



Baseline Evaluation - Investigator (Adult)

Patient ID ____ - ____ - ____

Date of Evaluation: ____ / ____ / ____

This information is to be provided by the physician investigator immediately following completion of the baseline evaluation. The information is to reflect the opinion of the physician investigator based on information available at the time of the baseline evaluation.

Physician Investigator Initials: ____

SECTION I: RISK ASSESSMENT

- 1. Has the patient ever had sexual contact with a person who had hepatitis B? Yes No Unknown
- 2. Has the patient ever been diagnosed by a doctor (or other health professional) with any sexually transmitted disease such as gonorrhea, syphilis, trichomonas, chlamydia or genital warts?
 Yes No Unknown

If Yes, how many times (all together) has the patient had a sexually transmitted disease?

- 1 1 time 2 2-4 times 3 More than 4 times Unknown

- 3. What is the best estimate of the total number of persons of the opposite sex that the patient has had sexual intercourse with even once (including their partner): _____ Unknown
- 4. Has the patient ever had sexual intercourse with a person of the same sex?
 Yes No Unknown

SECTION II: PHENOTYPE (refer to study definitions below)

1. Phenotype of patient (check one)

- 1 Acute hepatitis B
- 2 Immune tolerant chronic hepatitis B
- 3 HBeAg positive chronic hepatitis B
- 4 HBeAg negative chronic hepatitis B
- 5 Inactive carrier state
- 6 Indeterminate
- 7 Cannot determine (HIV Coinf only)

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: 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.

SECTION III: HBV DURATION AND SOURCE

- 1. Estimated duration of HBV infection: _____ 1 Years 2 Months 3 Weeks Unknown
- 2. Presumed source of hepatitis B? (check the most likely, check only one)
 - 1 Vertical transmission
 - 2 Horizontal transmission
 - 3 Adult household contact
 - 4 Sexually transmitted
 - 5 Occupational
 - 6 Medical/surgical
 - 7 Transfusion
 - 8 Injection drug use
 - 9 Intranasal drug use
 - 10 Other _____
- 3. Is the patient symptomatic of hepatitis B? Yes No Unable to determine

SECTION IV: HBV/HIV COINFECTED ANCILLARY STUDY ONLY

- 1. Estimated duration of HIV infection: _____ 1 Years 2 Months 3 Weeks Unknown
- 2. Has the patient ever had sexual contact with a person who had HIV? Yes No Unknown
- 3. Presumed source of HIV? (check the most likely, check only one)
 - 1 Vertical transmission
 - 2 Sexually transmitted
 - 3 Occupational
 - 4 Medical/surgical
 - 5 Transfusion
 - 6 Injection drug use
 - 7 Other _____
 - 8 Unknown