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# Perinatal Hepatitis B Prevention Program Guidelines

Washington State Department of Health Office of Infectious Disease



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Perinatal Hepatitis B Prevention Program Washington State Department of Health

This manual is available online at **www.doh.wa.gov/phbguidelines**.

If you have a disability and need this document in another format, please call 1-800-525-0127 (TDD/TTY 7-1-1).

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# Glossary

## Acronyms, Abbreviations and Terms

DMS	Data Management System
DOH	Department of Health
HBIG	Hepatitis B Immune Globulin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
LHJ	Local Health Jurisdiction
PHBPP	Perinatal Hepatitis B Prevention Program
WDRS	Washington Disease Reporting System

## Hepatitis B Serologic Tests, Post Exposure Prophylaxis, and Post Vaccination Testing

Hepatitis B Serologic Tests		
Anti-HBc <sup>1</sup>	Total antibody to hepatitis B core antigen	
Anti-HBs <sup>2</sup>	Hepatitis B surface antibody	
This test looks for the a	intibody formed in response to the surface protein of the hepatitis B virus. A	
positive test shows an immune response to HBV infection, and is produced in response to vaccination		
or recovery from an actual hepatitis B infection.		
HBsAg	Hepatitis B surface antigen	
The surface protein of	the hepatitis B virus is used as a marker to detect infection. If this blood test is	
positive, then the hepatitis B virus is present.		
HBV DNA	Hepatitis B Virus DNA	
A marker of viral load a	nd reflects viral replication. High levels of HBV DNA mean a patient's blood	
and body fluids are very infectious. HBV DNA, usually measured in international units per milliliter		
(IU/mL), is used to assess and monitor the treatment of patients with chronic HBV infection.		

Hepatitis B Post Exposure Prophylaxis		
HBIG	Hepatitis B Immune Globulin	
A medication that is given as a "post-exposure" treatment to prevent HI		

A medication that is given as a "post-exposure" treatment to prevent HBV. This means that HBIG is given after a person has been exposed to potentially infected blood or infected bodily fluids, which can include but is not limited to - contact with blood or through a needle-stick, **infants born to infected pregnant persons**, and through sexual contact or close household contact with an infected person.

Post Vaccination Testing			
PVST	Post-Vaccination Serology Testing		
PVST helps identify infa	ints born to HBV-infected pregnant people who may not have an adequate		
immune response to an initial hepatitis B vaccine series and might require additional vaccination.			
PVST also enables early identification of HBV-infected infants.			
CDC recommends that	CDC recommends that infants born to HBV-infected pregnant people receive PVST consisting of two		
HBV serologic tests: a hepatitis B surface antigen (HBsAg) test and an antibody to hepatitis B surface			
antigen (anti-HBs) test at age 9-12 months (or 1–2 months after the final dose of the vaccine series if			
the series is delayed).			
Sources:	Hepatitis B Foundation: Hepatitis B Blood Tests (hepb.org)		
	Guidelines for Perinatal Post-Vaccination Serologic Testing   Hepatitis B   CDC		
	Clinical Testing and Diagnosis for Hepatitis B   Hepatitis B   CDC		

<sup>&</sup>lt;sup>1</sup> Also referred to as HBcAb, though the term is not recommended as it may be confused with HBsAg.

<sup>&</sup>lt;sup>2</sup> Also referred to as HBsAb, though the term is not recommended as it may be confused with HBsAg.

## Program Overview

## Perinatal Hepatitis B Prevention Program Goal and Objectives

#### Federal Recommendations

The Washington State Department of Health (DOH) Office of Infectious Disease follows federal CDC and the Advisory Committee on Immunization Practices (ACIP) recommendations for the prevention of perinatal hepatitis B infection. CDC recommendations encompass multiple PHBPP strategies, including delivery hospital policies and procedures, and case management programs.

Please note newly released <u>Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations</u> — United States, 2023.

New recommendations:

- Hepatitis B screening using three laboratory tests (HBsAg, anti-HBs, and total anti-HBc) at least once during a lifetime for adults aged ≥18 years.
- Expand risk-based testing recommendations to include the following populations, activities, exposures, or conditions associated with increased risk for HBV infection:
  - persons incarcerated or formerly incarcerated in a jail, prison, or other detention setting;
  - persons with a history of sexually transmitted infections or multiple sex partners; and
  - persons with a history of hepatitis C virus infection.
- To provide increased access to testing, anyone who requests HBV testing should receive it, regardless of disclosure of risk, because many persons might be reluctant to disclose stigmatizing risks.

Screening continues to be recommended for all pregnant persons during each pregnancy, preferably in the first trimester, regardless of vaccination status or history of testing. (See original release for additional details including Clinical Considerations.)

To provide appropriate clinical care to a newborn, enter the pregnant person's data in the infant's medical record as recommended by ACIP. This does NOT violate the Health Insurance Portability and Accountability Act (HIPAA). The HIPAA Privacy Rule allows the use of some health information:

"A covered entity is permitted, but not required, to use and disclose protected health information, without an individual's authorization, for the following purposes or situations: (1) To the Individual; (2) Treatment, Payment, and Health Care Operations..."

Find a summary document of the <u>HIPAA Privacy Rule</u> here.

## Goal

Washington State's Perinatal Hepatitis B Prevention Program (PHBPP) has an overall goal to work with partners **to assure coordination of activities to prevent perinatal hepatitis B transmission to newborns**. The program has several key elements.

- It is both a surveillance and case management program to prevent and manage perinatal hepatitis B cases.
- It promotes the universal hepatitis B birth dose.
- It relies on multiple reporting mechanisms.
- It works with multiple partners to assure coordination of activities.

Local health jurisdictions (LHJs) in our state are key in completing these tasks, including supporting effective delivery hospital policies specifying birth dose vaccinations, standing orders, and case management to:

- Identify HBsAg-positive pregnant persons.
- Ensure HBV DNA testing is done for all HBsAg-positive pregnant people to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission.
- Make sure babies born to HBsAg-positive persons get proper post-exposure prevention. Correct post-exposure prevention for babies includes hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth, followed by two more doses of vaccine (at 1-2 months and 6 months of age).
- Make sure post-vaccination testing is completed.
- Report all data on administration of follow-up doses of vaccine and post-vaccination testing of the infant to the Washington State Department of Health (DOH).

## Objectives



## Hepatitis B Facts

Acute (short-term) and chronic (long-lasting) effects of hepatitis B virus (HBV) infection are a major health problem.

About 79,000 infections occur in the U.S. each year; 21,000 of those cases are acute (short-term) and symptomatic (showing symptoms) (Centers for Disease Control and Prevention).

CDC estimates that about 640,000 adults in the US have chronic (long-term) hepatitis Band can potentially spread the disease to others.

Hepatitis B is a leading cause of liver cancer in the U.S. HBV can be passed from mom to baby during birth (perinatal infection). Each year, about 4,000 to 5,000 people die from chronic liver disease.

In 2022, the rate of newly reported chronic HBV cases was 11 times higher among non-Hispanic Asian/Pacific Islander persons than among non-Hispanic White people

HBV can be passed from mom to baby during birth (perinatal infection). About 25,000 HBVinfected moms give birth each year in the U.S. 90% of infants who acquire HBV infection from their mothers at birth become chronically infected. One in four chronically infected babies will die from liver cancer or cirrhosis of the liver later in life.

While screening rates are high, reporting rates of HBsAg-positive pregnant women remain a problem. Nationally, about 95% of pregnant women receive prenatal HBsAg serologic testing, yet only 53% of expected births to HBsAg-positive pregnant women are identified and reported to perinatal hepatitis B programs (CDC Peritable Outcomes, 2021)

Getting immunized with hepatitis B vaccine is the most effective way to prevent HBV infection. Pregnant women who are infected with HBV can prevent giving HBV to their babies at birth if the baby gets:

- Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth.
- Additional doses of vaccine at 1-2 months and 6 months of age.

CDC recommends testing all pregnant women for HBV early in each pregnancy even if they already had the vaccine or test. Women who test HBsAg-negative early in pregnancy but are in a high-risk category for HBV should be retested at the delivery hospital.

Pregnant women who test HBsAg positive should be referred to the local health jurisdiction's PHBPP and receive counseling, medical management, and information about HBV. <u>Emerging</u> <u>evidence</u> suggests HBV treatment during the third trimester is safe and reduces rates of transmission.

## Required Notification

Washington state follows three levels of required notification for certain medical conditions to prevent and control communicable and noninfectious diseases. Different agencies manage each notification level.

- 1. Notification to local health jurisdictions (LHJ): by every prenatal health care provider or hospital.
- 2. Notification to the Washington State Department of Health (DOH): by every local health jurisdiction.
- 3. Notification to the Centers for Disease Control and Prevention (CDC): **by the Washington State Department of Health**.

Washington considers **EACH** pregnancy in any HBsAg-positive person a notifiable condition. This can increase the chance that babies born to HBsAg-positive persons will get proper post-exposure prevention. Because of this, notifications must occur in the following order:

- 1. Healthcare providers notify the LHJ PHBPP Coordinator of the pregnant person's HBsAg-positive status.
- 2. The LHJ PHBPP Coordinator then enrolls the pregnant person in the Perinatal Hepatitis B Prevention Program, manages their baby, household contacts, and sexual partners, and reports the case in the DOH data management system. ("Case" here is defined as the person who is pregnant and living with hepatitis B who will be overseen from pregnancy through delivery, vaccination and testing of their infant as part of the PHBPP.)
- 3. DOH notifies CDC weekly about all hepatitis B-infected infants via the National Notifiable Diseases Surveillance System (NNDSS). (<u>Viral Hepatitis Surveillance and Case Management -</u> <u>General Surveillance | CDC</u>)

## **Notification Process**

Pregnant woman tests HBsAg-positive at her prenatal care provider, healthcare provider, or the hospital.

**Provider** or h**ospital** notifies local health jurisdiction's Hepatitis B Coordinator.

#### Hepatitis B Coordinator

•Contacts HBsAgpositive woman to enroll her in Perinatal Hepatitis B Program.

 Notifies DOH of pregnancy and outcomes at:
 Communicable Disease Epidemiology at 206-418-5500 or in WDRS DOH staff notify CDC of each positive hepatitis B case.

## **Required Reportable Conditions**

#### Hepatitis B Surface Antigen (HBsAg) Positivity During Pregnancy

Since December 2000, HBsAg-positive status during pregnancy has been a required reportable condition per Washington state law (Washington Administrative Code [WAC] 246-101-101 and WAC 246-101-301). Healthcare providers and health care facilities, such as hospitals, must report this status to local health jurisdictions within three working days.

#### Why Report?

Identifying and reporting HBsAg-positive pregnant persons during each pregnancy helps prevent the spread of hepatitis B virus to their babies through the PHBPP case management services. These babies have a very high risk of getting the infection and developing serious long-term medical conditions unless they get proper post-exposure prevention.

Local public health jurisdiction staff work with health care providers to make sure that:

- Pregnant people get counseled about preventing the spread of HBV to their babies and their household contacts.
- Pregnant people get screened and, if appropriate, referred to a specialist during pregnancy.
- Sexual partner(s) get referred to a specialist for follow-up.
- Babies get hepatitis B immune globulin (HBIG) and 3 doses of hepatitis B vaccine at birth, 1-2 months, and 6 months of age.
- Babies get post-vaccination testing (HBsAg and anti-HBs) between 9 and 12 months of age (or at least 1 to 2 months after the third dose of hepatitis B vaccine if the series is delayed) to check for infection and immune status.

#### When to Report

A report should be made at any time during **each** pregnancy in which the pregnant person tests HBsAg positive. It is the prenatal care provider's responsibility to make sure the delivery hospital knows of an HBsAg-positive mother prior to the birth so the baby gets proper treatment. This does not always occur, therefore, LHJ PHBPP Coordinators should confirm with the delivery hospital that they are aware of every HBsAg positive pregnant person's status prior to the delivery date to ensure the hospital is prepared to administer HBIG and hepatitis B vaccine.

#### **Reporting Requirements**

Per <u>WAC 246-101-101</u> and <u>WAC 246-101-301</u>, healthcare providers and health care facilities who request the HBsAg test during prenatal care or at time of delivery must report all HBsAg-positive pregnant women to the provider's LHJ <u>within three working days</u>.

#### **Reporting Resources**

- List of Notifiable Conditions
- Hepatitis B Reporting Form
- If you have other questions, contact the Department of Health at 206-418-5500.

## The Role of Local Health Jurisdictions

#### Local Health Jurisdiction Tasks Overview

Local health jurisdictions (LHJs) receive funds from the state Department of Health for perinatal hepatitis B prevention and may contract with the state to receive funds for reporting PHBPP case management activities. (WAC 246-101-505)

#### Regardless of whether an LHJ contracts with the state, each LHJ must:

- 1. Identify and report HBsAg-positive mothers and their babies; and
- 2. Manage and track babies to make sure they get the correct doses at the correct ages and proper testing as follows:
  - a. The first dose of HBIG and hepatitis B vaccine within 12 hours of birth.
  - b. The second dose at 1-2 months of age.
  - c. The third dose at 6 months of age.
  - d. Post-vaccination testing at 9–12 months of age, or 1-2 months after the final dose of vaccine if the series is delayed.

Under this program:

- LHJs should manage and track cases<sup>3</sup> in the PHBPP data management system.
- State-supplied hepatitis B vaccine is available for all babies born to HBsAg-positive women and for household contacts and sexual partners who are younger than 19 years old. See Eligibility criteria here: <u>Washington State Childhood Vaccine Program Eligibility Guide for Providers</u>. Uninsured or underinsured adults may also get hepatitis B vaccine through the Adult Vaccine Program.

• LHJs use multiple systems to 1) identify HBsAg positive pregnant persons, 2) enroll cases in PHBPP, 3) verify lab results and vaccine administration; and 4) manage cases.

- These systems are:
  - Washington State Disease Reporting System (WDRS) an electronic disease surveillance system that allows public health staff in Washington State to receive, enter, manage, process, track and analyze disease-related data. As of November 2023, PHBPP case and data management transitioned to WDRS.
  - Washington State Immunization Information System (WA IIS) a lifetime immunization registry with records for Washington residents. The IIS is available to all licensed healthcare providers in Washington to support immunization activities.

<sup>&</sup>lt;sup>3</sup> "Case" here is defined as the person who is pregnant and living with hepatitis B who will be overseen from pregnancy through delivery, vaccination and testing of their infant as part of the PHBPP. Infants who test HBsAg positive as a result of perinatal transmission will be monitored and tracked separately.

#### LHJ Case Management



#### Perinatal Hepatitis B Reporting

LHJs must monitor and report PHBPP case management activities for HBsAg-positive pregnant persons and their babies in WDRS. (For further information see previous section.)

The Department uses data from WDRS to track status and to provide technical assistance and support to LHJs. To that end, LHJs are required to enter information into WDRS continuously with cases being confirmed, updated, and completed on a monthly basis. In addition to enabling oversight of PHBPP activities, data collected in WDRS is used to report outcomes to the CDC.

#### Managing Cases

#### Case Management Resources

Use the following resources to manage HBsAg-positive pregnant persons:

Washington State Disease Reporting System (WDRS)

- Verify case lab results and update records
- Add, review and update case records

Washington State Immunization Information System (WA IIS)

• Verify immunization status

These systems can also be used to search for HBsAg-positive pregnant persons, their infants, and contact information for family members and their various providers.

LHJ PHBPP Coordinators will need to contact their program administrator to obtain access to WDRS and WA IIS. Coordinators should reach out to the DOH Coordinator to determine WDRS system access needs.

#### Identification of HBsAg-positive pregnant people

- Maintain a list of prenatal care providers serving the highest number of HBsAg-positive pregnant persons and a list of birthing facilities.
- Remind providers about the need to notify LHJ Perinatal Hepatitis B Coordinators of all HBsAg-positive pregnant persons
- Investigate cases not reported to PHBPP and document findings for future reference. (Share these discoveries with WA DOH as appropriate.)

#### Protocol for Perinatal Hepatitis B Infection Case Management

Follow this protocol to manage cases of hepatitis B infected pregnant persons and their babies. Most tasks involve recall and reminders to hospitals, health care providers, and those infected. We encourage you to focus on relationship-building, strong communication skills, and organizing an efficient tracking system for follow-up calls and mailings.

If you don't get information on the pregnant person until after delivery, skip to number 4 (Reminder).

<ol> <li>1) RECALL - one week after case is identified- HBsAg+ pregnant person</li> <li>Contact Prenatal Provider to determine 1) whether case is aware of their HBsAg+ status and to gather general information such as contact info, delivery plan, and insurance status.</li> <li>Request lab results</li> <li>Educate provider</li> <li>Enter case information in WDRS</li> </ol>
<ul> <li>2) RECALL - 2 weeks after confirmation that case knows their status</li> <li>Follow up with case to counsel regarding the PHBPP process, potential testing of contacts, HBIG and infant hepatitis B vaccination series, HBV management during and after pregnancy.</li> <li>Provide educational resources</li> <li>Gather information: Encourage case to select pediatric provider. Once identified, collect contact information</li> <li>Confirm and coordinate with hospital</li> <li>Remind case of need for continued follow up</li> </ul>
<ul> <li>3) REMINDER - 4 weeks prior to estimated delivery date</li> <li>Connect Infection control staff with delivery providers regarding PHBPP protocols and reporting requirements.</li> <li>Connect with pediatric provider to confirm awareness of infant status</li> </ul>
<ul> <li>4) REMINDER - 2 weeks after birth</li> <li>Contact delivery provider to verify delivery date, and HBIG plus HepB vaccination administration.</li> <li>Update WDRS</li> <li>Send reminder to parent/guardian and pediatrician for vaccine #2</li> </ul>
5) RECALL - one week after appointment for second dose Follow up with parent/guardian and pediatric provider re: 2nd dose. • Update WDRS and verify 3rd dose is scheduled
6) REMINDER - 2 weeks before 3rd dose is due Send reminder to parent/guardian and pediatrician for vaccine #2.
<ul> <li>7) RECALL - 1 week after appointment for 3rd dose</li> <li>Follow up with pediatric provider re: 3rd dose and verify that PVST is scheduled.</li> <li>Confirm the date for the test, remind parent of timing interval of test. Update WDRS</li> </ul>
8) REMINDER- 2 weeks before PVST is due Send reminder to parent/guardian and pediatrician for PVST.
<ul> <li>9) RECALL - A week after post-vaccination test appointment</li> <li>Follow up with pediatric provider re: PVST and verify that it was completed.</li> <li>Collect results and document in WDRS. Coordinate if not completed</li> <li>Encourage case to continue their hepatitis B management with a provider</li> </ul>

#### Reporting HBsAg-Positive Babies

Investigate and follow up on all PVST results indicating an infant has not responded to the hepatitis B vaccination series. The pediatric provider may need guidance regarding this process as it may involve revaccination and conducting another round of post vaccination serology testing. If the infant is found to be HBsAg positive, follow the WA DOH case reporting guidelines outlined in this document.

If an infant's PVST shows that they did not respond to the first hepatitis series – HBsAg-positive or anti-HBs <10 mIU/mL – the CDC recommends they receive a single dose of hepatitis B vaccine immediately and have PVST repeated one to two months later.

Alternatively, HBsAg-negative infants with anti-HBs <10 mIU/mL may instead be revaccinated with a second, complete 3-dose series, followed by postvaccination serologic testing performed 1–2 months after the final dose of vaccine, based on clinical circumstances or family preference.

Source: 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 Recom Rep 2018; 67 (No. RR-1):1–31.

Check the effectiveness of the hepatitis B vaccination by making sure these babies get a blood test after their vaccination series is complete. Complete the testing at 9–12 months of age, generally at the infant's next routine well-child visit.

Correct reporting means you must:

- 1. Report the outcome of the pregnancy to the Department of Health Perinatal Hepatitis B Prevention Program by updating the record in the WDRS.
- 2. Relay information about HBsAg-positive babies to the LHJ communicable disease surveillance team. The surveillance team, in turn, reports it to DOH's Office of Communicable Disease Epidemiology.

Make sure you do proper follow-up and reporting, because:

- Not all babies become fully immune after vaccination. About 5% of vaccinated babies will not develop full immunity after the initial 3-dose series of hepatitis B vaccine. These babies need either re-vaccination or medical management. Of infants requiring a second series, 99% are found to be immune at series completion. (<u>Hepatitis B vaccine response among infants born to</u> <u>hepatitis B surface antigen-positive women</u>)
- Vaccinated babies may still get infected. Up to 6% of babies born to HBsAg-positive women may still get infected even after getting proper post-exposure prevention. These babies need either re-vaccination or medical management (<u>Prophylaxis for Infants of Mothers with Hepatitis B</u>)

Hepatitis B vaccine is 85% to 95% effective in preventing chronic HBV infection in infants who receive HBIG and a 3-dose series of hepatitis B vaccination.

 More than 90% of infants develop a protective antibody response following a complete hepatitis B vaccine series. (<u>Pinkbook: Hepatitis B | CDC</u>)

## **Closing Cases**

For most perinatal hepatitis B parent-infant pairs, LHJs will consider the PHBPP enrollment closed when the infant has completed the hepatitis B vaccination series and the PVST indicates immunity. To indicate a case as closed, update the infant's status in WDRS from 'Active Follow Up' to 'Inactive due to immune'.

There are times when cases are lost to follow up for various reasons such as when the pregnant person and/or the infant moves out of the district, refuses treatment, or is unable to be reached. In these cases, PHBPP coordinators will need to close the case by changing the infant's status in WDRS from 'Active Follow Up' to the appropriate status from the available options.

Follow this protocol when you have completed your tasks or when a situation makes further communication impossible or not applicable:

- The case or the infant has moved:
  - Notify the DOH PHBPP Coordinator of any move out of the state or country.
  - Try to get the new address and the name of providers at their new location and update WDRS.
  - Note in WDRS that you made a referral to the agency and provide any details that will help the new jurisdiction provide continued follow-up.
  - Change the status to 'Inactive due to move to another jurisdiction'.
- The pregnant person has a false positive HBsAg result:
  - Contact the prenatal provider to consult regarding testing protocol to verify HBV status.
  - Once the test is complete, request lab results and document in WDRS. If the confirmation test verifies the case is HBV negative, change the status to 'Inactive due to false positive' in WDRS
- The case or the infant can't be located:
  - 0 Document all efforts to locate them in WDRS. If you are not able to locate them after numerous attempts, change their status to "Inactive due to lost to follow-up and indicate the reason:
    - Cannot locate .
    - Parent refusal
    - Post-vaccination testing not complete
    - . Other
- The infant does not respond to hepatitis B vaccination and subsequent re-vaccination: 0
  - Change status to 'Inactive due to carrier'.
- In the event of an infant death, change their status to 'Inactive due to death'.

#### **Case Transfers**

#### In-State Transfers

When clients move from one reporting jurisdiction to another, the coordinator should:

- Gather all relevant information for continued case management (new address and contact information, medical notes, and labs) and forward it to the new jurisdiction.
- Wait for acknowledgement from the receiving jurisdiction before noting in WDRS that the case was transferred and to which jurisdiction.

#### *Out of State Transfers*

When clients move from one state to another, the coordinator should:

- Gather all relevant information for continued case management (new address and contact information, medical notes, and labs) and <u>forward it to the state PHBPP coordinator.</u>
- Wait for acknowledgement from the state coordinator before noting in WDRS that the case was transferred and to which state.

The state coordinator will forward the case information to the appropriate state coordinator when the transfer is complete.

#### Out of Country Transfers

When clients move out of the country, note it in WDRS and provide their new location, if known. (This information is reported to the CDC in the PHBPP Annual Report.) If possible, gather documentation to enable continued monitoring in their new location.

#### Locating Cases

Finding cases (pregnant persons living with chronic hepatitis B) is vital due to the infectious nature of hepatitis B. Before closing out an infant's enrollment, check with other communicable disease investigators and case managers. Case managers and staff may have additional methods or contacts that can assist in locating clients. All attempts to locate clients should be documented in WDRS. After all attempts to locate the client are exhausted, close the case. Based on local health's capacity, a policy addressing minimum criteria for investigation before closing a case as lost to follow-up is suggested. WDRS enables users to select from numerous options of reasons for closing cases lost to follow-up. (See <u>Closing Cases</u>.) Select the option that most closely represents the situation in your jurisdiction.

#### Client Locating Checklist

Tried?	Resource	Remarks/Comments/Date
	Contact last Health Care Provider (secure phone	
	number or ask for emergency contact number)	
	Search Washington State Immunization	
	Information System for contact information	
	Search Washington State Disease Reporting	Primary source for contact
	System for contact information	information
	Contact TB/STD/CD programs	
	Contact Provider One, Medicaid and WIC	
	programs	
	Phone book/directory (People search, reverse	
	phone/address search)	
	Hospitals	
	Prenatal/family planning clinic	
	Voter registration or Google voter lookup	
	Department of Motor Vehicles	
	US Post Office information request	
	https://faq.usps.com/s/article/Address-	
	information-requests-forms	
	Utility company (electric, water, gas, etc.)	
	PUBLICDATA.COM- a subscription service with an	
	online searchable database for public records	
	from local, state, and federal agencies.	
	Accurint – online searchable database.	
	Subscription required.	
	Internet search engine (Include person, phone	
	number or address. Try spousal search.)	

## The Role of Prenatal Care Providers

## Prenatal Care Providers Tasks Overview

The following seven strategies can help guide you, as a prenatal care provider, to prevent perinatal hepatitis B transmission:

1. Develop and follow a written policy to screen **every** pregnant person for HBsAg **early** in each pregnancy. Both the Centers for Disease Control and Prevention and the American College of Obstetricians and Gynecologists recommend this policy.

If the pregnant person tests HBsAg negative but remains or becomes high-risk for hepatitis B infection, or if they have clinical hepatitis, do the HBsAg testing on admission to hospital or birthing facility. High-risk behaviors or markers include injection drug use, multiple sexual partners, and having other sexually transmitted infections. If it is not possible to determine the person's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), infants should receive HBIG and hepatitis B vaccine within 12 hours of birth. They should then receive routine vaccination and follow up testing according to the recommended schedule.

- Screen all pregnant persons with a hepatitis B surface antigen test. If the HBsAg is positive, an HBV DNA test should be performed to guide use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. The American Association for the Study of Liver Diseases (AASLD) suggests antiviral therapy when maternal HBV DNA is >200,000 IU/mL.
- 3. Offer hepatitis B vaccine at any time during the pregnancy to HBsAg-negative pregnant persons who are at high risk of infection. It is safe to get vaccinated during pregnancy, however, consult with the patient's provider before giving any vaccine to a pregnant person. If you give hepatitis B vaccine during pregnancy, do HBsAg and anti-HBs serologic testing 1-2 months later to avoid transient HBsAg positivity.
- 4. Report every HBsAg-positive pregnant person to your local health jurisdiction (LHJ) within three working days. State law requires that you report every case of perinatal hepatitis B (see WAC 246-101-101). Your LHJ provides case management and follow-up services for infants, household contacts, and sexual partners. Refer to DOH's list of Local Health Jurisdiction contact information. (To be added later)
- 5. Tell each HBsAg-positive pregnant person about:
  - How hepatitis B spreads.
  - How to prevent hepatitis B.
  - The need to get medical follow-up with a liver specialist.
  - Their infant's need to get protection. The baby needs HBIG and hepatitis B vaccine within 12 hours of birth; two additional doses of hepatitis B vaccine at 1-2 and 6 months of age; and post-vaccine screening at 9-12 months of age.
  - The need for their household contacts and sexual partners to get pre-vaccination screening. If the household contacts and sexual partners are HBsAg-negative and anti-HBs negative, they need to get three doses of hepatitis B vaccine at intervals of 0, 1-2, and 4-6 months.
  - How and when their LHJ will contact them to follow up with necessary services for their family.
  - Referrals for infected household contacts and sexual partners.
- 6. As soon as HBsAg-positive lab results are available, send all lab results to the hospital before the pregnant person gets admitted for delivery to make sure their baby gets proper post-exposure prevention.
- 7. Provide educational materials about hepatitis B.

#### Prenatal Case Management



## Laboratory Screening

This section identifies which screening test(s) to order for pregnant persons and household contacts.

#### Pregnant Persons

- Screen for HBsAg early in pregnancy, regardless of vaccination status or history of testing.
  - Pregnant persons with a history of appropriately timed triple panel screening and without subsequent risk for exposure to HBV (i.e., no new HBV exposures since triple panel screening) only need HBsAg screening (CDC 2023 Screening and Testing for Hepatitis B Virus Infection)
- If HBsAg Positive, test for HBV DNA
- If HBsAg is inconclusive or patient is at high risk for HBV infection, repeat HBsAg in third trimester

A positive HBsAg screening test identifies HBV-infected pregnant people. HBV DNA testing should be done for all HBsAg-positive pregnant people to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. Babies born to HBsAg-positive persons are at high risk of infection unless they receive the proper post-exposure prevention. Published evidence indicates that maternal antiviral therapy during pregnancy further reduces perinatal HBV transmission; hence, AASLD suggests antiviral therapy when maternal HBV DNA is >200,000 IU/mL.

If HBsAg lab results during the current pregnancy are not available but other evidence is suggestive of HBV infection (e.g., presence of HBV DNA, HBeAg-positive, or the pregnant person is known to be chronically infected with HBV) manage the infant as if born to an HBsAg-positive person. In certain cases, HBsAg tests may be reported inconclusively as "indeterminate," "borderline," or "weakly positive." Check with the lab to make sure a repeat HBsAg confirmatory assay was done. If the repeat HBsAg assay is still not conclusive, repeat the HBsAg test in the last trimester of pregnancy. If the pregnant person's HBsAg status is still unknown at the time of delivery, assume they are HBsAg-positive and treat the infant accordingly. See guidance for Discrepant Results here: (Link to document)

If it is not possible to determine the pregnant person's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), HBIG and hepatitis B vaccine should be given within 12 hours of birth, and at 1-2 months of age, and 6 months of age.

#### Household Contacts and Sexual Partners

Household contacts and sexual partners of HBsAg-positive pregnant persons are at high risk of becoming infected. Both should get pre-vaccination testing if possible and those who are *susceptible* should be immunized. *Sexual contacts of HBsAg-positive persons should also get post-vaccination testing*. Health care providers make the decision about which test(s) to order. The following information may help in the decision-making process.

- 1. Testing for HBsAg identifies acute or chronic (carrier) HBV infections.
- 2. Testing for anti-HBs, a marker of immunity, indicates immunity to HBV infection or an immune response to vaccination.
- 3. Testing for anti-HBc identifies acute, chronic, or unresolved HBV infection. It is not a marker for immunity from vaccination.

#### Sources:

- MMWR, Centers for Disease Control, January 12, 2018.
- Interpretation of Hepatitis B Serologic Test Results | CDC
- Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book), 13<sup>th</sup> edition. <u>Hepatitis B chapter.</u>

## The Role of Hospitals

#### Hospital Tasks Overview

The following four strategies guide hospitals to prevent perinatal hepatitis B transmission. Also see the Immunization Action Coalition's hepatitis B hospital guide.

#### 1) Screening procedures

Develop and follow a written policy and procedure to screen **every** pregnant person admitted for delivery for HBsAg who has an unknown hepatitis B status or is at risk for HBV infection during pregnancy. (This includes those with no prenatal care or who have not already been tested.) Risk behaviors for HBV include:

- More than one sexual partner in the previous 6 months.
- Evaluation or treatment for sexually transmitted diseases.
- Recent or current injection drug use.
- HBsAg-positive sexual partner(s).
- Clinical hepatitis since previous testing.

Include in your written policy the following procedures for each stage of the hospital stay for individuals delivering babies: admission, after delivery, standing orders, and infant discharge.

#### Admission for Delivery:

- Review hepatitis B surface antigen (HBsAg) status of all pregnant persons.
- Review HBV DNA testing for all pregnant persons who are HBsAg-positive.
- Record pregnant person's HBsAg & HBV DNA test results on both the labor delivery record and on the infant's delivery summary sheet.
- Do HBsAg testing as soon as possible on pregnant persons who do not have an HBsAg test result available, who have risk for HBV infection during pregnancy, or who had clinical hepatitis since previous testing.

#### After Delivery:

• Identify and manage all infants born to HBsAg-positive pregnant persons and to those with unknown HBsAg status.

- Give HBIG and hepatitis B vaccine dose 1 to infants of all HBsAg-positive pregnant persons within 12 hours of birth. For information see <u>Vaccine Specifics</u>.
- If the pregnant person's HBsAg test results are unavailable but evidence suggests HBV infection, or the infant weighs <2,000 g, the infant should be managed as if born to an HBsAg-positive pregnant person and receive HBIG and hepatitis B vaccine within 12 hours.
- If the pregnant person's HBsAg test results are unavailable but pending, and if there is no evidence of HBV infection, and the infant is >2,000g, the infant should be given hepatitis B vaccine only (no HBIG). If the pregnant person is then found to be HBsAg positive, the infant should receive HBIG as soon as possible, but no later than 7 days of life.
- If it is not possible to determine HBsAg status, give HBIG and hepatitis B vaccine within 12 hours.
- Document the pregnant person's HBsAg-positive status and the infant's HBIG and hepatitis B vaccine doses at the hospital and give this information to the outpatient pediatric care provider.

#### Standing Orders

- Review HBsAg and HBV DNA test results for every pregnant person admitted for delivery. Make sure all have been tested for HBsAg prenatally or at time of admission. Document the test results.
- For pregnant persons with no HBsAg test results, test them as soon as possible after admission for delivery.

Premature babies born to HBsAg-positive pregnant persons or those with unknown status must get HBIG AND hepatitis B vaccine within 12 hours after birth. If these babies weigh less than 2,000 grams at birth, do not count the first dose of hepatitis B vaccine as one of the doses in the series. The baby should get 3 additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age. This will be a total of 4 doses. (For more information on this go to <u>MMWR, 2018</u> see 'Management of Infants Born to Women Who Are HBsAg-Positive').

• For all infants, add the pregnant person's HBsAg test results, the infant's birth weight, and the date and time the infant got HBIG and hepatitis B vaccine to the infant's medical record.

## Time of Infant Discharge:

• Give the infant's immunization record to the parent and remind them to take it to the baby's first pediatrician visit.

## 2) VFC (Vaccines for Children Program)

• For all delivery hospitals: Enroll in the federal VFC program to offer hepatitis B vaccine at no cost for all babies. For information about enrollment go to <u>Provider Enrollment for the Childhood</u> <u>Vaccine Program | Washington State Department of Health</u>.

#### 3) Notification

• Notify your local health jurisdiction (LHJ) of the birth of an infant to an HBsAg-positive pregnant person so follow-up can begin for the infant **and** for the parent's household contacts and sexual

partners. <u>State law requires you to report</u> every HBsAg-positive pregnant person. Your LHJ provides case management and follow-up services for these infants and contacts.

## 4) Information for the patient

Counsel and provide information to **every** HBsAg-positive person who is pregnant or has just delivered:

- How hepatitis B spreads.
- How to prevent hepatitis B.
- The need to get medical follow-up with a liver specialist throughout and post pregnancy.
- The baby needs HBIG and hepatitis B vaccine within 12 hours of birth, two additional doses of hepatitis B vaccine at 1-2 and 6 months of age, and post-vaccine screening at 9-12 months of age.
- The need for the pregnant person's household contacts and sexual partners to get prevaccination screening. If any of these people are not immune, they need to get three doses of hepatitis B vaccination at intervals of 0, 1-2, and 4-6 months.
- How the LHJ will contact them to follow-up with necessary services for their family.

#### Hospital Case Management



## Role of Pediatric Care Providers

#### Pediatric Care Providers Tasks Overview

The following five tasks help guide pediatric care providers to prevent perinatal hepatitis B transmission. Babies born to HBsAg-positive pregnant persons are at high risk of getting hepatitis B virus (HBV) infection themselves, becoming lifelong (chronic) carriers, and developing serious conditions later in life unless they get proper prevention.

#### Follow Recommendations

Follow the national Advisory Committee on Immunization Practices (ACIP) recommendations for infants born to HBsAg-positive pregnant persons. Use the <u>Provider Checklist</u> to record all vaccination and testing dates and results. Give your infant patients:

- HBIG and hepatitis B vaccine within 12 hours of birth. (If infant's birth weight is less than 2,000 grams, see note\*.)
- Hepatitis B vaccine dose 2 at 1-2 months of age.
- Hepatitis B vaccine dose 3 at 6 months of age.
- Post-vaccination testing including both HBsAg and anti-HBs at 9 to 12 months of age.

Note\*: For infants weighing <2,000 grams, the birth dose (i.e., the initial hepatitis B vaccine dose) should not be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants. Three (3) additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches 1 month of age.

#### Manage Cases

Work with your <u>local health jurisdiction (LHJ) Hepatitis B Coordinator</u> to manage all infants born to HBsAg-positive pregnant persons.

Your LHJ is likely already working with the HBsAg-positive pregnant persons in their region, so expect contact from them to follow up on the baby's hepatitis B vaccination and post-vaccination testing. LHJ staff will also follow up with the pregnant person's household contacts and sexual partners to get proper testing and/or treatment. Notify the LHJ of an infant's hepatitis B exposure status upon registration if you haven't already been contacted. This will ensure that the baby's family gets needed follow up. Share the information on your <u>Provider Checklist</u> with your LHJ.

#### Third Dose

Aim for all infants born to HBsAg-positive parents to get their 3<sup>rd</sup> dose of hepatitis B vaccine at 6 months of age. It is best to follow this 6-month schedule, provided the prior vaccines were given at the recommended intervals (birth and 1-2 months of age), to ensure the infant completes the series on schedule. This will also allow enough time to complete the PVST within the proper timeframe. Use the <u>Provider Checklist</u> to record all vaccine and testing dates and results. Notify your LHJ of the date baby got dose 3.

#### Post-Vaccination Testing

Complete post-vaccination testing for all infants born to HBsAg-positive pregnant persons at 9 to 12 months of age. Educate the baby's parents about the importance of this testing and be sure to tell them

the test will show if the infant has developed antibodies to or has become infected with HBV. Write an order for the test and send the infant to someone with experience in pediatric blood draws to reduce the infant's stress. Use the Provider Checklist to record all vaccination and testing dates and results. Send the date and laboratory results of the baby's post-vaccination screening to your LHJ's Hepatitis B Coordinator.

- HBsAg-positive indicates infection and need for appropriate referral and follow-up.
- HBsAg-negative with anti-HBs levels ≥10mIU/mL indicates immunity
- HBsAg-negative with anti-HBs levels < 10mIU/mL indicates non-immunity and additional vaccination needed See 'Repeat Vaccination'.

#### Repeat Vaccinations

- If the infant is not immune, a single dose of hepatitis B vaccine can be given with repeat serologic testing drawn 1-2 months later.
  - If anti-HBs remains <10mIU/mL after this dose, the patient should receive two additional doses of hepatitis B vaccines (one at 1-2 mo after repeat vaccine, and the other at 6 months after). Repeat testing should be performed 1-2 months after the final dose.</li>
- A full 3-dose series can be repeated if infants have anti-HBs <10mIU/mL after their first 3-dose series, depending on clinical circumstance and family preference. Repeat testing should be done 1-2 months after the final dose.
- No benefit has been shown for giving repeat doses of hepatitis B vaccine if the patient has not reached anti-HBs ≥10mIU/mL after the administration of two full vaccine series.

#### Pediatric Case Management



## Administering Hepatitis B Vaccine and HBIG

#### Administering Hepatitis B Vaccine

#### Route and Site

Give hepatitis B vaccine intramuscularly into the anterolateral thigh muscle of newborns and babies. **Do not** give hepatitis B vaccine intradermally or into the buttock.

You can give hepatitis B vaccine at the same time as other vaccines.

#### Dose and Schedule

Use single antigen hepatitis B vaccine for the birth dose, but a combination vaccine containing hepatitis B vaccine can be used for dose 2 and dose 3.

#### Administering HBIG

#### **Route and Site**

For newborns: Give HBIG intramuscularly into the anterolateral thigh muscle.

#### **Dose and Schedule**

Newborns should get 0.5 ml of HBIG and the first dose of hepatitis B vaccine within 12 hours of birth. Each should be given at a separate injection site.



HBIG can be given up to 7 days after delivery for infants born to HBsAg positive pregnant persons who did not receive it within 12 hours of delivery. The infant should receive an urgent referral to receive HBIG as soon as possible on discovery that pregnant person is HBsAg positive. If more than 7 days have passed since delivery, it is unlikely to be effective in preventing transmission. It is still important for the infant to complete the hepatitis B vaccine series, and providers should adhere to the minimum intervals between doses. Management of Infants Born to Women with Hepatitis B Virus Infection for Pediatricians (cdc.gov))

#### Vaccination of Premature Babies and Babies <2,000 grams

Follow these guidelines, based on the HBV status of the pregnant person, to vaccinate and administer HBIG to premature infants:

#### HBsAg positive pregnant person

- Give HBIG AND hepatitis B vaccine less than 12 hours after birth.
- For infants <2,000 grams, do not count the first dose of hepatitis B vaccine as dose #1 of the 3-dose series. The infant should receive 3 additional doses of hepatitis B vaccine, starting when medically stable and at least 1 month of age (MMWR, 2018). This will result in 4 total doses.

#### HBsAg negative pregnant person

- Infants <2,000 grams should have their first HBsAg delayed until the chronological age of one month . The remaining vaccines in the series can be given following the same schedule with the full recommended dose of each vaccine.
- Premature infants >2,000g can receive vaccinations at the same chronological age and schedule as term infants.

#### HBsAg unknown in pregnant person

- If there is other evidence suggestive of a hepatitis B infection in the pregnant person, treat as if they are HBsAg positive.
- Infants >2,000g infants should receive hepatitis B vaccine only, while awaiting maternal HBsAg test result. The infant should receive HBIG as soon as possible if the HBsAg returns positive, but no later than 7 days of life.
- Infants <2,000g should receive hepatitis B vaccine and HBIG within 12 hours after delivery.
- If it is not possible to determine HBsAg status in the pregnant person, vaccines should proceed according to the schedule recommended for infants born to pregnant persons with positive HBsAg.

The table below shows hepatitis B vaccine doses, with recommended ages, intervals, and minimum ages for getting the vaccines.

Vaccine and dose number	Recommended age for this dose	Minimum age for this dose	Minimum interval to next dose
HepB-dose 1**	Birth	Birth	4 weeks
HepB-dose 2	1-2 months	4 weeks	8 weeks
HepB-dose 3***	6- months	24 weeks	—

\* Source: Epidemiology and Prevention of Vaccine-Preventable Diseases, CDC

\*\* Combination vaccines with a hepatitis B component are available (Pediarix and Vaxelis). These vaccines **should not be administered to infants younger than 6 weeks** because other components in the vaccines are not suitable for this age group (i.e., Hib, DTaP, HepA, and IPV).

\*\*\* HepB-dose 3 should be administered at least 8 weeks after dose 2 and at least 16 weeks after dose 1.

#### Laboratory Screening: Interpreting Test Results

Use this table\* for help interpreting hepatitis B test results, also called the hepatitis B panel:

Tests	Results	Interpretation	Vaccinate?
HBsAg	negative	Susceptible	Vaccinate if
anti-HBc	negative		indicated
anti-HBs	negative		
HBsAg	negative	Immune due to vaccination (or	No vaccination
anti-HBc	negative	may represent passive transfer of	necessary
anti-HBs	positive with <a>10mIU/mL**</a>	antibodies from receipt of HBIG)	
HBsAg	negative	Immune due to natural infection	No vaccination
anti-HBc	positive		necessary
lgM anti-HBc	negative		
anti-HBs	positive		
HBsAg	negative	Acute resolving infection	No vaccination
anti-HBc	positive		necessary
IgM anti-HBc	positive		
anti-HBs	positive		
HBsAg	positive	Acutely Infected	No vaccination
anti-HBc	positive		necessary
lgM anti-HBc	positive		
anti-HBs	negative		
HBsAg	positive	Chronically infected	No vaccination
anti-HBc	positive		necessary (may
IgM anti-HBc	negative		need treatment)
anti-HBs	negative		
HBsAg	negative	Four interpretations possible †	Use clinical
anti-HBc	positive		judgment
anti-HBs	negative		

\* Postvaccination testing, when it is recommended, should be performed 1-2 months after the last dose of vaccine. Infants born to HBsAg-positive mothers should be tested for HBsAg and anti-HBs after completion of at least 3 doses of a licensed hepatitis B vaccination series, at age 9-12 months.

† Interpretation options:

- 1. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum
- 2. May be susceptible with a false positive anti-HBc
- 3. May be chronically infected and have an undetectable level of HBsAg present in the serum
- 4. Passive transfer of antibody following HBIG administration or from an HBsAg-positive pregnant person to their newborn

\* Source: <u>Ask The Experts: Hepatitis B | Immunize.org</u>

## Recommended Doses of Currently Licensed Monovalent Hepatitis B Vaccines

Group	Merck Recombivax HB Dosage	GSK* Engerix-B Dosage
Infants <sup>4</sup> , Children and	5 mcg (0.5 mL)⁵	10 mcg (0.5 mL) <sup>6</sup>
Addrescents	(Pediatric/Adolescent	(Pediatric/Adolescent formulation)
Merck: 0-19 years	formulation)	
GSK: 0-10 years	2 desse at 0, 1, and C months	3 doses at 0,1, and 6 months
	3 doses at 0, 1, and 6 months	
Adolescents	10mcg (1.0 mL)	10mcg (0.5 mL) or 20mcg (1.0 mL)
Merck: 11–15 years	(Adult Formulation)	depending on exposure risk. (See package insert.)
	2 doses at 0 and 4-6 months	(Adult Formulation)
	Adolescents (11 - 15 years of age)	3 doses at 0,1, and 6 months
	may receive either regimen:	
	3 x 5 mcg (Pediatric formulation)	
	or 2 x 10 mcg (Adult formulation)	
Adults (20 years &	10 mcg (1.0 mL)	20 mcg (1.0 mL)
older)	(Adult Formulation)	(Adult Formulation)
	3 doses at 0, 1, and 6 months	4 doses at 0, 1, 6 months
Pre-dialysis and dialysis	40 mcg (1.0 mL)	40 mcg (2.0 mL)
patients	(Dialysis Formulation)	(Adult Formulation)
	3 doses at 0, 1, and 6 months	0, 1, 2, 6 months

Recombivax HB and Engerix-B have three doses in their series to be given at 0, 1–2, and 6–18 mos.

\*GlaxoSmithKline Biologicals

Sources: MMWR, Centers for Disease Control, January 12th, 2018

Recombivax HB package insert, April 2022

Engerix B package insert, June 2021

<sup>&</sup>lt;sup>4</sup> Infants born to HBsAg-positive persons should also receive hepatitis B immune globulin (HBIG) 0.5 mL intramuscularly at a site different from that used for the hepatitis B vaccine.

<sup>&</sup>lt;sup>5</sup> Change in dose, licensed in 1998. Infants born to HBsAg-negative persons now receive the same dose as infants born to HBsAg-positive persons. "If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL."

<sup>&</sup>lt;sup>6</sup> Change in adolescent dose, licensed in 1995.

#### Storing and Handling Hepatitis B Vaccine and HBIG

#### Best Practices for Storing and Handling All Vaccines

**Always read the package insert.** Read the table below for storage and handling supplemental information, but this does **not** take the place of the package insert

- Have policies and procedures in place to rotate stock and check expiration date of vaccine weekly. Use vaccine with earliest expiration date so none become outdated.
- Do not use expired vaccine.
- Never store vaccine in refrigerator door.
- When transporting vaccine, always use an insulated container with ice packs.
- Vaccine storage and handling information from the Department of Health
- Vaccines Storage and Handling Toolkit | CDC
- Vaccine storage and handling recommendations and guidelines from the CDC

**Always read the <u>package insert</u>.** Read the table below for storage and handling supplemental information, but this does **not** take the place of the package insert.

Shipping Requirements:	Use an insulated container. Must ship with refrigerant.
Condition on Arrival:	Should not have been frozen. Refrigerate on arrival.
Storage Requirements:	Refrigerate immediately upon arrival. Store at 2°-8°C (35°- 46°F). <b>Do not freeze</b> .
Shelf Life/Expiration:	Hepatitis B vaccine - up to 3 years. Check date on container or vial. HBIG - up to 12 months. Check date on container or vial.
Instructions for Reconstitution or Use:	Inspect visually for particulate matter or discoloration. Shake vial or fill syringe well before use.
Shelf Life after Reconstituting or Opening:	Check expiration date on vial, or manufacturer-filled syringe. Give the vaccine shortly after withdrawal. If pre- filled syringe, administer after the needle is attached to the syringe.
Special Instructions:	Rotate stock so that you use the material with the earliest expiration date first.

## Laboratory Reporting and Screening

#### Laboratory Reporting

According to the <u>WAC 246-101-201</u>, labs are required to report acute hepatitis B infection within 24 hours to the LHJ. HBsAg, HBeAg, HBV Nucleic acid detection (NAT or NAAT), and IgM anti-HBc positive results are required to be reported monthly. Pregnancy is also reported, if associated with a positive result for any of these tests.

#### Laboratory Screening Guidelines

#### Guidelines

This section identifies which screening test(s) to order for pregnant persons and babies.

#### HBsAg: Pregnant People

A positive HBsAg screening test identifies HBV-infected pregnant people. HBV DNA testing should be done for all HBsAg-positive pregnant people to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. Babies born to HBsAg-positive persons are at high risk of infection unless they receive the proper post-exposure prevention. The American Association for the Study of Liver Diseases (AASLD) suggests antiviral therapy to reduce the risk of perinatal transmission of hepatitis B in HBsAg positive pregnant individuals with an HBV DNA greater than 200,000 IU/mL.

When HBsAg lab results during pregnancy are not available but other evidence is suggestive of maternal HBV infection (e.g., presence of HBV DNA, HBeAg-positive, or pregnant person known to be chronically infected with HBV) should have the infant managed as if born to an HBsAg-positive person. In certain cases, HBsAg tests may be reported inconclusively as "indeterminate," "borderline," or "weakly positive." Check with the lab to make sure a repeat HBsAg confirmatory assay was done. If the repeat HBsAg assay is still not conclusive, repeat the HBsAg test in the last trimester of pregnancy. If their HBsAg status is still unknown at the time of delivery, assume they are HBsAg-positive and treat their infant accordingly.

If it is not possible to determine the pregnant person's HBsAg status (e.g., when a parent or person with lawful custody safely surrenders an infant confidentially shortly after birth), the vaccine series should be completed according to the recommended schedule for infants born to HBsAg-positive persons.

#### HBsAg and Anti-HBs: Babies 9-12 months old, or 1-2 months after the final dose

For babies born to HBsAg-positive/unknown persons, blood (or serologic) testing after proper postexposure prevention shows whether the baby is infected with or fully protected against HBV. If the baby is on schedule with hepatitis B vaccine, testing should happen at 9-12 months of age or 1-2 months after the final vaccine dose if the series is delayed. **Testing should not be performed before age 9 months** to avoid detection of anti-HBS from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection (MMWR, 2018). Testing for HBsAg identifies infected babies who need medical follow-up. Testing for anti-HBs identifies HBsAg-negative babies who still need to repeat the series of hepatitis B vaccine for full protection.

#### Interpret results this way:

- 1. HBsAg (-) and anti-HBs (+) = infant is immune or fully protected against HBV.
- 2. HBsAg (+) and anti-HBs (-) = infant is infected and needs medical follow-up.
- 3. HBsAg (-) and anti-HBs (-) = infant is still susceptible and needs three additional doses of hepatitis B vaccine followed by re-testing.

#### HBsAg and Anti-HBs OR Anti-HBc only: Household Contacts and Sexual Partners

Household contacts and sexual partners of HBsAg-positive pregnant people are at high risk of becoming infected. Both should get pre-vaccination testing if possible and those who are susceptible should be immunized. **Sexual contacts of HBsAg-positive persons should also get post-vaccination testing**. Health care providers make the decision about which test(s) to order. The following information may help in the decision-making process.

- 1. Testing for HBsAg identifies acute and chronic (carrier) HBV infections.
- 2. Testing for anti-HBs, a marker of immunity, indicates immunity to HBV infection or an immune response to vaccination.
- *3.* Testing for anti-HBc identifies acute, chronic, or unresolved HBV infection. It is not a marker for immunity from vaccination.

Sources: MMWR, Centers for Disease Control, January 12, 2018. Hepatitis B Foundation: Hepatitis B Blood Tests (hepb.org) Pinkbook: Hepatitis B | CDC

## Laboratory Screening: Serologic Markers

Use the table below\* to find explanations of hepatitis B markers (antibodies) in blood serum.

## Tests and Interpretation

Hepatitis B Laboratory Nomenclature	
HBsAg	<i>Hepatitis B surface antigen</i> is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.
anti-HBs	Antibody to hepatitis B surface antigen is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. (It is also known as <b>HBsAb</b> , but this abbreviation is best avoided since it is often confused with abbreviations such as HBsAg.)
anti-HBc (total)	Antibody to hepatitis B core antigen is a nonspecific marker of acute, chronic, or resolved HBV infection. It is not a marker of vaccine-induced immunity. It may be used in pre- vaccination testing to determine previous exposure to HBV infection. (It is also known as <b>HBcAb</b> , but this abbreviation is best avoided since it is often confused with other abbreviations.)
lgM anti-HBc	IgM antibody subclass of anti-HBc. Positivity indicates recent infection with HBV ( $\leq$ 6 mos). Its presence indicates acute infection.
HBeAg	Hepatitis B "e" antigen is a marker of a high degree of HBV infectivity, and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.
Anti-HBe	Antibody to hepatitis B "e" antigen may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.
HBV-DNA	<i>HBV Deoxyribonucleic acid</i> is a measure of viral load and reflects viral replication. It correlates well with infectivity. It is used to assess and monitor the treatment of patients with chronic HBV infection.

Source: Ask The Experts: Hepatitis B | Immunize.org