TEST: HEPATITIS B SURFACE ANTIBODY (HBsAB) - QUANTITATIVE

PRINCIPLE:
Viral hepatitis is a major public health problem of global importance with an estimated 300 million persistent carriers of HBV worldwide. Infection with HBV results in a wide spectrum of acute and chronic liver diseases that may lead to cirrhosis and hepatocellular carcinoma.
HBV infection produces an array of unique antigens and antibody responses that, in general follow distinct serological patterns. Hepatitis B surface antigen (HBsAg), derived from the viral envelope, is the first antigen to appear following infection. The development of neutralizing anti-HBs occurs in 90% of patients infected with HBV and is associated with resolution of the infection and protective immunity.
Individuals who have resolved their HBV infection usually demonstrate both anti-HBs and antibody to hepatitis B core antigen (anti-HBc) in their serum. The absence of both anti-HBs and anti-HBc is indicative of susceptibility to HBV infection, and can identify individuals who may benefit from vaccination.

Both plasma derived and recombinant protein based vaccines have been developed and shown to be effective in inducing immunity to HBV through production of antibodies to HBsAg. Anti-HBs testing is useful for identifying HBV susceptible individuals in pre- and post-vaccination screening programs.

SPECIMEN REQUIREMENTS:
2ml collected in a serum separator tube (gel barrier). Separate serum from cells ASAP or within 2 hours of collection by centrifugation. Stability after separation from cells: Ambient: 5 Days; Refrigerated: 14 Days; Frozen: 30 Days (avoid repeated freeze/thaw cycles).

REJECTION CRITERIA: Plasma or other body fluids. Gross hemolysis

METHOD: Enzyme Linked Immunosorbent Assay (ELISA).

REFERENCES:
1. Maynard JE. et al. In Zuckermann AJ. (ed), *Viral Hepatitis and Liver Disease.* New York:Alan R. Liss Inc; 1988; 967-969.
2. Beasley RP, Hwang L. In Vyas GN. (ed), *Viral Hepatitis and Liver Disease.* New York:Grune & Stratton; 1984; 209-224.
3. Specter S. Hepatitis B Vaccines. In Specter S. (ed), *Viral Hepatitis, Diagnosis, Therapy and Prevention.* Totowa, NJ: Humana Press; 1999; 377-391.

CLINICAL INTERPRETATION OF IMMUNE STATUS:

-Less than 9.0 mIU/mL - NON-REACTIVE
Patient is considered to be not immune to infection with HBV.

-Greater than 9.0 mIU/mL and less than 12.0 mIU/mL - BORDERLINE
Unable to determine if antibodies against HepB surface antigen are present at levels consistent with immunity. Borderline results may indicate a low level of antibody that has clinical significance. Patient's immune status should be further assessed by considering other clinical information or retesting another specimen drawn at a later time.

-Greater than or equal to 12.0 mIU/mL - REACTIVE
Patient is considered to be immune to infection with HBV.

Turnaround Time: 7 business days