1. DISEASE REPORTING

A. Purpose of Reporting and Surveillance

1. To identify sources of infection and prevent further transmission from such sources.
2. To identify new groups at risk and reduce further cases.
3. To inform cases about treatment options.
4. To educate cases about transmission of hepatitis B and how to reduce the risk of transmission.
5. To identify contacts and recommend appropriate preventive measures.
6. To better understand the epidemiology of hepatitis B virus infection and the burden of morbidity from chronic infection.

B. Legal Reporting Requirements (See Appendix A)

1. Acute Hepatitis B
   a. Health care providers: notifiable to local health jurisdiction within 24 hours
   b. Health care facilities: notifiable to local health jurisdiction within 24 hours
   c. Laboratories: hepatitis B virus (acute) by IgM positivity notifiable within 24 hours. Specimen submission is on request only in outbreak settings.
   d. Local health jurisdictions: notifiable to Washington State Department of Health (DOH) Office of Communicable Disease Epidemiology (CDE) (206-418-5500) within 7 days of case investigation completion or summary information required within 21 days

2. Chronic Hepatitis B (initial diagnosis and previously unreported prevalent cases)
   a. Health care providers: notifiable to local health jurisdiction within one month
   b. Health care facilities: notifiable to local health jurisdiction within one month
   c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (e antigen), or HBV DNA notifiable to local health jurisdiction of patient residence (or ordering health care provider, if patient residence is unknown) on a monthly basis
   d. Local health jurisdictions: notifiable to DOH Office of Infectious Disease within 7 days of case investigation completion, or summary information required within 21 days of initial notification to local health authorities.

3. Hepatitis B Surface Antigen Positive (HBsAg+) Pregnant Women (each pregnancy)
   a. Health care providers: notifiable to local health jurisdiction within 3 business days
   b. Health care facilities: notifiable to local health jurisdiction within 3 business days
   c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (e antigen), or HBV DNA notifiable on a monthly basis.
d. Local health jurisdictions: notifiable to DOH Office of Immunization and Child Profile (OICP) (360-236-3595) Perinatal Hepatitis B Prevention Program within 7 days of case investigation completion, or summary information required within 21 days of initial notification to local health authorities.

4. **Perinatal Hepatitis B**
   
a. Health care providers: notifiable (as acute hepatitis B) to local health jurisdiction within 3 business days of receiving confirming test result.

b. Health care facilities: notifiable (as acute hepatitis B) to local health jurisdiction within 3 business days of receiving confirming test result.

c. Laboratories: all hepatitis B virus by HBsAg (surface antigen), HBeAg (e antigen), or HBV DNA notifiable on a monthly basis.

d. Local health jurisdictions: notifiable to CDE (206-418-5500) and OICP (360-236-3595) within 7 days of case investigation completion, or summary information required within 21 days.

C. **Local Health Jurisdiction Investigation Responsibilities**

Determine if the reported patient has been previously reported as an acute or chronic case of hepatitis B.

1. Acute hepatitis B – first time reported
   
a. Begin follow-up investigation within one working day.

b. Recommend hepatitis B immune globulin (HBIG) and/or vaccine as indicated for susceptible contacts.

c. Attempt to determine the source of infection, particularly medical or dental exposures including diabetes blood testing in residence facilities.

d. Educate the case about hepatitis B and how to reduce the risk of transmission.

e. Educate the case about minimizing disease progression, emphasizing the importance of vaccination for hepatitis A. If applicable, recommend measures such as not sharing injection drug equipment to prevent possible future infection with bloodborne agents.


g. If case meets the case definition for perinatal hepatitis B—i.e. HBsAg(+) in any infant 1-24 months of age born in the United States or U.S. territory to HBsAg(+) mother— also report the case to OICP Perinatal Hepatitis B Prevention Program (360-236-3595) and enter case details in the Perinatal Hepatitis B Module.

2. Chronic hepatitis B

Local health jurisdiction investigation responsibilities relate to all **confirmed** and **probable** cases of chronic hepatitis B, and will vary between two distinct groups of cases in the extent of investigation conducted. Systematic sampling of newly diagnosed cases by DOH will assign cases to: 1) cases sampled for enhanced surveillance investigation, or
2) cases not sampled, for whom more basic data collection and reporting are requested. From its initially limited scope, DOH will progressively expand this systematic sampling in 2014 to gradually broaden local health jurisdiction representation in sampled cases. Local health jurisdictions will be notified as they are included in enhanced surveillance.

a. For newly-diagnosed cases sampled for enhanced surveillance investigation, attempt healthcare provider contact and data collection, followed by patient contact and interview, collecting as much information as possible as specified on the “Hepatitis B, chronic — long form,” available at: (http://www.doh.wa.gov/Portals/1/Documents/Pubs/150-047-HepB-long.pdf). Local health jurisdictions will be notified immediately following a case being sampled for enhanced surveillance investigation, with each sampled case being assigned a unique sampling identification number. Within 7 days of completing enhanced surveillance investigations on sampled cases, enter data into PHIMS using the appropriate electronic form.

b. For newly-diagnosed cases not otherwise sampled for enhanced surveillance investigation, collect as much basic case reporting information as possible, as specified on the “Hepatitis B, chronic — short form,” available at (http://www.doh.wa.gov/Portals/1/Documents/Pubs/150-051-HepB-short.pdf). Using laboratory reporting data, along with healthcare provider contact and data collection as necessary, collect the most complete basic reporting data as possible. Within 7 days of completing investigations on non-sampled cases, enter data into PHIMS using the appropriate electronic form.

c. **Note:** Local health jurisdictions seeking to collect a broader scope of data on cases not otherwise sampled for enhanced surveillance may elect to conduct enhanced surveillance investigation on any of their unsampled cases at any time, using procedures and forms detailed above. However, enhanced surveillance data collected on unsampled cases may not be suitable for use in generating population estimates.

3. Report all HBsAg+ pregnant women to the Office of Immunization and Child Profile (OICP) Perinatal Hepatitis B Prevention Program during each pregnancy, and enter the case in the Perinatal Hepatitis B Module (PHBM) (see Section 7E). Investigate if the report is an initial diagnosis of chronic (or less likely acute) infection (see above). Track the pregnancy, ensure the infant is appropriately treated starting at birth, and test the infant at the appropriate time. See Section 7F for additional information.

4. Report all infants who meet the case definition for perinatal hepatitis B virus infection to the OICP Perinatal Hepatitis B Prevention Program, and to CDE. The positive test result update should be entered into the PHBM, and reported in PHIMS as new case of perinatal hepatitis B. Note that discrete onset of symptoms is **not** required for perinatal acute hepatitis B cases.

5. Local health jurisdiction priorities in conducting chronic hepatitis B case investigations should include follow-up of cases among women of child-bearing age (reported from sources other than an obstetrician), as well as cases for whom age or other risk factor(s) suggests new transmission (see Section 5 for more guidance). Whenever possible, the above and all other persons with chronic hepatitis B should receive messaging regarding ways to protect and promote liver as well as overall health, and to prevent transmission to others. Key messages include avoiding liver toxins (particularly alcohol), the importance
of both hepatitis-related and routine primary care, as well as recommendation for hepatitis C and HIV screening as necessary along with hepatitis A vaccination as indicated. All persons should be provided or otherwise directed to resources promoting patient education, access to care and self-management. Sources include the Hepatitis Education Project (http://hepeducation.org/) and CDC (CDC DVH - Hepatitis B - Patient Education Resources). See Section 6 below for further messaging details.

2. THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Hepatitis B virus (HBV) is a DNA virus in the Hepadnaviridae family. It is one of several viruses known to cause hepatitis in humans. Hepatitis B virus is completely unrelated to the viruses that cause hepatitis A, hepatitis C, hepatitis D, and hepatitis E.

B. Clinical Manifestations

Hepatitis B virus infection may be transient or chronic, and either may be asymptomatic. If acute symptoms occur, onset is usually insidious with loss of appetite, right upper quadrant abdominal discomfort, nausea and vomiting, fatigue, and sometimes arthralgias or rash, with illness often progressing to jaundice. Liver enzyme levels may be markedly elevated. Fever may be absent or mild. Rarely, acute infections result in fulminant liver necrosis and death. Hepatitis B cannot be reliably distinguished clinically from hepatitis A, hepatitis C, or other viral hepatitides. Asymptomatic infections are the rule in infants or young children, and are not uncommon even among adults. For this reason many people have serologic evidence of previous infection but do not recall a consistent illness.

Chronic hepatitis B infection greatly increases the risk of developing life-threatening sequelae (e.g., chronic active hepatitis, cirrhosis, or hepatic cancer) decades later. The likelihood of developing a chronic infection decreases with age at onset. Approximately 5-10% of acutely infected adults become chronically infected, compared with as many as 90% of perinatally infected infants. As a result, perinatal hepatitis B transmission carries a high health burden globally, particularly in countries with high prevalence.

C. Hepatitis B in Washington

In recent years, Department of Health received approximately 35–80 reports of acute hepatitis B and 1100–1200 reports of chronic hepatitis B per year. There is typically one death each year associated with fulminant acute hepatitis B virus infection.

The Office of Immunization’s Perinatal Hepatitis B Prevention Program follows approximately 380 reported hepatitis B surface antigen positive pregnant women per year and receives reports of 0 up to 7 cases of perinatal hepatitis B virus infections per year.

D. Reservoir

Infected humans. While relatively few persons with acute hepatitis B infection develop chronic infections, chronic cases are probably the most important sources of hepatitis B virus transmission because they are infectious for many years, compared to the few weeks that resolved acute hepatitis B are infectious. Efforts to identify persons with chronic infections and to offer prophylaxis to their contacts are thus at least as important as follow-up directed towards acute cases. Infected pregnant women particularly need follow-up so post-exposure prophylaxis to prevent hepatitis B transmission can be given
to the newborns, who are otherwise at high risk of developing chronic infection. About 10\% of perinatal infection will eventually result in cirrhosis or liver cancer.

E. Modes of Transmission

Hepatitis B virus is usually transmitted by contact with the blood, semen or vaginal secretions of an infected (HBV DNA-positive or HBsAg-positive) person. The virus must be introduced through mucous membranes or broken skin for infection to occur. HBV may also be found at low levels in saliva and other body fluids; breast feeding is *not* a significant route of transmission, however. Infection can occur with minor blood contact, such as within a household, and often a specific exposure event cannot be determined.

Well documented modes of transmission include sharing of blood-contaminated objects (e.g., needles, razor blades), sexual contact, perinatal transmission (with high prevalence in Africa; Southeast Asia including China, most of the Middle East, South and Western Pacific islands; interior Amazon River basin; and certain Caribbean areas), and less commonly blood or sexual fluid contacting mucosa or broken skin (e.g., blood splash in the eye), receipt of blood products or organs, or exposure to blood-contaminated medical equipment (e.g., endoscope, shared diabetes testing device) or medication vials; historically nosocomial transmission was of significance and occasional outbreaks still occur. In utero transmission is rare, but perinatal transmission occurs in about a third of deliveries to infected women. Under some conditions, hepatitis B virus can remain viable on environmental surfaces for over a week (e.g., in dried blood) but the contribution to disease transmission is unknown.

F. Incubation Period

Varies from 45 to 180 days—usually between 60 and 90 days.

G. Period of Communicability

A person is communicable during the time that HBsAg or HBV DNA is detectable in the blood. Viremia begins several weeks before the onset of symptoms and persists for several months if the infection resolves, or indefinitely for those who become chronically infected. Persistence of viremia is the same with asymptomatic infections.

H. Treatment

Treatment during an acute infection is generally supportive. Antiviral drugs are available for the treatment of chronic hepatitis B based on appropriate medical evaluation.

3. CASE DEFINITIONS

A. Acute Hepatitis B (2012)

1. Clinical case definition: An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

* A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive result (HBsAg, hepatitis B e antigen [HBeAg], or hepatitis B virus nucleic acid testing [HBV NAT] including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.
2. Laboratory criteria for diagnosis:
   - HBsAg positive, AND
   - Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

3. Case classification
   **Confirmed:**
   - a case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B, **OR**
   - a case with documented seroconversion regardless of symptoms

B. Chronic Hepatitis B (2012)

1. Clinical description: No symptoms are required. Persons with chronic HBV infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

2. Laboratory criteria for diagnosis
   - IgM antibodies to hepatitis B core antigen (IgM anti-HBc) negative **AND** a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing)
   **OR**
   - HBsAg positive **or** nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) **or** HBeAg positive lab result 2 times tested at least 6 months apart. (Any combination of 2 positive tests performed 6 months apart is acceptable.)

3. Case classification
   **Confirmed:** a case that meets either laboratory criterion for diagnosis
   **Probable:** a case with a single HBsAg positive **or** HBV DNA positive (including qualitative, quantitative and genotype testing) **or** HBeAg positive lab result **AND** does not meet the case definition for acute hepatitis B

4. Comment: Multiple laboratory tests indicative of chronic hepatitis B virus infection may be performed simultaneously on the same patient specimen as part of a “hepatitis panel.” Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative and HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of hepatitis B virus infection.
C. Hepatitis B Surface Antigen Positive Pregnant Women

1. Case classification

   **Confirmed**: Any pregnant woman who tests positive for hepatitis B surface antigen

2. Comment: Infants born to HBsAg-positive mothers should receive hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine as soon as possible but always within 12 hours of birth, followed by the second and third doses of vaccine at 1 and 6 months of age, respectively. Post-vaccination testing for HBsAg and anti-HBs (antibody to HBsAg) is recommended at an interval from 3 to 6 months following completion of the vaccine series (at 9 to 12 months of age). If HBIG and the initial dose of vaccine are delayed for over 1 month after birth, testing for HBsAg at that time may determine if the infant is already infected.


1. Clinical case definition: Perinatal hepatitis B in the newborn may range from asymptomatic to fulminant hepatitis

2. Laboratory criteria for diagnosis: Hepatitis B surface antigen (HBsAg) positive

3. Case classification

   **Confirmed**: HBsAg positivity in any infant aged 1–24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother

   Comment: Perinatal hepatitis B cases are reported to CDC by year of diagnosis (for the infant).

4. DIAGNOSIS AND LABORATORY SERVICES

A. Laboratory Diagnosis

Acute and chronic hepatitis B infections are most commonly diagnosed by identifying specific antigens or antibodies in the blood. The most common serologic markers and the interpretations are shown in Table 1. An explanation of the antigens/antibodies tested can be found in Appendix B. Recently, newer molecular tests have been developed to detect HBV DNA in serum. These tests are primarily used for patients with chronic hepatitis B to determine candidacy for and response to antiviral therapies.
Table 1: Typical interpretation of serologic test results for hepatitis B virus infection

<table>
<thead>
<tr>
<th>Serologic marker</th>
<th>Total anti-HBc</th>
<th>IgM anti-HBc</th>
<th>Anti-HBs</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>+*</td>
<td>–</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>–</td>
<td>+</td>
<td>+</td>
<td>+ or –</td>
<td>–</td>
</tr>
<tr>
<td>–</td>
<td>+</td>
<td>–</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>–</td>
<td>+</td>
<td>–</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>–</td>
<td>–</td>
<td>–</td>
<td>+</td>
<td>–</td>
</tr>
</tbody>
</table>

HBsAg = hepatitis B surface antigen; anti-HBc = antibody to hepatitis B core antigen; IgM = immunoglobulin M; anti-HBs = antibody to hepatitis B surface antigen; “–” = negative test result; “+” = positive test result

*To ensure that an HBsAg-positive test result is not a false-positive, samples with reactive HBsAg results should be tested with a licensed neutralizing confirmatory test if recommended in the manufacturer’s package insert.

**Persons positive only for anti-HBc are unlikely to be infectious except under unusual circumstances in which they are the source for direct percutaneous exposure of susceptible recipients to large quantities of virus (e.g., blood transfusion or organ transplantation).


The typical serologic course of acute hepatitis B with recovery and with progression to chronic HBV infection is shown in Figures 1 and 2. Occasionally, in the later stages of acute clinical illness, a person will have neither HBsAg nor anti-HBs detectable in the blood. The person may still remain infectious, however, for 1–2 weeks. During this so-called “window phase,” the only positive serological test for hepatitis B virus may be core antibodies (anti-HBc).
In occult HBV infection HBV DNA is detected without detection of HBsAg. An occult HBV infection may reactivate if the person develops immunosuppression due to disease or therapeutics such as during treatment for malignancy.

Rare hepatitis B virus “escape mutants” have been reported that have altered HBsAg. Serology of an infected person shows HBeAg and anti-HBs, and there will also be detectable HBV DNA. Vaccine and HBIG are not effective against escape mutant viruses, which can be responsible for vaccine failures. Other mutant forms of hepatitis B viruses have been found after liver transplant.
B. Tests Available at the Washington State Public Health Laboratories (PHL)

Tests for hepatitis B are widely available at commercial laboratories. In certain circumstances, Office of Communicable Disease Epidemiology may request a specimen from a case for molecular sequencing at the Centers for Disease Control and Prevention.

Note that PHL require all clinical specimens have two patient identifiers, a name and a second identifier (e.g., date of birth) both on the specimen label and on the submission form. Due to laboratory accreditation standards, specimens will be rejected for testing if not properly identified. Also include specimen source and collection date.

C. Specimen Collection

Anti-HBV serology can be done from onset of symptoms to 4–6 months after onset. Virus is detectable lifelong in chronic cases. Obtain a serum or EDTA tube, spin promptly, separate the serum into a shipping tube, and promptly ship cold with PHL Virology form: http://www.doh.wa.gov/Portals/1/Documents/5230/302-017-SerVirHIV.pdf

5. ROUTINE CASE INVESTIGATION

A. Evaluate the Diagnosis

Review laboratory tests to distinguish between acute cases of hepatitis B virus infections and chronic infections. Check PHIMS and follow up a newly diagnosed case of acute or chronic infection.

1. Health Care Provider or Health Care Facility Report of Acute Case or Laboratory Evidence of Acute Infection (i.e., IgM anti-HBc positive):
   - Obtain information from the health care provider, hospital infection control staff, or patient to determine if the patient meets the acute hepatitis B case definition.
   - If the patient meets the acute hepatitis B case definition, proceed to Section 5B.
   - Local health jurisdictions are encouraged to provide education (see Section 6) to patients who meet the chronic hepatitis B case definition, focusing efforts on those likely to have a new diagnosis or potential nosocomial exposure.

2. Laboratory Reports Only (including reports from hospital laboratories):
   - Determine if the report involves a pregnant woman. If so, also see Section 7E and F.
   - Determine if the patient has been previously reported as a case.
   - If the patient was previously reported as a confirmed chronic case, no further active investigation is needed. Update the existing case report as necessary with any descriptive (e.g. demographic) data newly reported in the current lab report.
   - If the patient was previously reported as a probable chronic case, and the new laboratory evidence suggests confirmed infection (i.e. IgM anti-HBc negative and HBsAg positive, OR HBsAg or HBV DNA positive 6 months or more following an initial positive), update the case classification to confirmed, enter any new laboratory test result data, and update the existing case record with any descriptive data newly reported.
   - If the patient was previously reported as an acute hepatitis B case, and new laboratory evidence indicates chronic infection, report the case separately as a
case of chronic hepatitis B, under the appropriate case classification (probable or confirmed) as indicated by the newly reported laboratory data.

- If the patient has not been previously reported, proceed with case investigation activities as described above in Local Health Jurisdiction Investigation Responsibilities (Section 1C), depending upon whether the newly-diagnosed case has, or has not, been sampled for enhanced surveillance investigation.

Local health jurisdictions are encouraged to contact the provider or laboratory to determine if the patient meets the acute hepatitis B case definition and/or is newly diagnosed. Persons who do meet the acute hepatitis B case definition should be investigated as described below (Section 5B) and the condition changed to acute hepatitis B. Local health jurisdiction priorities in conducting chronic hepatitis B case investigation should include those among women of child-bearing age, particularly if known to be pregnant, along with those in which age suggests new transmission occurring mainly under age 40 years. Priority in investigations should also be given to any case likely to be associated with a healthcare facility or medical device (e.g. dialysis). These cases may be identified by faxing the short form to the healthcare provider.

At every opportunity, local health jurisdictions are encouraged to provide patient education messaging, materials and resources (see above in Local Health Jurisdiction Responsibilities and in Section 6 below).

B. Identify the Source of Infection

For acute infections and those suspected to have been infected through medical, dental or commercial procedures, collect information about possible exposures, including high risk behaviors, during the period 45–180 days before the onset of illness. Particular emphasis should be placed on the 60–90 days before onset. However, detailed investigation of earlier exposures may be appropriate for a person with documented negative hepatitis status prior to a specific event such as a medical procedure with subsequent positive test.

Exposure information should include:

- Close contact with any household member, sexual partner or acquaintance with recent hepatitis or known chronic infection (obtain names, phone numbers, and addresses).
- Parenteral drug use.
- Occupational or other needlestick injuries.
- Receipt of blood transfusion, other blood products, tissues, or organs.
- Potential medical or dental exposures within the 6 months prior to onset of current illness, including organ or tissue transplant, dialysis, dental or surgical care, and diabetes blood testing in a long term residential facility.
- Other parenteral exposures within the 6 months prior to onset of current illness, including tattooing, piercing, or acupuncture.
- Accidental exposure of skin, eyes, mucous membranes, or a wound to blood of another person.
• Work in occupational settings with elevated risk of exposure (e.g., medical, dental, or clinical laboratory setting, or facilities for mentally disabled persons).

• Sexual contact (homosexual or heterosexual) with multiple sex partners or a sex partner with a risk for hepatitis B virus infection.

Identifying a specific source of infection for recently identified chronically infected persons may be difficult, if not impossible. Possible sources should be pursued if there is a good chance of identifying additional chronic hepatitis B infections or a preventable source. For example, if the newly diagnosed case is a child, it would be reasonable to screen parents and other household members for evidence of infection. Likely health or dental care associated exposures should also be investigated.

C. Identify Potentially Exposed Persons

1. Identify persons potentially exposed to the case during the communicable period. These include household members, sexual contacts, and needle sharing contacts and others potentially exposed to blood or sexual fluids. See Section 6 below for additional information regarding contact management.

2. If the case is a dentist, surgeon, or other health care worker, evaluate the potential for exposing patients (see Section 7A).

3. Determine if case has donated blood or plasma in the 6 months prior to onset or any time thereafter. If so, notify the blood bank or plasma center with particulars (date, etc.)

4. If the patient is pregnant, see Section 7D.

D. Environmental Evaluation

Usually none, unless transmission occurs in a child care center, dialysis center, or health care facility by means of environmental surfaces or inanimate objects.

6. CONTROLLING FURTHER SPREAD

A. Infection Control Recommendations/Case Management

1. Hospitalized patients should be cared for using standard precautions. All health care providers with risk for blood exposure should complete the hepatitis B vaccine series.

2. Residential or child care restrictions: The risk of transmission of hepatitis B virus in the residential or child care setting is usually low, and can be reduced through sound infection control procedures and environmental cleanliness. Personal items that could be contaminated with blood or saliva should not be shared. Contaminated objects or surfaces should be cleaned and disinfected as soon as possible. The risk is greatest for an individual with HBeAg-positive chronic infection, open skin lesions, demonstrated aggressive scratching or biting behavior, a bleeding disorder, or manifesting frank breaches of personal hygiene. Immunization is recommended for staff and patients in residential care settings with developmentally disabled patients. The health jurisdiction should carefully evaluate situations involving a child care facility to determine whether exclusion of the child from child care or vaccination of classroom contacts is indicated.

3. Health care work restrictions: If the case is a health care worker with potential for exposing patients, see Section 7A.
4. Persons who are HBV DNA-positive or HBsAg-positive should be instructed that their blood and other body fluids (particularly semen or vaginal secretions) are infectious to others, and should be educated about ways to reduce the spread of infection to others.

- Susceptible household and sexual contacts should be advised to obtain a full hepatitis B vaccination series.
- Surfaces contaminated with saliva and blood should be cleaned and properly disinfected.
- Cuts and skin lesions should be kept covered.
- Infected persons should not share items potentially contaminated with blood (e.g., needles, syringes, drug works, blood glucose testing equipment, razors, toothbrushes) with other people. Disposable needles should be used only once. As a last resort, undiluted household bleach can be used to clean syringes and needles. Direct active injection drug users to needle exchange programs and drug rehabilitation services.
- Infected persons should be educated to practice abstinence, use barrier methods, or otherwise practice “safer” sex with potentially susceptible partners. Susceptible partners should be vaccinated against hepatitis B.
- Infected persons should not donate blood, plasma, tissue, organs or semen.
- Infected pregnant women and their healthcare providers should make sure prompt preventive treatment is given to the newborn.
- HBsAg-positive persons who seek medical or dental care should notify involved personnel of their hepatitis B status.

5. Persons with acute hepatitis B should have a repeat test for HBV DNA or HBsAg six months after the first test to determine the clearance or continued presence of viremia. Those who continue to be HBV DNA-positive or HBsAg-positive are considered confirmed chronic infections, and should be counseled accordingly.

6. Persons with chronic hepatitis B virus infection should be educated to avoid further harm to the liver. They should:

- See a provider with experience managing chronic hepatitis B infections and treatment.
- Ask their provider about use of over-the-counter drugs (e.g., acetaminophen) that can damage the liver.
- Stop behaviors that could result in transmission of hepatitis B virus.
- Not drink alcohol.
- Get vaccinated against hepatitis A if susceptible.

7. Pregnant or sexually active women who could become pregnant should be told about the risk of hepatitis B infection for newborns of infected mothers, and of the importance of prophylaxis for such newborns. If the woman is pregnant, see Section 7D.

B. Contact Management
1. Postexposure Prophylaxis

Passive immunization with HBIG and active vaccination with hepatitis B vaccine together can prevent infection in contacts of acute case and those newly exposed to a chronic hepatitis case (e.g., needle stick injury in a health care provider or new sexual partner). For greatest effectiveness, give prophylaxis as soon as possible after exposure. Consider the exposed person’s prior history of hepatitis B infection, vaccination, and vaccine response status (if known), but treatment should not be unduly delayed while awaiting test results.

Postexposure prophylaxis is appropriate in the following situations:

- **Perinatal exposure** to HBV DNA-positive or HBsAg-positive mother (see Section 7D).
- **Nonoccupational exposure** to a HBV DNA-positive or HBsAg-positive individual through sexual contact or percutaneous/permucosal exposure to blood. For greatest effectiveness, prophylaxis should be given as soon as possible after exposure. There are no data to indicate that HBIG is of any value more than 7 days after a percutaneous exposure or 14 days after a sexual exposure. See Table 2.
- **Occupational exposure** to a HBV DNA-positive or HBsAg-positive or potentially infected individual. For greatest effectiveness, prophylaxis should be given as soon as possible after exposure. There are no data to indicate that HBIG is of any value more than 7 days after a percutaneous exposure. See Table 3.
- **Household exposure of an infant < 12 months old** to a primary care giver with acute hepatitis B.

Table 2: Guidelines for postexposure prophylaxis* of persons with non-occupational exposure to blood or infected body fluids of a HBV DNA or HBsAg-positive individual

<table>
<thead>
<tr>
<th>Vaccination status of exposed person</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated</td>
<td>HBIG§ x 1 and initiate HB vaccine</td>
</tr>
<tr>
<td>Incomplete vaccine series</td>
<td>HBIG§ x 1 and complete vaccine series</td>
</tr>
<tr>
<td>Written documentation of a completed series but antibody response unknown</td>
<td>Single vaccine booster dose</td>
</tr>
</tbody>
</table>

* When indicated, immunoprophylaxis should be initiated as soon as possible, preferably within 24 hours. Studies are limited on the maximum interval after exposure during which postexposure prophylaxis is effective, but the interval is unlikely to exceed 7 days for percutaneous exposures or 14 days for sexual exposures. The hepatitis B vaccine series should be completed once initiated.

§ Hepatitis B immunoglobulin; dose is 0.06 ml/kg administered IM
Adapted from: MMWR 2006;55(RR-16):30.

Table 3: Recommended postexposure prophylaxis for occupational exposure to HBV
### Healthcare personnel status*

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Source HBsAg Positive or Unknown</th>
<th>Source HBsAg Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unvaccinated or incompletely vaccinated</td>
<td>Test baseline total anti-HBs. HBIG§ x 1 and initiate HB vaccine series. Retest HBsAg and total anti-HBs at 6 months.</td>
<td>Initiate HB vaccine series.. Test anti-HBs 1-2 months after vaccination. Completed</td>
</tr>
<tr>
<td>Documented nonresponder after 6 doses††</td>
<td>HBIG§ x 2 separated by 1 month Test baseline total anti-HBs and retest HBsAg and total anti-HBs at 6 months.</td>
<td>No action needed.</td>
</tr>
<tr>
<td>Antibody response unknown after 3 doses</td>
<td>Test anti-HBs. If anti-HBs ≥ 10mIU/mL no action needed. If &lt; 10mIU/mL HBIG§ x 1 and initiate revaccination. Retest HBsAg and total anti-HBs at 6 months.</td>
<td>Test anti-HBs. If &lt; 10mIU/mL initiate revaccination. Retest anti-HBs 1-2 months after vaccination completed.</td>
</tr>
<tr>
<td>Documented responder after ≥3 doses**</td>
<td>No action needed.</td>
<td>No action needed.</td>
</tr>
</tbody>
</table>

*Persons who have been documented as previously infected with HBV do not require postexposure prophylaxis  
§ Hepatitis B immunoglobulin; dose is 0.06 ml/kg administered IM  
**A responder is a person with adequate levels of serum antibody to HBsAg (anti-HBs ≥ 10mIU/mL after ≥3 doses)  
††A nonresponder is a person with inadequate response to vaccination (anti-HBs < 10mIU/mL)  
§§ The option of giving one doses of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second series but failed to respond, two doses of HBIG are preferred.

Adapted from: MMWR 2013;62 (RR-10):14  
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6210a1.htm?s_cid=rr6210a1_w

### 2. Contacts of Persons with Chronic Hepatitis B

Long-term sexual contacts and persons who have had direct (percutaneous or mucosal) exposure to blood (e.g., needle-sharing partners) should be educated about transmission of hepatitis and tested for HBsAg and HBsAb if they are not known to be immune or infected. Vaccination can be started when testing is initiated if the contact is unlikely to return for results. If susceptible, the contact should complete the hepatitis B vaccine series and if susceptible the hepatitis A vaccine series. Contacts found to be HBsAg-positive should be evaluated as cases.

Active injection drug users should be directed to needle exchange programs and drug rehabilitation services.

### C. Environmental Measures

Ensure that surfaces and objects contaminated with blood are properly disinfected using gloves and appropriate disinfectant solutions.
7. MANAGING SPECIAL SITUATIONS

A. Needlesticks and Similar Exposures

The risk of hepatitis B virus (HBV) transmission following unintentional parenteral exposure is 6-20%. See Section 6B for post-exposure prophylaxis.

B. Case is a Health Care Worker

If the case is a dentist, physician, nurse, or other health care worker with potential for exposing patients by blood or other body fluids:

1. The person should be discouraged from working until the acute clinical illness has resolved.

2. Upon return to work, special precautions should be practiced until the worker is no longer infectious, including:
   - Wearing gloves for all procedures during which the hands will be in contact with the patients’ mucosal surfaces or broken skin;
   - Avoiding situations involving sharps that could lead to exposures of susceptible persons to blood or objects contaminated with blood of the case;
   - Careful and frequent hand washing.

3. Chronically infected health care workers, particularly those who may be HBeAg-positive, should be encouraged to voluntarily seek confidential counseling from employee health services regarding risk reduction strategies, which evaluation would include a review of their practice by an expert panel.

C. Case is a Suspected Iatrogenic Infection

If two or more possible iatrogenic cases occur in patients of the same dental or healthcare provider, and the cases have no other identified plausible source of infection, or other circumstances suggesting the possibility of iatrogenic infection, notify Office of Communicable Disease Epidemiology. If available, hold frozen serum or EDTA tube (at -70°C) on the cases for potential future laboratory work.

If one case underwent a medical or dental procedure and has no other identified plausible source of infection, contact the dental or health care provider and review infection control procedures. Consider storing serum or EDTA tube (if available) at -70°C for genotyping in the event an additional case is identified with a potential shared exposure. Contact Office of Communicable Disease Epidemiology for instructions.

D. Case Is a Recent Blood Donor or Recipient

The blood bank should be notified so that any unused product can be recalled and other persons be tested as appropriate (e.g., other recipient or donor for case).

E. Testing Pregnant Women for Hepatitis B

All women should be tested during each pregnancy for HBsAg. It is particularly important to screen women born in high prevalence regions or whose mothers were born in such regions (e.g., Africa, Southeast Asia including China, most of the Middle East, South and Western Pacific islands, the interior Amazon River basin, and certain parts of the Caribbean). High-risk women who are HBsAg negative early in pregnancy should be
retested late in pregnancy so that results are available at the time of delivery. Women who test positive for HBsAg should have a complete hepatitis panel performed, receive education about hepatitis B, and be enrolled in the Perinatal Hepatitis B Prevention Program.

**F. Perinatal Hepatitis B Prevention Program (PHBPP)**

Each state (and several of the U.S. territories) maintains a perinatal hepatitis B prevention program (PHBPP). In 1989, the Department of Health (DOH) received a grant from CDC to establish such a program in Washington State. This program is part of the activities of the DOH Office of Immunization and Child Profile (OICP). The goal of the PHBPP is to reduce the incidence of hepatitis B in infants born to infected (HBsAg+) mothers by identifying HBsAg+ pregnant women and their household/sexual contacts and establishing an effective follow-up system to assure that each infant born to an HBsAg+ woman receives appropriate post-exposure prophylaxis and that susceptible contacts receive a three-dose series of hepatitis B vaccine. Information about this program can be found at [http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/PerinatalHepatitisBPreventionProgram.aspx](http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/PerinatalHepatitisBPreventionProgram.aspx).

Each local health jurisdiction in Washington should have an established local PHBPP and designated PHBPP coordinator. Pregnant women who test positive for HBV DNA or HBsAg should be enrolled in the program during each pregnancy. OICP should be notified each time a woman is enrolled and informed when hepatitis B immunoglobulin (HBIG) and vaccine doses have been given to the infant. PHBPP guidance for local coordinators (including information regarding the management of premature infants) is available in the DOH Perinatal Hepatitis B Prevention Program Manual which can be found at: [Perinatal Hepatitis B Prevention Program Guidelines](http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/PerinatalHepatitisBPreventionProgram Guidelines) or obtained by contacting the OICP at 360-236-3595.

The key steps of the program are briefly summarized below:

1. **Maternal hepatitis B surface antigen testing:**
   
   All pregnant women must be tested for HBsAg once during the pregnancy and again upon admittance for delivery for each pregnancy.

2. **Report and track HBsAg-positive women:**
   
   All HBsAg+ pregnant women must be reported to the local perinatal hepatitis B prevention program. Contacts for local health are found at: [PerinatalHepatitisBCoordinatorsList.pdf](http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/PublicHealthSystemResourcesandServices/Immunization/PerinatalHepatitisBCoordinatorsList.pdf)

3. **Treat Infants at Birth with HBIG and Hepatitis B Vaccine**
   
   As soon as possibly but always within 12 hours of birth, infants of HBV DNA-positive or HBsAg+ mothers (including preterm and low birth weight infants) should have received hepatitis B immune globulin (HBIG) (0.5 ml IM) and, like all other newborns, the first dose in the hepatitis B vaccination series (0.5 ml IM). HBIG and vaccine can be given simultaneously, but should be administered at different body sites.
4. Complete Hepatitis B Vaccine Series

Full-term infants should receive the second and third doses of vaccine at ages one to two months and six months. The local health jurisdiction should encourage providers to adhere to this schedule as much as possible. In addition to the vaccine dose at birth, infants weighing <2 kg at birth should receive a full three-dose hepatitis B vaccine series initiated at age one month (four doses of vaccine all together).

5. Test Infants

Perinatally-exposed infants should be tested for both anti-HBs and HBsAg 3-6 months following the last dose of vaccine (usually at ~9-12 months of age). The presence of anti-HBs indicates immunity to hepatitis B. Hepatitis B-immunized children who do not show serologic evidence of immunity after the initial series should repeat the three-dose series. Children who fail to respond to the receipt of six doses of vaccine probably never will.

The local PHBPP coordinator should notify the state PHBPP coordinator of all children who are HBsAg+ at the time post-immunization serologic testing is done or before age 2 years. In addition, the children should be reported to the communicable disease section of the local health jurisdiction so that they can be investigated and reported to Office of Communicable Disease Epidemiology and to CDC as perinatal hepatitis B cases.

8. ROUTINE PREVENTION

A. Immunization Recommendations

Hepatitis B vaccination is recommended for all infants and children ages 0–18 years old who have not been previously vaccinated. For infants the usual vaccine schedule includes a series of 3 vaccine doses administered at birth, 1–2 months, and 6–18 months.

Hepatitis B vaccination is also indicated for anyone at increased risk of infection because of lifestyle, medical history, occupation, or ongoing intimate contact with a chronically infected case. Routine vaccination is recommended for the following persons, if susceptible:

- Persons at risk for infection by sexual exposure, particularly those with a sexually transmitted disease, those with more than one partner in the previous 6 months, men who have sex with men, and sexual contacts of infected persons
- Injection-drug users
- Household contacts of persons with chronic HBV infection
- Developmentally disabled persons and staff in long-term and nonresidential child care facilities
- Persons at risk for occupational exposure to hepatitis B virus, particularly healthcare workers
- Hemodialysis patients and staff
- Persons with chronic liver disease including hepatitis C infection
• Adults younger than age 60 years with diabetes (when diagnosed); consider for adults 60 years and older with diabetes based on likely need for assisted blood glucose monitoring, risk of infection, and likelihood of immune response to vaccination

• Inmates of correctional facilities

• Travelers to HBV-endemic areas

• Hepatitis C-infected persons

• HIV-infected persons

• Infants/children of immigrants from areas with high rates of HBV infection

• All other persons seeking protection from HBV infection (regardless of risk factors)

Some of these groups should also receive hepatitis A vaccine routinely. For additional information regarding vaccine scheduling, dosing, contraindications, and testing for seroconversion, please see:


B. Routine Prevention (Source: http://www.cdc.gov/hepatitis/index.htm)

Provide the following information to persons at risk of infection:

• Hepatitis B vaccine is the best protection. Everybody should be vaccinated.

• If you are having sex, but not with one steady partner, use barrier methods correctly and every time you have sex. The efficacy of barrier methods in preventing infection with hepatitis B virus is unknown, but their proper use might reduce transmission.

• If you are pregnant, you should get a blood test for hepatitis B infection. Infants born to HBV-infected mothers should be given HBIG (hepatitis B immune globulin) and vaccine within 12 hours after birth.

• If you are of Asian descent and had parents or grandparents from a risk area, you should get a blood test for hepatitis B infection.

• Do not shoot drugs; if you shoot drugs, stop and get into a treatment program; if you can't stop, never share drugs, needles, syringes, water, cleaning material, or "works", and also get vaccinated against hepatitis A infection.

• Do not share personal care items that might have blood on them (razors, toothbrushes).
- Consider the risks if you are thinking about getting a tattoo or body piercing. You might get infected if the tools have someone else's blood on them or if the artist or piercer does not follow good infection control practices.
- If you have or had hepatitis B, do not donate blood, organs, or tissue.
- If you are a healthcare or public safety worker, get vaccinated against hepatitis B, and always follow routine barrier precautions and safely handle needles and other sharps.

C. Identifying and Testing Persons at Risk for Chronic Infection

Many persons with chronic HBV infection are unaware of their infection and therefore will not receive education for routine prevention. HBV testing should be offered to:

- Pregnant women
- Infants born to HBsAg-positive mothers
- Household contacts and sex partners of HBV-infected persons
- Persons who are the source of blood or body fluid exposures that might warrant postexposure prophylaxis (e.g., needlestick injury to a healthcare worker)
- Persons infected with HIV
- Persons born in geographic regions with HBsAg prevalence of ≥2%
- U.S.-born persons not vaccinated as infants whose parents were born in geographic regions with HBsAg prevalence of ≥8%
- Injection-drug users
- Men who have sex with men
- Persons with elevated ALT/AST of unknown etiology
- Persons with selected medical conditions who require immunosuppressive therapy

For specifics see: [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5708a1.htm)

**ACKNOWLEDGEMENTS**

This document is a revision of the Washington State Guidelines for Notifiable Condition Reporting and Surveillance published in 2002 which were originally based on the Control of Communicable Diseases Manual (CCDM), 17th Edition; James Chin, Ed. APHA 2000. We would like to acknowledge the Oregon Department of Human Services for developing the format and select content of this document.

**UPDATES**

January 2011:
The Legal Reporting Requirements section has been revised to reflect the 2011 Notifiable Conditions Rule revision. Criteria were specified for prioritizing investigations of cases likely to be new diagnoses (Section 5).

February 2012:
In Section 3 case definition updated with the required aminotransferase level going from 200 to 100 IU/L. Laboratory criteria include any hepatitis B virus nucleic acid testing including genotype. Documented asymptomatic seroconversion is a confirmed case.
In Section 8, routine vaccination is now recommended for adults with diabetes under 60 years of age.

May 2014: Chronic hepatitis investigations transitioned to sampling framework for enhanced surveillance.
Appendix A: Hepatitis B Reporting Requirements

HEPATITIS B
REPORTING REQUIREMENTS
Washington State

<table>
<thead>
<tr>
<th>Health Care Providers</th>
<th>Hospitals</th>
<th>Laboratories</th>
<th>Department of Corrections</th>
<th>Local Health Jurisdictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report to Local Health Jurisdiction</td>
<td>Report to Local Health Jurisdiction</td>
<td>Report to Local Health Jurisdiction</td>
<td>Report to DOH - locations listed below</td>
<td>Report to DOH - locations listed below</td>
</tr>
<tr>
<td>Within 7 days of case investigation completion, or summary information required within 21 days</td>
<td>Within 7 days of case investigation completion, or summary information required within 21 days</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td>Within 3 working days</td>
<td>Within 3 working days</td>
<td>Within 1 month</td>
<td>Communicable Disease Epidemiology</td>
</tr>
<tr>
<td><strong>Pregnancy in HBV surface antigen + women, each pregnancy</strong></td>
<td>Within 3 working days</td>
<td>Within 3 working days</td>
<td>Within 1 month</td>
<td>Immunization Program</td>
</tr>
<tr>
<td><strong>Perinatal Hepatitis B</strong> *</td>
<td>Within 3 working days of receiving test result</td>
<td>Within 3 working days of receiving test result</td>
<td>Within 1 month</td>
<td>Communicable Disease Epidemiology &amp; Office of Immunization and Child Profile</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td>Within 1 month</td>
<td>Within 1 month</td>
<td>Within 1 month</td>
<td>Infectious Disease</td>
</tr>
</tbody>
</table>

* Perinatal Hepatitis B is defined as a child:
  1) under 24 months of age
  2) born to a Hepatitis B surface antigen positive (HBsAg+) mother
  3) testing positive for HBsAg

* These infants are reported as acute Hepatitis B, even though most have no symptoms

**DOH Office of Infectious Disease**
PO Box 47838
Tumwater, WA 98501-7838
360-236-3418

**DOH Communicable Disease Epidemiology**
1610 NE 150th Street
Shoreline, WA 98155
206-418-5500
877-539-4344 (24 hr)

**DOH Office of Immunization and Child Profile**
PO Box 47843
Olympia, WA 98504-7843
360-236-3595
Appendix B: Glossary of Terms

ALT/AST: these are both liver enzymes classified as serum aminotransferases or transaminases and are useful indicators of liver damage. Alanine aminotransferase is usually abbreviated as ALT (or SGOT) and is particularly sensitive for assessing liver damage secondary to HCV. Aspartate aminotransferase is referred to as AST (or SGPT). In acute hepatitis A or B, an elevation in either one is required to meet the case definition, while the hepatitis C case definition requires an elevation in the ALT to over 400 IU/L.

Hepatitis A Testing

IgM anti-HAV: IgM antibody to HAV. Indicates acute infection with HAV.

Anti-HAV total: combined antibody to HAV including IgM with acute infection and IgG with long term protection.

Hepatitis B Testing

HBsAg: hepatitis B surface antigen, a marker of replicating virus. It occurs as part of acute infection and persists in chronic infection. Its presence indicates that the patient is considered to be infectious.

Anti-HBs: hepatitis B surface antibody. It demonstrates immunity through infection or vaccination.

IgM Anti-HBc: IgM antibody to hepatitis B core antigen, indicative of recent infection with hepatitis B virus. Antibody to core antigen only occurs following infection, not immunization.

Anti-HBc: total antibody to hepatitis B core antigen. This marker becomes positive at the onset of symptoms in acute hepatitis B then persists for life. Therefore, it does not distinguish between recent, past, or chronic infection.

HBeAg: hepatitis B e antigen, a core protein exported from infected liver cells and a marker of high levels of infectivity. Similar to HBsAg, it occurs (albeit transiently) as part of acute infection and may persist in chronic infections.

HBeAb: hepatitis B e antibody is produced by the immune system temporarily during acute HBV infection and may persist in chronic infections. Spontaneous conversion from e antigen to e antibody is a predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV. Chronic hepatitis B surface antigen carriers can be positive for either HBeAg or anti-HBe, but are less infectious when anti-HBe is present.

Hepatitis B virus DNA: signifies active replication of the virus and indicates that the patient is infectious. It is usually measured to test for chronic infection, and the viral load may be used to decide whether treatment is warranted.

Hepatitis C

Anti-HCV EIA: enzyme immunoassay to measure HCV antibody. Indicates presence of antibody only and cannot be used to distinguish between recent and past infection. Additional testing is required to determine if the individual is chronically infected.

Signal-cutoff ratio: can be used to help determine the likelihood that a positive anti-HCV EIA represents a true positive. Each assay has a cut-off value that is considered a “positive” result; the signal-cutoff ratio can be calculated by dividing the optical density (OD) value of the sample being tested (e.g., the client’s test result) by that particular assay’s cut-off value. Each test kit or
assay has a signal-cutoff ratio above which the client has a 95% probability of being HCV-positive and should be reported as a case.

**PCR:** polymerase chain reaction, used to measure HCV RNA and indicates active replication of the virus (e.g., the chronic infection state). The qualitative PCR is more sensitive than the quantitative assay and is preferred for the initial test. The quantitative PCR is often used to guide initial treatment decisions and to follow the progress of individuals undergoing treatment.

**HCV genotype:** HCV can be divided into at least 6 different genotypes. Genotype 1 is the most common in the United States, accounting for 70–75% of infections. A positive genotype indicates the presence of HCV RNA.