

E. coli (BL21) HCP ELISA Kit

Product Introduction

Escherichia coli (*E. coli*) remains the most widely used and cost-effective host organism for recombinant protein production, accounting for approximately one-third of hosts of approved protein therapeutics. *E. coli* (BL21) is the most commonly used expression host among *E. coli* strains. Detection of *E. coli* (BL21)-derived Host Cell Proteins (HCPs) is essential for ensuring product purity, evaluating purification efficiency, and maintaining batch-to-batch consistency throughout biopharmaceutical manufacturing.

The United States Pharmacopeia (USP) recommends HCP levels in final products lower than 100 ng/mg, and European Pharmacopoeia (Ph. Eur.) requires that the HCP acceptance limit be scientifically justified based on the HCP clearance capability of the purification process and the potential impact of residual HCPs on patients.

SHENTEK® *E. coli* (BL21) HCP ELISA Kit is designed for the quantitative measurement of HCP contamination in recombinant protein samples produced using the *E. coli* (BL21) expression system. The assay has been fully validated and complies with pharmacopeial requirements. The quantification standards and capture antibodies have been thoroughly characterized, and antibody coverage of the *E. coli* (BL21) HCP antigen has been validated using 2D electrophoresis and LC-MS/MS analyses. The assay meets the requirements of both bioprocess development and QC release testing, eliminating the need to develop a custom or process-specific assay. Kit manufacturing complies with the ISO 13485 quality management standard.

Product Number	Product Name	Quantity
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	1 mg



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For Research Use Only.

Not for diagnostic or therapeutic use.

Key Features

- ✓ Assay type: Sandwich ELISA kit
- ✓ Linear range: 1 ng/mL to 243 ng/mL, $R^2 > 0.9990$
- ✓ Limit of quantitation (LOQ): ≤ 1 ng/mL
- ✓ Precision (Repeatability): CV < 15%
- ✓ Accuracy: $80\% \leq \text{Recovery} \leq 120\%$
- ✓ Specificity: No cross-reactivity with different host cell proteins (e.g., Vero, HEK293T, Hensenula and CHO)
- ✓ Robustness: Consistent assay performance across different sample matrices, and consistent sample linearity throughout a dilution series
- ✓ Stability: Highly consistent product quality within and among batches for reliable QC results
- ✓ Coverage:
Risk factors of immunogenicity: Coverage of high-risk *E. coli* (BL21) HCPs in ELISA standards and antibodies
Coverage assessment: Coverage of the *E. coli* (BL21) HCP antibodies to the standards was validated by orthogonal methods of IMBS®-2D and IMBS®-LC/MS.

E. coli (BL21) HCP Standard & Antibody Coverage Analysis by IMBS®-2D & IMBS®-LC/MS

- ✓ Orthogonal proteomic methods to assess anti-HCP antibody coverage;
- ✓ Process-specific and high-risk HCP analyses to ensure accurate and specific detection by ELISA;
- ✓ Comprehensive study of coverage and specificity of the HCP standards to ensure reliability of immunoassays.

Figure 1 SHENTEK® Antibody Coverage Assessment Platform

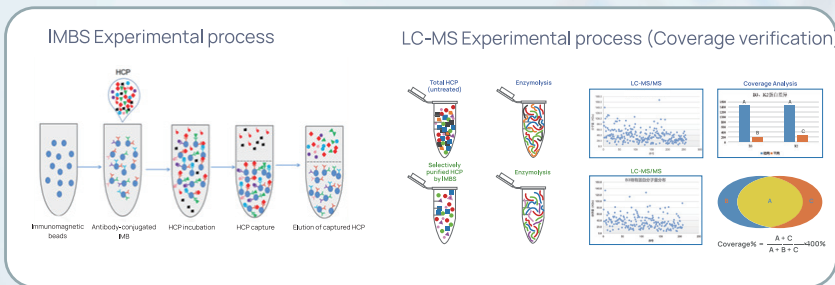
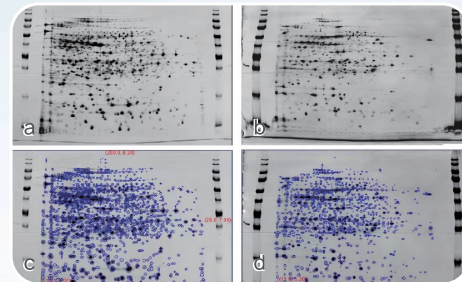


Figure 2 Coverage Assessment of *E. coli* (BL21) HCP Antibody by 2D analysis



Case Study

E. coli (BL21) HCP ELISA: Dilution Linearity Assessment

Dilution factor	OD 1	OD 2	Mean	Assay result (ng/mL)	Recovery of sample HCP ratio to the previous dilution factor
1	0.6683	0.7087	0.6885	43.22	/
10	0.1938	0.1658	0.1798	5.58	129.2%
20	0.1383	0.1426	0.1405	3.25	116.4%
40	0.1122	0.1076	0.1099	1.48	91.2%

Sample diluted by 20-fold and concentration spiked by 100ng/mL

OD	1.3032	Assay Result (ng/mL)	122.33
Recovery	112.5%	HCP ratio in sample	0.06%