

Host Cell Protein ELISA Kits

SHENTEK® HCP ELISA kits are intended for biologics - host cell protein quantitation analysis, and they cover a wide range of regularly used cell lines, including bacteria, insect, mammalian, and human host cells. Host cell proteins (HCPs) are a key class of process-related impurities, and regulatory requirements call for HCP levels to be kept as low as feasible. Each SHENTEK® assay has been validated with process-specific performance and has been developed by immunizing with high and low molecular weight protein fractions, resulting in improved detection of small proteins. Furthermore, SHENTEK® HCP antigen is created as a good representation of the product- or process-specific cell harvest sample, containing the majority of HCPs that could potentially end up in the final product. SHENTEK® produces a sufficient amount of antibody for potential bridging studies and re-validation of GMP release testing.

Product Number	Product Name	Size
1301301	SHENTEK® E.coli (Protein Expression Strains) HCP ELISA Kit	96 Tests
1301301-1	SHENTEK® E.coli (Protein Expression Strains) HCP ELISA Kit (One-step ELISA)	96 Tests
1301301-Ab01	SHENTEK® Anti-E.coli (Protein Expression Strains) HCP Antibody	1mg
1301302	SHENTEK® E.coli (K-12 & Alkaline Lysis) HCP ELISA Kit	96 Tests
1301302-Ab01	SHENTEK® Anti-E.coli (K-12 & Alkaline Lysis) HCP Antibody	1mg
1301304-1	SHENTEK® CHO HCP ELISA Kit (One-step ELISA)	96 Tests
1301304-Ab01	SHENTEK® CHO HCP Antigen	1mg
PNM001	SHENTEK® Anti-CHO HCP Antibody	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-Ab01	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
1301311	SHENTEK® HEK293 HCP ELISA Kit (One-step ELISA)	96 Tests
1301311-Ab01	SHENTEK® Anti-HEK293 HCP Antibody	1mg
1301313	SHENTEK® P. pastoris HCP ELISA Kit (One-step ELISA)	96 Tests
1301313-Ab01	SHENTEK® Anti-P.pastoris HCP Antibody	1mg

The assay performance has been fully validated and complies with regulatory requirements. These kits have been applied successfully to QC tests for regulatory filings in China, USA, 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 in ELISA standards and antibodies
Coverage assessment: Coverage of the HCP antibodies to the standards was validated by orthogonal methods of IMBS®-2D & MS.
- ✓ **Stability:** Highly consistent product quality within and between batches for reliable QC results.

In addition, SHENTEK® provides an integrated solution of development and validation of customized kits for process or product-specific HCP quantitation, as well as antibody coverage assessment for ELISA kits. A customized assay aims to satisfy the detection needs due to different hosts or bioprocessing, meet regulatory filing requirements, and be used for batch release of various biological products.

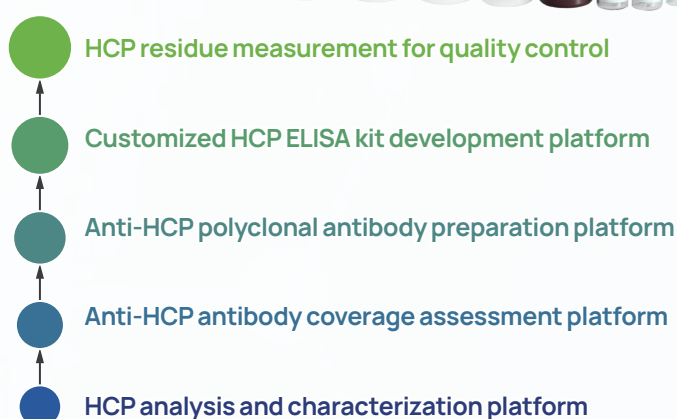
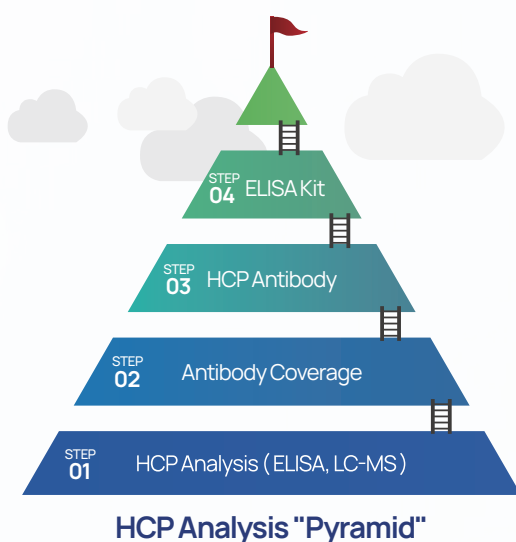


Figure 1 SHENTEK® Residual Host Cell Protein Analysis Service Platforms

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