

Octet® Residual Protein A Detection Kit

Rapid Detection and Quantitation of Protein A

Key Features

- Designed for measurement of recombinant Protein A and MabSelect SuRe™
- Accurate quantitation down to 100 pg/mL
- Analyze 96 samples in under 2 hours on the Octet® RH96 system
- Automated detection with minimal hands-on time



Overview

Detecting and minimizing Protein A contamination is a critical quality control step in antibody therapeutic development and production. The Residual Protein A Detection Kit from Sartorius applies the principles of BLI to enable sensitive, accurate quantitation of leached Protein A in bioprocess samples while maintaining a simple workflow. The kit utilizes a validated sample treatment method for dissociating Protein A from antibodies that does not require boiling, neutralization or centrifugation steps.

The kit has been developed as an easier, faster alternative to ELISA with reduced hands-on time and minimal experimenter intervention. It is intended for research and manufacturing use only and is not for diagnostic use in humans or animals.

The Residual Protein A Detection Kit comes with biosensors and reagents required for detection and quantitation of leached Protein A in up to 96 samples. The kit is compatible with all Octet® systems with the exception of the Octet® R2 system.

Example Data

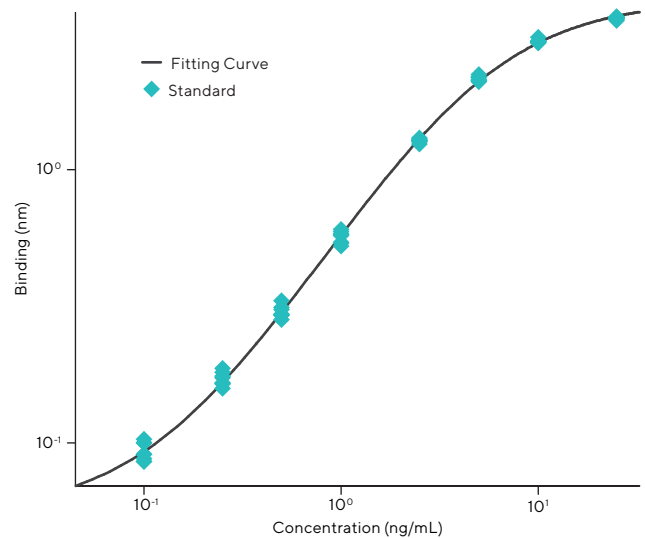
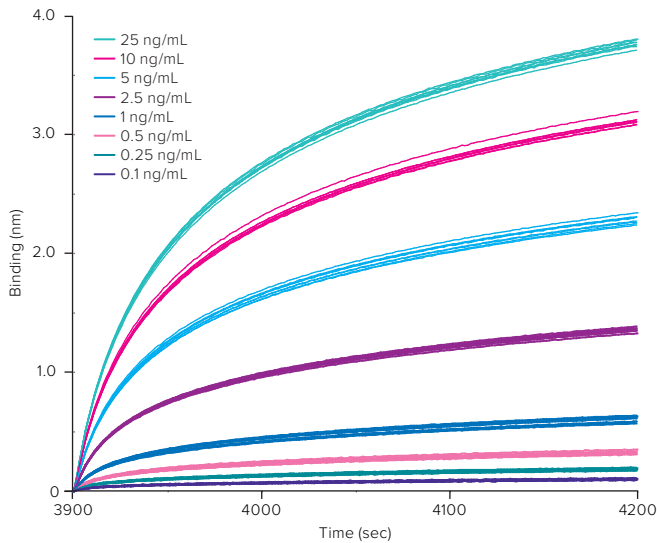


Figure 1: A standard curve was generated using Protein A Standard provided in the kit. Samples were run on the Octet® RH96 system using 16-channel detection mode. Curve fitting was performed using weighted 4 parameter logistic model.

Performance and Validation

Protein A Standard (included) n = 8			MabSelect SuRe™ n = 8		
Target (ng/mL)	% CV	% Recovery	Target (ng/mL)	% CV	% Recovery
10	3.6	105	10	3.7	99
2.5	1.6	98	2.5	3.5	105
0.5	4.4	101	0.5	2.5	92
0.1	12.5	100	0.1	11.7	100

Table 1: Precision (%CV where %CV = Standard Deviation x 100 / Average) and Accuracy (% Recovery where % Recovery = Calculated Conc x 100 / Expected Conc) were calculated for data generated on the Octet® RH96 system using 16-channel detection mode. Results are shown for standard curves generated with Protein A Standard included in the kit and with MabSelect SuRe™.

Protein A Standard (included) n=3			MabSelect SuRe™ n=3		
No. Tests	Target (ng/mL)	% CV	No. Tests	Target (ng/mL)	% CV
3	5	6.4	3	5	7.3
3	2.5	6.6	3	2.5	7.8
3	0.5	4.8	3	0.5	7.0

Table 2: Inter-assay precision was determined using 3 different preparations of sample in 3 independent assays. Protein A Standard or MabSelect SuRe™ was spiked into Sample Dilution Buffer containing 0.5 mg/mL human IgG.

Octet® instrument	LOD (ng/mL)		LLOQ (ng/mL)	
	Protein A Standard	MabSelect SuRe™	Protein A Standard	MabSelect SuRe™
HTX (96-Channel Detection)	0.07	0.08	0.1	0.25
HTX (16-Channel Detection)	0.03	0.06	0.1	0.1
RED384	0.03	0.06	0.1	0.1
QK384	0.07	0.08	0.1	0.25
RED96	0.03	0.06	0.1	0.1
QK®	0.07	0.08	0.1	0.25

Table 3: LOD was determined for various assay formats as the concentration corresponding to binding rate signal three standard deviations above the mean of the zero standard. LLOQ was determined based on the lowest concentration where recovery is within 20% of the expected/theoretical value and precision (%CV) is below 20%. LOD and LLOQ values for both Protein A Standard and MabSelect SuRe™.

Dilution Linearity

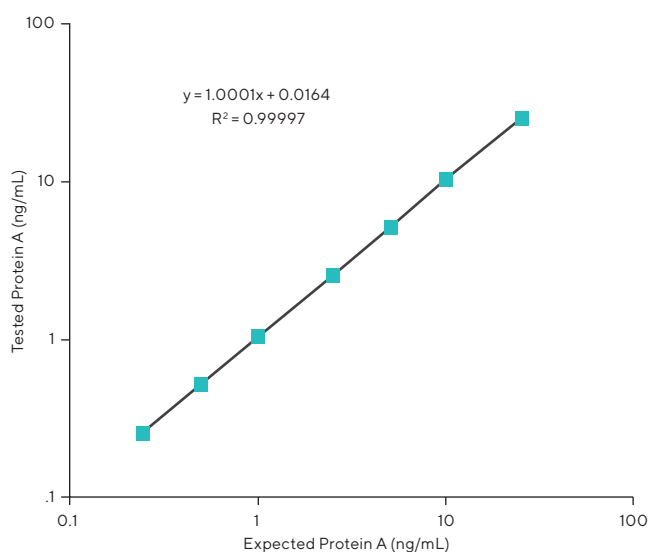


Figure 2: Linearity of dilution was established by comparing expected concentration to calculated concentration in buffer containing 0.5 mg/mL IgG. The graph shows excellent correlation of calculated concentrations in the presence of human IgG throughout the range of the assay.

Ordering Information

Part No.	UOM	Description
18-5128	Kit	Octet® Residual Protein A Detection Kit. Contains 1 tray of 96 Octet® Residual Protein A Biosensors and reagents for analysis of 96 samples.

Note: additional materials are required to run this assay. Please consult Technical Note 45, Ready BLI Detection Kit – Residual Protein A.

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