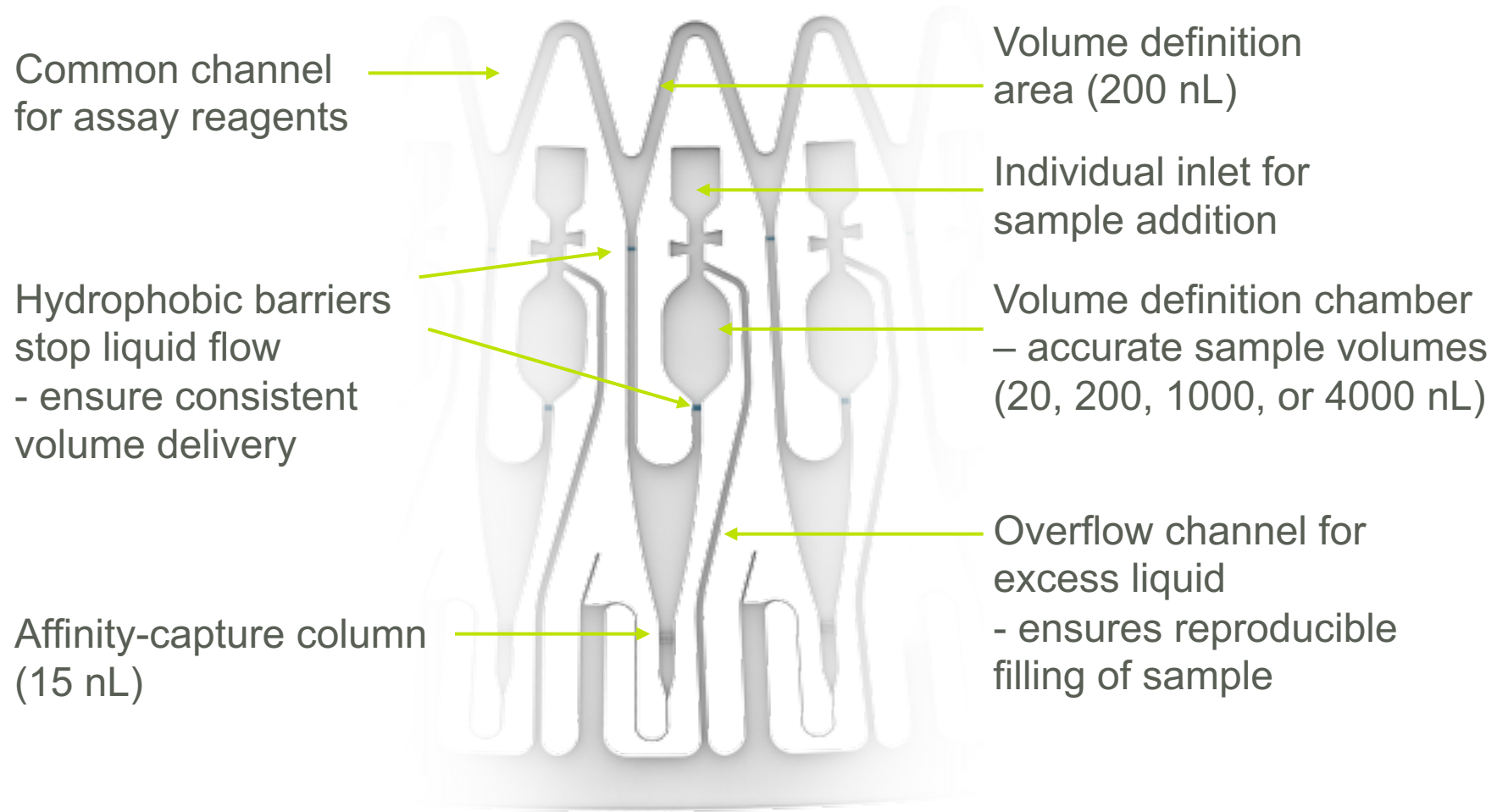
# THE CORE OF GYROLAB CD TECHNOLOGY

Data in less than an hour



# NANOLITER-SCALE PRECISION

ONE MICROSTRUCTURE — ONE DATA POINT — NO CROSS TALK



# A SELECTION OF GYROLAB® BIOAFFY CD'S FOR A BROAD RANGE OF APPLICATIONS

Gyrolab Bioaffy CDs differ in the sample volume processed, which determines the sensitivity of the assay



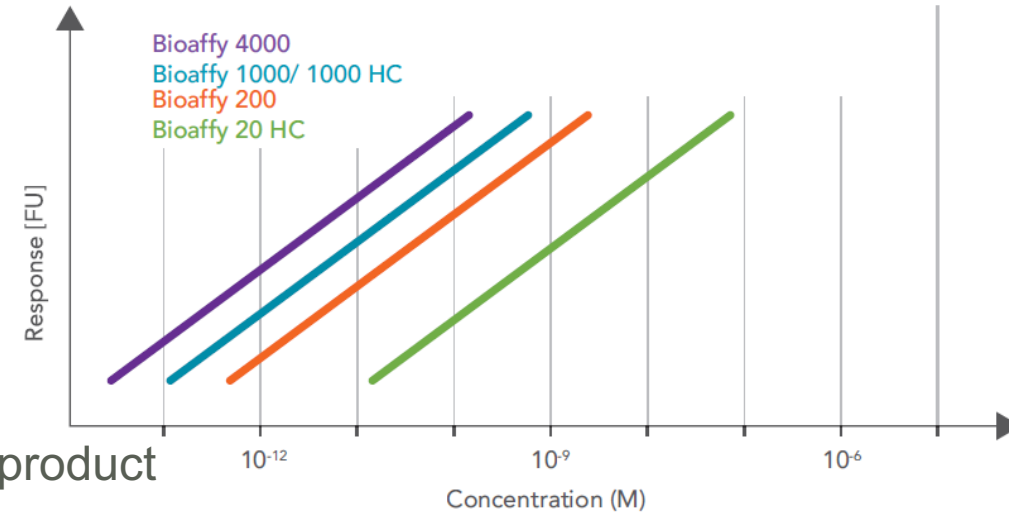
CD	Sample volume (nL)	Data points	Particle	Sensitivity <sup>1</sup>	Application <sup>2</sup>
Gyrolab Bioaffy 20 HC	20	112	Porous	1X	Higher binding capacity for higher concentrations e.g. IgG titer, TK
Gyrolab Bioaffy 200	200	112	Solid	10X	Standard CD for any application e.g. PK
Gyrolab Bioaffy 1000	1000	96	Solid	50X	Applications requiring higher sensitivity e.g. PK, biomarker
Gyrolab Bioaffy 1000 HC	1000	96	Porous	50X	High binding capacity e.g. Low affinity reagents
Gyrolab Bioaffy 4000	4000	96	Solid	200X	Applications requiring highest sensitivity e.g. PK, biomarkers
Gyrolab Mixing CD 96	200	96	Solid	N/A	Applications requiring Sample pre-treatment e.g. acid dissociation

- Reproducible data
- Less consumption of precious samples and costly reagents
- Broad dynamic range
- Short process times

New Bioaffy CD available soon:  
Gyrolab Bioaffy 4000

# GYROLAB BIOAFFY 4000 CHARACTERISTICS

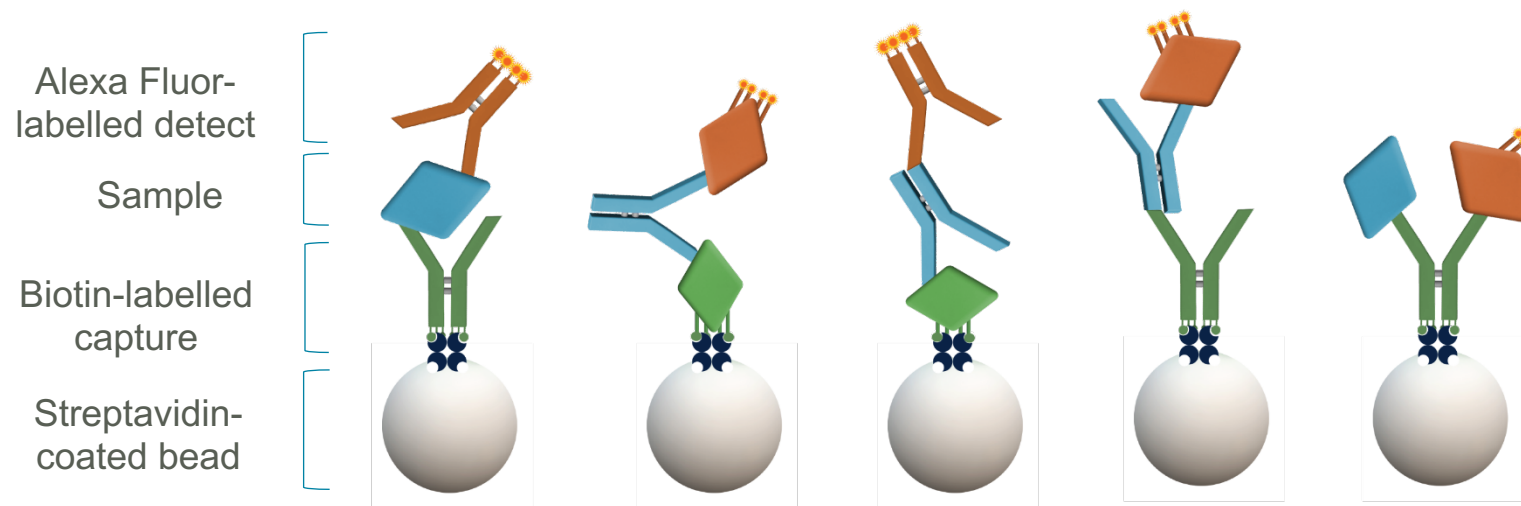
- Why did we develop the Gyrolab Bioaffy 4000?
  - Increased PK profile for FIH
  - New modality low dose PK
  - Biomarker quantification
- Based on Gyrolab Bioaffy 1000 CD design
  - Main functionalities proven to work well in established product
- Deeper sample volume definition structures for higher sensitivity
  - Larger sample volumes give higher sensitivity
- Affinity column is filled with the standard solid streptavidin-coated particle





# FLEXIBLE ASSAY FORMAT – OPEN PLATFORM

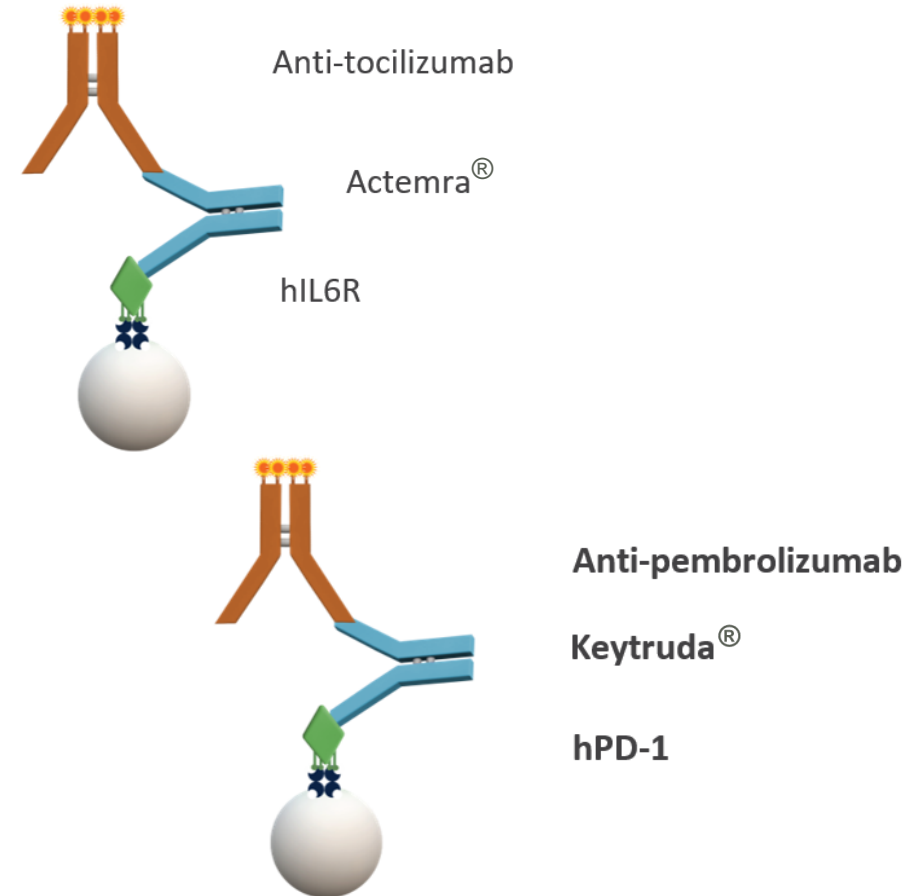
- Reduced matrix interference
  - Nanoliter-scale, flow-through technology
- Compatible with many matrices
  - Human or animal serum, plasma, sputum, CSF
  - Cell culture supernatant





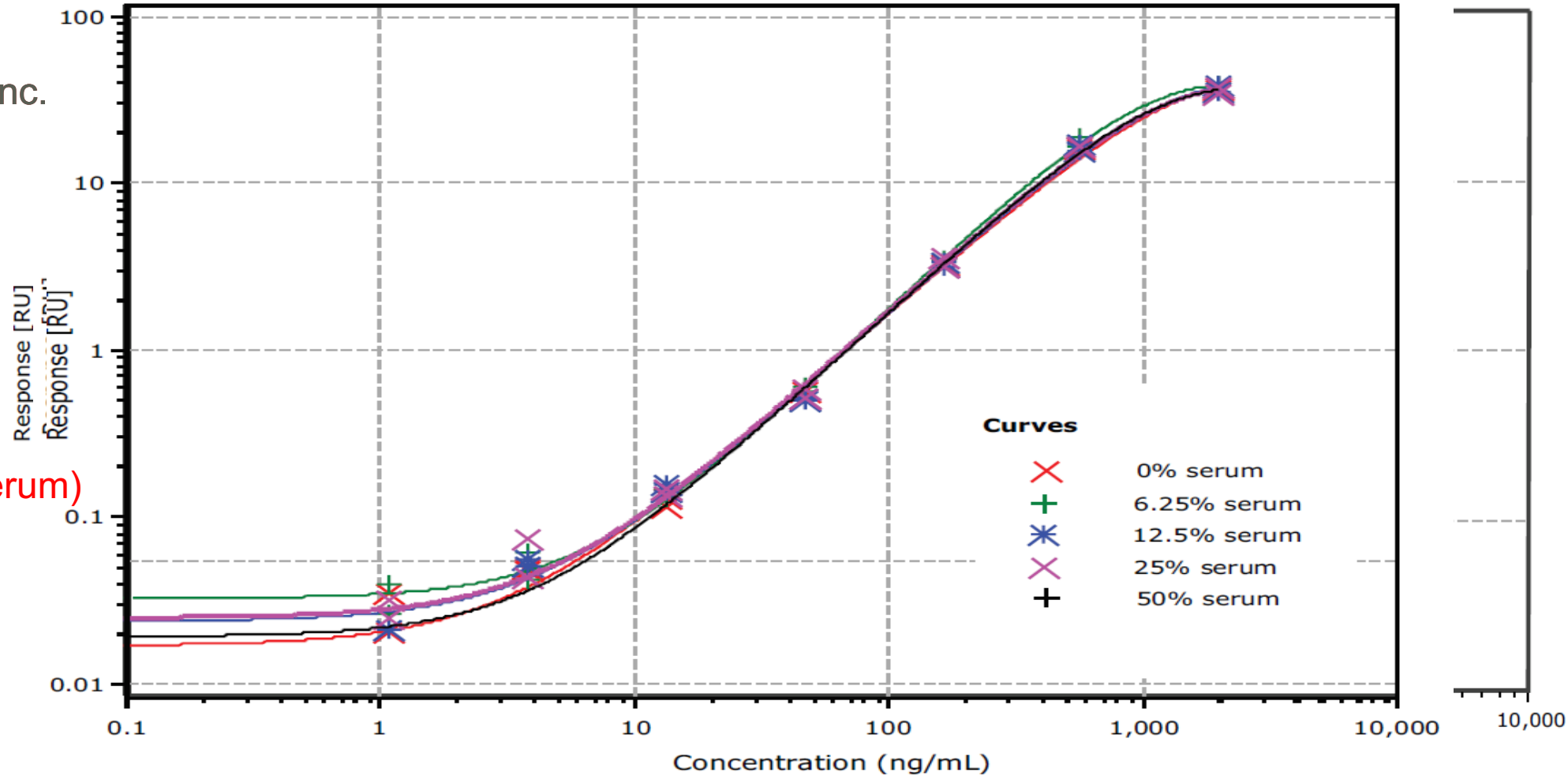
# HOW LOW DOES THE GYROLAB BIOAFFY 4000 PK GO?

- Previously validated and published on our website
- Initially developed on Bioaffy 1000 in 2019
- Bridging Sandwich Assays Format
  - PK assay detecting free drug
  - Range 160 – 60,000 ng/mL
- Biotinylated target capture reagent
  - Biotinylated BSA (bBSA) used as spacer to prevent bivalent binding
- Alexa labelled anti ID detection reagent



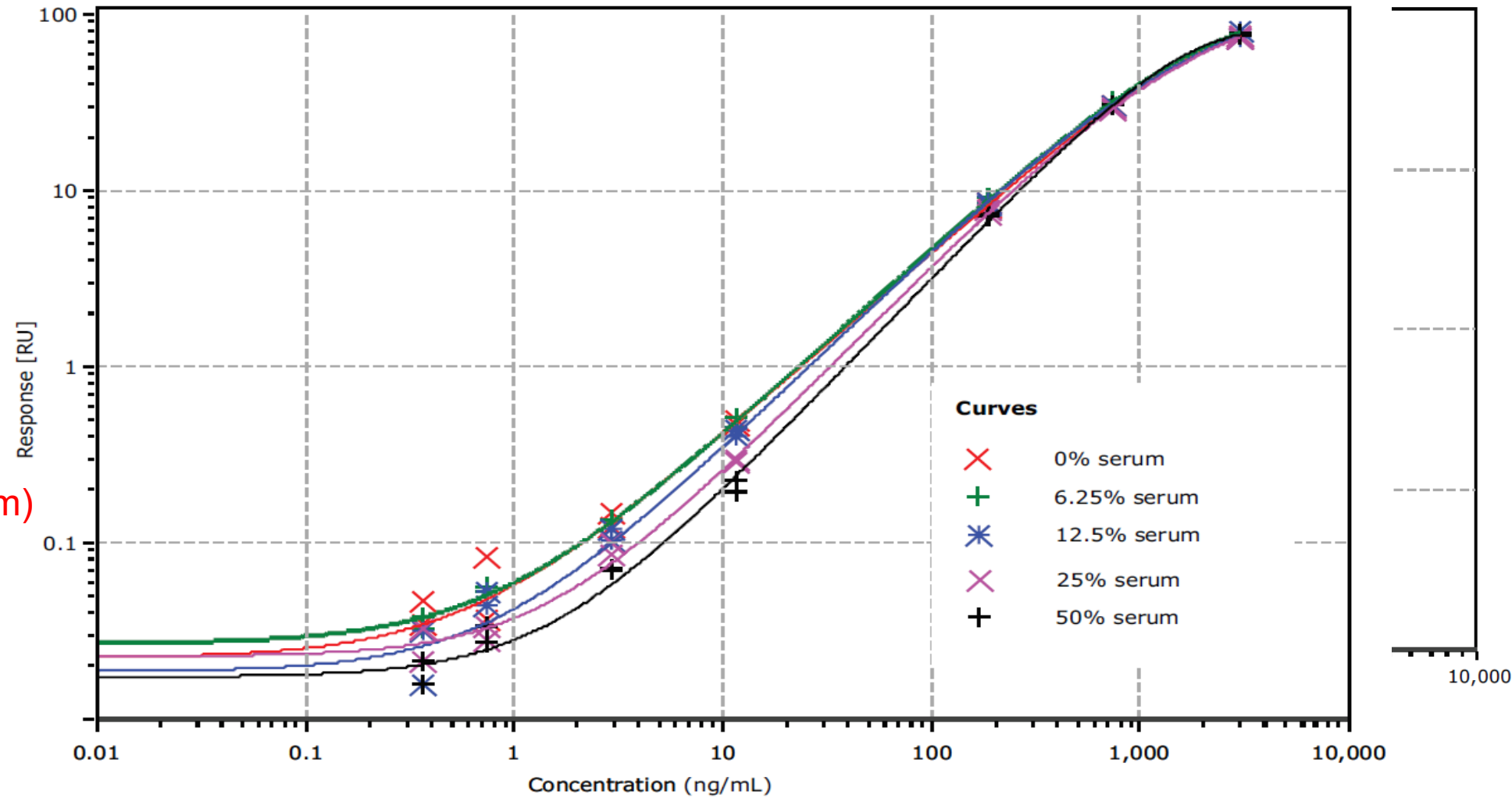
# REEVALUATING THE ASSAY CONDITIONS – KEYTRUDA

- bBSA Conc.
  - 50% Molar Conc.
- Detect Conc.
  - 35 nM
- **MRD**
  - 1-in-4 (25% serum)

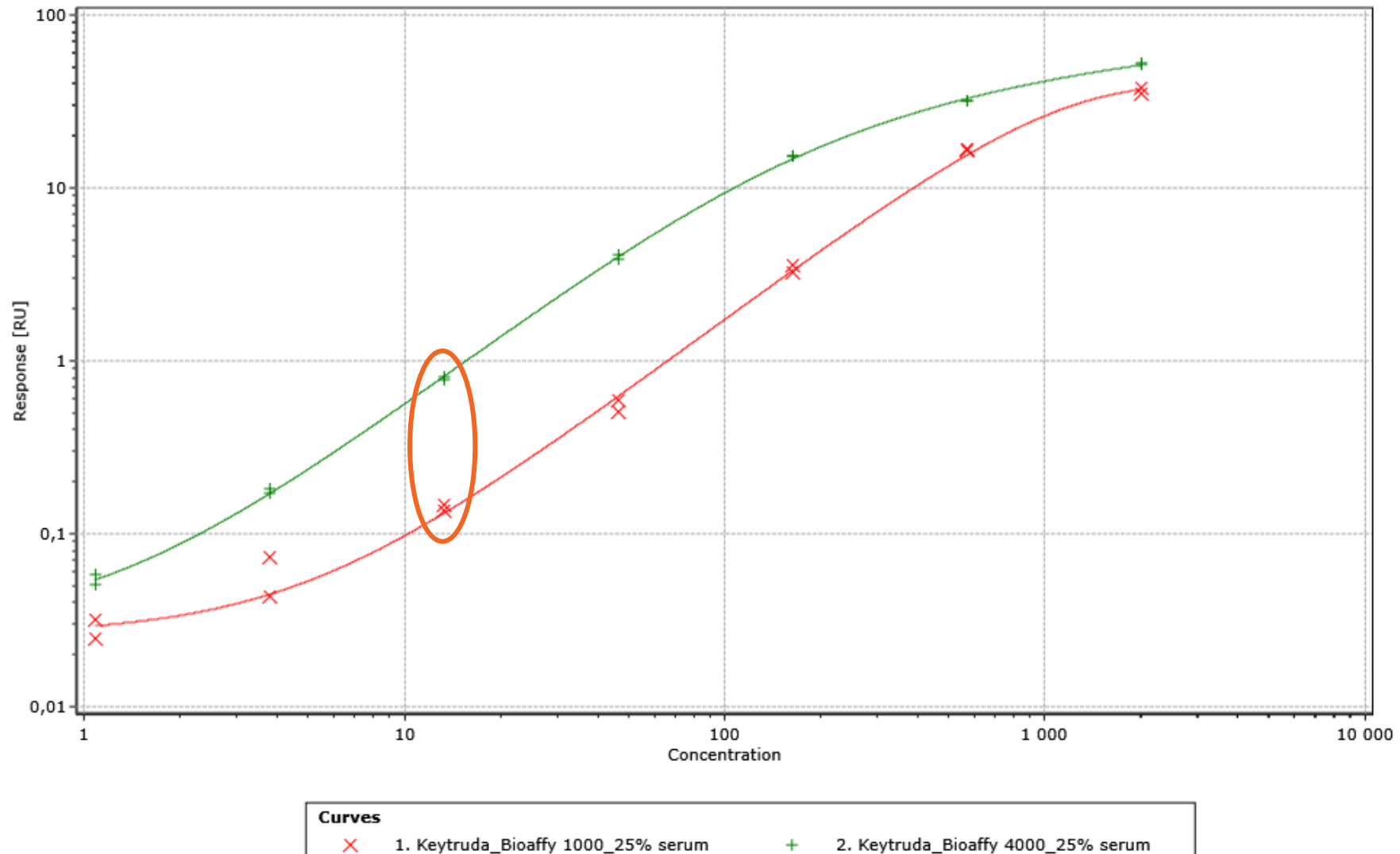


# REEVALUATING THE ASSAY CONDITIONS - ACTEMRA

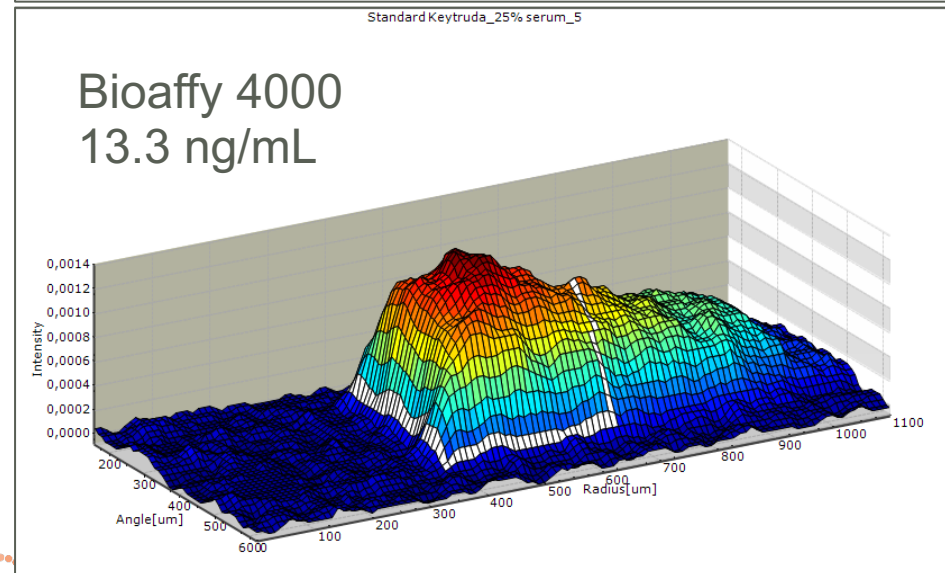
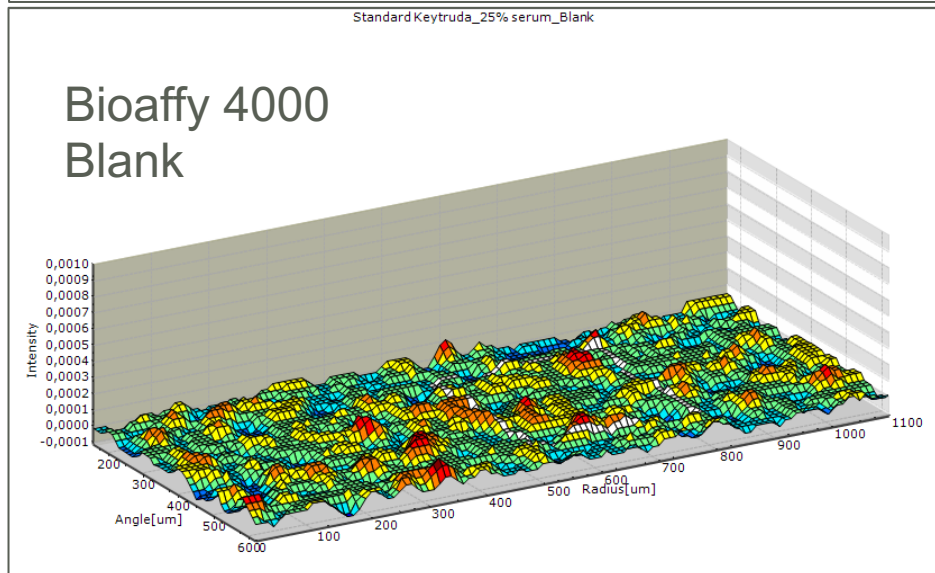
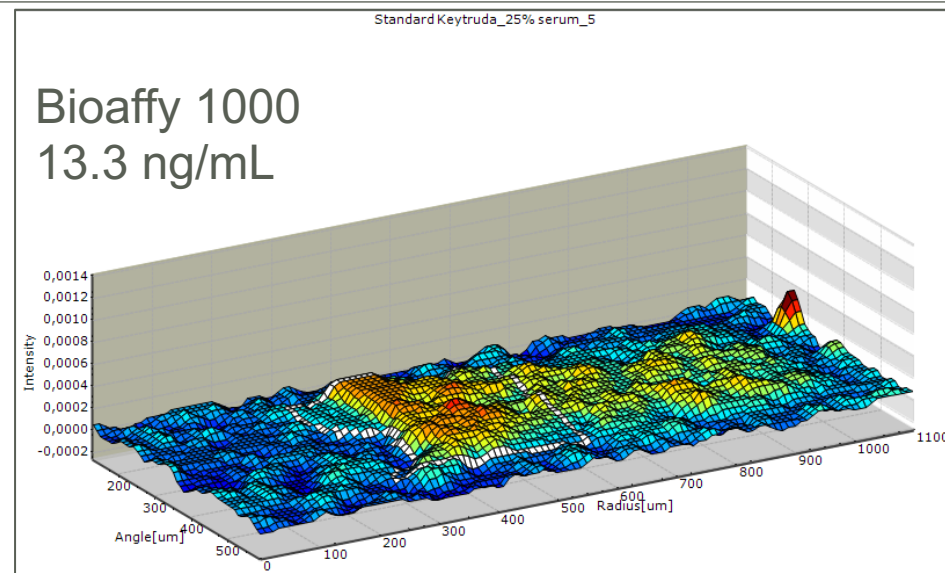
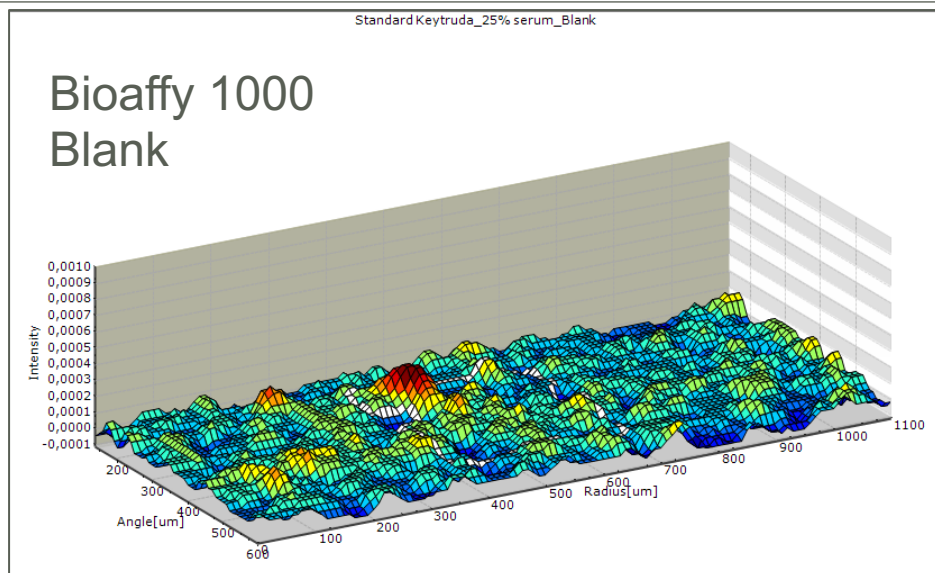
- bBSA Conc.
  - 75% Molar Conc
- Detect Conc.
  - 35 nM
- **MRD**
  - 1-in-20 (5% serum)



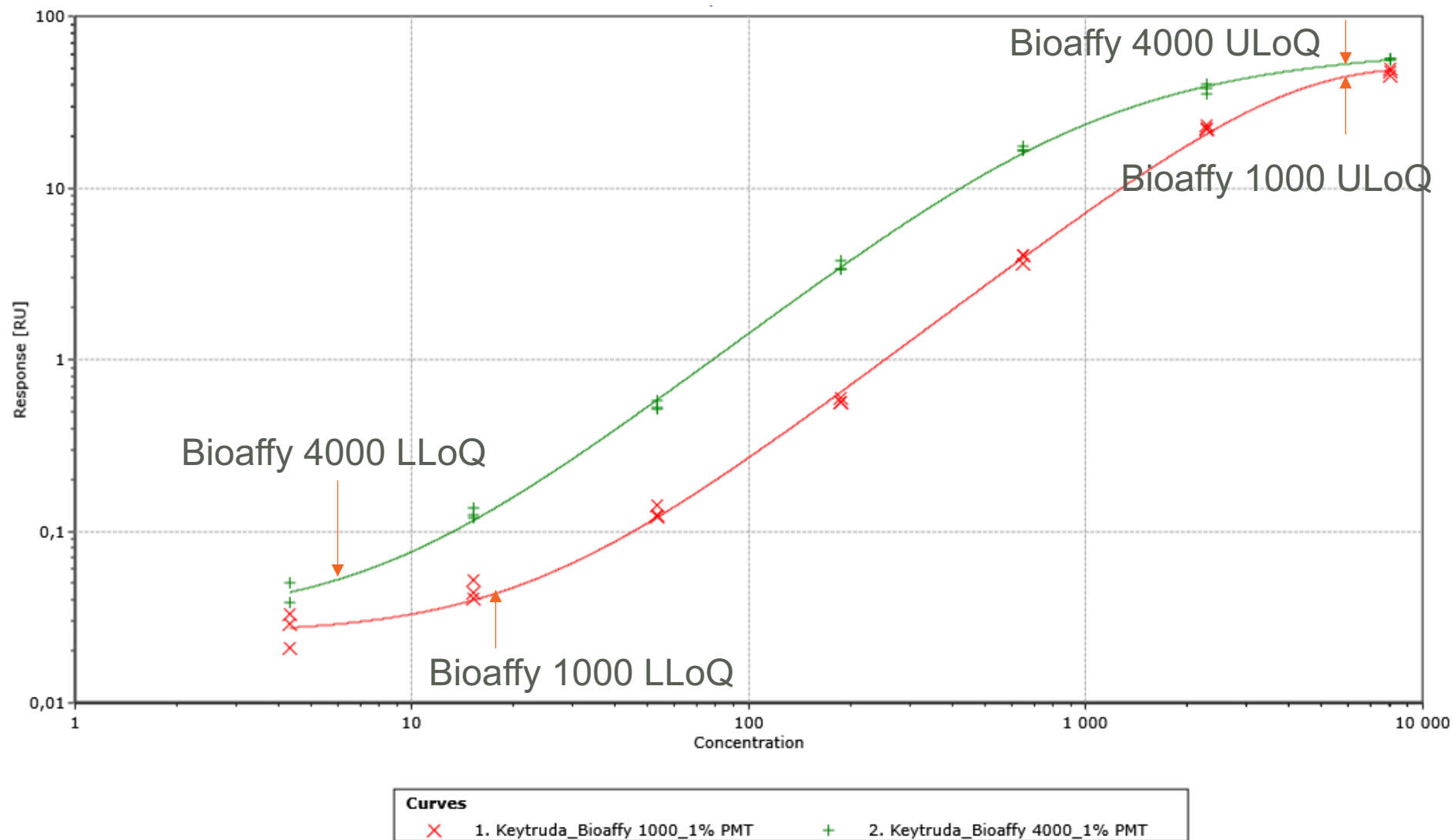
# SEAMLESS TRANSFER TO GYROLAB BIOAFFY 4000 - KEYTRUDA



# SEAMLESS TRANSFER TO GYROLAB BIOAFFY 4000 - KEYTRUDA



# KEYTRUDA HIGH SENSITIVITY PK ASSAY RANGE FINDING

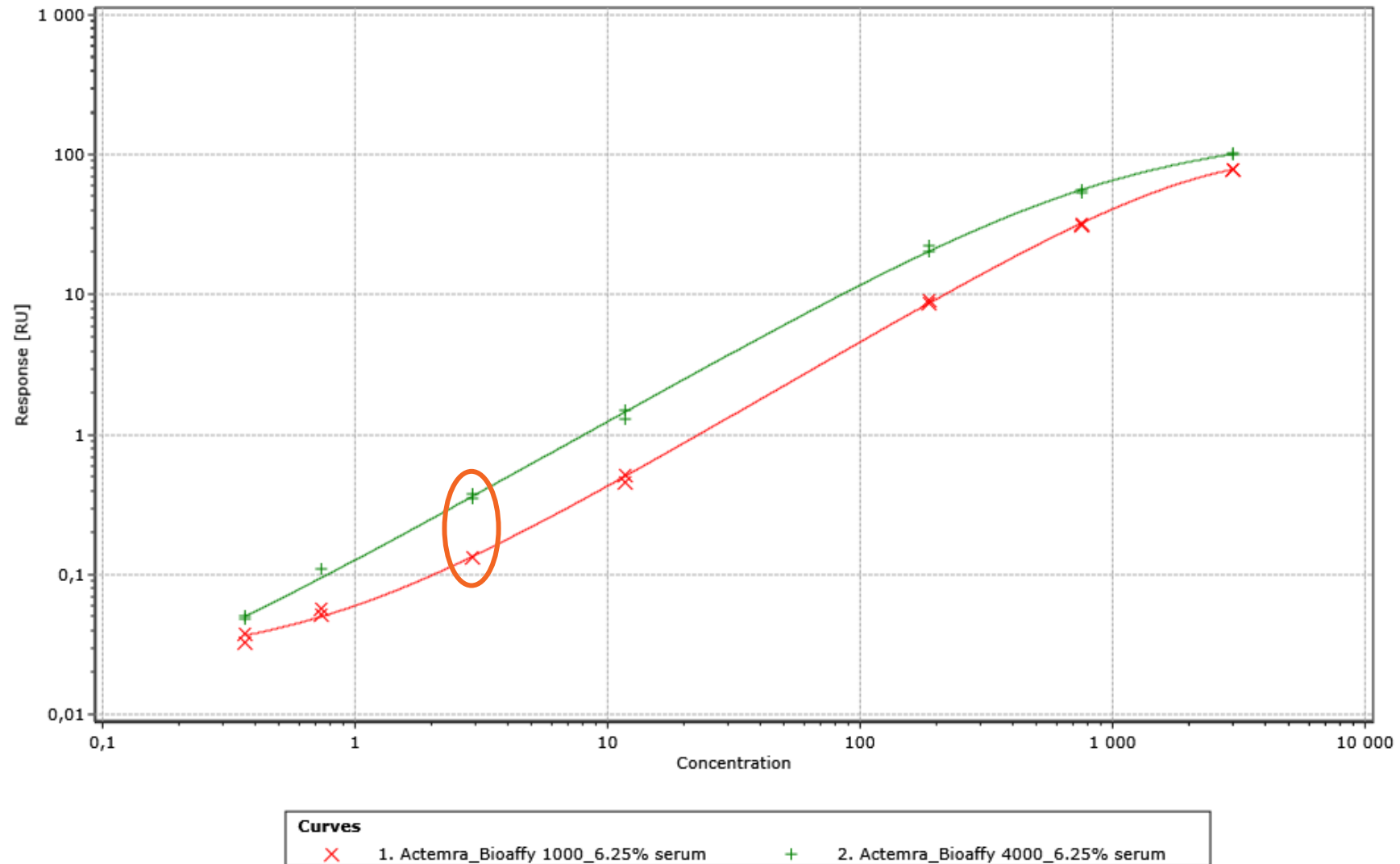


# KEYTRUDA PK ASSAY RESULTS

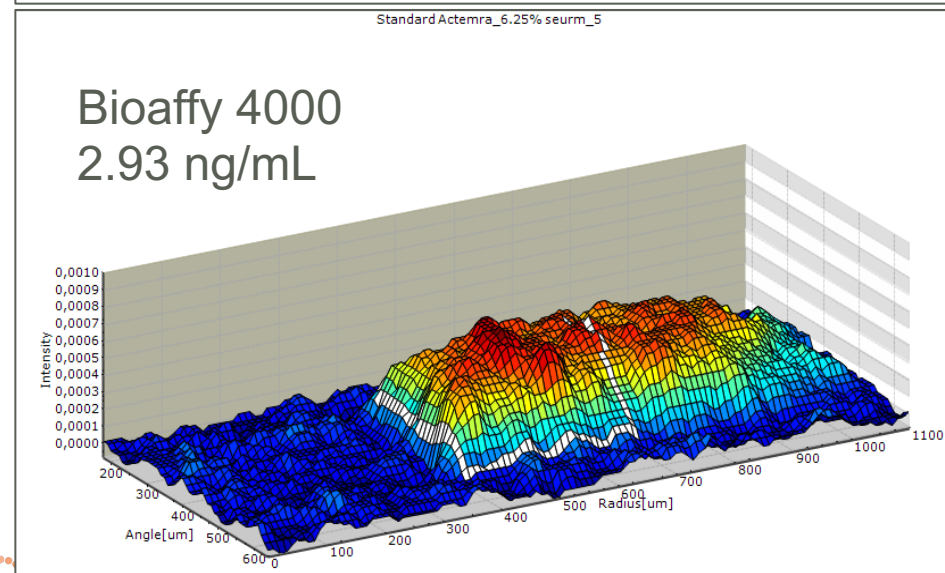
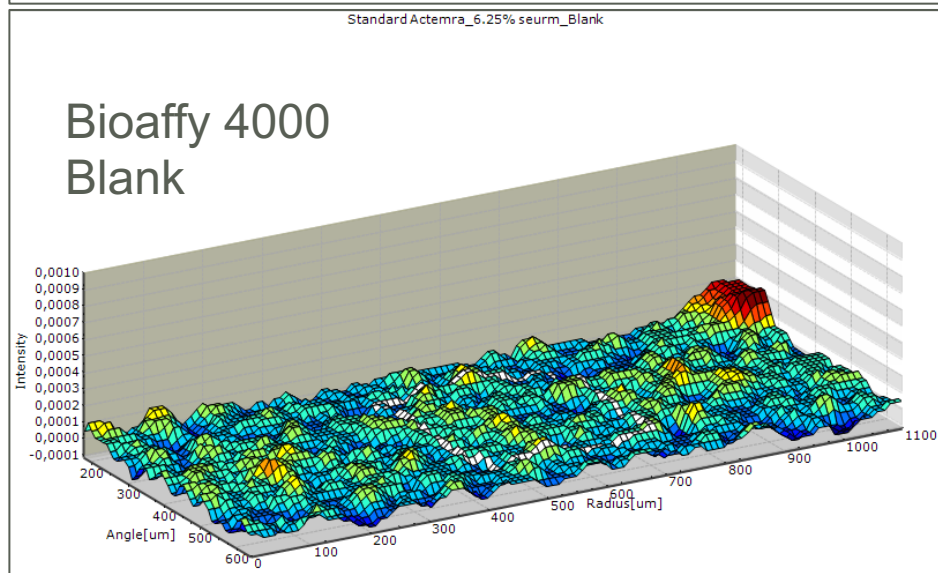
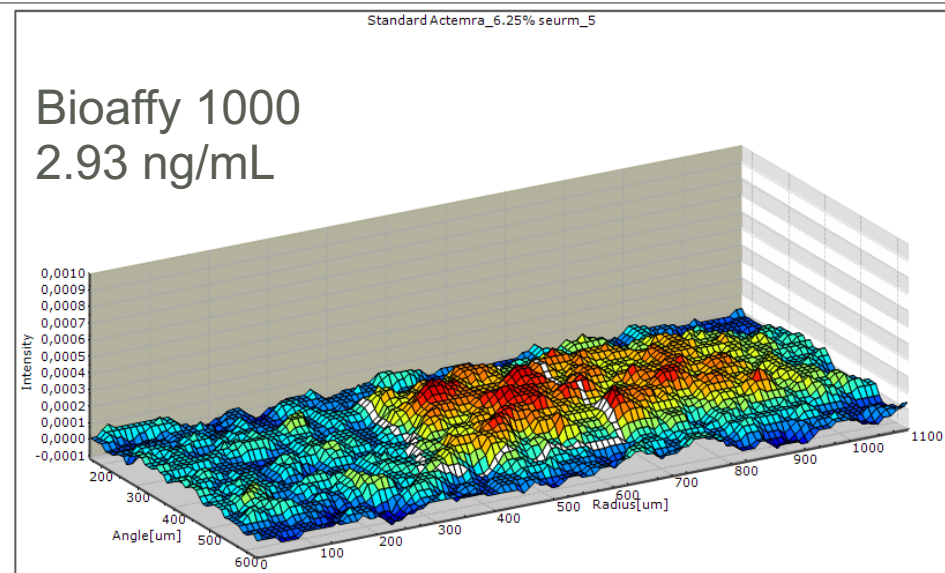
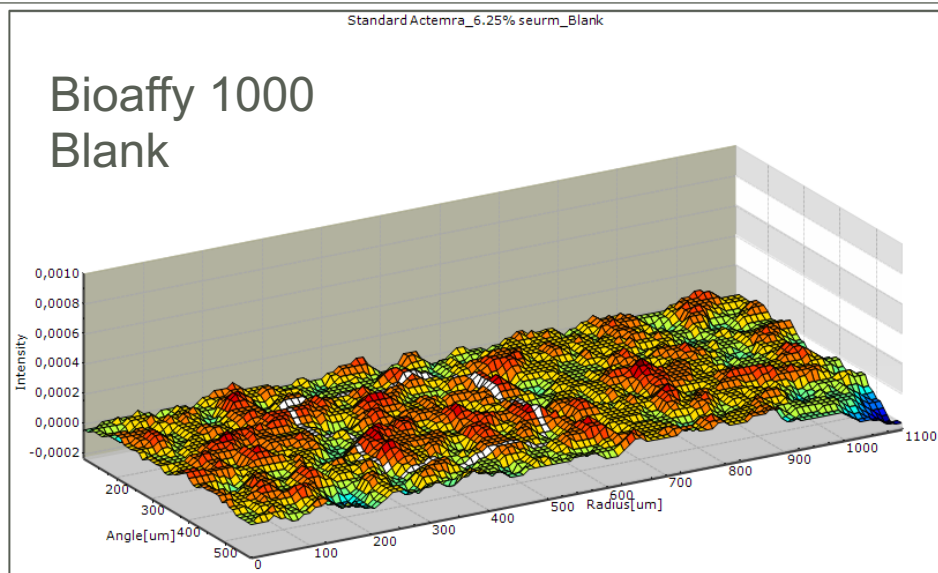
Criteria	Bioaffy 1000 CD	Bioaffy 4000 CD
Capture reagent	350 nM bPD-1 + 350 nM bBSA	
Detection reagent	35 nM Alexa labelled $\alpha$ -pembrolizumab	
MRD (Serum conc.)	1-in-4 (25% serum)	
ULoQ	6 000 ng/mL	
LLoQ	18 ng/mL	6 ng/mL
Selectivity result	80% of individuals met acceptance criteria	80% of individuals met acceptance criteria
Specificity result	100% of unspiked individuals < LLoQ	100% of unspiked individuals < LLoQ



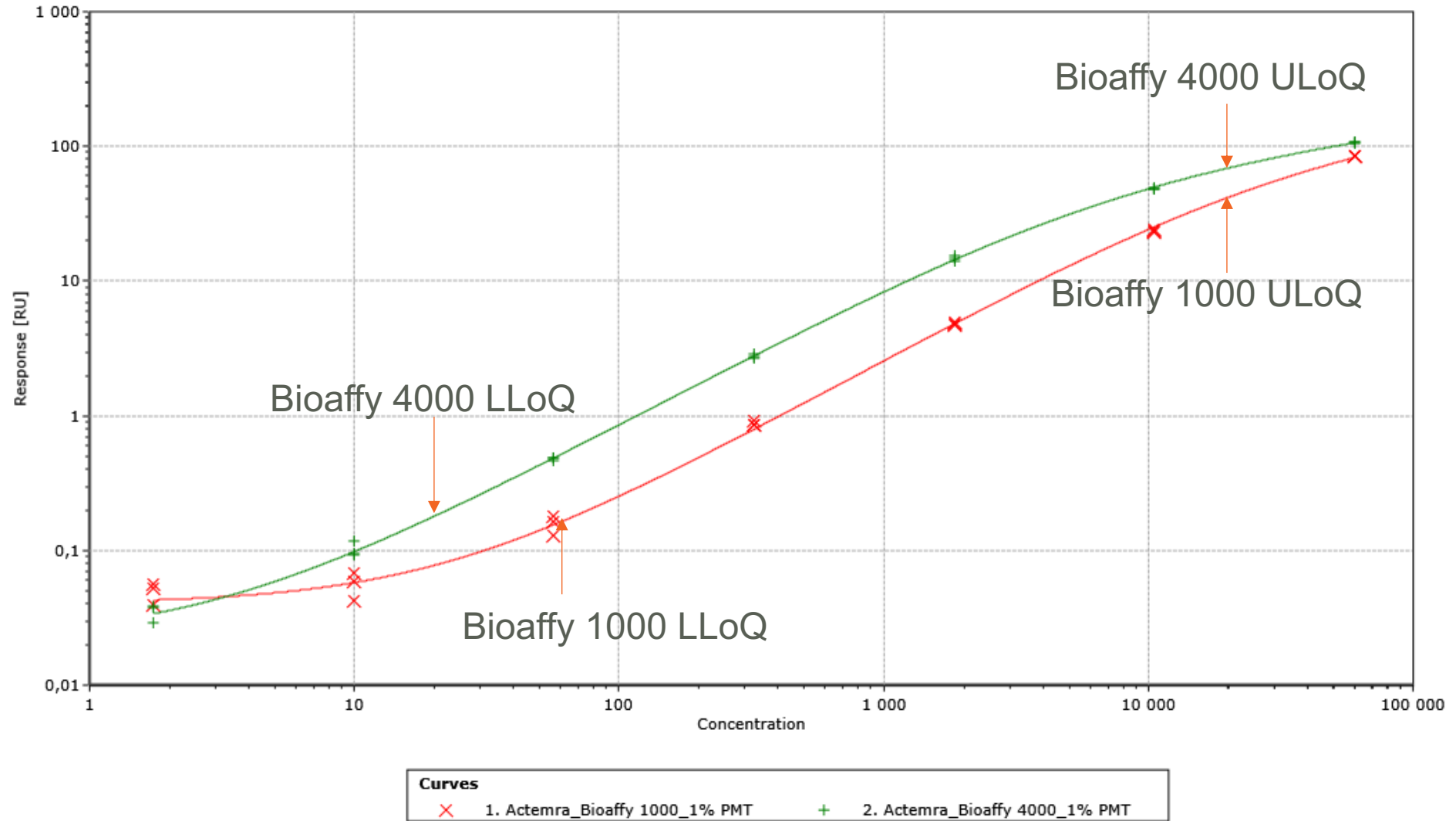
# SEAMLESS TRANSFER TO GYROLAB BIOAFFY 4000 - ACTEMRA



# SEAMLESS TRANSFER TO GYROLAB BIOAFFY 4000 - ACTEMRA



# ACTEMRA HIGH SENSITIVITY PK ASSAY RANGE FINDING



# ACTEMRA PK ASSAY RESULTS

Criteria	Bioaffy 1000 CD	Bioaffy 4000 CD
Capture reagent	175 nM bIL-6R + 525 nM bBSA	
Detection reagent	35 nM Alexa labelled $\alpha$ -toxcilizumab	
MRD (Serum conc.)	1-in-20 (5% Serum)	
ULoQ	20 000 ng/mL	
LLoQ	60 ng/mL	20 ng/mL
Selectivity result	80% of individuals met acceptance criteria	100% of individuals met acceptance criteria
Specificity result	100% of unspiked individuals < LLoQ	100% of unspiked individuals < LLoQ

# CONCLUSIONS

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- Increased signal due to increased sample volume passed over the column, without a comparable increase in background
- Assay capture and detect reagents remain unchanged, demonstrates the seamless plug and play ability of transferring methods to the Bioaffy 4000 CD
- Development of new consumables for existing technologies allows us to be agile when selecting the appropriate methods for expected results, including low ng/mL levels seen in First in Human
- New Gyrolab Bioaffy 4000 CD demonstrates heightened sensitivity which could support LBAs for new modalities dosed at lower concentrations

# THANKS AND ACKNOWLEDGEMENTS

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Maritha Lundin

## EBF Organisers



