

# CHO HCP ELISA Kits

## Product Introduction

CHO cells are the most prevalent host organism for the production of recombinant proteins. Their main advantages include easy to scale up for manufacturing, stable clones of high productivity, low virus susceptibility and human-compatible post-translational modifications (e.g., glycosylation). Different biotherapeutics, monoclonal antibodies in particular, are mostly produced in CHO cells in the biopharmaceutical industry.



### • SHENTEK® CHO HCP ELISA Kit

The SHENTEK® CHO HCP ELISA Kit delivers highly sensitive detection and quantitation of CHO protein impurities across a wide range of samples, including monoclonal antibodies, recombinant proteins, and vaccines, derived from different stages of CHO expression systems. Both the calibration standards and capture antibodies have been thoroughly characterized, and the coverage of anti-CHO HCP antibodies was validated by 2D and LC-MS/MS analysis.

### • SHENTEK® CHO PLBL-2 HCP ELISA Kit

The SHENTEK® CHO PLBL-2 HCP ELISA Kit provides precise quantification of the specific high-risk CHO PLBL-2 protein in biologics produced from CHO expression systems. The assay is compatible with a variety of sample types, such as cell culture supernatant, process analytical technology (PAT) samples, and drug substance (DS) or drug product (DP) samples.

### • SHENTEK® CHO-K1 HCP ELISA Kit

Designed specifically for the quantitative detection of CHO-K1 protein residues in biopharmaceuticals produced with CHO-K1 cells, the assay meets the needs of both bioprocess development and quality control (QC) release.

All the kits are produced in compliance with ISO 13485 quality standards, ensuring consistent and reproducible results; also the assays were fully validated and complies with pharmacopeial requirements.

Product Number	Product Name	Quantity
1301304-1	SHENTEK® CHO HCP ELISA Kit (One-step ELISA)	96 tests
1301304-Ab01	SHENTEK® Anti-CHO HCP Antibody	1mg
PNM001	SHENTEK® CHO HCP Antigen	1mg
1301305	SHENTEK® CHO-K1 HCP ELISA Kit (One-step ELISA)	96 tests
1301305-1	SHENTEK® CHO-K1 HCP ELISA Kit (One-step ELISA)	96 tests
1301305-1-Ab01	SHENTEK® Anti-CHO-K1 HCP Antibody	1mg
1301315	SHENTEK® CHO PLBL-2 HCP ELISA Kit	96 tests

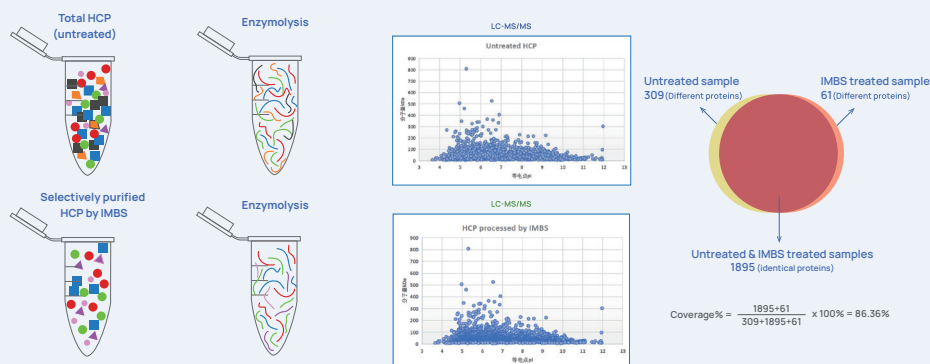
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## Anti-CHO HCP Antibody coverage



### Anti-CHO HCP antibody Coverage Analysis by LC-MS/MS

Anti-CHO HCP antibody coverage (>85%) assessment

(Over 2000 CHO HCPs identified by IMBS & LC-MS/MS analysis, including high-risk HCPs in the published literature)



## High-risk CHO HCPs

HCPsThe risk of HCPs depends on an individual HCP's ability to co-purify with the product, to modify or degrade the drug and/or the excipient, with its potential for immunogenicity; high-risk HCPs can cause:

- 1 Immunogenic response in humans;
- 2 Potential adjuvant effects to elicit the immune activation;
- 3 Biological impact that could be functional in humans;
- 4 Drug quality or formulation impact, like enzymatic activity to degrade or aggregate the product.

SHENTEK® uses LC-MS/MS to identify the high-risk HCPs in the quantitation standards and the CHO HCPs isolated by antibody-conjugated immunomagnetic beads for risk assessment as shown in the right figure.

### The Impact of High-risk CHO HCPs

PLBL2	Immunogenic response
S100A6	
RPL30	
ANXA5	
Lipoprotein lipase	Degradation of mAbs
Matrix metalloproteinases	
Cathepsin D Protease	
Serine proteases	
PDI9	Aggregation of product
BiP	



## Key Features of SHENTEK® CHO HCP ELISA Kit

- ✓ **Assay type:** Sandwich ELISA kit
- ✓ **LOQ (Limit of quantitation):** 1.5 ng/mL
- ✓ **Precision (Repeatability):** CV < 15% at all concentrations except at or below LOQ where CV ≤ 20%
- ✓ **Specificity:** No cross-reactivity with different host cell proteins (e.g., Vero, HEK293T, Hensenula and E. coli)
- ✓ **Robustness:** Consistent assay performance across different sample matrices, and consistent sample linearity throughout a dilution series
- ✓ **Coverage:**
  - **Risk factors of immunogenicity:** Coverage of high-risk CHO HCPs in CHO HCP standards and antibodies
  - **Coverage assessment:** Coverage of the CHO HCP antibodies to the standards was validated by orthogonal methods of IMBS®-2D and IMBS®-LC/MS
- ✓ **Stability:** Highly consistent product quality within and among batches for reliable QC results

Standard concentration (ng/mL)	Average test value (ng/mL)	%CV
128	122.66	3.4
64	62.43	3
2	2.26	9.2
1.5	1.77	5.6