

TABLE 5. Interpretation of serologic test results* for hepatitis B virus infection

Serologic marker				Interpretation
HBsAg	Total anti-HBc	IgM anti-HBc	Anti-HBs	
—	—	—	—	Never infected
+†	—	—	—	Early acute infection; transient (≤ 18 days) after vaccination
+	+	+	—	Acute infection
—	+	+	—	Acute resolving infection
—	+	—	+	Recovered from past infection and immune
+	+	—	—	Chronic infection
—	+	—	—	Past infection; low-level chronic infection [§] ; passive transfer to infant born to HBsAg-positive mother; false positive (no infection)
—	—	—	+	Immune if concentration is >10 mIU/mL after vaccination, passive transfer after HBIG administration

Source: Adapted from Schillie S, Vellozzi C, Reingold A, et al. Prevention of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2018;67(No. RR-1).

Abbreviations: anti-HBc = antibody to hepatitis B core antigen; anti-HBs = antibody to hepatitis B surface antigen; HBIG = hepatitis B immune globulin; HBsAg = hepatitis B surface antigen; IgM = immunoglobulin M.

* — = negative test result; + = positive test result.

† To ensure that an HBsAg-positive test result is not false positive, samples with repeatedly reactive HBsAg results should be tested with a neutralizing confirmatory test cleared by the Food and Drug Administration.

§ Persons positive for only anti-HBc are unlikely to be infectious, except under unusual circumstances involving direct percutaneous exposure to large quantities of blood (e.g., blood transfusion or organ transplantation) or mutant HBsAg-related infection.

Prevention

Two products have been approved for HBV prevention: hepatitis B immune globulin (HBIG) for PEP and hepatitis B vaccine (12). HBIG provides temporary (i.e., 3–6 months) protection from HBV infection and is typically used as PEP as an adjunct to hepatitis B vaccination for previously unvaccinated persons or for persons who have not responded to vaccination. HBIG is prepared from plasma known to contain high concentrations of anti-HBs. The recommended dose of HBIG is 0.06 mL/kg body weight.

Hepatitis B vaccine contains HBsAg produced in yeast by recombinant DNA technology and provides protection from HBV infection when used for both pre-exposure vaccination and PEP. The three available monovalent hepatitis B vaccines for use in the United States are Recombivax HB, Engerix-B, and Heplisav-B. A combination hepatitis A and hepatitis B vaccine for use among persons aged ≥ 18 years, Twinrix, also is available.

When selecting a hepatitis B vaccination schedule, health care providers should consider the need to achieve completion of the vaccine series. The recommended HBV dose and schedule varies by product and age of recipient (Table 6). Three different 3-dose schedules for adolescents and adults have been approved for both monovalent hepatitis B vaccines (i.e., Engerix-B and Recombivax HB); these vaccines can be administered at 0, 1, and 6 months; 0, 1, and 4 months; or 0, 2, and 4 months. A 4-dose schedule of Engerix-B at 0, 1, 2, and 12 months is licensed for all age groups. A 2-dose schedule of Recombivax HB adult formulation (10 μ g) is licensed for adolescents aged 11–15 years, with a 4-month minimal interval between doses. When scheduled to receive the second dose, adolescents

aged 16–19 years should be switched to a 3-dose series, with doses 2 and 3 consisting of the pediatric formulation (5 μ g) administered on a recommended schedule. Heplisav-B is a new single-antigen recombinant hepatitis B vaccine with a novel cytosine-phosphate-guanine 1018 oligodeoxynucleotide adjuvant for prevention of HBV infection among persons aged ≥ 18 years, administered as a 2-dose series at 0 and 1 month (>4 weeks apart) (156). Twinrix is a 3-dose schedule administered at 0, 1, and 6 months to persons aged ≥ 18 years at risk for both HAV and HBV infections.

Hepatitis B vaccine should be administered IM in the deltoid muscle and can be administered simultaneously with other vaccines. If the vaccine series is interrupted after the first or second dose of vaccine, the missed dose should be administered as soon as possible. The series does not need to be restarted after a missed dose. HBV vaccination is available for eligible children and adolescents aged <19 years through the VFC program (<https://www.cdc.gov/vaccines/programs/vfc/contacts-state.html>). When feasible, the same manufacturer's vaccines should be used to complete the series; however, vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable (1324).

Among adolescents and healthy adults aged <40 years, approximately 30%–55% achieve a protective antibody response (i.e., anti-HBs ≥ 10 mIU/mL) after the first single-antigen vaccine dose, 75% after the second, and $>90\%$ after the third. Recent clinical trials reported a protective antibody response achieved among approximately 90% of participants receiving Heplisav-B, compared with 70.5%–90.2% of participants receiving Engerix-B (12). Vaccine-induced immune memory has been demonstrated to persist for >30 years (1325–1327).