HEV ELISA

INSTRUCTION MANUAL

FOR RESEARCH USE ONLY

NOT FOR USE IN DIAGNOSTIC PROCEDURES

HEV ELISA

For the detection of IgG antibodies to Hepatitis E Virus (HEV) in serum or plasma samples.

TRADENAME AND INTENDED USE

The GENELABS DIAGNOSTICS (GLD) HEV ELISA is an enzyme-linked immunosorbent assay for IgG antibodies to Hepatitis E Virus (HEV) in serum or plasma.

This kit is supplied for research purposes only. It is not intended for use in the diagnosis or prognosis of disease. In particular this test cannot be used to evaluate blood specimens for the purposes of donor screening or as confirmatory diagnostic.

INTRODUCTION

The GENELABS DIAGNOSTICS HEV ELISA utilizes recombinant HEV antigens from the structural region of the viral genome to detect the presence of HEV antibodies in serum or plasma specimens.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The wells of the polystyrene microplate strips are coated with three recombinant HEV antigens which correspond to the structural regions of the Hepatitis E virus.

Human serum or plasma, diluted in diluent buffer, are incubated in these coated wells. HEV specific antibodies, if present, will bind to the solid phase HEV antigens. The wells are thoroughly washed to remove unbound materials and an affinity-purified anti-human IgG labelled with horseradish peroxidase is added to the wells. This labelled antibody will bind to any antigen-antibody complexes previously formed and excess, unbound labelled antibodies are removed by washing. A substrate solution containing hydrogen peroxide and o-Phenylenediamine (OPD.2HCI) is then added to each well. The presence of specific antibodies is indicated by the presence of a yellow-orange color after substrate addition. Reaction is terminated by addition of sulphuric acid. The intensity of the color is measured spectrophotometrically at 492nm and is proportional to the amount of antibodies present in the specimen.