Performance of the BioScale ViBE™ Workstation Host Cell Protein Assay

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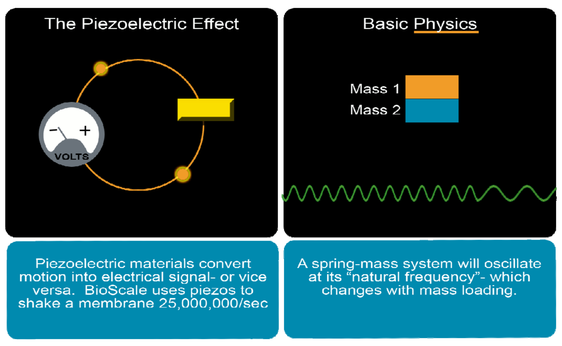
Abstract

Measurement of host cell protein (HCP) contaminants is essential for developing and monitoring an effective purification process for recombinant proteins. Of the multiple techniques available to quantify the concentrations of these contaminants, the most popular format uses polyclonal antisera in a sandwich ELISA. The purpose of this work is to evaluate the performance of a newly emerging technology; the BioScale ViBE™ Platform. Using an assortment of bioprocess samples selected from multiple stages of the purification process, ViBE Workstation performance was compared with a commercially available ELISA.

ViBE Workstation performance was evaluated for inter- and intra-assay precision, quantitation range, and the ability to accurately measure the concentration of controls spiked into a sample. Both measurement techniques were able to accurately measure the concentrations of Chinese Hamster Ovary (CHO) HCP contaminants in 102 bioprocess samples. The results agreed well across the entire quantitation range, with a 3 ng/mL average difference between the two data sets. These data show that the ViBE Workstation produces results comparable to established techniques and offers significant advantages with respect to work-flow and hands-on-time.

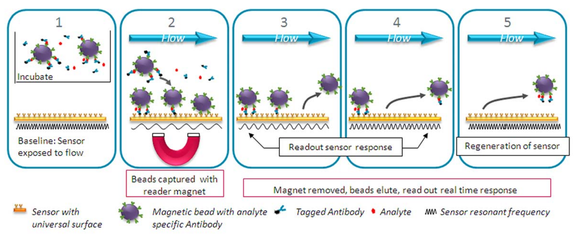
Technology and Instrumentation

A. Technology Basics



B. ViBE Workstation

C. Assay Format



Traditional assay format with novel detection technology allows easier use and faster assay development.

Results

Figure 1: Assay Performance

•Repeatability – 3 standards of known concentration were tested twenty times with one cartridge.

Sample (ng/mL)	Measured Conc (ng/mL)	SD	CV (%)
50	53.2	5.4	10%
25	24.8	2	8%
5	5.4	0.3	6%

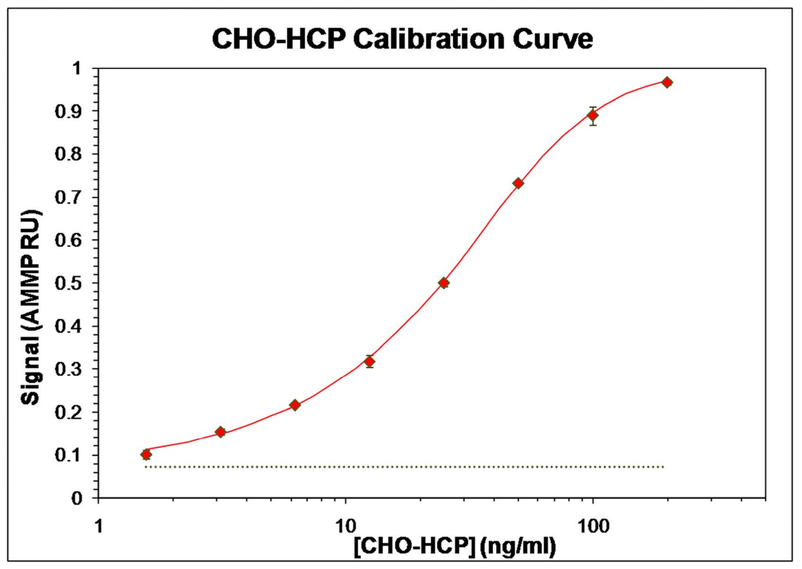
•Reproducibility – 3 samples were tested in duplicate across three lots of cartridges on three different days

Sample (ng/mL)	SD	CV
44.1	2.5	6%
19.6	1.2	6%
5.2	0.6	12%

•Comparative Performance – A control sample was run at two dilutions on a commercially available ELISA and the ViBE Workstation. The data are compiled from eight separate assays run over a time period of several weeks

	ELISA		ViBE	
Dilution	1:5000	1:10,000	1:5000	1:10,000
Average	52.8	23.3	69.4	30.2
SD	8.5	3.0	4.8	3.8
CV	16%	13%	7%	13%

Figure 2: Calibration Range



Typical calibration curve. Dashed horizontal line is the signal from antigen negative samples.

Results (cont'd)

Figure 3: Accuracy of ViBE Assay in Bioprocess Samples

A. Dilution recovery

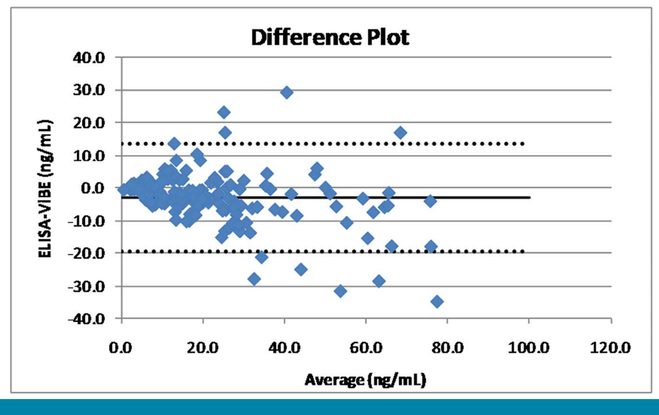
Sample A	Dilution	Measured conc. (ng/mL)	Calculated Conc. (ng/mL)	Linearity
	1:16	16.5	329.3	
	1:32	7.8	311.6	95%
	1:64	3.8	302.9	97%
	1:128	1.8	289.5	96%
	1:256	0.9	302.2	104%

B. Spike recovery

Sample A Spike	Dilution	Measured conc. (ng/mL)	Theoretical Conc. (ng/mL)	Recovery
	1:16	26.0	30.0	87%
	1:32	20.9	20.0	104%
	1:64	16.7	15.0	111%
	1:128	13.8	12.5	111%
	1:256	14.8	11.3	132%

A sample was spiked with either diluents (A) or calibrator (B). Within the quantitation range of the assay the recovery of the calibrators was within 20% of nominal.

Figure 4: Comparative Assay Performance with Samples



One hundred and two samples were measured by both the ViBE CHO-HCP assay and ELISA. The results from both assays were averaged (x axis) and plotted versus the difference between the assays (y axis). The plot shows a slight bias (solid line) of -3 ng/mL. Dashed lines are the 95% confidence limits.

Conclusions

The BioScale ViBE CHO–HCP assay performs similarly to a validated commercial ELISA and offers significant advantages with respect to workflow and hands–on time.

Acknowledgement

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