



## Baseline Evaluation - Investigator (Adult)

### **General Instructions**

The Baseline Evaluation Investigator form is completed by the physician investigator that evaluates the patient at the baseline visit. This form is to be completed immediately following the baseline visit, which may be completed in two visits with the second baseline visit occurring before, or at the time of, the 12 week follow-up visit. The Baseline Evaluation Investigator form captures information about the patient's hepatitis B risk factors and reflects the opinion of the physician investigator in regard to the patient's hepatitis B phenotype, hepatitis B disease duration, and source of infection.

### **Specific Instructions**

- Patient ID: Record the Patient ID in the top right hand corner.
- Date of Evaluation: Record the date (month/day/year) of the evaluation when the information was obtained.
- Physician Investigator initials: Record the initials of the physician investigator completing the form.

### **Section I: Risk Assessment**

- Sexual contact: Check "Yes", "No", or "Unknown" to indicate if the patient has ever had any type of sexual contact with someone who had hepatitis B, including oral, vaginal, or anal sex.
- STD diagnosis: Check "Yes", "No", or "Unknown" to indicate if the patient has ever been diagnosed by a doctor or other health professional with a sexually transmitted disease. Examples include but are not limited to gonorrhea, syphilis, trichomonas, Chlamydia, genital warts or HPV, and genital herpes.
- If yes, check the appropriate box to indicate the total number of times the patient has had a sexually transmitted disease. If the number of times cannot be determined, record "Unknown".
- Number of partners opposite sex: Record the best estimate of the number of persons of the opposite sex, including their current partner, with whom the patient has had sexual intercourse. If the number cannot be determined, record "Unknown".
- Sexual intercourse same sex: Check "Yes", "No", or "Unknown" to indicate if the patient has ever had sexual intercourse with a person of the same sex.

### **Section II: Phenotype**

Check the appropriate box to indicate the physician investigator's opinion of the patient's hepatitis B phenotype, according to the following study definitions:

Acute Hepatitis B: Presence of HBsAg and IgM anti-HBc with serum ALT values greater than 300 IU/L and absence of known history of HBsAg positivity. Probable acute hepatitis B is when all above criteria are met except serum ALT is less than or equal to 300 IU/L or if there is any suspicion of chronic disease.

Immune tolerant: Definite: Presence of HBsAg and HBeAg and normal ALT levels on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than 1,000,000 IU/mL.

**HBeAg-positive chronic hepatitis:** Definite: Presence of HBsAg and HBeAg and abnormal serum ALT levels (at least twice the ULN) on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than 10,000 IU/mL. Probable: Presence of HBsAg and HBeAg and HBV DNA greater than 10,000 IU/mL, but ALT levels between 1-2 times the ULN.

**HBeAg-negative chronic hepatitis:** Definite: Presence of HBsAg without HBeAg but with abnormal serum ALT levels (at least twice the ULN) on two occasions or more over a period of at least 6 months. HBV DNA levels of greater than or equal to 1,000 IU/mL. Probable: Presence of HBsAg without HBeAg and HBV DNA greater than or equal to 1,000 IU/mL, but ALT levels between 1-2 times the ULN.

**Inactive carrier:** Definite: Presence of HBsAg without HBeAg and normal ALT levels on two occasions or more over a period of at least 6 months. HBV DNA levels of less than 1,000 IU/mL. Probable: Presence of HBsAg without HBeAg and HBV DNA between 1,000-10,000 IU/mL, but ALT levels normal.

**Indeterminate:** Does not fit into any of the above categories.

**Cannot be determined:** applies to HBV/HIV co-infected patients only when HBV phenotype cannot be determined

Criteria for phases or phenotypes of chronic hepatitis B (CHB)

	<b>HBeAg</b>	<b>ALT</b>	<b>HBV DNA (IU/mL)</b>
<b>Immune tolerant</b>	Positive	Normal	>1,000,000
<b>HBeAg+ CHB</b>	Positive	Elevated*	>10,000
<b>HBeAg- CHB</b>	Negative	Elevated*	≥1,000
<b>Inactive carrier</b>	Negative	Normal	<1,000**

\* > 2 times ULN = definite, 1-2 times ULN = probable (ULN=30 IU/L for males, 20 IU/L for females)

\*\* HBV DNA 1,000-10,000 IU/mL with normal ALT and no HBeAg-probable

Notes:

- The phase will be assigned based on HBeAg, ALT and serum HBV DNA level, regardless of the presence or absence of anti-HBe in serum
- Probable: 1) if all other criteria for chronic hepatitis B are met and serum ALT is elevated 1-2x ULN, participant will be assigned to “probable” chronic hepatitis B (HBeAg positive or negative) or 2) if all other criteria for immune tolerant are met and serum HBV DNA is between 100,000 and 1,000,000 IU/mL, participant will be assigned to “probable” immune tolerant or 3) if all other criteria for inactive carrier are met and serum HBV DNA is between 1,000 and 10,000 IU/mL, participant will be assigned to “probable” inactive carrier
- Indeterminate: The phase or phenotype will be “indeterminate” if the participant does not clearly fall into any one of the above definite or probable categories or two or more sets of results at baseline are contradictory.
- The phrase “abnormal serum ALT levels (at least twice the ULN) on two occasions or more over a period of at least 6 months” in some of the phenotype definitions should be interpreted as “abnormal ALT levels on at least two occasions at least 6 months apart”.



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### **Section III: HBV duration and Source**

- Duration  
HBV infection: (1) Record the estimated time of HBV infection.  
(2) Check "Years", "Months" or "Weeks" to indicate the unit of time.  
(3) If the duration of HBV infection is not known, check "Unknown".
- Presumed source: Check the appropriate box to indicate the most likely source of the patient's hepatitis B infection, in the opinion of the physician investigator. Check only one presumed source.
- Vertical transmission: person who was born to a HBV infected woman.
- Horizontal transmission: The patient lived as a child in an endemic area such as Asia, Africa, South Pacific Islands, Middle East (except Cyprus and Israel), Malta, Spain, Indigenous populations of Alaska, Canada and Greenland, Ecuador, Guyana, Suriname, Amazon regions, Eastern Europe (except Hungary), Caribbean, Guatemala and Honduras or the patient lived with one or more siblings that are HBsAg positive.
- Adult household contact: At some point in time the patient lived with someone who had hepatitis B at the time they were living together, or the patient has shared household items such as razors, toothbrushes, or nail clippers with someone who had hepatitis B.
- Sexually transmitted: The patient has had sexual contact with someone who had hepatitis B, multiple sex partners (past or present, opposite sex or same sex), or has a history of sexually transmitted disease.
- Occupational: The patient has worked in a hospital, other health care settings such as health centers/clinics, nursing homes, hospice/home care, psychiatric centers or dental centers, or the patient has worked in an occupation where handling blood or blood products is routine.
- Medical/surgical: The patient has had one or more medical or surgical procedures that could put them at risk for acquiring hepatitis B infection.
- Transfusion: The patient has had a transfusion procedure which includes but is not limited to blood transfusions or receipt of blood components or derivatives.
- Injection drug use: The patient has a history of intravenous/injection drug use, including (but are not limited to) heroin, cocaine, PCP, barbiturates, morphine, amphetamines, and methamphetamine.
- Intranasal illicit drug use: The patient has a history of any illicit drug use by inhalation through the nose, which includes but is not limited to cocaine, heroin, and amphetamines.
- Other: If a risk factor that is not listed is identified, then check "Other" and specify the risk factor in the space provided.
- Unknown: If the source of infection cannot be determined or is unknown, check "Unknown".
- Symptomatic: Check "Yes", "No", or "Unable to determine" to indicate if, in the opinion of the physician investigator, the patient currently has any symptoms of hepatitis B.



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### **Section IV: HBV/HIV Ancillary Study Only**

- Duration  
HBV infection: (1) Record the estimated time of HIV infection.  
(2) Check "Years", "Months" or "Weeks" to indicate the unit of time.  
(3) If the duration of HIV infection is not known, check "Unknown".
- Sexual contact: Check "Yes", "No", or "Unknown" to indicate if the patient has ever had any type of sexual contact with someone who had HIV, including oral, vaginal, or anal sex.
- Presumed source: Check the appropriate box to indicate the most likely source of the patient's HIV infection, in the opinion of the physician investigator. Check only one presumed source.
- Vertical transmission: person who was born to a HIV infected woman.
- Sexually transmitted: The patient has had sexual contact with someone who had hepatitis B, multiple sex partners (past or present, opposite sex or same sex), or has a history of sexually transmitted disease.
- Occupational: The patient has worked in a hospital, other health care settings such as health centers/clinics, nursing homes, hospice/home care, psychiatric centers or dental centers, or the patient has worked in an occupation where handling blood or blood products is routine.
- Medical/surgical: The patient has had one or more medical or surgical procedures that could put them at risk for acquiring HIV infection.
- Transfusion: The patient has had a transfusion procedure which includes but is not limited to blood transfusions or receipt of blood components or derivatives.
- Injection drug use: The patient has a history of intravenous/injection drug use, including (but are not limited to) heroin, cocaine, PCP, barbiturates, morphine, amphetamines, and methamphetamine.
- Other: If a risk factor that is not listed is identified, then check "Other" and specify the risk factor in the space provided.
- Unknown: If the source of infection cannot be determined or is unknown, check "Unknown".