



User's Manual

HEK 293 HCP ELISA Kit

REF DEIABL482

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This product is for research use only and is not intended for diagnostic use.

For illustrative purposes only. To perform the assay the instructions for use provided with the kit have to be used.

Creative Diagnostics

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PRODUCT INFORMATION

Intended Use

This kit is intended for use in determining the presence host cell protein contamination in products manufactured by expression in HEK 293 host cells. The kit is for Research and Manufacturing Use Only and is not intended for diagnostic use in humans or animals.

Principles of Testing

The HEK 293 Host Cell Protein assay is a two-site immunoenzymetric assay. Samples containing HEK 293 cell proteins are reacted in microtiter strips coated with an affinity purified capture antibody. An HRP labeled antiHEK 293 antibody is reacted simultaneously, forming a sandwich complex of solid phase antibody-HEK 293 HCPenzyme labeled antibody. The microtiter strips are then washed to remove any unbound reactants. After the washes, the substrate tetramethylbenzidine is then reacted. The amount of hydrolyzed substrate is read on a microtiter plate reader and is directly proportional to the concentration of HEK 293 Host cell proteins present.

Reagents And Materials Provided

Anti-HEK 293:HRP: Affinity purified goat antibody conjugated to HRP in a protein matrix with preservative. 1x12mL

Anti-HEK 293 coated microtiter strips: Blend of goat and rabbit antibodies coated on 12x8 well strips in a bag with desiccant.

HEK 293 HCP Standards: HEK 293 HCPs in a non-protein buffer matrix with preservative. Standards at 0, 4, 10, 25, 75, 200, 1 mL/vial.

Stop Solution: 0.5M sulfuric acid. 1x12mL

TMB Substrate: 3,3',5,5' Tetramethylbenzidine. 1x12mL

Wash Concentrate (20X): Tris buffered saline with preservative. 1x50mL

Storage

- If the kit will not be utilized within 1 week after receipt it is recommended to store the standards at -10°C to -30°C. All other reagents should be stored at 2°C to 8°C for stability until the expiration date printed on the kit.
- Reconstituted wash solution is stable until the expiration date of the kit.
- After prolonged storage, you may notice a salt precipitate and/or yellowing of the wash concentrate. These changes will not impact assay performance. To dissolve the precipitate, mix the wash concentrate thoroughly and dilute as directed in the 'Preparation of Reagents' section.

Sensitivity

The lower limit of detection (LOD) is defined as that concentration corresponding to a signal two standard

deviations above the mean of the zero standard. LOD is ~1 ng/mL.

The lower limit of quantitation (LOQ) is defined as the lowest concentration, where concentration coefficients of variation (CVs) typically are <20%. The LOQ is ~2 ng/mL.