

Host Cell Protein ELISA Kits

SHENTEK® HCP ELISA Kits are intended for the quantitative analysis of host cell proteins (HCPs) in biopharmaceutical products and cover a broad range of commonly used expression systems, including bacterial, insect, mammalian, and human host cells. HCPs are a major class of process-related impurities, and regulatory expectations call for their levels to be controlled to levels that are as low as reasonably achievable.

Each SHENTEK® assay is developed and validated for process-specific HCP detection. Immunogens are prepared from both high- and low- molecular-weight protein fractions to enhance antibody coverage and improve the detection of low-molecular-weight HCPs. Furthermore, SHENTEK® HCP antigens are generated from representative product- or process-specific cell harvest samples, supporting broad coverage of HCPs that may potentially be present in the final product.

SHENTEK® maintains a sufficient supply of qualified antibodies to support potential bridging studies, method revalidation, and GMP QC release testing, which ensure assay continuity throughout the product lifecycle

Product Number	Product Name	Size
1301301	SHENTEK® <i>E. coli</i> (Protein Expression Strains) HCP ELISA Kit	96 Tests
1301301-1	SHENTEK® <i>E. coli</i> (Protein Expression Strains) HCP ELISA Kit (One-step ELISA)	96 Tests
1301301-Ab01	SHENTEK® Anti- <i>E. coli</i> (Protein Expression Strains) HCP Antibody	1mg
1301302	SHENTEK® <i>E. coli</i> (K-12 & Alkaline Lysis) HCP ELISA Kit	96 Tests
1301302-Ab01	SHENTEK® Anti- <i>E.coli</i> (K-12 & Alkaline Lysis) HCP Antibody	1mg
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
1301305-1	SHENTEK® CHO-K1 HCP ELISA Kit (One-step ELISA)	96 Tests
1301305-Ab02	SHENTEK® Anti-CHO-K1 HCP Antibody	1mg
1301315	SHENTEK® CHO PLBL-2 HCP ELISA Kit	96 Tests
1301308	SHENTEK® MDCK HCP ELISA Kit (One-step ELISA)	96 Tests
1301308-Ab01	SHENTEK® Anti-MDCK HCP Antibody	1mg
1301309	SHENTEK® Vero HCP ELISA Kit (One-step ELISA)	96 Tests
1301309-Ab01	SHENTEK® Anti-Vero HCP Antibody	1mg
1301312	SHENTEK® Sf9 HCP ELISA Kit (One-step ELISA)	96 Tests
1301312-Ab01	SHENTEK® Anti-Sf9 HCP Antibody	1mg
1301311Z01	SHENTEK® HEK293 HCP ELISA Kit (One-step ELISA)	96 Tests
1301311-Ab01	SHENTEK® Anti-HEK293 HCP Antibody	1mg
1301313	SHENTEK® <i>P. pastoris</i> HCP ELISA Kit (One-step ELISA)	96 Tests
1301313-Ab01	SHENTEK® Anti- <i>P. pastoris</i> HCP Antibody	1mg

The assay performance has been fully validated in accordance with applicable regulatory requirements, and the kits have been successfully used for QC testing in support of regulatory submissions in the United States, Europe and other countries.

Key Features

- ✓ **Assay type:** Sandwich ELISA format
- ✓ **Linear range:** Refer to the specific cell line, $R^2 > 0.990$
- ✓ **Limit of quantitation (LOQ):** 1-10 ng/mL
- ✓ **Precision (Repeatability):** CV < 15%
- ✓ **Accuracy:** $80\% \leq \text{Recovery} \leq 120\%$
- ✓ **Specificity:** No cross-reactivity with host cell proteins from different species
- ✓ **Robustness:** Consistent assay performance across different sample matrices, and consistent sample linearity throughout a dilution series
- ✓ **Coverage:**
 - Risk factors of immunogenicity: High-risk and process-specific HCPs are covered by ELISA standards and antibodies
 - Coverage assessment: Antibody coverage to the HCP standards was validated by orthogonal methods of IMBS®-2D & MS.
- ✓ **Stability:** High consistency of inter- and intra-lot quality for reliable QC results.

In addition, SHENTEK® offers integrated services for the development and validation of customized kits for process- or product-specific HCP quantitation, together with antibody coverage assessment for ELISA kits. These customized assays are tailored to the specific requirements of different host systems and bioprocesses, supporting regulatory submissions, and enable batch release testing for a wide range of biological products.

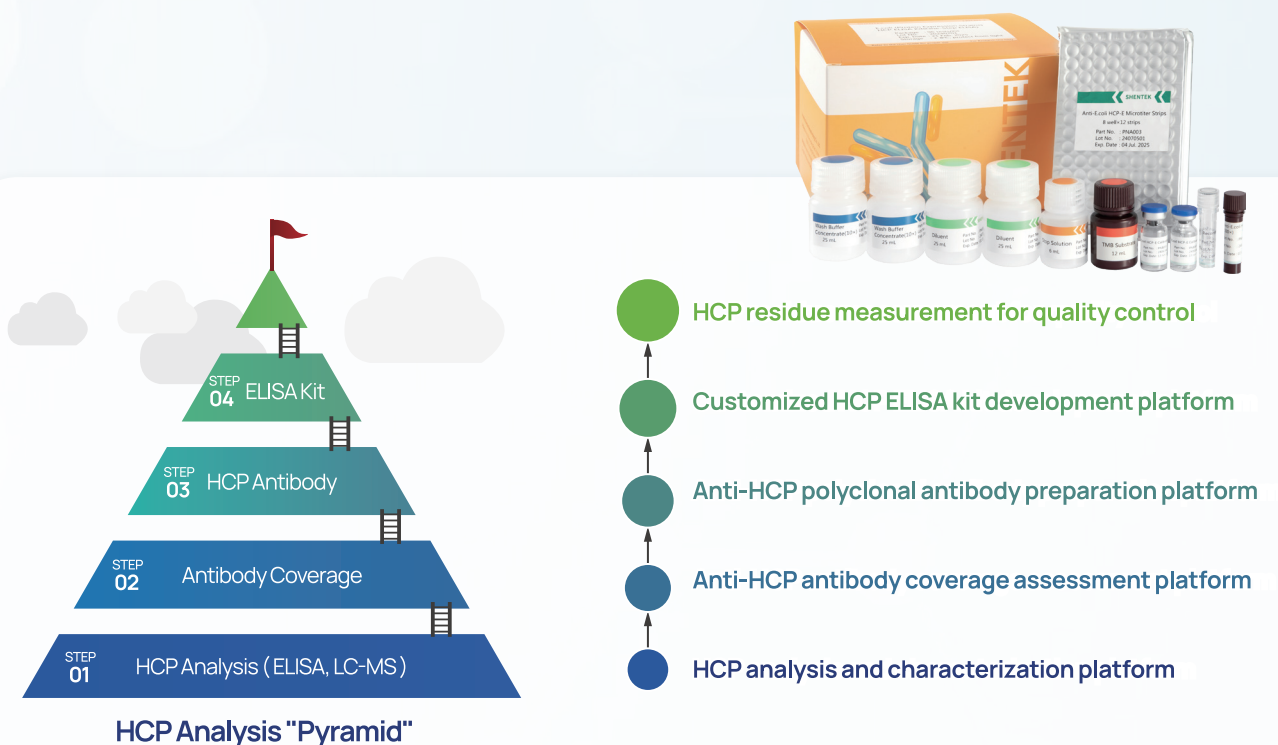


Figure 1 SHENTEK® Residual Host Cell Protein Analysis Service Platform

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