Hepatitis B and Healthcare Personnel Q&A

CDC answers frequently asked questions about how to protect healthcare personnel

The Immunization Action Coalition thanks experts at the Centers for Disease Control and Prevention for answering the following questions.

Hepatitis B Vaccination

Which people who work in healthcare settings need hepatitis B vaccine?

The Occupational Safety and Health Administration (OSHA) requires that hepatitis B vaccine be offered to healthcare personnel (HCP) who have a reasonable expectation of being exposed to blood or body fluids on the job. This requirement does not include personnel who would not be expected to have occupational risk (e.g., general office workers).

At what anatomic site should hepatitis B vaccine be administered to adults? What needle size should be used?

For adults, administer hepatitis B vaccine intramuscularly (IM) in the deltoid muscle. A 22- to 25-gauge, 1–1½-inch needle should be used. The gluteus muscle should *not* be used as a site for administering hepatitis B vaccine. For optimal protection, it is crucial that the vaccine be administered IM, not subcutaneously.

If a person who works in a healthcare setting had one dose only of hepatitis B vaccine 1 year ago, should the series be restarted?

No. The hepatitis B vaccine series should not be restarted when doses are delayed; rather, the series should be continued from where it stopped. The person should receive the second dose of vaccine now and the third dose at least 8 weeks later. There needs to be at least 8 weeks between the second and third doses and at least 16 weeks between the first and the third doses of vaccine.

Is it safe for HCP to be vaccinated during pregnancy?

Yes. Many years of experience with hepatitis B vaccines indicate no apparent risk for adverse events to a developing fetus. Current hepatitis B vaccines contain noninfectious hepatitis B surface antigen (HBsAg) and pose no risk to the fetus. If not vaccinated, a pregnant woman could contract hepatitis B virus (HBV) infection during pregnancy, which might result in severe disease for the newborn. Women who breastfeed their babies can be vaccinated as well. Receipt of hepatitis B vaccine is not a reason to discontinue breastfeeding.

Is there a recommendation for routine booster doses of hepatitis B vaccine?

No. HCP who have documentation of receiving a 3-dose series of hepatitis B vaccine and who subsequently tested positive for anti-HBs (defined as anti-HBs of ≥10 mIU/mL) are considered to be immune to hepatitis B. Immunocompetent persons who also have followed the protocol, have long-term protection against HBV and do not need further testing or vaccine doses. Some immunodeficient persons, including those on hemodialysis, may need periodic booster doses of hepatitis B vaccine, as described in the 2006 adult hepatitis B vaccine ACIP recommendations (*MMWR* 2006;55[RR-16]:26–29).

In December 2013, CDC released a new document titled *CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management* (*MMWR* 2013;62[RR-10]) available at www.cdc.gov/mmwr/pdf/rr/rr6210.pdf. Does the content of this document update ACIP recommendations on healthcare personnel vaccination and hepatitis B?

The new guidance published by CDC does not constitute new recommendations of ACIP. The CDC guidance was created based on the opinions of an expert panel convened by CDC. According to the document, the guidance from CDC "augments the 2011 recommendations" of the ACIP document titled *Immunization of Health-Care Personnel* published November 25, 2011 (www.cdc.gov/mmwr/pdf/rr/rr6007.pdf), for evaluating hepatitis B protection among healthcare personnel and administering postexposure prophylaxis.

Post-vaccination Anti-HBs Testing

Which HCP need serologic testing after receiving 3 doses of hepatitis B vaccine?

All HCP, including trainees, who have a high risk of occupational percutaneous or mucosal exposure to blood or body fluids (e.g., HCP with direct patient contact, HCP who have the risk of needlestick or sharps injury, laboratory workers who draw, test or handle blood specimens) should have postvaccination testing for antibody to hepatitis B surface antigen (anti-HBs). Postvaccination testing should be done 1–2 months after the third dose of vaccine. Postvaccination testing for persons at low risk for mucosal or percutaneous exposure to blood or body fluids (e.g., public safety workers and HCP without direct patient contact) likely is not cost-effective. Those who do not undergo postvaccination testing should be counseled to seek immediate testing if exposed.

What should be done if HCP postvaccination anti-HBs test is negative (less than 10 mIU/mL) 1–2 months after the third dose of vaccine?

Repeat the 3-dose series and test for anti-HBs 1–2 months after the last dose of the vaccine. If the test is still negative after a second vaccine series, HCP should be tested for HBsAg and total anti-HBc to determine their HBV infection status. HCP who test negative for HBsAg and total anti-HBc should be considered vaccine non-responders and susceptible to HBV infection. They should be counseled about precautions to prevent HBV infection and the need to obtain hepatitis B immune globulin (HBIG) prophylaxis for any known or likely exposure to HBsAg-positive blood or blood or body fluids from a person whose HBsAg status is unknown.

HCP found to be HBsAg negative but total anti-HBc positive were infected in the past and require no vaccination or treatment.

If the HBsAg and total anti-HBc tests are positive, HCP should receive appropriate counseling for preventing transmission to others as well as referral for ongoing care to a specialist experienced in the medical management of chronic HBV infection. HCP should not be excluded from work.

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www.immunize.org/catg.d/p2109.pdf ▪ Item #P2109 (4/15)

How often should I test HCP after they've received the hepatitis B vaccine series to make sure they're protected?

For immunocompetent HCP, periodic testing or periodic boosting is not needed. Postvaccination testing (anti-HBs) should be done 1–2 months after the third dose of the hepatitis B vaccine series. If adequate anti-HBs (at least 10 mIU/mL) is present, nothing more needs to be done. This information should be made available to the individual and recorded in the his or her health record. If postvaccination testing is less than 10 mIU/mL, the 3-dose vaccine series should be repeated and anti-HBs testing should be completed 1–2 months after the last dose of the second series.

Does CDC now recommend routine preexposure anti-HBs testing for all HCP who were previously vaccinated but not tested?

In general, no, but the type of testing (preexposure or postexposure) depends on the setting. An expert panel convened by CDC acknowledged that the risk for HBV infection for vaccinated HCP can vary widely by setting and profession (see reference at the end of this answer). The risk might be low enough in certain settings that assessment of anti-HBs status and appropriate follow-up can be done at the time of exposure to potentially infectious blood or body fluids. This approach relies on HCP recognizing and reporting blood and body fluid exposures and might be applied on the basis of documented low risk, implementation, and cost considerations. Trainees, some occupations (such as those with frequent exposure to sharp instruments and blood), and HCP practicing in certain populations are at greater risk of exposure to blood or body fluid from an HBsAg-positive patient. Vaccinated HCP in these settings/occupations would benefit from a pre-exposure approach. HCP with documentation of a complete 3-dose HepB vaccine series but no documentation of anti-HBs ≥10 mIU/mL who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation. The algorithm (Figure 1) on page 3 will assist in the management of these people. It was adapted from *CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management*, *MMWR* 2013; 62(RR-10), p. 13, available at www.cdc.gov/mmwr/pdf/rr/rr6210.pdf.

We test all our new employees for immunity to hepatitis B. Some of our new employees have documentation of completing hepatitis B vaccination as children or adolescents but now test negative for anti-HBs (that is, antibody level less than 10 mIU/mL). How should we manage these employees?

CDC published guidance for this situation in December 2013. For persons vaccinated in the past who were not tested for a response following the completed vaccination series and who now test negative for anti-HBs, it is recommended to administer 1 "booster" dose of hepatitis B vaccine, then test for anti-HBs 1–2 months later. Those who test positive for anti-HBs after the single "booster" dose are considered to be immune and no further testing or vaccination is needed. Those who test negative for anti-HBs after the "booster" dose should receive 2 additional doses to complete a second 3-dose series. Anti-HBs testing should be repeated 1–2 months after completion of the second vaccination series. An algorithm (Figure 1) adapted from the CDC guidance document is provided on page 3.

At our facility we do routine pre-employment anti-HBs testing regardless of whether the employee has documentation of a hepatitis B vaccination series and consider those with a positive antibody to be immune. Is this the recommended strategy?

No. HCP with written documentation of receipt of a properly spaced 3-dose series of hepatitis B vaccine AND a positive anti-HBs can be considered immune to HBV and require no further testing or vaccination. However, anti-HBs testing of unvaccinated or incompletely vaccinated HCP and those without written documentation of vaccination is not recommended and is potentially misleading because anti-HBs of ≥10 mIU/mL as a correlate of vaccine-induced protection has only been determined for persons who have completed a vaccination series. Persons who cannot provide written documentation of a complete hepatitis B vaccination series should complete a documented 3-dose series, then be tested for anti-HBs 1–2 months after the final dose.

Several physicians in our group have no documentation showing they received hepatitis B vaccine. They are relatively sure, however, that they received the doses many years ago. What do we do now?

Because there is no documentation of vaccination, the 3-dose vaccination series should be administered and anti-HBs postvaccination testing should be performed 1–2 months after the third dose of vaccine. There is no harm in receiving extra doses of vaccine. Care should always be taken to document vaccine lot, date, manufacturer, route, and vaccine dosages. Postvaccination testing results should also be documented, including the date testing was performed. All healthcare settings should develop policies or guidelines to assure valid hepatitis B immunization and anti-HBs testing when indicated.

An employee thinks she had 3 doses of hepatitis B vaccine in the past but has no documentation of receiving those doses. We obtained an anti-HBs titer and the result was greater than 10 mIU/mL. With this lab result, can't we assume she is immune?

No. A positive anti-HBs indicates that the vaccinated person is immune at the time the person was tested but does not assure that the person has long-term immunity. Long-term immunity has been demonstrated only for people attaining an adequate anti-HBs result of at least 10 mIU/mL after completing a full hepatitis B vaccination series. The most direct way to deal with this is to vaccinate the employee with a 3-dose series of hepatitis B vaccine; test for anti-HBs in 1–2 months and document the result in the employee's health record. An adequate anti-HBs result from a documented 3-dose vaccine series would assure not only seroprotection, but long-term protection.

I'm a nurse who received the 3-dose hepatitis B vaccine series more than 10 years ago and had a positive follow-up titer (at least 10 mIU/mL). At present, my titer is negative (<10 mIU/ mL). What should I do now?

Nothing. Data show that vaccine-induced anti-HBs levels might decline over time; however, immune memory (anamnestic anti-HBs response) remains intact following immunization. People with adequate anti-HBs concentrations that have declined to less than 10 mIU/mL are still protected against HBV infection. For HCP with normal immune status who have demonstrated adequate anti-HBs (≥10 mIU/mL) following full vaccination, booster doses of vaccine or periodic anti-HBs testing are not recommended.

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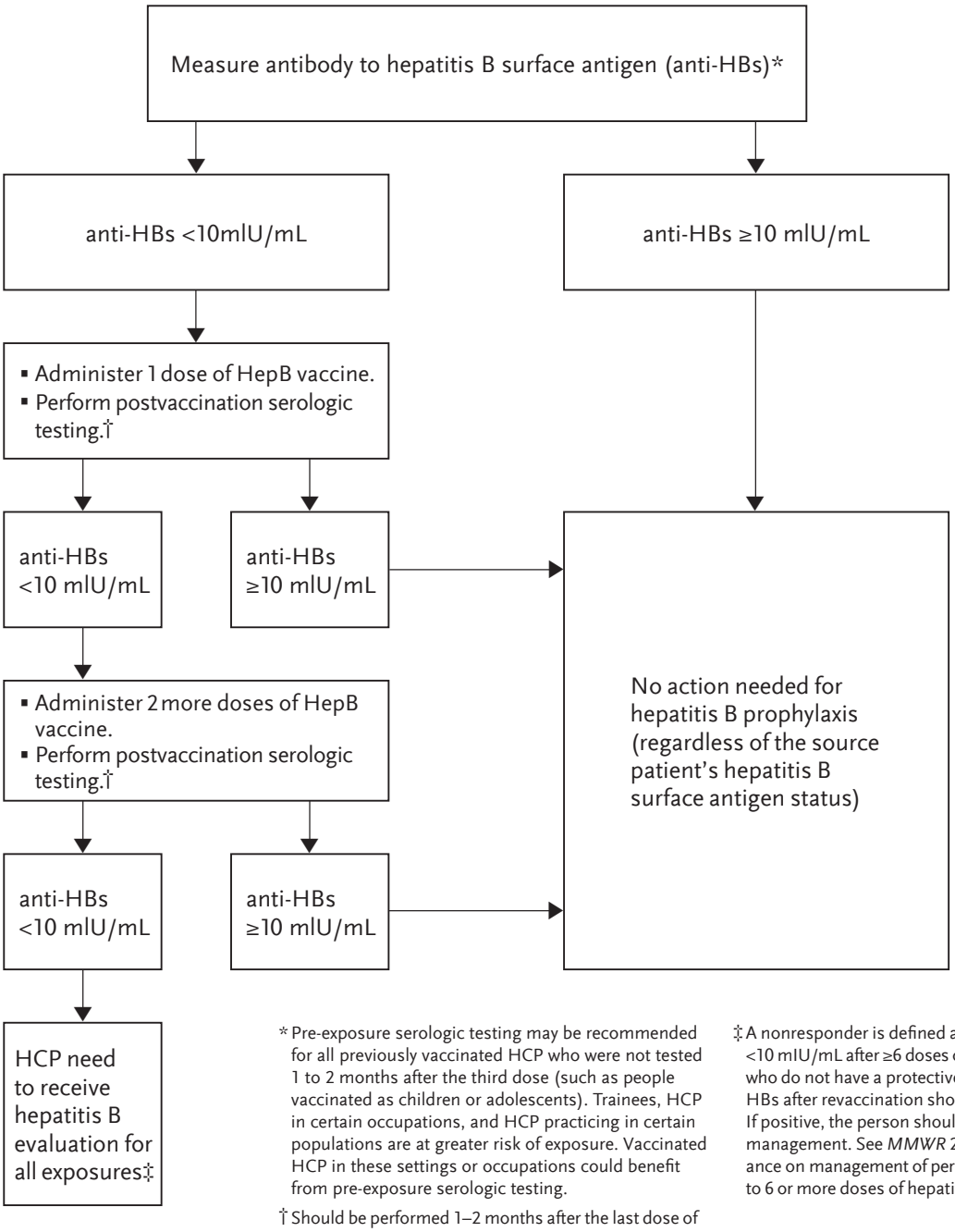
FIGURE 1.

Pre-exposure Management for Healthcare Personnel with a Documented Hepatitis B Vaccine Series Who Have Not Had Post-vaccination Serologic Testing

Healthcare personnel (HCP) with documentation of a complete ≥3-dose HepB vaccine series but no documentation of anti-HBs ≥10 mIU/mL who are at risk for occupational blood or body fluid exposure might undergo anti-HBs testing upon hire or matriculation. The algorithm below will assist in the management of these people.

It was adapted from *CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management*, *MMWR* 2013; 62(RR-10), p. 13, available at www.cdc.gov/mmwr/pdf/rr/rr6210.pdf.

NOTE: Also available as standalone form at www.immunize.org/catg.d/p2108.pdf.



* Pre-exposure serologic testing may be recommended for all previously vaccinated HCP who were not tested 1 to 2 months after the third dose (such as people vaccinated as children or adolescents). Trainees, HCP in certain occupations, and HCP practicing in certain populations are at greater risk of exposure. Vaccinated HCP in these settings or occupations could benefit from pre-exposure serologic testing.

† Should be performed 1–2 months after the last dose of vaccine using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL) (e.g., enzyme-linked immunosorbent assay [ELISA]).

‡ A nonresponder is defined as a person with anti-HBs <10 mIU/mL after ≥6 doses of HepB vaccine. Persons who do not have a protective concentration of anti-HBs after revaccination should be tested for HBsAg. If positive, the person should receive appropriate management. See *MMWR* 2013;62(RR-10) for guidance on management of persons who do not respond to 6 or more doses of hepatitis B vaccine.

Should a healthcare professional who performs invasive procedures and who once had a positive anti-HBs result be revaccinated if the anti-HBs titer is rechecked and is less than 10 mIU/mL?

No. Immunocompetent people known to have responded to hepatitis B vaccination in the past do not require additional passive or active immunization. Postvaccination testing should be done 1–2 months after the original vaccine series is completed. In this situation, the initial postvaccination testing showed that the healthcare professional was protected. Substantial evidence suggests that adults who respond to a 3-dose hepatitis B vaccine series (anti-HBs of >10 mIU/ mL) are protected from chronic HBV infection for at least 22 years, even if there is no detectable anti-HBs currently. Only immunocompromised people (e.g., dialysis patients, some HIV-positive people) need to have anti-HBs testing performed periodically. Booster doses of vaccine to maintain their protective anti-HBs concentrations to >10 mIU/mL are recommended for dialysis patients and may be given to some HIV-positive patients.

Non-responders or HCP with Chronic HBV Infection

If an employee does not respond to hepatitis B vaccination (employee has had two full series of hepatitis B vaccine), does s/he need to be removed from activities that expose her/him to bloodborne pathogens?

No. There are no regulations that require removal from job situations where exposure to bloodborne pathogens could occur; this is an individual policy decision within an organization. OSHA regulations require that employees, in jobs where there is a reasonable risk of exposure to blood, be offered hepatitis B vaccine. In addition, the regulation states that adequate personal protective equipment be provided and that standard precautions be followed. Check your state OSHA regulations regarding additional requirements. If there are no state OSHA regulations, federal OSHA regulations should be followed. Adequate documentation should be placed in the employee record regarding non-response to vaccination.

HCP who do not respond after 6 doses of vaccine should be tested for HBsAg and total anti-HBc to determine if they have chronic HBV infection. If the HBsAg and total anti-HBc tests are positive, HCP should receive appropriate counseling for preventing transmission to others as well as referral for ongoing care to a specialist experienced in the medical management of chronic HBV infection. People who are HBsAg-positive and who perform exposure-prone procedures should seek counsel from a review panel comprised of experts with a balanced perspective (e.g., infectious disease specialists and their personal physician[s]) regarding the procedures that they can perform safely. They should not be excluded from work.

Nonresponders who test negative for HBsAg should be considered susceptible to HBV infection. They should be counseled about precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known exposure to blood that is HBsAg-positive or if the HBsAg status of the source is unknown (see Table 1 on page 5).

Can a person with chronic HBV infection work in a healthcare setting?

Yes. HCP should not be discriminated against because of their hepatitis B status. All HCP should practice standard precautions, which are designed to prevent HBV transmission, both from patients to HCP and from HCP to patient. There is, however, one caveat concerning HBV-infected HCP. Those who have HBV levels 1000 IU/mL or 5000 genomic equivalents/mL or higher should not perform exposure-prone procedures (e.g., gynecologic, cardiothoracic surgery) unless they have sought counsel from an expert review panel and been advised under what circumstances, if any, they may continue to perform these procedures. For more information on this issue, see *Updated CDC Recommendations for the Management of Hepatitis B Virus–Infected Health-Care Providers and Students, MMWR, 2012; 61(RR03):1-12. This docum*ent is available at www.cdc.gov/mmwr/pdf/rr/rr6103.pdf.

Post-exposure Management

How should a fully vaccinated employee with an unknown anti-HBs response be managed if they have a percutaneous or mucosal exposure to blood or body fluids from an HBsAg-positive or HBsAg-unknown source?

Management of the exposed HCP depends on both the anti-HBs status of the HCP and the HBsAg status of the source patient. The HCP should be tested for anti-HBs and the source patient (if known) should be tested for HBsAg as soon as possible after the exposure. Testing the source patient and the HCP should occur simultaneously; testing the source patient should not be delayed while waiting for the HCP anti-HBs test results, and likewise, testing the HCP should not be delayed while waiting for the source patient's HBsAg results. See Table 1 for management recommendations based on the results of testing.

If an employee receives both HBIG and hepatitis B vaccine after a needlestick from a patient who is HBsAg positive, how long should one wait to check the employee's response to the vaccine?

Anti-HBs testing for HCP who receive both hepatitis B immune globulin (HBIG) and hepatitis B vaccine can be conducted as soon as 4 months after receipt of the HBIG. However, a new recommendation in the 2013 document is to test for hepatitis B core antibody (anti-HBc) and hepatitis B surface antigen (HBsAg) among certain HCP (those previously unvaccinated, incompletely vaccinated, or revaccinated) with an exposure from an HBsAg-positive or unknown HBsAg-status patient at the time of the exposure as well as at approximately 6 months after the exposure (that is, after the HBV incubation period). The CDC expert panel determined that it would be more efficient to do all the follow-up testing at one time, and recommended testing at 6 months after the exposure. Anti-HBs could be measured at a minimum of 4 months after the administration of HBIG, but testing for infection would then follow approximately 2 months later.

For more information on vaccination recommendations for healthcare personnel, see the following:

1 CDC. CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management, *MMWR*, 2013; 62(10):1–19, www.cdc.gov/mmwr/pdf/rr/rr6210.pdf

2 CDC. Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices, *MMWR*, 2011; 60(7): 1–48, www.cdc.gov/mmwr/pdf/rr/rr6007.pdf

3 Immunization Action Coalition. "Healthcare Personnel Vaccination Recommendations," www.immunize.org/catg.d/p2017.pdf

4 Immunization Action Coalition. "Pre-exposure Management for Healthcare Personnel (HCP) with a Documented Hepatitis B Vaccine Series Who Have Not Had Post Vaccination Serologic Testing," www.immunize.org/catg.d/p2108.pdf

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TABLE 1. Post-exposure management of healthcare personnel after occupational percutaneous and mucosal exposure to blood and body fluids, by healthcare personnel HepB vaccination and response status

Healthcare personnel status	Postexposure testing		Postexposure prophylaxis		Postvaccination serologic testing†
	Source patient (HBsAg)	HCP testing (anti-HBs)	HBIG*	Vaccination	
Documented responder§ after complete series (≥3 doses)	No action needed				
Documented nonresponder¶ after 6 doses	Positive/ unknown	—**	HBIG x2 separated by 1 month	—	No
	Negative	No action needed			
Response unknown after 3 doses	Positive/ unknown	<10mIU/mL**	HBIG x1	Initiate revaccination	Yes
	Negative	<10mIU/mL	None		
	Any result	≥10mIU/mL	No action needed		
Unvaccinated/incompletely vaccinated or vaccine refusers	Positive/ unknown	—**	HBIG x1	Complete vaccination	Yes
	Negative	—	None	Complete vaccination	Yes

* HBIG should be administered intramuscularly as soon as possible after exposure when indicated. The effectiveness of HBIG when administered >7 days after percutaneous, mucosal, or nonintact skin exposures is unknown. HBIG dosage is 0.06 mL/kg.

† Should be performed 1–2 months after the last dose of the HepB vaccine series (and 4–6 months after administration of HBIG to avoid detection of passively administered anti-HBs) using a quantitative method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL).

§ A responder is defined as a person with anti-HBs ≥10 mIU/mL after ≥3 doses of HepB vaccine.

¶ A nonresponder is defined as a person with anti-HBs <10 mIU/mL after ≥6 doses of HepB vaccine.

** HCP who have anti-HBs <10mIU/mL, or who are un-vaccinated or incompletely vaccinated, and sustain an exposure to a source patient who is HBsAg-positive or has unknown HBsAg status, should undergo baseline testing for HBV infection as soon as possible after expo-sure, and follow-up testing approximately 6 months later. Initial baseline tests consist of total anti-HBc; testing at approximately 6 months consists of HBsAg and total anti-HBc.

ABBREVIATIONS

HCP = healthcare personnel

HBsAg = hepatitis B surface antigen

anti-HBs = antibody to hepatitis B surface antigen

HBIG = hepatitis B immune globulin

Adapted from *CDC Guidance for Evaluating Health-Care Personnel for Hepatitis B Virus Protection and for Administering Postexposure Management*, *MMWR* 2013; 62(RR10): 1–19; www.cdc.gov/mmwr/pdf/rr/rr6210.pdf.