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SHENTEK

# CHO HCP ELISA Kit

## 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.

US Pharmacopeia states that the final products should have HCP levels ranging from <1 to 100 ng/mg, and Chinese Pharmacopoeia specifies CHO HCPs in the final product must be lower than 0.05% of the total protein content.

SHENTEK® CHO HCP ELISA Kit is used for detection and quantitation of HCP impurities across a broad range of samples (e.g., monoclonal antibodies, recombinant proteins, vaccines) from different stages of CHO expression systems. The assay was fully validated and complies with pharmacopeial requirements. The quantitation standards and capture antibodies were characterized. In addition, the coverage of anti-CHO HCP antibodies to the antigen was validated by 2D and LC-MS/MS analysis. The assay performance meets the needs of not only as a bioprocess development tool, but also a QC release test, eliminating the need to develop a custom- or process-specific assay. Kit manufacturing complies with ISO13485 quality standard.

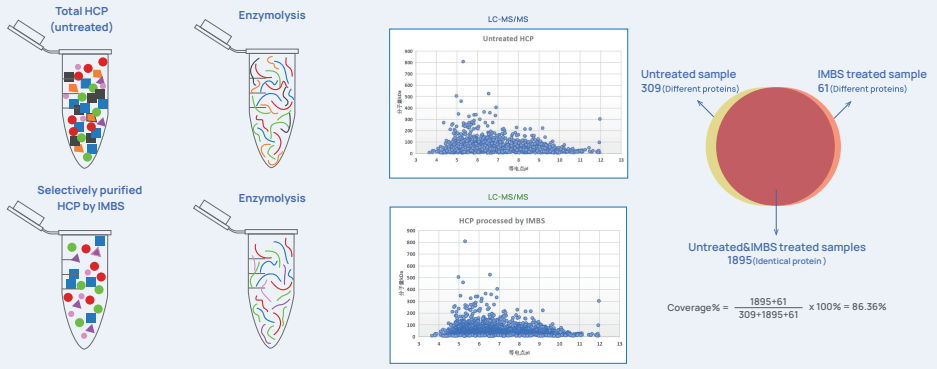
| Product Number | Product Name | Quantity |
|---|---|---|
| 1301304-1 | SHENTEK® CHO HCP ELISA Kit (One-step ELISA) | 96 tests |
| 1301304-Ab01 | SHENTEK® Anti-CHO HCP Antibody | 1 mg |


Huzhou Shenke Biotechnology Co., Ltd.

info@shentekbio.com

+1-908-822-3199/ +86-400-878-2189

## Antibody coverage




**CHO-HCP antibody Coverage Analysis by LC-MS/MS**

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.

| High-risk CHO HCPs | 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

- **Assay type:** Sandwich ELISA kit
- **Linear range:** 1-128 ng/mL, $R^2$ > 0.990
- **LOQ (Limit of quantitation):** 1.5 ng/mL
- **Accuracy:** 80%≤Recovery≤120%， %CV ≤ 20%
- **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 |