

Chapter 6

Laboratory and Reporting



This page intentionally left blank.

Laboratory Parameters

A positive anti-HBs of ≥ 10 mIU / mL indicates adequate immunity to hepatitis B; this immunity can be from either a past hepatitis B infection or hepatitis B vaccination. After receiving a primary hepatitis B vaccine series, individuals with anti-HBs levels of ≥ 10 mIU/mL are considered protected and immune to the HBV, in accordance with the CDC guidelines.

A negative result indicates a lack of recovery from acute or chronic hepatitis B or inadequate immune response to hepatitis B vaccination. Infants with a negative anti-HBs and a negative HBsAg should be revaccinated with a second three-dose series. The ACIP does not recommend more than two hepatitis B vaccine series for non-responders.

Indeterminate results indicate an inability to determine if anti-HBs is present at levels consistent with immunity. Repeat testing is recommended in one to three months.

Please refer to Appendix C for Interpretation of PVST.

Inconclusive Laboratory Results

Contact the Reporting Laboratory for information clarifying reports of inconclusive laboratory results such as equivocal anti-HBs and appropriate follow-up instructions for re-testing.

Reporting Sources

One of the most difficult challenges for a PHBPP is obtaining reports of HBsAg-positive pregnant women. To have a successful reporting system, a PHBPP should have several overlapping sources of information to identify HBsAg-positive pregnant women. Three main reporting sources are laboratories, prenatal care providers, and delivery hospitals. Additional sources for reporting may include:

1. Midwife centers / home births;
2. Pediatricians / Family Practices;
3. Planned Parenthood;
4. Federally Qualified Health Clinics (FQHCs); and
5. Rural Health Clinics (RHCs).

Laboratory Reports

A primary reporting source for the PHBPP is the laboratory. Nationwide, there are 244,000 certified laboratories under the 1988 Clinical Laboratory Improvement Amendments (CLIA). The objective of CLIA is to ensure quality laboratory testing for all lab testing performed on humans, except for research purposes. Laboratory reporting is more consistent and reliable than provider reporting and is often automatic or electronic. Additionally, reporting by laboratories can be made a condition of licensure, but non-laboratory reporting sources require constant reminders and education.

The following are a few examples of problems encountered using laboratory reporting as a source of perinatal cases:

- Provider information, including contact information, may be omitted

- Appropriate serology tests markers may not have been ordered
- Pregnancy status is often not indicated

Having alternate reporting sources can compensate for the deficiencies or periodic problems that may occur in laboratory reporting. When information is missing on the electronic lab report (ELR), the reporting laboratory should be provided education pertaining to the information that is required by law for reporting of certain conditions. Please refer to Chapter 3 for additional information pertaining to statutes and rules of reporting.

Labor and Delivery Hospital Reports

The PHBPP also uses hospital reports to identify infants born to HBsAg-positive women. In order for the labor and delivery hospital to be an effective reporting source, it is necessary to educate individuals responsible for determining a pregnant woman's HBsAg status and administering HBIG and the hepatitis B vaccine to the newborn. In order to achieve this, the program must collaborate with staff physicians, labor and delivery nursing staff, newborn nursery staff, pharmacy staff, and infection control staff. When possible, program assistance should be offered to develop hospital policies and procedures regarding screening and treatment standards that are reflected in Appendix D.

The PHBPP staff should encourage reporting by making the process as easy as possible and by helping the collaborating facilities in identifying what works best for them (i.e., should reporting be done by nursing staff or by infection control staff). Hospital staff designated to identify and report cases should either call to report a case or mail / fax in the completed case report form: Hospital / Provider Report of HBsAg-Positive Mother (Stock # EF11-11015). This form is available at www.texasperinatalhepb.org.

The DSHS HSR and LHD program staff are responsible for completing the paperwork on all cases that are reported by hospitals. Instructions and form samples can be found online at www.texasperinatalhepb.org.

Flow charts located in Appendix B document the flow of information on serology testing and case management of HBsAg-positive women that must occur for a PHBPP to succeed.

Submitting Specimens to DSHS - Austin Laboratory

If your agency does not already have a submitter identification (ID), one must be created with the DSHS Laboratory prior to submitting specimens for testing. To request a submitter ID, the *Submitter Identification (ID) Number Request Form* should be completed and is available at the DSHS laboratory website www.dshs.state.tx.us/WorkArea/DownloadAsset.aspx?id=8589956433. Once completed, the form should be faxed to (512) 776 – 7533. Once the lab has received the completed form, a submitter ID will be created. Specimens cannot be shipped until a submitter ID has been acquired and given to your facility. For questions, please call (512) 776 – 7578.

Tip: Do not collect a specimen until you have a submitter ID. This process may take several days to complete.

To submit a specimen for testing at the DSHS Laboratory, please do the following:

- Complete the DSHS Specimen Submission Form (G-2A) for the corresponding sample. The information below is required for all specimens submitted to the DSHS Laboratory. Submissions missing any of the information below will not be processed. For additional guidance, please see visit http://www.dshs.state.tx.us/lab/MRS_forms.shtm for a current sample of the G-2A submission form and detailed instructions.
 - **Section 1**
 - Submitter
 - ◇ Name
 - ◇ Submitter ID
 - ◇ National Provider Identifier (NPI) Number
 - ◇ Address and Contact Information
 - **Section 2**
 - Patient
 - ◇ Name and Date of Birth (DOB)
 - ◇ Address and Contact Information
 - Collection
 - ◇ Date and Time (must match the specimen)
 - **Section 3**
 - Specimen Source (serum, plasma, etc.)
 - **Section 7**
 - Requested test(s): (check all boxes that apply)
 - ◇ Hepatitis B surface antibody (anti-HBs)
 - ◇ Hepatitis B surface antigen (HBsAg)
 - ◇ Hepatitis B core antibody (anti-HBc)
 - ◇ Hepatitis B core IgM antibody (IgM)
 - **Section 8**
 - Ordering Physician Information (including NPI Number)
 - **Section 9**
 - Payor Source
 - ◇ Immunizations
 - Retain a copy of the G2-A for your records

Tip: *Keep a copy of the submission form in the patient's case management chart;*
 - Clearly label the red top or tiger top tube and paperwork with:
 - Patient's full name and DOB;
 - Date and time of collection; and
 - Initials of person collecting specimen.
- Note:** All information (name, date, and time) on the submission form must match the information on the specimen tube. If any information does not match, the specimen will be rejected and no testing will be performed.

- Obtain 6 - 8 mL of venous blood (minimum of 2 mL) in a red top tube (serum tube) or tiger top tube (Serum Separator Tube [SST]).
- Single or Separated serum may be submitted; whole blood is not accepted.
- The tiger top SST tubes cannot be frozen. If specimen needs to be frozen, remove the separated serum and place in a red top tube. If frozen, the date and time removed from the freezer must be noted in the section at the bottom right corner of the G-2A form.
- Do not send specimens to be delivered on Saturday as staff will not be available to receive deliveries.
- Do not ship on Fridays or day before state holidays. State holidays / closures can be found at www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=34563&id=34296&terms=holiday.

For additional guidance, please visit http://www.dshs.state.tx.us/lab/MRS_forms.shtm for a current sample of the G-2A submission form and detailed instructions.

DSHS Lab Criteria for Hepatitis B Specimen Testing

Test	Specimen Type	Time from collection to arrival at the laboratory	Temperature	Shipping Requirement
Anti-HBs HBsAg Anti-HBc IgM	Serum separated from the clot (red top or tiger top)	Up to 48 hours	Cold 2° to 8°C	Ship on cold packs
	Serum separated from the clot (red top only)	More than 48 hours	Frozen - 20°C or colder	Ship on dry ice

For additional information on protocols for shipping biological specimens, please visit www.dshs.state.tx.us/lab/mrs_shipping.shtm.

For any other questions regarding laboratory submission, please visit www.dshs.state.tx.us/lab, or call (512) 776 – 7578.

For frequently asked questions (FAQs) about the laboratory, please visit: www.dshs.state.tx.us/lab/ab_faqs.shtm.

To obtain laboratory results, status on laboratory tests, or to have a duplicate report sent, please call (512) 776 – 7578.

Specimens and their G-2A form should be shipped by overnight carrier to:

Walter Douglas
Texas Department of State Health Services
Laboratory Services Section
MC – 1947
1100 West 49th Street
Austin, Texas 78756 – 3194

CPT Codes for Hepatitis B Serology Testing

SEROLOGY TEST	CPT CODE
HBsAg	87340
HBsAg – confirmatory test	87341
Anti-HBs (Qualitative)	86706
Anti-HBs (Quantitative) - <i>preferred</i>	86317
HBeAg	87350
Anti-HBe	86707
HBcAb	86704
Prenatal Profile with HBsAg	80055
Hepatitis B IgM antibody	86705
HBV DNA (Quantitative)	87517

This page intentionally left blank.