



User's Manual

CAP® cell line HCP ELISA Kit



DEIABL477



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 of host cell protein contamination in products manufactured by expression in the CAP® human cell line. The kit is for Research and Manufacturing Use Only and is not intended for diagnostic use in humans or animals.

Principles of Testing

The CAP® cell line assay is a two-site immunoenzymetric assay. Samples containing CAP® cell HCPs are reacted simultaneously with a horseradish peroxidase (HRP) enzyme labeled anti-CAP® cell antibody (goat polyclonal) in microtiter strips coated with an affinity purified capture anti-CAP® cell antibody. The immunological reactions result in the formation of a sandwich complex of solid phase antibody-HCP-enzyme labeled antibody. The microtiter strips are washed to remove any unbound reactants. The substrate, tetramethylbenzidine (TMB) is then reacted. The amount of hydrolyzed substrate is read on a microtiter plate reader and is directly proportional to the concentration of CAP® cell line HCPs present.

Reagents And Materials Provided

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

Anti-CAP® cell coated microtiter strips: 12x8 well strips in a bag with desiccant

CAP® cell HCP Standards: CAP® cell HCPs in a bovine serum albumin matrix with preservative. 8 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 ~0.9 ng/mL.

The lower limit of quantitation (LOQ) is defined as the lowest concentration, where concentration coefficients

of variation (CVs) are <20%. The LOQ is ~1.5 ng/mL.