

Merlin disease code: 07030 Hepatitis B, Acute

<u>Paper case report form</u> Merlin extended data required

## **Background**

Acute hepatitis B is characterized by discrete onset of symptoms consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, abdominal pain) and either jaundice or elevated liver enzymes (serum alanine aminotransferase [ALT] level >100 IU/L).

A documented negative hepatitis B virus (HBV) surface antigen (HBsAg) result followed within 180 days by a positive result (either HBsAg; HBV e antigen [HBeAg]; or nucleic acid test for HBV DNA, including quantitative, qualitative, and genotype testing [HBV NAT]) does not require an acute presentation to meet the surveillance case definition.

## Clinical criteria for case classification

#### Confirmatory:

Both of the following:

- Discrete onset of symptoms
- And either of the following:
  - Jaundice
  - Or elevated liver enzymes (ALT level >100 IU/L).

#### Presumptive:

Discrete onset of symptoms.

#### Reclassifying chronic hepatitis B as acute:

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 ALT >1000 IU/L,
- **Or** a person <18 years old.

# Laboratory criteria for case classification

#### Confirmatory:

- (1) Both of the following with confirmatory clinical criteria:
  - Positive HBsAg >4 weeks after last dose of HBV vaccine
  - **And** if done, positive IgM antibody to HBV core antigen (IgM anti-HBc).
- (2) With no clinical criteria:

Negative HBsAg followed within 180 days by a positive result (either HBsAg, HBeAg, or HBV NAT).

#### **Presumptive:**

Positive IgM anti-HBc.

# Hepatitis B, Acute (Continued)

#### Reclassifying acute hepatitis B as chronic:

If the case was asymptomatic, does not meet the criteria for an acute case, and has any of the following, the case will be reclassified as chronic hepatitis B:

- Positive HBsAg,
- **Or** positive HBeAg,
- **Or** positive HBV NAT,
- Or any combination of positive HBsAg, HBeAg, or HBV NAT results performed >180 days apart.

#### Reclassifying chronic hepatitis B as acute:

Chronic hepatitis B cases with a positive IgM anti-HBc 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).

## Epidemiological criteria for case classification

Either of the following:

- A child ≤24 months old whose mother is known not to be infected with HBV
- **Or** a person >24 months old who is epidemiologically linked to a confirmed acute or chronic hepatitis B case.

### Case classification

#### Confirmed:

Either of the following:

- A child ≤24 months old with confirmatory clinical criteria, confirmatory laboratory criteria (1), and epidemiological criteria;
- **Or** a child ≤24 months old with confirmatory laboratory criteria (2) and epidemiological criteria;
- **Or** a person >24 months old with confirmatory clinical criteria and confirmatory laboratory criteria (1);
- Or a person >24 months old with confirmatory laboratory criteria (2).

#### Probable:

One or more of the following:

- A child ≤24 months old with presumptive clinical criteria, presumptive laboratory criteria, and epidemiological criteria;
- **Or** a person >24 months old with presumptive clinical criteria and presumptive laboratory criteria;
- Or a person >24 months old with presumptive clinical criteria and epidemiological criteria.

## Criteria to distinguish a new case from previous reports

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

# Hepatitis B, Acute (Continued)

### **Comments**

Multiple laboratory tests indicative of 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., a negative HBsAg result and positive HBV DNA result on the same specimen). For the purposes of this case definition, any positive result among the laboratory tests mentioned above is acceptable,

regardless of other testing results from the same specimen collection date. Negative HBeAg results and negative HBV DNA results 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.

