



User's Manual

CHO-CM HCP ELISA kit



DEIABL480



96T



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.

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PRODUCT INFORMATION

Intended Use

This kit is intended for use in determining the presence of CHO Host Cell Proteins (HCPs) in products manufactured by recombinant expression in CHO cells. The antibodies used in this kit were generated from HCPs typically found in protein-free conditioned growth media. The kit is for Research and Manufacturing Use Only and is not intended for diagnostic use in humans or animals.

Principles of Testing

The CHO HCP assay is a sequential, two-site immunoenzymetric assay also termed ELISA. Samples potentially containing CHO proteins are reacted in microtiter strips coated with an affinity purified capture antibody. After a wash step, a horseradish peroxidase enzyme labeled anti-CHO antibody is reacted sequentially forming a sandwich complex of solid phase antibody-CHO protein-enzyme labeled antibody. The microtiter strips are then washed to remove any unbound reactants. The substrate tetramethyl benzidine (TMB) is then reacted. The amount of hydrolyzed substrate is read on a microtiter plate reader and is directly proportional to the concentration of CHO proteins present.

Reagents And Materials Provided

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

Anti-CHO coated microtiter strips: 12x8 well strips in a bag with desiccant

CHO HCP Standards: Solubilized CHO HCPs obtained from media with preservative. Standards at 0, 0.7, 2, 8, 25, 75, and 200ng/mL. 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

All reagents should be stored at 2°C to 8°C for stability until the expiration date printed.

Reconstituted wash solution is stable until the expiration date of the kit.

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 was <100pg/mL.

The lower limit of quantitation (LOQ) is defined as the lowest concentration, where concentration coefficients of variation (CVs) are <20%. The LOQ is ~0.7 ng/mL.