FACT SHEET

HEPATITIS C VIRUS ANTIBODY — Test: 5800

The San Luis Obispo County Public Health Laboratory performs an enzyme-linked immunosorbent assay (ELISA)—ORTHO® HCV Version 3.0 ELISA Test System—for qualitative detection of antibody to hepatitis c virus (anti-HCV) in human serum or plasma. The test utilizes three HCV recombinant antigens—c22-3, c200, and NS5—to screen for anti-HCV antibodies.

HCV recombinant protein, c22-3, is encoded by the core region of the HCV genome. HCV recombinant protein, c200, is encoded by the NS3 (viral helicase) and NS4 (membrane binding) regions of the HCV genome. HCV recombinant protein, NS5, is encoded by the NS5 region (nonstructural) of the HCV genome.

The primary purpose of the assay is to screen blood donations for units containing anti-HCV antibody. It is also used to screen organ donors.

The presence of anti-HCV antibody does not constitute a diagnosis of HCV infection. The determination of anti-HCV may be used as an aid in the diagnosis of Hepatitis C and in the differential diagnosis of non-A, non-B hepatitis in conjunction with determination of liver enzymes, additional serological markers, and clinical evaluation. A positive test should be confirmed by a nucleic acid amplification test (NAAT) or viral load test to confirm presence of HCV. Anti-HCV antibodies will persist after a Hepatitis C infection is treated and resolved.

Specificity For anti-HCV, specificity was determined to by 99.95% in a low prevalence population.

Sensitivity

The frequency of anti-HCV detection was found to be 75.3% in persons with acute infections and 88.1% in persons with chronic infections.

Specimens

Blood specimens (serum or plasma) at a volume of 3 to 5 mL collected in glass, plastic, or serum-separator tubes are acceptable.

Unacceptable specimens

Whole blood stored at room temperature for longer than 24 hours, whole blood that has been frozen, and serum or plasma stored for longer than 10 days at 2–8 °C before or after centrifugation are not acceptable.

CPT Code 86803

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