

## Laboratory Site Visit Report Hepatitis B Virus Testing

Region/County \_\_\_\_\_ Evaluator \_\_\_\_\_ Date of Visit \_\_\_\_/\_\_\_\_/\_\_\_\_

Laboratory Name and Address \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Lab Contact Person \_\_\_\_\_  
 Phone Number \_\_\_\_\_  
 Email Address \_\_\_\_\_

Contact for Electronic  
 Laboratory Reporting \_\_\_\_\_  
 Phone Number \_\_\_\_\_  
 Email Address \_\_\_\_\_

1. Type of laboratory  Hospital  Doctor's office  Clinic  Private laboratory  Health dept.  
 Other \_\_\_\_\_

2. What type of testing does your laboratory routinely perform? (check all that apply)

Serology:  HBsAg  anti-HBs  anti-HBc  
 IgM anti-HBc  HBeAg  HBeAb  Other \_\_\_\_\_  
 -----  
 NAT\*:  Hepatitis B DNA Qualitative  Hepatitis B DNA Quantitative  
\*nucleic acid testing

3. Hepatitis HBsAg serology tests are  Conducted in-house  Contracted to an outside laboratory

4. If contracted to an outside laboratory, a) Is that laboratory in-state?  Yes  No  
 b) Which laboratory is responsible for submitting positive reports to the health department?  This lab  Contract lab

5. If conducted in-house, are positive results reported to the health department?  Yes  No

6. If your laboratory performs HBsAg testing, which lab kit is used?

	Manufacturer	Brand Name	Confirmation Required (per test kit)
<input type="checkbox"/>	Abbott Lab	Auszyme Monoclonal	Yes, neutralization
<input type="checkbox"/>	Abbott Lab	Abbott Prism	Yes, neutralization
<input type="checkbox"/>	Abbott Lab	Axsym	Yes, neutralization
<input type="checkbox"/>	Bayer	Bayer Centaur	Yes (perform repeat testing in duplicate and/or supplemental testing)
<input type="checkbox"/>	Bio Rad	Genetic Systems HBsAg EIA 3.0	Yes, neutralization
<input type="checkbox"/>	Diagnostic Product Corp	Immulite HBsAg	Yes, neutralization
<input type="checkbox"/>	DiaSorin	ETI-MAK-2 Plus (HBsAg)	Yes, neutralization
<input type="checkbox"/>	Ortho Diag.	Ortho Vitros ECi	If 2 of 3 are >5.00 s/c, the sample is positive and no further testing required
<input type="checkbox"/>	Roche	Elecsys 2010	Yes, neutralization
<input type="checkbox"/>	Other:		

7a. If confirmation by neutralization or other supplementary testing is required, is this routinely done for each HBsAg-positive result?  Yes  No

7b. If the confirmatory result is positive, how are the results reported to the health department?  
 the initial HBsAg positive result and confirmatory positive result are reported together  
 the initial HBsAg positive result and confirmatory positive result are reported separately  
 other: \_\_\_\_\_

7c. If the confirmatory result is negative, is the initial HBsAg positive result reported to the health department?  Yes  No

8. By what mechanism are reports submitted to the health department (e.g., mail, fax, electronic)? \_\_\_\_\_  
 (Attach sample of report to health department)

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Hepatitis B Virus Testing (Page 2)**

9. How often are reports submitted to the health department? \_\_\_\_\_

10. What data are contained in the laboratory report?

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Type of specimen                                 | <input type="checkbox"/> Name of patient       | <input type="checkbox"/> Patient birth date            |
| <input type="checkbox"/> Specific test (descriptive)                      | <input type="checkbox"/> Patient age           | <input type="checkbox"/> Patient sex                   |
| <input type="checkbox"/> Specific test (descriptive) (standardized coded) |  |  |
| <input type="checkbox"/> Address of patient                               | <input type="checkbox"/> Date of test          | <input type="checkbox"/> Test result                   |
| <input type="checkbox"/> Ordering physician/agency name                   | <input type="checkbox"/> Medical record number | <input type="checkbox"/> Pregnancy status              |
| <input type="checkbox"/> Ordering physician/agency address                | <input type="checkbox"/> Specimen number       | <input type="checkbox"/> Any other data? Specify _____ |

11. Please describe the steps of reporting from the laboratory to the health department \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

12. How are the results of hepatitis serology tests performed maintained at the facility (e.g., lab log, computerized database)?  
\_\_\_\_\_  
\_\_\_\_\_

13. Time period for the evaluation of completeness and timeliness of laboratory reporting (should be at least 3 months)  
Begin date: \_\_\_\_/\_\_\_\_/\_\_\_\_ End date \_\_\_\_/\_\_\_\_/\_\_\_\_

**Completeness**

14. How many total specimens were tested for HBsAg in this laboratory during the time period? \_\_\_\_\_

15. How many of the total specimens tested for HBsAg were positive during the time period? \_\_\_\_\_

16. How many positive HBsAg serologies were reported to the health department during the time period? \_\_\_\_\_

17. Proportion of positive HBsAg serologies reported to the health department \_\_\_\_\_% (see Worksheet if needed)

**Timeliness**

18. Mean reporting time for the laboratory is \_\_\_\_\_ days (see Worksheet if needed)

**Laboratory Site Visit Report  
Completeness and Timeliness of Reporting Worksheet**

**Completeness of reporting**

- A. Pick a time period for the evaluation. Should be at least 3 months.
- B. How many total positive HBsAg serologies (including neutralization if required by test kit) were processed at this laboratory during the time period? \_\_\_\_\_
- C. How many total positive HBsAg serologies were reported to the health department from this laboratory during the time period? \_\_\_\_\_
- D. Divide C by B = \_\_\_\_\_ = Proportion of positive HBsAg serologies reported from the laboratory to the health department, or **completeness of reporting**.

**Timeliness of reporting**

- A. Pick a time period for the evaluation. Should be at least 3 months.
- B. Review reports of positive HBsAg serology (screening-test positive AND screening-test positive plus neutralization positive) received by the health department from the laboratory for the time period under evaluation.
- C. Make three columns: date HBsAg performed, date report of HBsAg received by the health department, and number of days between those two dates. For each HBsAg reviewed, record the following:  
  
Date HBsAg serology performed by laboratory \_\_\_/\_\_\_/\_\_\_  
  
Date HBsAg serology report received by health department \_\_\_/\_\_\_/\_\_\_  
  
Number of days between HBsAg serology performed and report received by health department \_\_\_\_\_  
  
THEN
- D. Sum column “days between serology performed and report received.”
- E. Divide the sum of “days between serology performed and report received” by the number of serologies evaluated.
- F. The result will equal the **mean reporting time** for the laboratory.