



User's Manual

NS/O HCP ELISA kit



DEIABL488



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

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PRODUCT INFORMATION

Intended Use

This kit is intended for use in determining the presence of NS/0 host cell protein contamination in products manufactured by recombinant expression in NS/0 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 NS/0 assay is a two-site immunoenzymetric assay. Samples containing NS/0 HCPs are reacted with a horseradish peroxidase (HRP) enzyme labeled antiNS/0 antibody in a test tube or simultaneously in microtiter strips coated with an affinity purified capture anti-NS/0 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 NS/0 HCPs present.

Reagents And Materials Provided

Anti-NS/0:HRP: Affinity purified rabbit antibody conjugated to HRP in a protein matrix with preservative. 1x12mL

Anti-NS/0 coated microtiter strips: 12x8 well strips in a bag with desiccant

NS/0 HCP Standards: Solubilized NS/0 HCPs in human immunoglobulin with preservative. Standards at 0, 1, 3, 8, 25, 75, and 200ng/mL. 1 mL/vial, Store at $\leq -20^{\circ}\text{C}$ upon receipt.

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

- Store Standards at $\leq -20^{\circ}\text{C}$. All other reagents should be stored at 2°C to 8°C for stability until the expiration date printed on 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. 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 ~ 0.8 ng/mL in the Standard Assay Protocol and 300 pg/mL in the High Sensitivity Protocol.

The lower limit of quantitation (LOQ) is defined as the lowest concentration, where concentration coefficients of variation (CVs) are <20%. The LOQ is ~3 ng/mL in the Standard Assay Protocol and ~1ng/mL in the High Sensitivity Protocol.