



User's Manual

MDCK HCP ELISA Kit



DEIABL486



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.

Creative Diagnostics

 Address: 45-1 Ramsey Road, Shirley, NY 11967, USA

 Tel: 1-631-624-4882 (USA) 44-161-818-6441 (Europe)  Fax: 1-631-938-8221

 Email: info@creative-diagnostics.com  Web: www.creative-diagnostics.com

PRODUCT INFORMATION

Intended Use

This kit is intended for use in determining the presence host cell protein contamination in products manufactured by expression in MDCK host cells. The kit is for Research and Manufacturing Use Only and is not intended for diagnostic use in humans or animals. Users should qualify this assay for use with their product samples.

Principles of Testing

The MDCK Cell Host Cell Protein assay is a two-site immunoenzymetric assay. Samples containing MDCK cell proteins are reacted in microtiter strips coated with an affinity purified capture antibody. A second HRP labeled anti-MDCK Cell antibody is reacted simultaneously, forming a sandwich complex of solid phase antibody-MDCK HCP-enzyme 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 MDCK Host Cell proteins present.

Reagents And Materials Provided

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

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

MDCK HCP Standards: MDCK HCPs in a protein matrix with preservative. Standards at 0, 3, 6, 12, 25, 50, 100, 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 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 0.5 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 1.5 ng/mL.