**Laboratory Site Visit Report**  
**Hepatitis B Virus Testing**

**Region/County** ____________  
**Evaluator** ____________________  
**Date of Visit** ______/______/______

<table>
<thead>
<tr>
<th>Laboratory Name and Address</th>
<th>Lab Contact Person</th>
<th>Phone Number</th>
<th>Email Address</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**Contact for Electronic Laboratory Reporting**

<table>
<thead>
<tr>
<th>Phone Number</th>
<th>Email Address</th>
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</tbody>
</table>

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

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?**

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

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)
9. How often are reports submitted to the health department? ____________________________________________

10. What data are contained in the laboratory report?

- Type of specimen
- Specific test (descriptive)
- Specific test (descriptive) (standardized coded)
- Address of patient
- Ordering physician/agency name
- Ordering physician/agency address
- Name of patient
- Patient age
- Patient birth date
- Patient sex
- Date of test
- Medical record number
- Test result
- Pregnancy status
- Specimen number
- 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.