West Virginia Department of Health and Human Resources
OFFICE OF LABORATORY SERVICES
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INSTRUCTIONS FOR THE COLLECTION, SUBMISSION FORM, AND MAILING OF HEPATITIS SPECIMENS

(includes A, B, and C)

NOTE: These instructions cover both NO CHARGE and FEE FOR SERVICE Testing.

The Office of Laboratory Services (OLS) provides the following supplies in our collection kits:

1. 8.5mL SST blood tubes (gray and red top tubes)
2. Eclipse 21G needle hub assembly
3. A copy of the Diagnostic Immunology ***Hepatitis*** test request submission form
   - **TIP** – Facilities can fill in the submitter data and then make copies for use.
   - **TIP** – Some sites copy forms onto a specific color of paper for easy recognition. If your site chooses to do this OLS recommends the use of pastel colors to prevent eye strain when filling out and performing data entry from the form.

Blood Specimen Collecting Instructions:

1. Collect venous blood into clean SST tubes filling approximately 2/3 full, following your facility's proper phlebotomy procedures.
2. It is best practice to provide one well-filled blood tube for each test type being requested **(1 for Hepatitis A, 1 for Hepatitis B, 1 for Hepatitis C)**. However, if not possible one well-filled blood tube is acceptable for the lab to complete the Hepatitis B and C testing.
3. At a minimum, place patient's first and last name and draw date on the collection tube. The use of pre-printed labels is acceptable (the information on the tube and form must match exactly).
4. Best practice is to gently invert the tubes after collection and allow the specimen to clot (20-30 minutes) and then centrifuge at 2800 RPMs for a **minimum** of 10 minutes.
5. Allowing the serum to sit on the clot for long periods can cause hemolysis. Badly hemolyzed(bloody), very lipemic (fatty) or bacterially contaminated blood produces unreliable results.
6. Package and send specimens to the lab immediately after collection, to ensure best results.
7. ***If your facility is unable to centrifuge the samples, contact the lab for more information*.**

Form Instructions:

PLEASE PRINT LEGIBLY.

The Clinical Laboratory Improvement Amendment of 1988 (CLIA) requires the following information for the lab to be able to process the specimen for testing. If any of this information is missing, by federal law, the lab cannot perform the test.

a. A unique identifier on both the form and the specimen;
b. Address of submitter;
c. Date of birth or age of patient;
d. Sex of patient;
e. The test to be performed;

f. **The source of the specimen (i.e. blood/serum, urine);**
g. **Date of collection;**
h. **Any additional Information relevant to testing (i.e. information necessary by the program)**

NOTE: For your convenience, a fillable form is available on our website at www.dhhr.wv.gov/ols.

1. **Patient Information:**
   a. **Patient ID** --- This refers to a chart number, medical record number, or some other internal ID that your facility uses to identify patients. A maximum of 15 characters is allowed.
   b. **Last Name, First Name, MI** --- Patient's full name (i*nformation on tube and form must match)*
   c. **Date of Birth** --- CLIA requires DOB or AGE of patient.
   d. **Social Security Number** *(optional)* --- last 4 digits only
   e. **County of Residence** --- The patient's county of residence is not always the same as the provider's county *(required by program)*
   f. **Sex** --- at birth *(required by CLIA)*
   g. **Street Address, City, State, Zip Code** --- *(required by program)*
   h. **Patient Phone Number – include area code** *(required by program)*
   i. **Race** --- More than one can be marked *(required by program)*
   j. **Ethnicity** --- *(required by program)*
   k. **Patient Type** --- Mark one of the three options

PATIENT INFORMATION

PATIENT ID (Chart #, MRN, etc.) [*optional*]		
LAST NAME	FIRST NAME	MI
DATE OF BIRTH	SS# (last 4 digits only)	
COUNTY OF RESIDENCE	SEX (at birth) ❑ Female ❑ Male	
STREET ADDRESS		
CITY	STATE	ZIP
PATIENT PHONE NO. (include area code)		
RACE ❑ White ❑ Asian ❑ Black ❑ Other ❑ American Indian/Alaskan ❑ Native Hawaiian or other Pacific Islander	ETHNICITY ❑ Not Hispanic or Latino ❑ Hispanic or Latino ❑Unknown	
PATIENT TYPE: ❑ Employee ❑ Patient ❑ Investigation		

2. **Submitter Information:**
   a. **Facility Name** --- The official name of the site as listed on the Memorandum of Understanding (MOU) or application to the STD program. **Do not use the initials of your site.** *(required by CLIA)*
   b. **Street Address, City, State, Zip Code** --- *(required by CLIA)*
   c. **County** --- (*required by program)*
   d. **Attention To** --- This line is to be filled out if the results are to go to a specific individual or department within the facility. *(optional)*
   e. **Phone Number and Fax Number – include area code** *(required by program).*

SUBMITTER INFORMATION

FACILITY NAME		
MAILING ADDRESS		
CITY	STATE	ZIP
COUNTY		
ATTENTION TO:		
PHONE NO. (include area code)		
FAX NO. (include area code)		

TIP: Fill in submitter information section and then make copies of the form.

3. **Comments** --- This section is for any additional information or notes.

4. **Date of Collection** --- (*required by CLIA)* The date that the specimen was collected.

DATE OF COLLECTION:

5. **Program/Clinic Type**
   a. **Hepatitis A IgM (no charge testing)** --- No charge Hepatitis A testing is only performed for approved cluster/outbreak investigations.
   b. **Hepatitis B (no charge testing)** --- Patients that meet the criteria for no charge testing. (See "Hepatitis B Information – Risk Factors" section below for more information.)
   c. **Hepatitis C (no charge testing)** --- Patients that met the criteria for no charge testing. (See "Hepatitis C Information – Risk Factors" section below for more information.)

PROGRAM / CLINIC TYPE: (Select ONE Only)	
❑ Hepatitis A IgM (no charge testing)*	❑ Fee for Service Testing
❑ Hepatitis B (no charge testing)*	❑ Investigation
❑ Hepatitis C (no charge testing)*	❑ Project HRP
❑ Project # _____	
* no charge testing requires PRIOR approval	

   d. **Fee for Service Testing** --- Patients that do not meet the criteria for no charge testing may still have Hepatitis testing performed for a fee. See "Hepatitis Fee for Services Chart" for cost information.
   e. **Investigation** --- If a patient is part of an on-going investigation.
   f. **Project HRP** --- if your site provides syringe service or harm reduction services to patients.
   g. **Project # _____** --- for special projects such as outbreaks, investigations, or outreach events (*assigned by OLS*).

6. **Test Requested** (*required by CLIA*)
   a. **Hepatitis A IgM** --- Unless part of an approved investigation, a fee will be charged for this test.
   b. **Hepatitis Post-Vaccine (HBsAb) ---** 4 to 6 weeks after a patient has received their final Hepatitis B vaccination shot, a blood should be drawn and tested to see if they have developed antibodies. This is usually a **FEE FOR SERVICE** test. See "Hepatitis Fee for Services Chart" for cost information.

TEST REQUESTED: (Select ONE Only)	
❑ Hepatitis A IgM	❑ Hepatitis B Screen
❑ Hepatitis B Post-Vaccine (HBsAb)	❑ Hepatitis C Antibody

   c. **Hepatitis B Screen** --- A screen consist of two tests: Hepatitis B Surface Antigen and Hepatitis B Core Antibody. If one or both are Reactive further testing will be performed.
   d. **Hepatitis C Antibody** --- An IgM screen for Hepatitis C antibodies.

7. **Source of Specimen** --- This has pre-marked for your convenience.

8. **Hepatitis B Information – Risk Factors**
   a. **No Charge Testing:** To determine if the patient is eligible for no charge testing, the patient must have one of the listed risk factors within the last 12 months.
      - If the patient answers **YES** to any of the risk factors, **they qualify for no charge Hepatitis B testing**. Make sure to check any risk factors that apply in the Hepatitis B Information – Risk Factors box.

HEPATITIS B INFORMATION - RISK FACTORS	
For Hepatitis B - NO CHARGE TESTING: patient must have at least one of the risk factors marked to be eligible. Mark any additional Hepatitis B risk factors that apply to the patient. All risk factors must have occurred within the last 12 months.	
❑ Body piercing (non-commercial)	❑ Multiple partners
❑ Tattoo (non-commercial)	❑ Healthcare worker
❑ Needle stick / blood splash	❑ Current non-IV drug user
❑ Currently injecting drugs	❑ Blood transfusions
❑ Pregnant (due date _____)	❑ Hemodialysis
❑ History of incarceration	❑ Sexual contact
❑ Symptoms / Diagnosis of STD	❑ Household contact

NOTE: If no risk factors are marked at the time the test request is received, the facility will be charged for the testing. NO adjustments will be made.

Fee for Service Testing: For any patient that does not met the criteria for NO CHARGE Testing but still wants to know their Hepatitis B status. See "Hepatitis Fee for Services Chart" for cost.

9. **Hepatitis C Information – Risk Factors**
   a. **No Charge Testing:** To determine if the patient is eligible for no charge testing, the patient must have one of the listed risk factors within the last 12 months.
      - If the patient answers **YES** to any of the risk factors, **they qualify for no charge Hepatitis C testing**. Make sure to check any risk factors that apply in the Hepatitis C Information – Risk Factors box.

HEPATITIS C INFORMATION - RISK FACTORS	
For Hepatitis C – NO CHARGE TESTING: patient must have at least one of the risk factors marked to be eligible. Mark any additional Hepatitis C risk factors that apply to the patient. All risk factors must have occurred within the last 12 months.	
❑ Contact with POSITIVE+ Hepatitis C patient	
❑ Current non-IV drug user	❑ Current IV drug user
❑ Tattoo (non-commercial)	❑ Blood transfusion
❑ Body Piercing (non-commercial)	❑ Healthcare worker
❑ Needle stick / blood splash	❑ Hemodialysis
❑ Pregnant (due date _____)	❑ Sexual contact
❑ Symptoms / Diagnosis of STD	❑ History of incarceration

NOTE: If no risk factors are marked at the time the test request is received, the facility will be charged for the testing. NO adjustments will be made.

Fee for Service Testing: For any patient that does not met the criteria for NO CHARGE Testing but still wants to know their Hepatitis C status. See "Hepatitis Fee for Services Chart" for cost.

Mailing Instructions:

The Office of Laboratory Services provides testing supplies ordered by using the DI Supply Requisition Form that is available on our website or by calling 304-558-3530. Packaging provided by OLS meets current Department of Transportation (DOT) and all other federal regulations.

Preparing Specimen(s) for Mailing:

Using mailing tubes:

a. Place blood tube(s) in the inner plastic container (maximum 8 tubes per container).
b. Make sure that two (2) absorbent pads are in the inner plastic container with the tubes.
c. Screw lid on plastic container.
d. Fold the DI requisition form in half, length-wise and wrap forms around the outside of the plastic container.
e. Place inner container and forms into outer cardboard container, screw lid on container, apply postage, and mail.

At this time, the Office of Laboratory Services does not supply return postage for the shipment of specimens. The facility is responsible for the cost to ship the container to us for testing. If your facility is interested in setting up a FedEx account with reduced state contract pricing, please contact us for more details.

NOTE: If your site is sending less than eight (8) tubes and concerned about the tubes 'rattling' around in the container during transport, we suggest adding some additional padding such as a paper towel to the inner container.

Should you have any questions or need any additional information, please contact the Diagnostic Immunology Section at 304-558-3530 extension 2405 or 2407. Our normal business hours are Monday through Friday from 8:00am to 4:30pm. OLS is closed on weekends and state holidays.