

CHO Host Cell Protein (High Sensitivity) ELISA Kit

High sensitivity sandwich ELISA for quantification of residual CHO host cell proteins

The **CHO Host Cell Protein (High Sensitivity) ELISA Kit** is a quantitative sandwich immunoassay for measuring residual Chinese Hamster Ovary (CHO) host cell protein (HCP) impurities in biologics manufactured by recombinant expression in CHO cells. This kit uses a proprietary mix of polyclonal chicken IgY antibodies raised against CHO HCPs from CHO-S, CHO-K1 and Expi-CHO cell lines. Designed for use in process development, manufacturing process control, and product release testing, the kit employs a **two-step sequential sandwich format**: samples are first captured on wells pre-coated with **chicken IgY** anti-CHO HCP antibody, followed by sequential addition of a **biotin-labeled chicken IgY** detection antibody and Streptavidin-HRP conjugate, delivering a robust colorimetric signal proportional to the HCP content. Method validation as per **ICH Q2(R2) 2023 guidelines**. The method validation report is available upon request. Suitable for Research and Manufacturing Use.

Chinese Hamster Ovary (CHO) cells are widely used to produce biologics, but they also produce host cell proteins (HCPs) that must be removed during downstream purification. Residual HCPs are process-related impurities that can affect product quality through immunogenicity, product instability, or enzymatic activity. ENZ-KIT268 provides a sensitive ELISA-based solution for routine CHO HCP quantification of these impurities.

Ordering Information

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ENZ-KIT268-0001	
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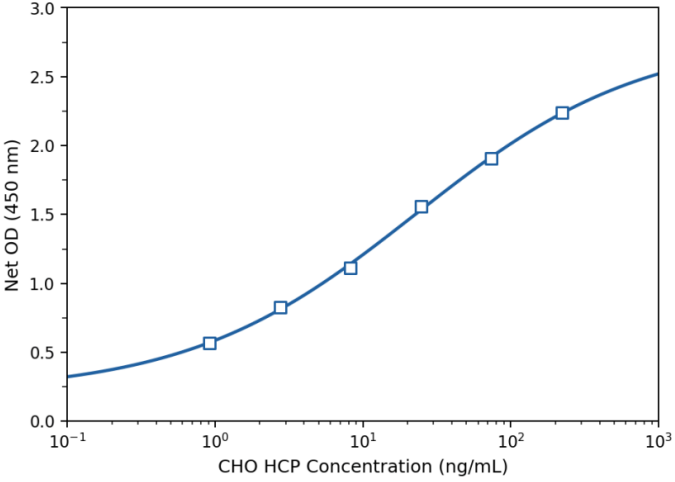
Manuals, SDS & CofA

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- **~94% antibody coverage** by 4D-DIA LC-MS (~1,700 CHO proteins assessed)
- All **17 priority high-risk HCPs** detected, including : PLBL2 · Clusterin · LPL · Cathepsins B/D/Z
- **ICH Q2(R2) 2023 method validation report available upon request**

CHO HCP ELISA Kit

Representative Standard Curve



Handling & Storage

Use/Stability	When stored and handled as directed, the kit is stable until the expiration date on the label.
Handling	Store all kit components at 4°C upon receipt, except the Standard, which should be stored at -20°C. Do not freeze the other kit components. Do not use buffers containing sodium azide.
Short Term Storage	+4°C
Long Term Storage	+4°C
Shipping	Blue Ice

Regulatory Status RUO - Research Use Only

Product Details

Application	ELISA
Application Notes	For quantification of residual CHO HCPs in purified biologics and in-process samples.
Assay Time	2 hours 45 minutes
Compatibility	Colorimetric 96-well microplate reader capable of reading absorbance at 450 nm.
Contents	96-well microplate with break-apart strips coated with chicken IgY anti-CHO HCP antibody (1 plate); CHO Standard, 2000 ng/mL ; Assay Buffer; Wash Buffer Concentrate 20×; Biotin-labeled chicken IgY anti-CHO HCP detection antibody ; Streptavidin-HRP Conjugate; TMB Substrate ; Stop Solution; Plate Sealers
Sensitivity	~0.3 ng/mL (3.3SD, ICH Q2(R2)), range 0.9 – 222 ng/mL
Specificity	CHO host cell proteins
Technical Info / Product Notes	Two-step sequential sandwich ELISA. Capture: 96-well microplate pre-coated with chicken IgY anti-CHO HCP antibody (break-apart strips). Detection: biotin-labeled chicken IgY anti-CHO HCP antibody followed by Streptavidin-HRP conjugate. Colorimetric readout: TMB substrate; stopped with 1N HCl; measured at 450 nm.



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