

Rapid & Sensitive HCP analysis

CHO-HCP detection with BLI technology

fortéBIO

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Pall ForteBio is a Leader in Label-Free Protein Analysis

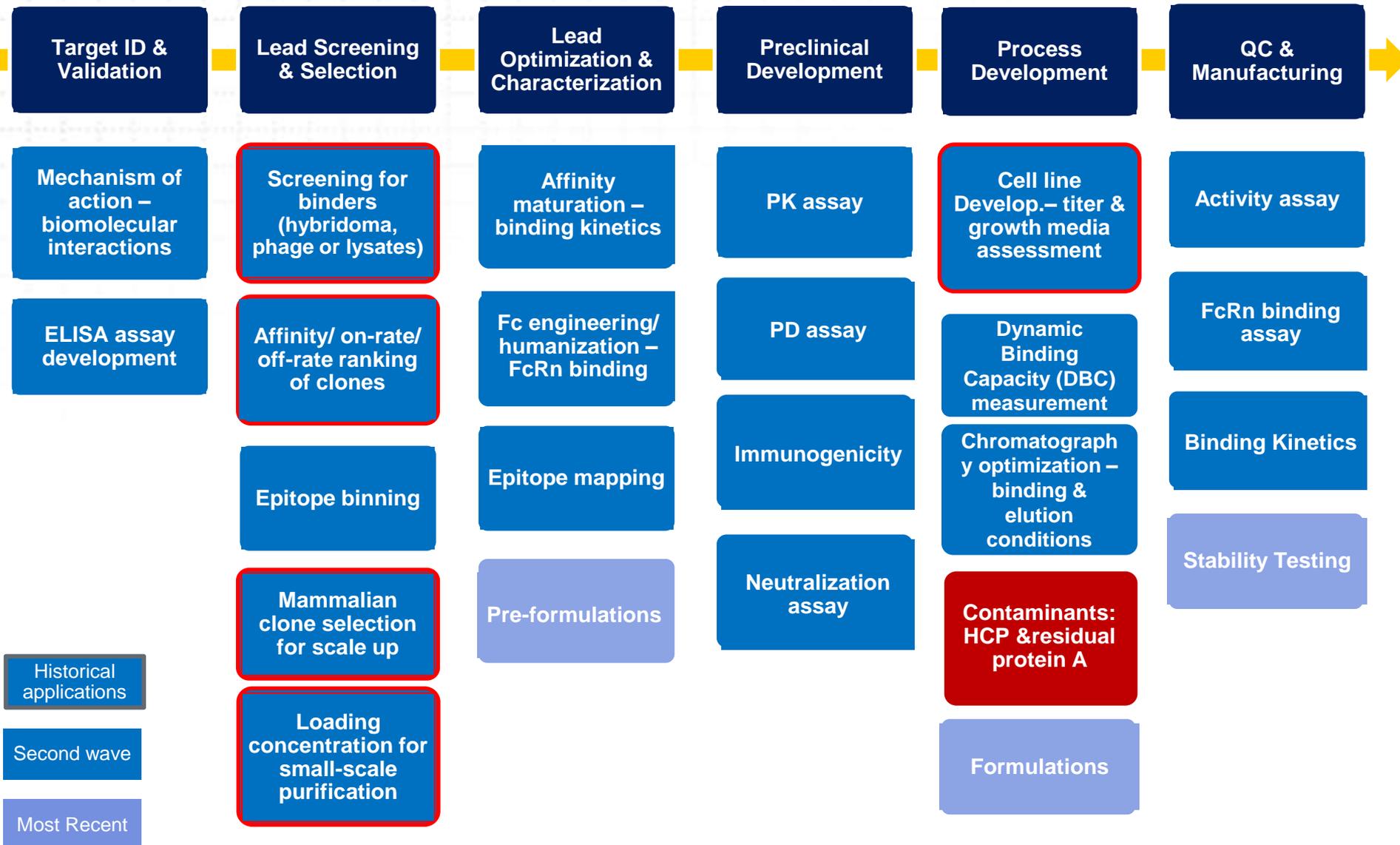


Biomolecular interactions analyzers for

- Affinity
- Kinetics
- Quantitation
- Quantitation of impurities
- Immune reaction

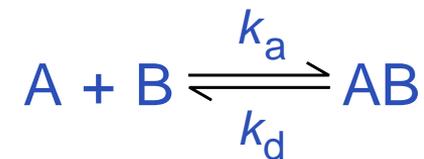
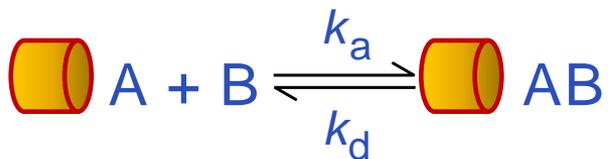
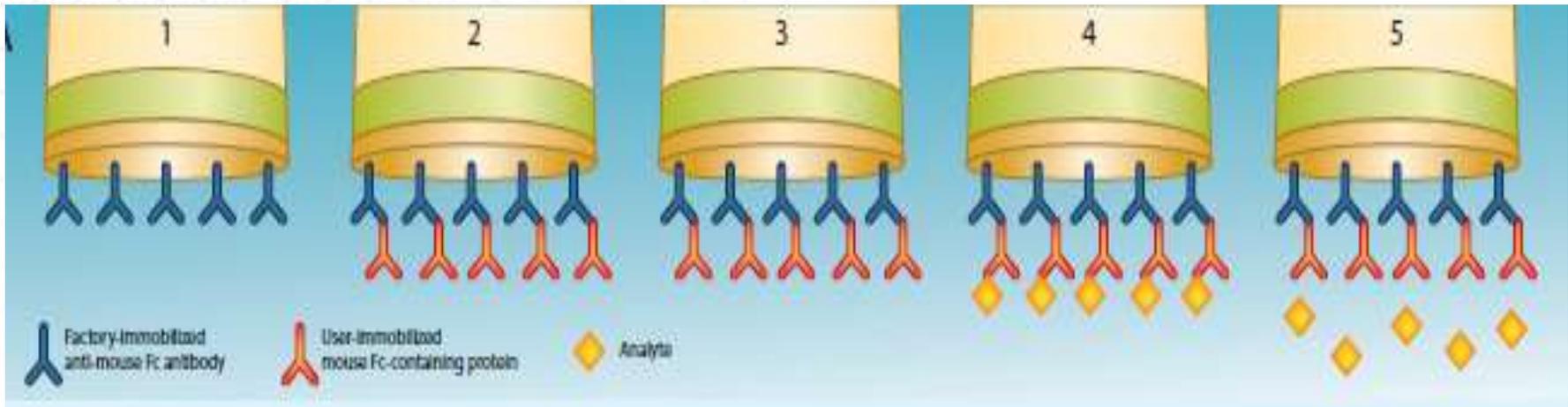
**26 registration dossier
38 in process of registration**

Application Map - ForteBio



- Historical applications
- Second wave
- Most Recent

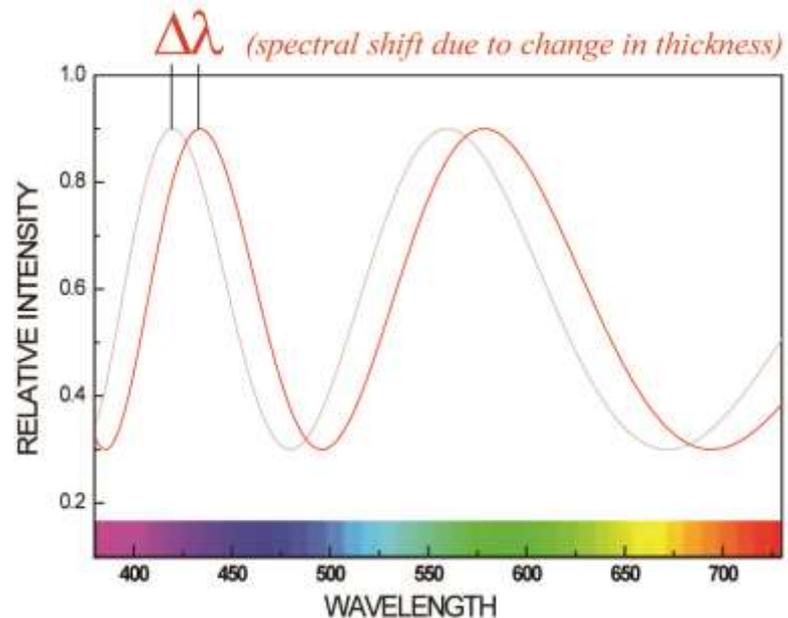
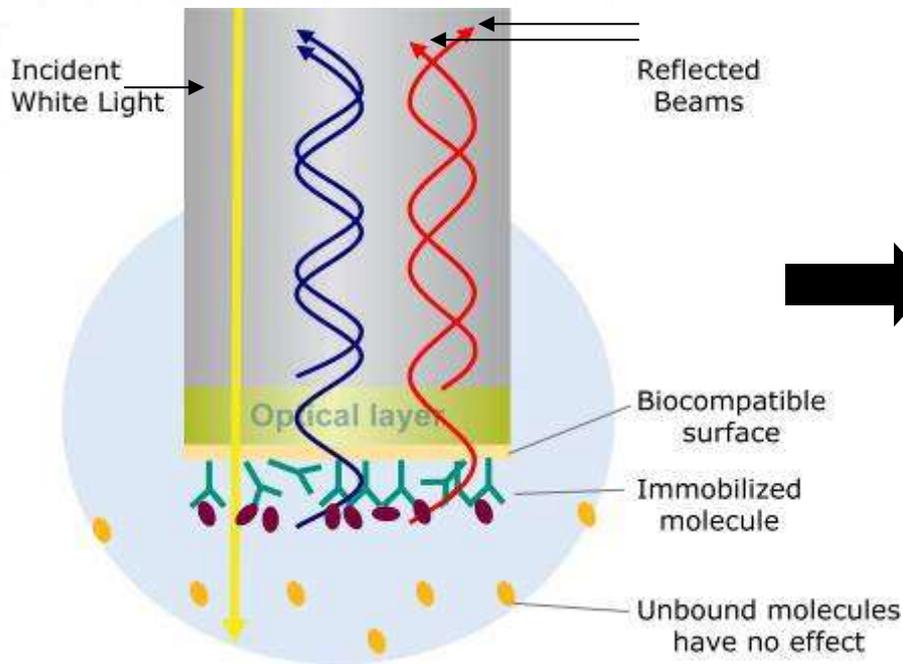
BLI Analytical Instruments : Sensors measuring interaction



- Protein Concentration
- Association rate
- Dissociation rate
- Binding Affinity

Myszka et. al. *Direct Comparison of Binding Equilibrium, Thermodynamic and Rate Constants Determined by Surface- and Solution-based Biophysical Methods*
Protein Science 2002, 11 (5), 1017-1025.

Simple Optical Method to detect Proteins



ForteBio-Cygnus Anti-CHO HCP Detection Kit



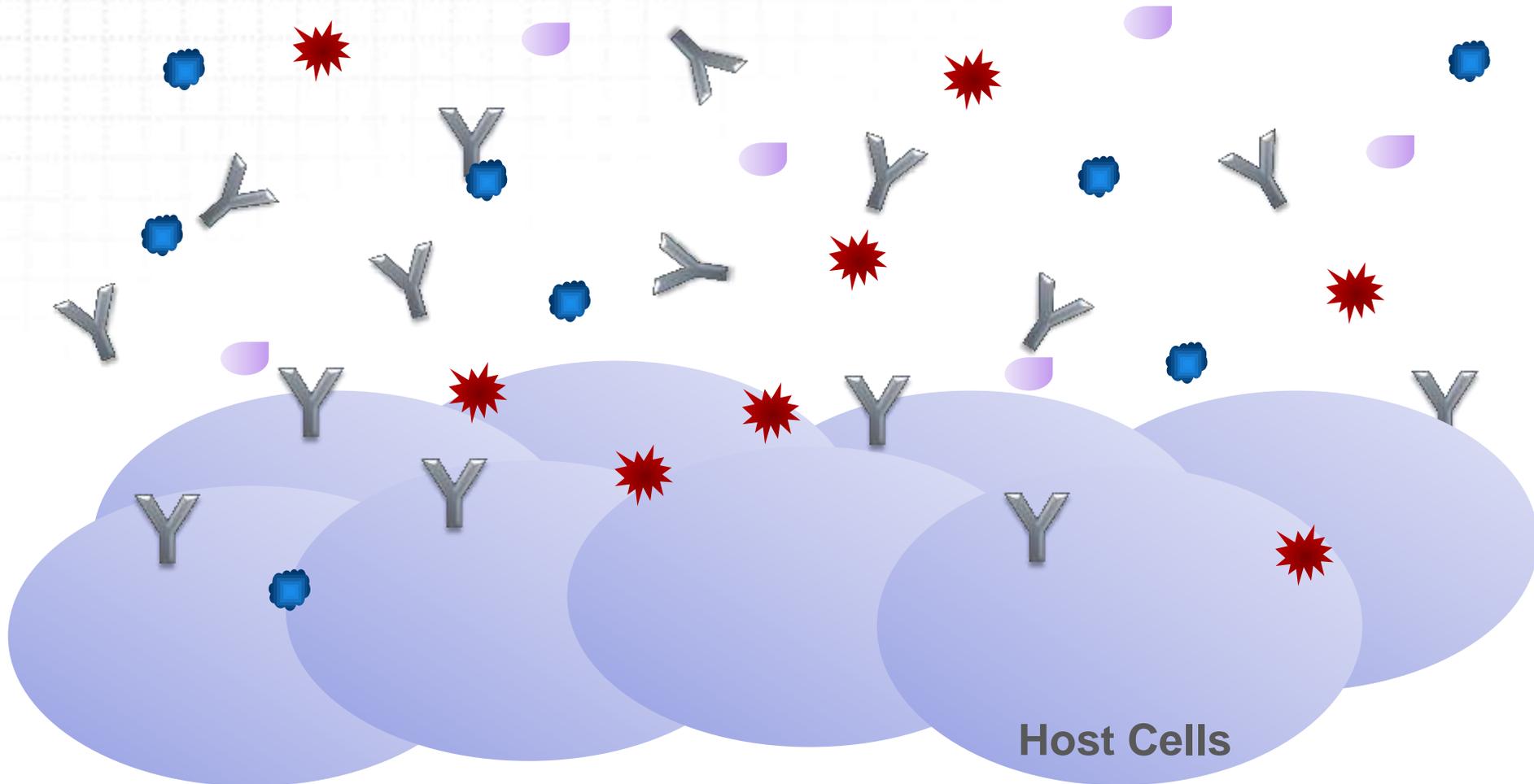
Fast and Accurate Host Cell Protein Detection

HCP – Process Impurities

Removal to the lowest detectable levels required

Y Biotherapeutic Drug

★ ● Host Cell Proteins



Host Cells

ForteBio-Cygnus Kit for Generic HCP Testing



Generic HCP Assays

Specific HCP Assays

Process
Development

Phase I
Clinical Trials

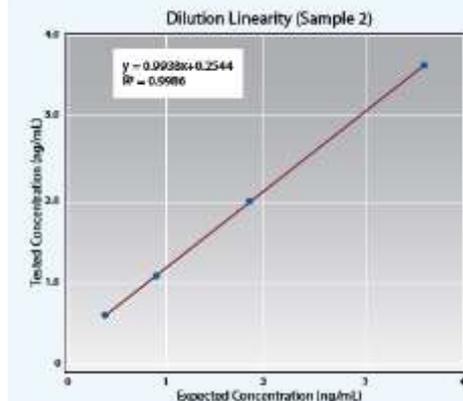
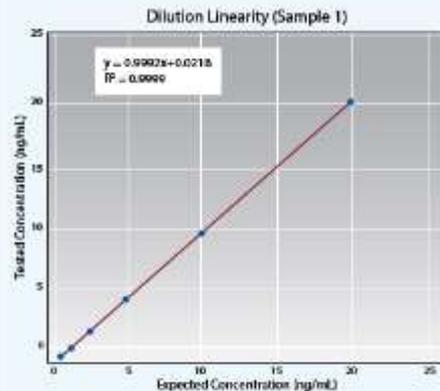
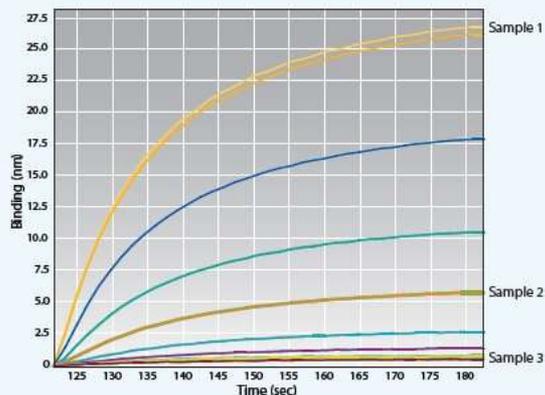
Phase II
Clinical Trials

Phase III
Clinical Trials

Product
Release

In-Process Samples

Excellent assay accuracy, precision, and dilution linearity



	Well Conc. (ng/mL)	Dilution Factor	Calc. Conc. (ng/mL)	%CV	Avg. HCP (ng/mL)	Drug Substance (mg/mL)	HCP (ppm)
Sample 1	19.95	1,000	2,0347	2.5%	19,967	0.02	998,367
	9.96	2,000	19,977	0.4%			
	5.08	4,000	20,327	0.2%			
	2.59	8,000	20,803	0.5%			
	1.18	16,000	18,839	0.3%			
	0.63	32,000	20,175	0.9%			
Sample 2	3.63	20	72	4.2%	81	0.32	253
	2.02	40	81	2.2%			
	1.12	80	89	0.9%			
	0.63	160	101	1.2%			
Sample 3	0.32	20	6.4	2.9%	6	10	0.6

FIGURE 1: HCP quantitation on the Octet QK® system. Example data from the duplicate analysis of three unknown samples run in serial dilution (left). Calculated concentrations and %CV values are shown in the accompanying table (bottom). The dilution linearity graphs for Sample 1 and Sample 2 are shown (top and bottom right).

ForteBio-Cygnus Anti-CHO HCP Detection Kit



- Rapid streamlined workflow
- Faster than any other method
- Easier to use, less hands-on labor
- Wider dynamic range
- Higher sensitivity
- Better assay robustness
- Less prone to human error
- More data consistency