E. coli Host Cell Protein (High Sensitivity) ELISA Kit

High sensitivity sandwich ELISA for quantification of residual E. coli host cell proteins

The **E. coli Host Cell Protein (High Sensitivity) ELISA Kit** is a quantitative sandwich immunoassay for measuring residual *E. coli* host cell protein (HCP) impurities in biologics manufactured by recombinant expression in *E. coli*. Designed for use in process development, manufacturing process control, and product release testing, the kit employs a **one-step simultaneous sandwich format** in which samples and HRP-conjugated polyclonal detection antibody are added concurrently — reducing assay time to just 2 hours 30 minutes. Method validation as per **ICH Q2(R2) 2023 guidelines**. The method validation report is available upon request. Suitable for Research and Manufacturing Use.

Biologics produced using host cells can contain residual host cell proteins (HCPs) that must be removed during downstream purification. These process-related impurities can affect product quality through immunogenicity, product instability, or enzymatic activity, making reliable HCP monitoring essential. ENZ-KIT267 uses rabbit polyclonal antibodies raised against E. coli HCPs to provide broad detection of residual host cell proteins, supporting reliable HCP monitoring throughout process development and manufacturing.

Ordering Information

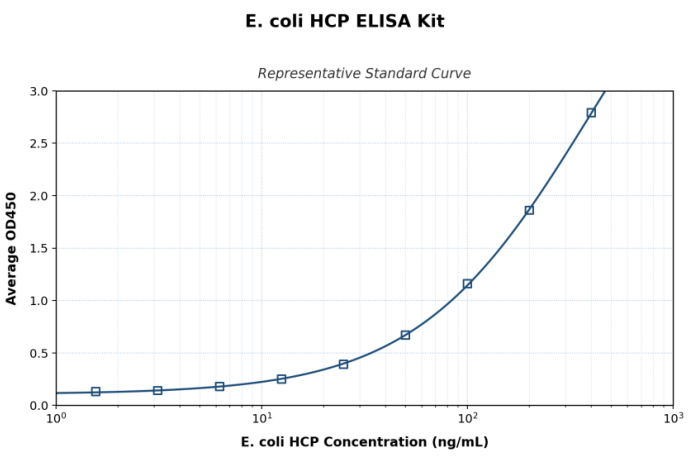
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ENZ-KIT267-0001	

Manuals, SDS & CofA

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- **One-step simultaneous sandwich format** — samples and HRP-conjugated detection antibody added concurrently; reduces procedural steps and variability
- **98% antibody coverage** by 4D-DIA LC-MS (2,417/2,466 *E. coli* proteins captured)
- All **19 priority high-risk HCPs** detected, including: SlyD · DnaK · GroEL · Trigger Factor · OmpA · OmpC · OmpF · Flagellin
- **ICH Q2(R2) 2023 method validation report available upon request**


E. coli HCP ELISA Kit
Representative Standard Curve
Average OD450
E. coli HCP Concentration (ng/mL)
3.0
2.5
2.0
1.5
1.0
0.5
0.0
10^0
10^1
10^2
10^3

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 E. coli HCPs in purified biologics and in-process samples.
Assay Time	2 hours 30 minutes
Compatibility	Colorimetric 96-well microplate reader capable of reading absorbance at 450 nm.
Contents	96-well microplate with break-apart strips coated with rabbit anti-E. coli HCP IgG (1 plate); E. coli HCP Standard, 1 mg/mL; Assay Buffer; Wash Buffer Concentrate 20×; HRP-conjugated rabbit polyclonal anti-E. coli HCP antibody; TMB Substrate ; Stop Solution; Plate Sealers
Sensitivity	0.28 ng/mL (3.3SD, ICH Q2(R2)), range 1.56 – 400 ng/mL
Specificity	E. coli host cell proteins
Technical Info / Product Notes	One-step simultaneous sandwich ELISA. Capture: 96-well microplate pre-coated with rabbit anti-*E. coli* HCP IgG (break-apart strips). Detection: HRP-conjugated rabbit polyclonal anti-*E. coli* HCP antibody (ready-to-use, 100 µL/well), coincubated with samples/standards – faster assay time. Colorimetric readout: TMB substrate; stopped with 1N HCl; measured at 450 nm.
Wavelength	450 nm

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