

HEK293 HCP ELISA Kit

Product Introduction

The HEK293 cell line and its subtypes are widely used in the production of biotherapeutics such as recombinant proteins and viral vectors. SHENTEK® HEK293 HCP ELISA kit enables sensitive and reliable quantitation of residual HCPs in recombinant proteins and CGT products from HEK293 and its derivative, e.g., HEK293T. The assay has been fully validated in accordance with applicable pharmacopeial requirements. The quantitative HCP standards and capture antibodies have been thoroughly characterized, and the antibody coverage of HEK293 or HEK293T HCP has been comprehensively evaluated by 2D electrophoresis and mass spectrometry (MS) analyses. The assay performance supports applications ranging from bioprocess development needs to QC release testing. The kit is manufactured under an ISO 13485-certified quality management system to ensure consistent quality and reliable performance.

Product Number	Product Name	Quantity
1301311Z01	SHENTEK® HEK293 HCP ELISA Kit(One-step ELISA)	96 tests
1301311-Ab01	SHENTEK® Anti-HEK293 HCP Antibody	1 mg



Key Features

- ✓ Assay type: Sandwich ELISA kit
- ✓ Linear range: 6 ng/mL to 540 ng/mL, $R^2 > 0.990$
- ✓ 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. Sf9, *E. coli*, *Pichia*)
- ✓ Robustness: Consistent assay performance across different sample matrices, and excellent sample linearity across serial dilutions.
- ✓ Stability: Shelf life of 12 months and high intra- and inter-lot consistency for reliable QC results
- ✓ Coverage:

Risk factors of immunogenicity: Coverage of high-risk HEK293 & HEK293T HCPs by ELISA standards and antibodies;

Coverage assessment: Antibody coverage of the HEK293 & HEK293T HCP was validated by orthogonal methods of IMBS-2D & MS; the coverage and specificity of HCP standards were comprehensively characterized ensure the accuracy and reliability of immunoassays.

Performance of HEK293 HCP ELISA Kits from Different Vendors

Figures 1 and 2 demonstrate substantial differences in assay results, using commercially available HEK293 HCP ELISA kits, highlighting the importance of comprehensive characterization of HCP standards and antibody coverage and specificity. SHENTEK® assays are designed to provide robust and reliable detection of process-specific HEK293 HCPs, supporting effective HCP monitoring throughout viral vector manufacturing and downstream process development.

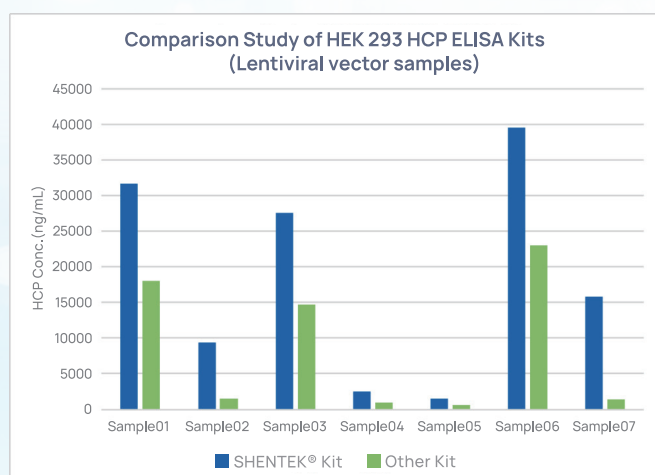


Fig 1. Comparison Study of HEK 293 HCP ELISA Kits (Lentiviral vector samples)

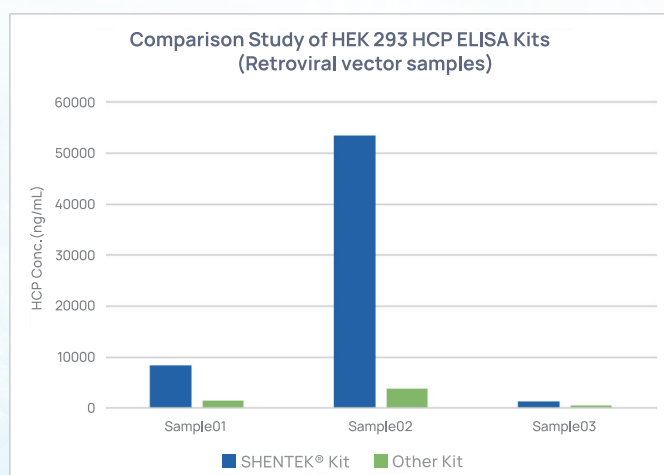


Fig 2. Comparison Study of HEK 293 HCP ELISA Kits (Retroviral vector samples)



info@shentekbio.com

US Mobile: +1-908-822-3199

US Tel: +1-800-960-3004 ext 720

CN Tel: +86-400-878-2189

https://www.shentekbio.com

For Research Use Only.

Not for diagnostic or therapeutic use.