



User's Manual

PER.C6 HCP ELISA kit



DEIABL490



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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 of host cell protein contamination in products manufactured by expression in the PER.C6 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 PER.C6® cell line assay is a two-site immunoenzymetric assay. Samples containing PER.C6® cell HCPs are reacted simultaneously with a horseradish peroxidase (HRP) enzyme labeled anti-PER.C6® cell antibody (goat polyclonal) in microtiter strips coated with an affinity purified capture anti-PER.C6® 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, 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 PER.C6® cell line HCPs present.

Reagents And Materials Provided

Anti-PER.C6®cell:HRP: Affinity purified goat antibody conjugated to HRP in a protein matrix with preservative. 1x12mL

Anti- PER.C6®cell coated microtiter strips: 12x8 well strips in a bag with desiccant

PER.C6®cell HCP Standards: PER.C6® cell HCPs in bovine albumin with preservative. Standards at 0, 2, 8, 25, 75, and 200ng/mL. 1 mL/vial

Stop Solution: 0.5N 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.
- * The substrate reagent should not be used if its stopped absorbance at 450nm is greater than 0.1.
- * 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 is ~0.5 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 ng/mL.