

# KRIBIOLISA™ High Five (H5) HCP ELISA

**Sandwich assay for the Quantitative Determination of H5 Host Cell Protein contamination in cell culture supernatant and biological solutions**

KBBP21  
1 x 96 wells

## ABOUT GLP-1 AGONISTS

High Five cells (sometimes referred to as High-Five or Hi5) represent a safe, effective and inexpensive platform for protein production. Indeed, their remarkable ability to produce very large amounts of recombinant proteins – such as diagnostic reagents and recombinant vaccines – remains unmatched. High Five cells were originally isolated from insects in BTI's Granados lab in the late 1980's.

The baculovirus expression vector system (BEVS) in insect cells offers highly scalable and inexpensive protein production. High Five cells and sub-clones have been reported to produce 2-10x high levels of recombinant proteins compared to Sf9/Sf21 insect cells. BTI is the sole proprietor of High Five cells and related sub-clones. (BTI; Boyce Thomson Institute, NY, USA).

## ASSAY PRINCIPLE:

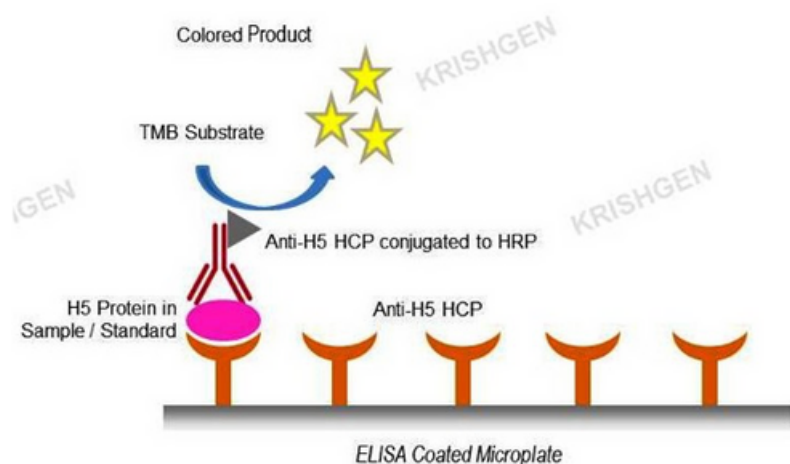
The method employs sandwich ELISA technique. Monoclonal antibodies are pre-coated onto microwells. Samples and standards are pipetted and H5 HCP present in the sample are bound by the antibodies. HRP conjugated antibody is added and incubated to form a complex. After washing microwells in order to remove any non-specific binding, the substrate solution (TMB) is added and color develops proportionally to the amount of H5 HCP in the sample. Color development is then stopped by addition of stop solution. Absorbance is measured at 450 nm.

**Assay Range:** 3 - 100 ng/ml

**Sensitivity:** LOQ (3 ng/ml), LOD (0.188 ng/ml)

### Reactivity:

Krishgen has Semaglutide ELISA for both human (serum and plasma) and rat serum samples. We can also customise for mouse, if needed.



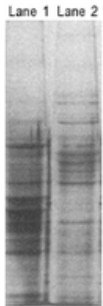
# KRIBIOLISA™ High Five HCP ELISA is well validated, robust and accurate.

- validated as per EMA/FDA guidelines in line with ICH Code for Harmonization of Biological Assays.
- Cross reactivity data available
- Robust Lot-to-Lot consistency and reproducibility in data
- Standard, 96 well break-apart wells
- Availability: 2 weeks



**ALL KIT COMPONENTS INCLUDED**

## SPECIFICITY



This assay has high sensitivity and excellent specificity for detection of H5 HCP. No significant cross-reactivity or interference between H5 HCP and analogues was observed. The antigen used was developed from mock fermented H5 media. The western blot was done to view the coverage of the HCP proteins.

The antibodies developed against the purified antigen are rabbit polyclonals affinity purified.

## STABILITY

12 months from the date of manufacturing.

## SENSITIVITY

**Limit of Quantitation:** It is defined as the lowest detectable concentration that can be determined with an acceptable repeatability and the LOQ was found to be 0.188 ng/ml.

**Limit of Detection (LOD):** It is defined as the lowest concentration at which CV is less than 20% with acceptable accuracy and the LOD is 3 ng/ml.

## PRECISION

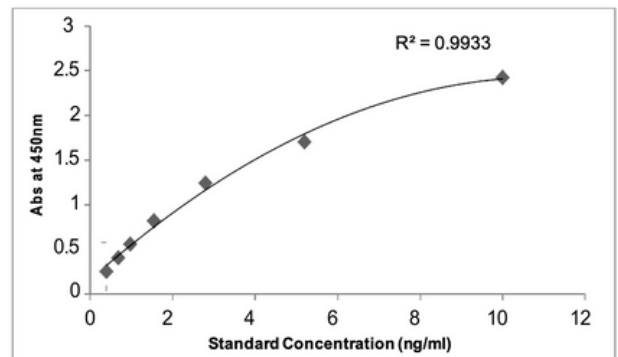
Precision is defined as the percent coefficient of variation (%CV) i.e. standard deviation divided by the mean and multiplied by 100. Assay precision was determined by both intra (n=5 assays) and inter assay (n=5 assays) reproducibility on two pools with low (3 ng/ml) and high (100 ng/ml) concentrations.

Pool	Intra Assay %CV	Inter Assay %CV
Low	~9.78%	~9.53%
High	~3.45%	~7.64%

The KRIBIOLISA H5 (High Five) HCP ELISA kit is designed to quantitatively measure HCPs contamination in pharmaceutical products manufactured using the High Five Cells expression systems.

## Typical Data

Standard Concentration (ng/ml)	Abs1	Abs2	Mean Abs	Interpolated Concentration	% Interpolated Concentration against Actual Concentration
0	0.17	0.15	0.16	0.13	---
3	0.31	0.33	0.32	2.56	85.39
6	0.49	0.48	0.48	5.73	95.54
12	0.73	0.78	0.75	12.32	102.67
25	1.20	1.18	1.19	26.46	105.85
50	1.66	1.68	1.67	47.87	95.74
100	2.4	2.44	2.42	101.03	101.03



## PRECISION

The linearity of the kit was assayed by testing samples spiked with appropriate concentration of E.coli HCP and their serial dilutions. The results were demonstrated by percentage of calculated concentration to the expectation.

Sample	1:2	1:4	1:8
Cell Culture Supernatant (n=10)	91-105%	92-106%	90-111%

### Also available from Krishgen:

*E. coli* HCP ELISA

CHO HCP ELISA

Vero HCP ELISA

HEK293 HCP ELISA



Scan to view product details: