

HEK 293 HCP ELISA Kit, 3G

The Industry Gold Standard for HEK 293 Host Cell Protein Analysis

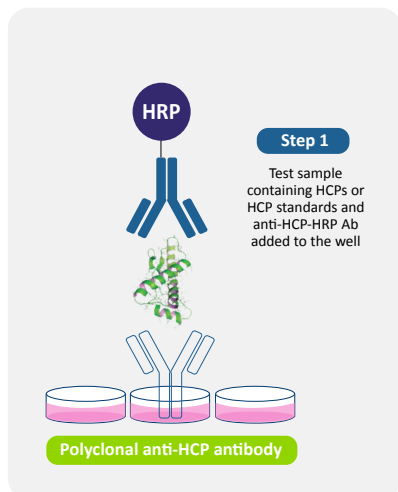
Regulatory guidelines for gene therapy product manufacturing require sensitive analytical assays to measure levels of residual host cell impurities in viral vectors used for gene therapies or genetically modified cell therapies. Supported by decades of in-house technical expertise, **Cygnus Technologies HEK 293 HCP ELISA Kit, 3G** (F650S) provides the specificity and sensitivity to detect HEK 293 host cell protein impurities with reproducibility that supports regulatory compliance.

- Supports **ALL** commercialized gene therapies and CAR-T cell therapies utilizing HEK 293 and HEK 293T cell lines for viral vector manufacturing
- **Trusted** by biopharmaceutical industry and regulatory agencies for purification process development, lot release and QC testing
- Based on the HEK 293 HCP Antibody **immunoreactive with 95% of HEK 293 HCPs**
- Detects **all problematic HEK 293 HCPs** as identified by mass spectrometry
- The **most sensitive HEK 293 HCP ELISA kit** on the market: **LOD ~0.35 ng/ml, LLOQ ~2 ng/ml**
- Assay results in **2 hours 30 minutes**

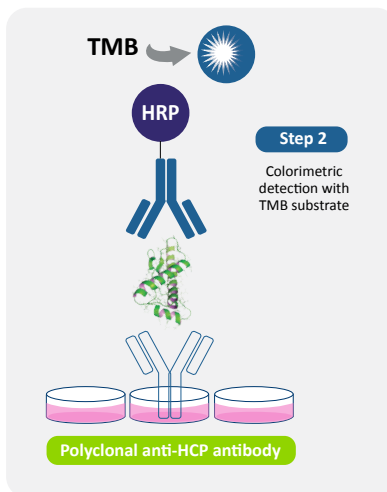


Assay Workflow

Incubate 2h @ RT and 400-600 rpm



Incubate 30' @ RT



Wash,
5 min

Accuracy

Average	% Recovery
Low (7.1 ng/ml)	89%
Middle (23 ng/ml)	113%
High (132 ng/ml)	106%

Accuracy is defined as the ability of the assay to correctly quantitate known concentrations of HEK 293 HCPs in a given sample matrix.

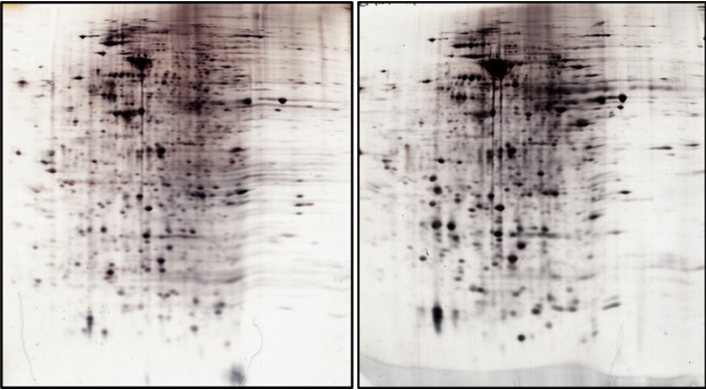
Precision

Mean (ng/ml)	Intra-Assay CV (n=24 reps)	Inter-Assay CV (n=10 assays)
7.1	4.4%	4.3%
23	4.2%	5.2%
132	5.0%	6.6%

Precision is defined as %CV calculated by dividing the standard deviation by the mean for a number of replicate determinations of three different control samples in the low, mid and high concentration range of the assay.

Whether you are submitting your IND application, manufacturing your viral vector for Phase 1-3 clinical trials or getting ready for BLA submission, you can trust your results from Cygnus Technologies HEK 293 HCP ELISA Kit, 3G (F650S).

Anti-HEK 293 HCP Antibody Coverage Analysis by AAE™ with 2D-PAGE

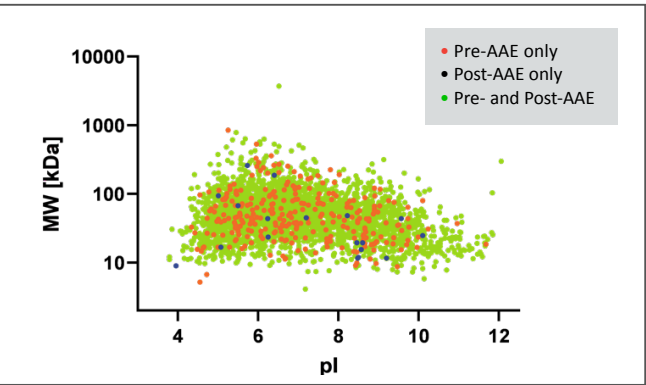


Silver Stain of “Pre-AAE” HEK 293 Harvest Sample (**All HCPs**)

Silver Stain of “Post-AAE” HEK 293 Harvest Sample (**Immunoreactive HCPs**)

HEK 293 mild cell lysate sample was loaded on AAE Column with anti-HEK 293 HCP Antibody (from F650S HEK 293 HCP ELISA Kit, 3G). 1604 spots of the 1687 total spots (gel images on the right and on the left, respectively) were found in the AAE elution fraction for a **coverage of 95%**.

Anti-HEK 293 HCP Antibody Coverage Analysis by AAE-MS™



Virtual two-dimensional gel of harvest sample: molecular weight versus isoelectric point

Combining AAE™ with mass spectrometry (AAE-MS) allows for identification of HCPs in the harvest material and HCPs reactive with the antibody, yielding protein molecular weight and pI (isoelectric point) information.

Anti-HEK 293 HCP Antibodies have **91% antibody coverage** of HEK 293 HCPs found in HEK 293 null cell lysate (Pre-AAE Sample).

Detection Method	Pre-AAE (all HCPs)	Post-AAE (Immuno-reactive HCPs)	% pAb Coverage
2D-PAGE/ Silver Stain	1687	1604	95
MS	3075	2812	91

Visit cygnus.expert/AAE to learn more about AAE.

Ordering Information

Product	Catalog No.
HEK 293 HCP ELISA Kit, 3G	F650S
HEK 293 HCP ELISA 3G, Robotics Kit	F650S-4
HEK 293 HCP Assay Reagent Set for Gyrolab®	G650S-1
Simple Plex HEK 293 HCP 3G Assay	SPCKB-OT-007066



Scan here to learn more.