

# 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 provides the quantitative measurement of HCP contamination in recombinant proteins and CGT products from HEK293 and its derivative, e.g., HEK293T. The assay is fully validated and complies with pharmacological requirements. The quantitation standards and capture antibodies were characterized, and the coverage of HEK293 or HEK293T HCP antibodies to the antigen was validated by 2D and MS analyses. The assay performance met not only bioprocess development needs but also those of QC release test. Kit manufacturing complies with the ISO13485 quality standard.

Product Number	Product Name	Quantity
1301311	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):  $\leq 1$  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 consistent sample linearity throughout a dilution series
- ✓ Stability: Shelf life of 12 months and highly consistent product quality within and among batches for reliable QC results
- ✓ Coverage:

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

Coverage assessment: Coverage of the HEK293 & HEK293T HCP antibodies was validated by orthogonal methods of IMBS-2D & MS;

Comprehensive study of coverage and specificity of the HCP standards to ensure reliability of immunoassays;

## Performance of HEK293 HCP ELISA Kits from Different Vendors

Figures 1 and 2 from an experimental study show the stark contrast between the assay outcomes of various HEK293 HCP ELISA kits. Therefore, in order to ensure assay accuracy and reliability, a thorough analysis of the coverage and specificity of the immunogen/standard and antibodies is required, particularly for the monitoring of the HEK293 HCPs that are process-specific in the viral vector production.

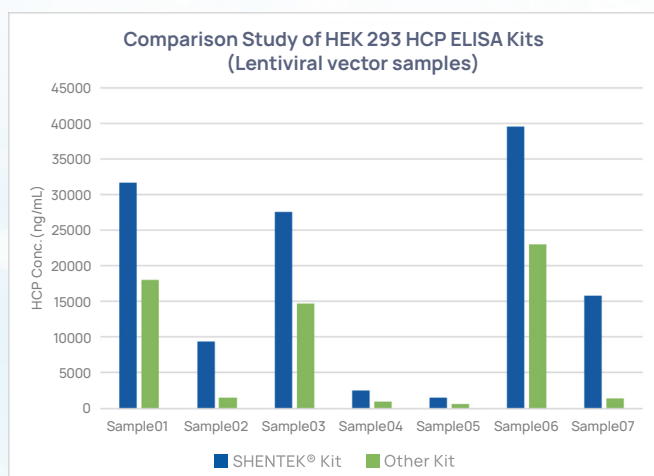


Fig 1. Comparison Study of HEK 293 HCP ELISA Kits (Lentiviral vector samples)

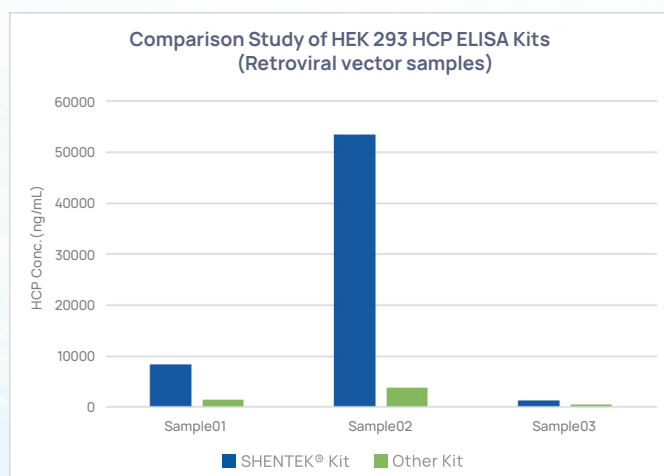


Fig 2. Comparison Study of HEK 293 HCP ELISA Kits (Retroviral vector samples)

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