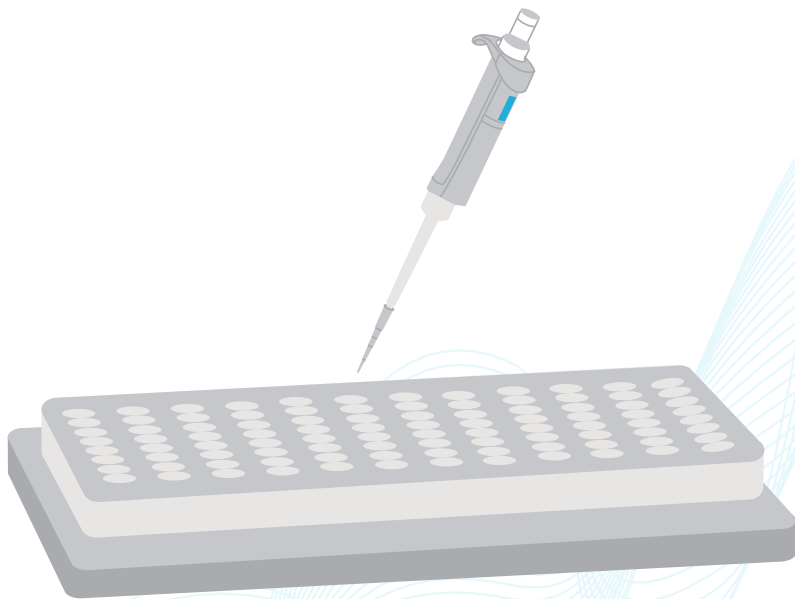




# CHO HCP ELISA Kit



CHO HCP (Host Cell Protein) residue assay kit is designed to detect host cell protein (HCP) residues from the manufacturing process of biologics based on Chinese hamster ovary (CHO) cell CHO-K1 cell line. Specific antibodies can recognize and detect more than 80% of HCP molecules, including low and high molecular weight species. The assay kit can be used in the early or late process development stages of projects using CHO-K1 expression system, and quality control labs. It can analyze the removal efficiency of HCP during the process development process, as well as the quality control for product release test.

## Application

The CHO HCP ELISA kit from Duoning adopts one-step enzyme-linked immunosorbent assay method. Samples containing HCP can react simultaneously with HRP-labeled goat anti-CHO-K1 antibody and anti-CHO-K1 antibody coated on microtiter plate. Finally, a sandwich complex of solid-phase antibody-HCP-labeled antibody is formed. Unbound antigen and antibody can be removed by washing the plate. After the TMB substrate was added to the wells for sufficient reaction, termination solution was added to terminate color development, and the OD values of the reaction solution at 450 nm and 650 nm were analyzed with a microplate reader. The value of OD 450 nm - OD 650 nm is positively correlated with the HCP content in the solution, and the HCP concentration can be calculated according to the standard curve.

## Product Feature

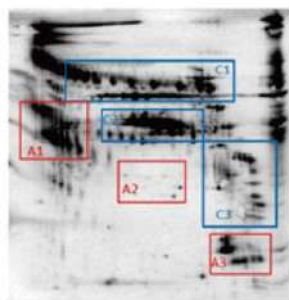
- Higher coverage rate of 81% (using 2D Gel/Western Blot assay): The detection antibody used by Duoning HCP Assay Kit has a wider recognition efficiency for host cell proteins of different sizes and isoelectric points. After 2D electrophoresis and Western Blot assay, the coverage rate can reach > 80%.
- Good batch consistency and stable supply reduce the inconvenience caused by frequent bridging studies.
- With multiple successful IND applications, it is your best choice for release testing.
- The newly upgraded ready-to-use kit reduces the time required for reagent preparation and greatly improves operational repeatability and analysis efficiency.



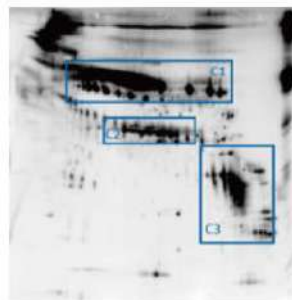
CHO HCP ELISA Kit (Ready-to-use)

## Case Study

The blue box in the figure is the host cell proteins recognized by both Duoning kit and other commercial kits on the market, while the red box is the additional host cell proteins recognized by the Duoning Kit.



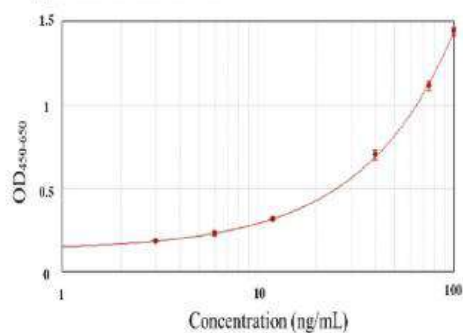
Duoning HCP ELISA Kit (81%)



HCP ELISA Kit on Market (63%)

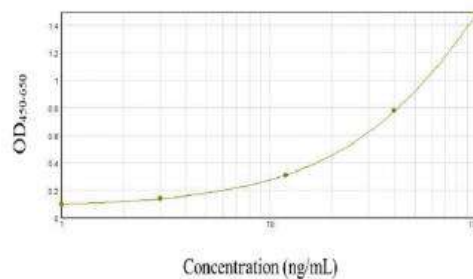
**Good linearity:** The measurement of CHO-K1 host cell protein shows that Duoning HCP assay kit provides good linearity in a wide range (3 ng/mL-100 ng/mL).

Example Standard Curve



Duoning HCP ELISA Kit

Example Standard Curve



HCP ELISA Kit on Market

**Excellent solvent compatibility and assay specificity:**

Buffer system	Measurement concentration with spiked 20 ng/ml HCP standard samples (ng/ml)	Recovery (%)
PBS buffer, pH 7.4 / Triton X-100	17.9	87-93%
Histidine buffer, pH 6.0 / PS80	20.3	97-106%
Histidine buffer pH 6.0 / Sucrose and PS80	19.4	92-102%

**Good precision and accuracy:** The repeatability and precision of the kit were investigated at three different sample concentrations: low, medium, and high. The results showed that the kit had good repeatability and accuracy under different concentrations and meet requirements of quality control standards.

	Repeatability (RSD%, n=4)	Intermediate precision (PSD%, n=12)	Accuracy (%Recovery, n=12)
Low (3 ng/ml )	<16%	10%	70-105%
Medium (12 ng/ml )	<6%	6%	92-114%
High (75 ng/ml )	<5%	4%	93-107%

**Good sensitivity and lowest quantification limit:** The operation index of the kit was investigated at the lowest quantification limit (3 ng/mL), and the results showed that the kit still had good signal-to-noise ratio, precision, and accuracy at the lowest quantitation limit.

	Average (n=6 )	Range (n=6 )
Signal-to-noise ratio	7.8	7.1-8.3
Precision (%)	2%	0-4%
Accuracy (%)	95%	90-96%

### Ordering Information

Product Name	Part No.
CHO HCP (Host Cell Protein ) ELISA Kit (uncoated )	DNRG030101
CHO HCP (Host Cell Protein) ELISA Kit (Pre-coated )	DNRG030102
CHO HCP (Host Cell Protein) ELISA Kit (Ready-to-use)	DNRG030103

# Duoning Biotechnology Group

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