



# Host Cell Protein Assay Development Services

*Contract Services that Enable Robust Host Cell Protein Detection  
Using the Octet™ System*

## Key Features

- Fast, less than 2 hours assay time, broad dynamic range, more robust than ELISA HCP assays
- Production and delivery of custom host cell protein detection kits for the Octet system
- Conjugation of host cell protein detection antibody to ForteBio biosensors
- Complete assay development including buffer and reagent optimization

ForteBio offers a range of high-quality, custom assay development services to help customers develop specific assays for its Octet platform of instruments, including host cell protein (HCP) detection assays. ForteBio's HCP assays allow Octet users to cost-effectively accelerate their research efforts and maximize the utility of their Octet system. Since no two HCP detection assays are identical, the custom services team will work closely with each customer to tailor each assay to the customer's specifications using customer-defined capture reagents and analytes. All custom products are developed by ForteBio's world-class product development group to deliver the best quality-controlled products possible for the Octet platform.

Host cell protein detection requires an assay that consistently delivers a broad, linear dynamic range, sensitivity to meet FDA guidelines, and unmatched reproducibility from each and every experiment. The Octet platform delivers consistency in quantitation unlike any other real-time detection tool available. Octet instruments use Dip and Read™ biosensors with specific capture antibodies immobilized on their tip surfaces to detect and quantify specific proteins of interest, including host cell proteins. The unique detection method employed by the Octet system provides the sensitivity, accuracy, and robustness required by this critical biopharmaceutical assay.

Custom HCP detection kits contain biosensors and all the reagents required to quantitate customer-designated host cell proteins.

## INTENDED USE

All custom biosensors and assay kits are intended for the detection of customer-defined analytes and are intended for research and

manufacturing use only. They are not intended for diagnostic use in humans or animals.

## ASSAY PRINCIPLES

Figure 1 illustrates a CHO host cell protein detection assay. An anti-CHO antibody is immobilized onto ForteBio biosensors and dipped into a microplate well to capture CHO cell proteins in solution. A fluorescein-conjugated anti-CHO antibody is used to sandwich the CHO cell protein, then an HRP-conjugated anti-FITC antibody is used to specifically localize horseradish peroxidase (HRP) to the complex. Finally, to amplify the mass on the biosensor in a concentration dependent manner, metal DAB was precipitated onto the biosensor surface using HRP.

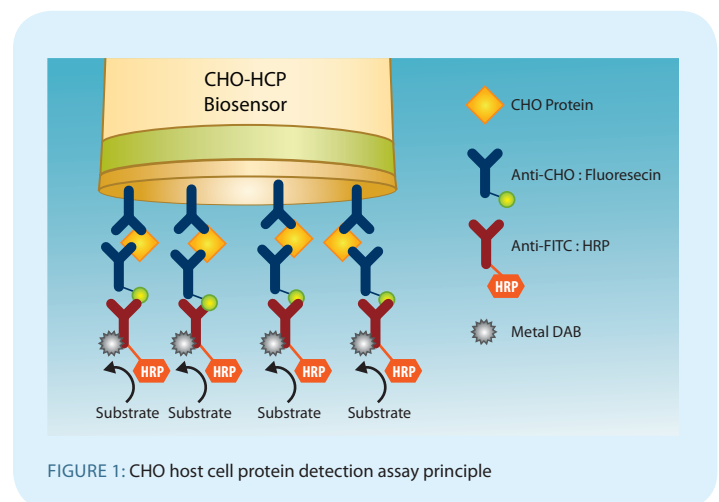


FIGURE 1: CHO host cell protein detection assay principle

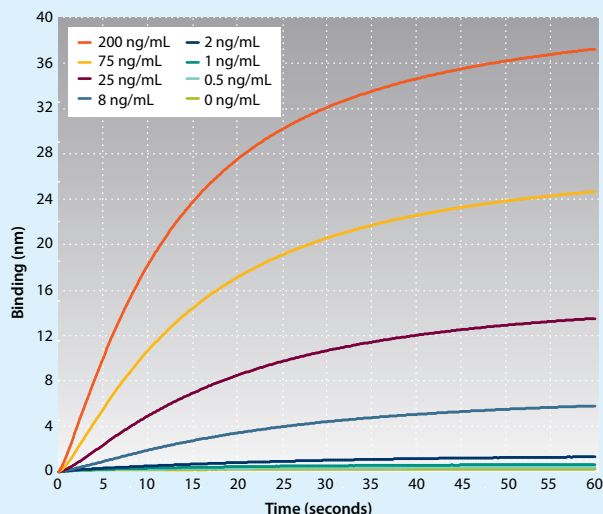


FIGURE 2: Raw data from the final amplification step of the CHO HCP assay using Octet RED.

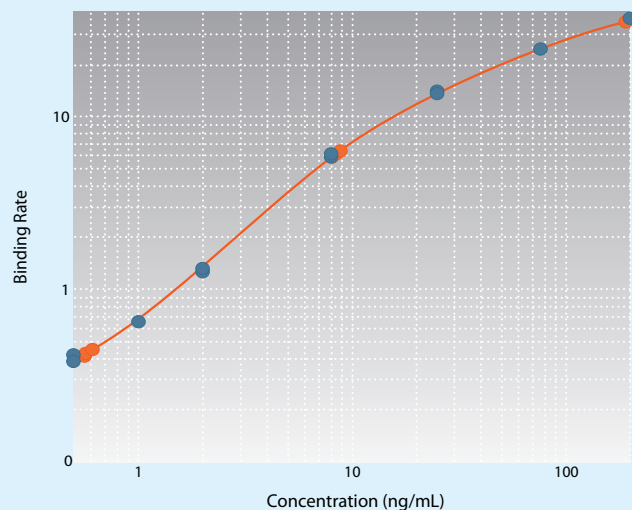


FIGURE 3: Standard curve showing standards (n = 3 for each standard) and unknown samples (n = 8 for each unknown). The lower limit of detection in this assay was less than 0.5 ng/mL.

Spike Conc. (ng/mL) *	Calculated Conc.	%CV of Calculated Conc.	% Recovery
200	201.6	4	101
8	8.5	4	106
0.5	0.57	7	114

\* CHO Cell Protein, n = 8 for each.

TABLE 1: Accuracy and robustness of CHO host cell protein quantitation. In this assay, CV's of less than 10% were achievable across the entire dynamic range.

### EXAMPLE DATA

CHO cell host cell proteins were detected using an enzymatic amplification protocol (Figure 1) based on a commercially available anti-CHO HCP antibody and standards. Raw data and a standard curve for the Octet host cell protein assay are shown in Figures 2 and 3. Accuracy and precision of the host cell protein quantitation are shown in Table 1.

## Ordering Information

Part No.	UOM	Description
Custom	Kit	1 tray of 96 Custom HCP biosensors and all the necessary reagents and buffers required to detect and quantify specific host cell proteins

Minimum order of 20 kits required for all custom orders.

### FORTEBIO NOTES

All custom Dip and Read™ biosensors are compatible with all Octet instruments including the new Octet 384 series.

For more information about ForteBio's Custom Services, please visit our website at [www.fortebio.com](http://www.fortebio.com) or contact us directly at [customservices@fortebio.com](mailto:customservices@fortebio.com).

For more information about ForteBio's Octet platform for label-free, real-time detection of biomolecular interactions, and applications, visit our website at [www.fortebio.com](http://www.fortebio.com) or contact us directly.