E.coli (BL21) HCP ELISA Kit

Product Introduction

Escherichia coli remains the most widely used, cost-effective organism for the generation of one third of the approved protein therapeutics, especially E. coli BL21 as the most commonly used strain for recombinant protein production. Chinese Pharmacopoeia specifies E. coli HCPs, in the final product, not higher than 0.1% of the total protein content, and US Pharmacopeia defines HCP levels in the final products ranging from < 1 to 100ng/mg.

SHENTEK® provides SHENTEK® E. coli (BL21) HCP ELISA kit for the quantitative measurement of HCP contamination in recombinant protein samples from E. coli (BL21) expression system. The assay is fully validated; and complies with pharmacopeial requirements. The quantitation standards and capture antibodies were characterized, and the coverage of E. coli (BL21) HCP antibodies to the antigen was validated by 2D and LC-MS/MS analyses. The assay performance met not only bioprocess development needs, but also that of 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
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	1 mg

Huzhou Shenke Biotechnology Co., Ltd.

✉ info@shentekbio.com

📞 +1-908-822-3199/ +86-400-878-2189

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%≤Recovery≤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.

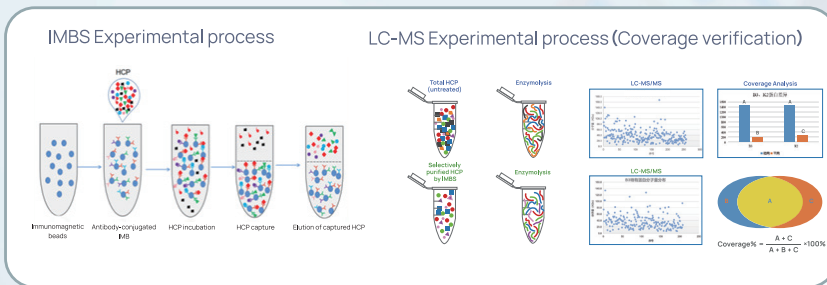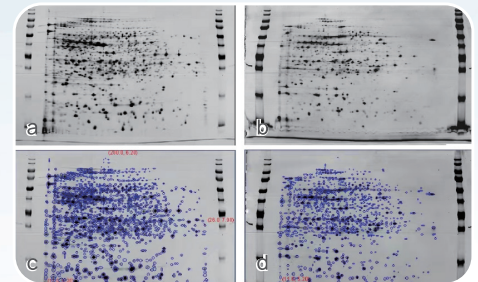Figure 1 SHENTEK® Antibody Coverage Assessment Platform

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

A & C: HCPs sample, 100ug;
B & D: HCPs sample isolated by IMBS, 100μg, 2D Page, pH 5-8, 18cm

Case Study

Table 1 E. coli (BL21) HCP ELISA Linearity-of-dilution Results

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%