



## Host Cell Proteins(HCPs)

HCPs are cellular structural and secretory proteins produced during cell culture process. It's reported that HCPs can stimulate the human immune system, triggering allergic reactions or other adverse responses. Besides, HCPs may induce the production of antibodies against protein drugs in the body, affecting the therapeutic effects of the drugs.



Global pharmacopoeias and drug quality supervision agencies have issued the requirements for detecting HCPs residue

USA Pharmacopeia stipulates that residual HCPs in monoclonal antibody products should be lower than 1-100 ppm, while Australian government requires that HCPs residue in biological products should be less than 100 ppm.

In China, the Pharmacopoeia specifies clear requirements for the residue of host DNA, HCPs in Chinese hamster ovary (CHO) cells, African green monkey kidney (vero) cells and human embryonic kidney (293T) cells, bacterial proteins in yeast and Escherichia coli, ovalbumin etc.



Chinese Pharmacopoeia (2020 edition) indicates that HCPs residue should be less than 500 ppm of the total protein volume

ELISA is a widely used method for residual HCPs detection. Sandwich ELISA, in particular, has advantages such as good repeatability, high efficiency, simple operation, and wide applications etc. The sensitivity can reach 0.5 ng/ml, which is 200 times higher than that of CIE (Co-immunoprecipitation), and currently it has been the recognized method for detecting residual HCPs.



To meet customers' demands for HCPs residue detection, FineTest has developed corresponding detection kits, which can be also customized according to customers' requirements.



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Cat NO	Product Name	Sensitivity	Range	Price(96T)
EMK0179	VERO HCPs ELISA Kit	0.188ng/ml	0.313-20ng/ml	\$400
EU2624	E.coli HCPs ELISA Kit	1.875ng/ml	3.125-200ng/ml	\$400
EU2614	CHO HCPs ELISA Kit	0.188ng/ml	0.313-20ng/ml	\$400
EU3135	OVA ELISA Kit	0.469ng/ml	0.781-50ng/ml	\$400
EU3133	PEA ELISA Kit	18.75pg/ml	31.25-2000pg/ml	\$400
EH4435-CM	HEK 293 HCPs ELISA Kit	46.875ng/ml	78.125-5000ng/ml	\$400
EU3126	LPS ELISA Kit	0.188ug/ml	0.313-20ug/ml	\$400
EP0253	Pig TRY ELISA Kit	0.938ng/ml	1.563-100ng/ml	\$500
EB0148	Bovine serum albumin ELISA Kit	0.094ug/ml	0.156-10ug/ml	\$450

Strong R & D and production capacity for proteins and antibodies; Most self-produced raw materials for controllable quality.

Self-established cell bank and blood tissue sample bank, providing abundant samples for detection.

GMP workshops can ensure the cleanliness of the production environment and improve product reliability.



Amplification technology, enabling flexible adjustment of the sensitivity of the detection kits and improving the detection rate of customers' samples.

High-precision production and strict quality control to ensure batch differences are less than 5%, with extensive sample testing to ensure reliable quality.

Utilizing unique stabilization technology, maintaining the kits activity at room temperature for up to one month, facilitating transportation and use.

### GMP certified workshop

