

HEPATITIS B**NON-IMMEDIATE NOTIFICATION****EPIDEMIOLOGY PROGRAM**

Event Name:	HEPB
Event Time Period:	Lifelong immunity

ACUTE

Clinical Criteria (CSTE 2023):	<p>In the absence of a more likely, alternative diagnosis*, acute onset or new detection of at least one of the following: jaundice, total bilirubin > 3.0mg/dL, or elevated serum alanine aminotransferase (ALT) levels > 200 IU/L.</p> <p><i>* Alternative diagnoses may include evidence of acute liver disease due to other causes or advanced liver disease due to hepatitis B reactivation, pre-existing chronic HBV infection, other causes including alcohol exposure, other viral hepatitis, hemochromatosis, or conditions known to produce false positives of hepatitis B surface antigen, etc.</i></p>	
CSTE Event Classification (2023):	Acute Confirmed	<ul style="list-style-type: none"> • Detection of HBsAg* AND detection of IgM anti-HBc, or • Detection of HBeAg AND detection of IgM anti-HBc, or • Detection of HBV DNA** AND detection of IgM anti-HBc, or • Detection of HBsAg,* HBeAg, or HBV DNA within 12 months (365 days) of a negative HBsAg test result. (i.e., HBsAg seroconversion) <p>OR</p> <p>A case that meets clinical criteria and:</p> <ul style="list-style-type: none"> • Detection of HBV surface antigen (HBsAg)* AND IgM antibody to HBV core antigen (IgM anti-HBc) test not done or result not available, OR • Detection of HBV DNA** AND IgM anti-HBc test not done or result not available <p><i>* If information on HBsAg test method is available and HBsAg confirmatory neutralization was performed as recommended, HBsAg positive by confirmatory neutralization.</i></p> <p><i>** DNA detection by nucleic acid test, including qualitative, quantitative, or genotype testing</i></p>
	Acute Probable	<p>A case that meets clinical criteria and:</p> <ul style="list-style-type: none"> • Detection of IgM anti-HBc, AND • Negative or not done for HBsAg, HBV DNA, or HBeAg
Massachusetts Event Classification (2024):	<i>Acute Confirmed</i>	Same as CSTE definition
	<i>Acute Probable</i>	Same as CSTE definition
	<i>Acute Suspect</i>	Positive IgM antibody to hepatitis B core antigen (IgM anti-HBc) that does not meet the confirmed or probable acute case definition.
	<i>Acute Revoked</i>	Any case that does not meet the confirmed, probable or suspect acute case definition.

PERINATAL

Clinical Presentation (CSTE 2017):	Perinatal HBV infection in a child ≤ 24 months of age may range from asymptomatic to fulminant hepatitis.	
CSTE Event Classification (2017):	<i>Confirmed</i>	Child born in the US to a HBV-infected mother and positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age OR positive for HBeAg or HBV DNA ≥ 9 months of age and ≤ 24 months of age.
	<i>Probable</i>	Child born in the US and positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age OR positive for HBeAg or HBV DNA ≥ 9 months of age and ≤ 24 months of age, but whose mother's hepatitis B status is unknown (i.e. epidemiologic linkage not present).
Massachusetts Event Classification (2017):	<i>Follows CSTE definition</i>	

HEPATITIS B (continued)

CHRONIC

Clinical Description (CDC 2023):	Persons with HBV infection may be asymptomatic or symptomatic.	
CSTE Event Classification (2023):	<i>Confirmed Chronic</i>	<ul style="list-style-type: none"> • Detection of HBsAg* in two clinical specimens taken ≥ 6 months apart, OR • Detection of HBeAg in two clinical specimens taken ≥ 6 months apart, OR • Detection of [HBsAg* OR HBeAg] AND total anti-HBc, OR • Detection of HBsAg* AND HBeAg, OR • Detection of HBV DNA** <p><i>* If information on HBsAg test method is available and HBsAg confirmatory neutralization was performed as recommended, HBsAg positive by confirmatory neutralization.</i></p> <p><i>** DNA detection by nucleic acid test, including qualitative, quantitative, or genotype testing</i></p>
	<i>Probable Chronic</i>	Detection of [HBsAg* OR HBeAg] AND IgM anti-HBc test negative, not done, or result not available
Massachusetts Event Classification (2013):	<i>Confirmed Chronic</i>	Same as CSTE definition
	<i>Probable Chronic</i>	Same as CSTE definition
	<i>Suspect Chronic</i>	Anti-HBc IgM antibody positive that does not otherwise meet the confirmed or revoked case definition
	<i>Revoked</i>	<p>In an individual who has not had at least 2 positive HBV tests* at least 6 months apart, any of the following:</p> <ul style="list-style-type: none"> • Recent documented vaccination (≤ 1 month prior to positive HBsAg) • Negative HBsAg confirmation/neutralization results for the same specimen as a reported positive HBsAg • Two negative HBsAg ≥ 24 hours apart • Two negative HBV DNA tests at least one month apart in a person NOT on treatment • Negative HBV DNA in a person NOT on treatment AND any of the following: negative HBsAg, positive anti-HBs, negative anti-HBc • Negative HBsAg AND positive anti-HBs AND negative anti-HBc <p><i>* Includes any combination of HBsAg, HBeAg, and HBV DNA.</i></p>

HEPATITIS B (continued)

Note: If any other viral hepatitis results are included (for Hepatitis A, C, D or E) refer to the appropriate CCM for guidance on how to enter. Any Hepatitis B negative test results should be entered into an existing Hepatitis B event only. If ALT or Bilirubin are available, enter in the Lab Section.

Report Type	Test Type	Source	Result	New report?	Data Entry
Laboratory report	Hepatitis B core IgM antibody OR HBc-IgM OR Hepatitis Bc Ab, IgM, P/S OR Hepatitis B core AB (IgM)	Serum/ Blood	Positive	Yes	New event SUSPECT
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
<i>Select:</i>	Hep B virus core Ab.IgM ACnc: Pt: Ser: Ord:				
Laboratory report	Total anti-HBc OR Hepatitis B core OR anti-HBc OR Hepatitis Bc Ab, IgG & IgM, P/S	Serum/ Blood	Positive	Yes	New event SUSPECT
				No	Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
<i>Select:</i>	Hep B virus core Ab: ACnc: Pt: Ser: Ord:				
Laboratory report	Genotyping	Serum/ Blood	Letter value	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
<i>Select:</i>	Hep B virus genotype: Prid: Pt: Ser/Plas: Nom: Probe. Amp. Tar				
Laboratory report	HBsAg OR HBAg OR	Serum/ Blood	Positive	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
<i>Select:</i>	Hep B virus surface Ag: ACnc: Pt: Ser: Ord:				

HEPATITIS B (continued)

Note: If any other viral hepatitis results are included (for Hepatitis A, C, D or E) refer to the appropriate CCM for guidance on how to enter. Any Hepatitis B negative test results should be entered into an existing Hepatitis B event only. If ALT or Bilirubin are available, enter in the Lab Section.

Report Type	Test Type	Source	Result	New report?	Data Entry
Laboratory report	HBsAg Neutralization OR HBsAg Confirmation	Serum/ Blood	Positive	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
Select:	Hep B virus surface Ag: ACnc: Pt: Ser: Ord: Neut:				
Laboratory report	HBeAg OR Hepatitis B virus little E Ag(EIA, RIBA or other test)	Serum/ Blood	Positive	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
Select (EIA):	Hep B virus little e Ag: ACnc: Pt: Ser: Ord: EIA				
Select (RIA):	Hep B virus little e Ag: ACnc: Pt: Ser: Ord: RIA				
Laboratory report	HBeAb OR Hepatitis B virus little E Ab(EIA, RIBA or other test)	Serum/ Blood	Positive	Yes	Do NOT create a new event. Enter these results only with an existing event.
				No	Same event
Select:	Hep B virus little e Ab: ACnc: Pt: Ser: Qn:				
Laboratory report	rRNA (ribosomal RNA)	Serum/ Blood	Positive	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
Select:	Hep B virus rRNA: ACnc: Pt: xxx: Ord: Probe				

HEPATITIS B (continued)

Note: If any other viral hepatitis results are included (for Hepatitis A, C, D or E) refer to the appropriate CCM for guidance on how to enter. Any Hepatitis B negative test results should be entered into an existing Hepatitis B event only. If ALT or Bilirubin are available, enter in the Lab Section.

Report Type	Test Type	Source	Result	New report?	Data Entry
Laboratory report	PCR for HBV DNA OR Hepatitis B Viral DNA OR RT-PCR OR Viral load **	Serum/ Blood	Results may be numeric, positive, negative or trace. Select “trace” if the numeric result appears negative (e.g., shown as <20) but a comment or interpretation is included stating that the virus was detected but could not be quantified. Refer to SOP: HEPATITIS NUMERIC PCR TEST INTERPRETATIONS	Yes	New event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
				No	Same event Consult “ Interpreting Hepatitis B Laboratory Results ” table for status
<i>Select (quantitative or numeric results):</i>	Hepatitis B virus DNA : ACnc : Pt : Ser/Plas : Qn: Probe.Amp.Tar				
<i>Select (qualitative result only):</i>	Hep B virus DNA: ACnc: Pt: xxx: Ord: Probe.Amp.Tar				
Laboratory report	Hepatitis B Surface antibody OR HBsAb	Serum/ Blood	Results may be numeric (ex. <10), positive or negative	Yes	Do NOT create a new event. Enter these results only with an existing event.
				No	Same event
<i>Select (qualitative result only):</i>	HBV surface Ab Ser QI				
<i>Select (quantitative or numeric results):</i>	Hep B virus surface Ab: Acnc: Pt: Ser: Qn				

Data entry notes

** If a single HBV PCR/DNA result is reported with multiple reference ranges, see example below, enter the IU/mL value.

Hep B Viral DNA	copies/mL	3250 *	4921 *
Hepatitis B DNA Viral Load	IU/mL	953 * (1)	1443 * (3)
(1) This test was performed using the Aptima HBV Quant assay, performed on the Hologic Panther instrument. The lower limit of quantification is 10 IU/mL.			
(3) This test was performed using the Aptima HBV Quant assay, performed on the Hologic Panther instrument. The lower limit of quantification is 10 IU/mL.			
Hepatitis B DNA Viral Load, Log	Log IU/mL	2.98 *	3.16 *

When entering results from Eurofins/VRL labs:

Ultrio Elite test results noted as non-discriminatory mean that the sample tested positive for HBV/HCV/HIV but this particular assay does not differentiate between the three viruses. It's a screening test done to see if further testing is warranted. Positive non-discriminatory results will be followed up by specific tests for each of the three viruses. These may include repeat Ultrio Elite tests with discriminatory results or tests for HBV core Ab, HBV surface antigen and HCV antibody. Do not enter any results noted as "non-discriminatory".