



## User's Manual

# L.lactis HCP ELISA kit



DEIABL485



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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### Creative Diagnostics

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## PRODUCT INFORMATION

### Intended Use

This kit has been specifically developed and validated for use in detecting L. lactis HCPs as contaminants in products produced by recombinant expression in Lactococcus lactis. This kit utilizes antibodies raised against and affinity purified from HCPs derived from L. lactis spent culture 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 L. lactis assay is a two-site immunoenzymetric assay. Samples containing L. lactis HCPs are reacted with a horseradish peroxidase (HRP) enzyme labeled anti-L. lactis antibody simultaneously in microtiter strips coated with an affinity purified capture anti-L. lactis 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 L. lactis HCPs present.

### Reagents And Materials Provided

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

Anti-L. lactis coated microtiter strips: 12x8 well strips in a bag with desiccant

L. lactis Standards: L. lactis HCPs in a bovine albumin matrix with preservative. Standards at 0, 1, 3, 12, 40, and 100ng/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 in our laboratories was determined to be ~0.125 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 conservatively stated as <0.5 ng/mL in our laboratories.