# **Hepatitis B, Chronic**



Merlin disease code: 07032 Hepatitis B, Chronic

Paper case report form
Merlin extended data required

# **Background**

Persons with chronic hepatitis B virus (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. Persons with chronic infection may be asymptomatic. Note that a nucleic acid test for HBV DNA (HBV NAT) includes quantitative, qualitative, and genotype testing.

## Clinical criteria for case classification

#### Reclassifying chronic hepatitis B as acute:

In the absence of a negative result for IgM antibodies to HBV core antigen (IgM anti-HBc), chronic hepatitis B cases with one or more of the following will be reclassified as acute for investigation (if the person is determined to be asymptomatic or symptoms cannot be determined, the case will be reclassified as chronic):

- Bilirubin ≥3.0 mg/dL,
- **Or** alanine aminotransferase (ALT) >1000 IU/L,
- **Or** a person <18 years old.

# Laboratory criteria for case classification

## **Confirmatory:**

Either of the following:

- Any combination of positive HBV surface antigen (HBsAg), HBV e antigen (HBeAg), or HBV NAT results performed >180 days apart
- Or both of the following:
  - Negative IgM antibodies to HBV core antigen (IgM anti-HBc)
  - o **And** one or more of the following:
    - Positive HBsAg,
    - Or positive HBeAg,
    - Or positive HBV NAT.

#### Presumptive:

One or more of the following:

- Positive HBsAg,
- Or positive HBeAg,
- **Or** positive HBV NAT.

### Reclassifying chronic hepatitis B as acute:

Cases with either of the following will be reclassified as acute hepatitis B:

- Negative HBsAg followed within 180 days by a positive HBsAg, IgM anti-HBc, HBeAg, or HBV NAT
- **Or** positive IgM anti-HBc in the absence of a negative IgM anti-HBc (if the person is determined to be asymptomatic or symptoms cannot be determined, the case will be reclassified as chronic).

# Epidemiological criteria for case classification

# Hepatitis B, Chronic (Continued)

A child ≤24 months old whose mother is known not to be infected with HBV.

## Case classification

#### Confirmed:

Either of the following:

- A person ≤24 months old with confirmatory laboratory criteria and epidemiological criteria
- **Or** a person >24 months old with confirmatory laboratory criteria.

#### Probable:

Either of the following:

- A person ≤24 months old with presumptive laboratory criteria and epidemiological criteria who does not meet the case definition for acute hepatitis B
- **Or** a person >24 months old with presumptive laboratory criteria who does not meet the case definition for acute hepatitis B.

# Criteria to distinguish a new case from previous reports

If a person has a previous diagnosis or Merlin case of chronic hepatitis B case, a new chronic hepatitis B case should **not** be created.

## Comments

Multiple laboratory tests indicative of chronic HBV 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 from the same specimen collection date. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

Report all available liver enzyme results for every case under liver function tests (Merlin disease code: 00000).

See graphic for additional information related to the serological course of disease.

