

Hepatitis B & C Serology Protocol for Submitting Specimens to the Office of Laboratory Services

Introduction to Hepatitis Program Guidelines:

Since 2009, the Office of Epidemiology and Prevention Services (OEPS), has provided free hepatitis B and C screening, through the Office of Laboratory Services (OLS), for patients seen in local health departments' STD clinics/services. This protocol provides serology assay definitions, screening criteria for hepatitis B and C in local health departments, submission classifications for hepatitis B and C and OEPS contact information.

Definition of Terms:

"Hepatitis" means inflammation of the liver and also refers to a group of viral infections that affect the liver. The most common types of viral hepatitis are Hepatitis A, Hepatitis B, and Hepatitis C.¹

"Assay" means analysis (as of an ore, drug *or in this case blood sample*) to determine the presence, absence, or quantity of one or more components; *also*: a test used in this analysis.²

Overview of Testing offered through OLS:

Hepatitis A Virus (HAV)- Note: *Screening is confined to outbreak investigations only.*

HAV-IgM assay is used to determine acute HAV infection.

- Only specimen submitted for outbreak investigation and approved by Division of Infectious Disease Epidemiology (DIDE) will be tested.
- DIDE's phone number is 304-558-5358.

Hepatitis B Virus (HBV)

- **Hepatitis B Screen** – includes the following serology assays:
 - The HBsAg assay is used to determine if the patient has been exposed to the hepatitis B virus. The presence of HBsAg indicates that a person is infectious regardless of whether the infection is acute or chronic.
 - The HBcAb assay determines the presence of anti-HBc which indicates previous or ongoing infection with hepatitis B virus (HBV) in an undefined time frame.
 - If one or both assays are positive, further testing is performed to determine acute or recent HBV infection status.
- **Hepatitis Post Vac** (HBsAb also known as anti-HBs, post vaccine testing or titer testing)
 - The presence of anti-HBs is generally interpreted as indicating recovery and immunity from HBV infection.
 - Anti-HBs will also develop in a person who has been successfully vaccinated against hepatitis B.

¹ <http://www.cdc.gov/hepatitis/index.htm>

² <http://www.merriam-webster.com/dictionary/assay>

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Hepatitis C Virus (HCV)

- **Hepatitis C Antibody (also known as anti-HCV)**
 - The anti-HCV assay detects hepatitis C antibody and is interpreted as a positive screening test.
 - A signal to cut off ratio (s/co) is also reported. This s/co indicates if additional testing should be performed on the patient to further determine their hepatitis C status.
 - For additional information on s/co please follow the link to the CDC's Hepatitis C for Health Professionals page at <http://www.cdc.gov/hepatitis/HCV/LabTesting.htm> or contact the Diagnostic Immunology Section at the Office of Laboratory Services.

Program Screening Criteria for Hepatitis B and C Testing:

Local health departments are permitted to offer hepatitis B and C screening through their STD clinics or through STD services by following the hepatitis B and C screening criteria listed below.

NOTE: A separate submission form must be completed for hepatitis B and hepatitis C.

Hepatitis B Screen:

The patient **must** have one or more of the following four bolded risk factors for HBV transmission within the past 12 months to qualify for no cost hepatitis B screening:

- **multiple sex partners**
- **IV drug use**
- **body piercing (non-commercial facility)**
- **tattoo (non-commercial facility)**
- Also mark any other listed risk factors the patient has had within the last 12 months.
- Patients must wait 3 months, after their last test was reported, before they can be retested for hepatitis B.

If a bolded risk factor is not marked, the submitter will be billed for the test(s).

HEPATITIS INFORMATION - RISK FACTORS (R. F.)			
For Hepatitis B testing - patient must have at least one of the bolded risk factors to be eligible for Hepatitis B testing. Then mark all risk factors for hepatitis B. All R.F. should have occurred within the past 12 months. For Hepatitis C testing- mark if patient EVER had a history of any of the listed risk factors. One form for Hepatitis B and One form for Hepatitis C			
<input checked="" type="checkbox"/>	BODY PIERCING (NON-COMMERCIAL)	<input type="checkbox"/>	MULTIPLE PARTNERS
<input type="checkbox"/>	IV DRUG USER	<input checked="" type="checkbox"/>	TATTOO (NON-COMMERCIAL)
<input type="checkbox"/>	Blood transfusions	<input checked="" type="checkbox"/>	Illicit non-IV drug use
<input type="checkbox"/>	Healthcare worker	<input type="checkbox"/>	Needle stick/blood splash
<input type="checkbox"/>	Hemodialysis	<input type="checkbox"/>	Pregnant (due date _____)
<input type="checkbox"/>	History of incarceration	<input type="checkbox"/>	Sexual contact
<input type="checkbox"/>	Household contact	<input checked="" type="checkbox"/>	Symptoms / Diagnosis of STD

Hepatitis B Post-Vac (titer):

A post-vac is NOT part of a routine hepatitis B screen and should not be requested, unless:

- the specimen submission is part of a hepatitis B investigation and has been prior approved by Division of STD, HIV and Hepatitis (DSHH); or
- the post-vac is being offered to a contact of a HBV positive patient and is deemed necessary by DSHH.

DSHH will electronically notify the OLS when specimens have been approved for testing (see the Specimen Submission Process for more information).

NOTE: Post-vac test may be submitted to OLS, without prior approval from Division of STD, HIV and Hepatitis (DSHH), if it is a fee for service test. For more information contact the DSHH.

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Hepatitis C

The patient must have at least one risk factor marked to qualify for no cost testing.

- Mark any listed risk factors that are appropriate.
- Hepatitis C risk factors are based across the patients' life span (the risk could have occurred at any time)
- Patients must wait 3 months, after their last test was reported, before they can be retested for hepatitis C.

HEPATITIS INFORMATION -RISK FACTORS (R. F.)	
For Hepatitis B testing - patient must have at least one of the bolded risk factors to be eligible for Hepatitis B testing. Then mark all risk factors for hepatitis B. All R.F. should have occurred within the past 12 months. For Hepatitis C testing- mark if patient EVER had a history of any of the listed risk factors. One form for Hepatitis B and One form for Hepatitis C	
<input type="checkbox"/> BODY PIERCING (NON-COMMERCIAL)	<input type="checkbox"/> MULTIPLE PARTNERS
<input type="checkbox"/> IV DRUG USER	<input type="checkbox"/> TATTOO (NON-COMMERCIAL)
<input type="checkbox"/> Blood transfusions	<input type="checkbox"/> Illicit non-IV drug use
<input type="checkbox"/> Healthcare worker	<input type="checkbox"/> Needle stick/blood splash
<input type="checkbox"/> Hemodialysis	<input type="checkbox"/> Pregnant (due date _____)
<input type="checkbox"/> History of incarceration	<input checked="" type="checkbox"/> Sexual contact
<input checked="" type="checkbox"/> Household contact	<input type="checkbox"/> Symptoms / Diagnosis of STD

How to complete the Submission Form:

All specimens submitted to the OLS for hepatitis screening must be classified according to the five patient types described below:

1. **Employee** – is classified as an individual who:
 - is an employee of the provider performing the test, and/or
 - is an employee of an agency that contracts with the local health department to perform the test.

In "Patient Type" section mark **employee** and mark "Fee for Service" in the "Program Type" box.

Submitter will be billed for test(s).

PATIENT TYPE(for Hepatitis Testing only)	
<input checked="" type="checkbox"/> Employee	<input type="checkbox"/> Medically Indigent
<input type="checkbox"/> Patient	<input type="checkbox"/> Investigation
PROGRAM TYPE (Select ONE Only):	
<input type="checkbox"/> APC	<input type="checkbox"/> Jail / Prison
<input type="checkbox"/> College / University -FP	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> College / University -STD	<input type="checkbox"/> Project # _____
<input type="checkbox"/> Family Planning	<input type="checkbox"/> STD Clinic/STD Services
<input checked="" type="checkbox"/> Fee for Services	<input type="checkbox"/> TB Clinic
<input type="checkbox"/> Hospital	

2. **Medically indigent** – is classified as an individual who does not have health insurance or is not eligible for other health care coverage such as Medicaid, Medicare, or private health insurance.

Hepatitis B:

- Individual must have one or more of the following risk factors for HBV transmission, within the past 12 months:
 - **history of multiple sex partners;**
 - **injection drug users (IDUs);**
 - **tattoo(s) from a non-commercial facility and/or;**
 - **body piercing(s) from a non-commercial facility.**
 - If appropriate, mark any other listed risk factors (Must be within the past 12 months)

Hepatitis C

- Mark all listed risk factors that are appropriate
- Unlike hepatitis B, risk factors for hepatitis C are based across the patients' life span

PATIENT TYPE(for Hepatitis Testing only)	
<input type="checkbox"/> Employee	<input checked="" type="checkbox"/> Medically Indigent
<input type="checkbox"/> Patient	<input type="checkbox"/> Investigation
HEPATITIS INFORMATION -RISK FACTORS (R. F.)	
For Hepatitis B testing - patient must have at least one of the bolded risk factors to be eligible for Hepatitis B testing. Then mark all risk factors for hepatitis B. All R.F. should have occurred within the past 12 months. For Hepatitis C testing- mark if patient EVER had a history of any of the listed risk factors. One form for Hepatitis B and One form for Hepatitis C	
<input type="checkbox"/> BODY PIERCING (NON-COMMERCIAL)	<input type="checkbox"/> MULTIPLE PARTNERS
<input checked="" type="checkbox"/> IV DRUG USER	<input type="checkbox"/> TATTOO (NON-COMMERCIAL)
<input type="checkbox"/> Blood transfusions	<input checked="" type="checkbox"/> Illicit non-IV drug use
<input type="checkbox"/> Healthcare worker	<input type="checkbox"/> Needle stick/blood splash
<input type="checkbox"/> Hemodialysis	<input type="checkbox"/> Pregnant (due date _____)
<input type="checkbox"/> History of incarceration	<input checked="" type="checkbox"/> Sexual contact
<input type="checkbox"/> Household contact	<input type="checkbox"/> Symptoms / Diagnosis of STD

Division of STD, HIV and Hepatitis

350 Capitol Street, Room 125,
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- Patients must wait 3 months, after their last test was reported, before they can be retested for hepatitis C.

HEPATITIS INFORMATION -RISK FACTORS (R. F.)	
For Hepatitis B testing - patient must have at least one of the bolded risk factors to be eligible for Hepatitis B testing. Then mark all risk factors for hepatitis B. All R.F. should have occurred within the past 12 months. For Hepatitis C testing- mark if patient EVER had a history of any of the listed risk factors. One form for Hepatitis B and One form for Hepatitis C	
<input type="checkbox"/> BODY PIERCING (NON -COMMERCIAL)	<input type="checkbox"/> MULTIPLE PARTNERS
<input type="checkbox"/> IV DRUG USER	<input type="checkbox"/> TATTOO (NON-COMMERCIAL)
<input type="checkbox"/> Blood transfusions	X Illicit non-IV drug use
<input type="checkbox"/> Healthcare worker	X Needle stick/blood splash
<input type="checkbox"/> Hemodialysis	<input type="checkbox"/> Pregnant (due date _____)
X History of incarceration	X Sexual contact
<input type="checkbox"/> Household contact	X Symptoms / Diagnosis of STD

In "Patient Type" section mark *medically indigent* and leave "Program Type" blank.

PATIENT TYPE (for Hepatitis Testing only)	
<input type="checkbox"/> Employee <input checked="" type="checkbox"/> Medically Indigent <input type="checkbox"/> Patient <input type="checkbox"/> Investigation	
PROGRAM TYPE (Select ONE Only):	
<input type="checkbox"/> APC	<input type="checkbox"/> Jail / Prison
<input type="checkbox"/> College / University -FP	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> College / University -STD	<input type="checkbox"/> Project # _____
<input type="checkbox"/> Family Planning	<input type="checkbox"/> STD Clinic/STD Services
<input type="checkbox"/> Fee for Services	<input type="checkbox"/> TB Clinic
<input type="checkbox"/> Hospital	

Specimen Submission Process

- Before submitting a specimen for hepatitis screening using "medically indigent" as the patient type, the provider **must** receive prior approval from either the:
 - Hepatitis B Epidemiologist
 - Adult Viral Hepatitis Prevention Coordinator
 - Director of the STD, HIV and Hepatitis Division
 - or the State Epidemiologist
- If one of the officials listed above determines the patient is medically indigent, with risk factors, then the DSHH will notify the OLS of the patient's status and screening will be conducted. The DSHH will email the OLS and the requesting local health department
 - the name of the patient
 - his/her date of birth
 - and the name of the person who requested the test.
- Local health departments must write the name of the person who approved the screening in the Patient ID box (in top left corner of Diagnostic Immunology Laboratory Specimen Submission Form).
- The OLS will verify the approval by matching the name submitted in the email from the DSHH with the name that appears in the Patient ID box.

If any of the information does not correspond, the submitter will be billed for the test(s).

IMPORTANT:

- **Ensure the correct "Patient Type" is selected before submitting the Diagnostic Immunology Laboratory Specimen Submission Form and specimen to the OLS. If medically indigent is not marked in the "Patient Type" section the submitter will be billed for the test(s).**

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- *If the OLS receives a Diagnostic Immunology Laboratory Specimen Submission Form with medically indigent selected and prior approval is not received from the DSHH, the submitter will be billed for the test(s).*

3. **Fee for Service Patient** - is classified as an individual who receives care from the local health department or a medical provider who offers for a fee:

- a hepatitis B screen;
- hepatitis Post-Vac screening for their patients

In "Patient Type" section mark *patient* and mark *Fee for Services* in the "Program Type" Section.

PATIENT TYPE(for Hepatitis Testing only)	
<input type="checkbox"/> Employee <input type="checkbox"/> Medically Indigent <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Investigation	
PROGRAM TYPE (Select ONE Only):	
<input type="checkbox"/> APC	<input type="checkbox"/> Jail / Prison
<input type="checkbox"/> College / University -FP	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> College / University -STD	<input type="checkbox"/> Project # _____
<input type="checkbox"/> Family Planning	<input type="checkbox"/> STD Clinic/STD Services
<input checked="" type="checkbox"/> Fee for Services	<input type="checkbox"/> TB Clinic
<input type="checkbox"/> Hospital	

All fees for service tests will be billed to the provider submitting the specimen.

4. **STD Clinic Patient** – is classified as an individual who receives care through a local health department’s STD Clinic / STD Services and can receive:

- a hepatitis B screen, and/or;
- a hepatitis C antibody screen.

In "Patient Type" section mark *patient* and in "Clinic Type" section mark *STD Clinic/Services*.

PATIENT TYPE(for Hepatitis Testing only)	
<input type="checkbox"/> Employee <input type="checkbox"/> Medically Indigent <input checked="" type="checkbox"/> Patient <input type="checkbox"/> Investigation	
PROGRAM TYPE (Select ONE Only):	
<input type="checkbox"/> APC	<input type="checkbox"/> Hospital
<input type="checkbox"/> College / University -FP	<input type="checkbox"/> Jail / Prison
<input type="checkbox"/> College / University -STD	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> Family Planning	<input type="checkbox"/> Project # _____
<input type="checkbox"/> Fee for Services	<input checked="" type="checkbox"/> STD Clinic/STD Services

If risk factors are not marked correctly on the OLS submission form the submitter will be billed for the test(s).

5. **Investigation** – is classified as an individual who is identified through case investigation by local health departments, DIS or the Hepatitis B Epidemiologist, as a sexual, and/or needle sharing, and/or household contact of a positive HBsAg, HBcAb IgM, HBeAg and/or HBV DNA.

- With prior approval, from the DSHH, positive hepatitis B patients may be retested to determine their chronic status.

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- If deemed necessary by the DSHH, Hepatitis Post-Vac may be offered to the contacts of HBV positive patients.

In "Patient Type" section mark *investigation* and in "Clinic Type" section mark *STD Clinic/Services*.

PATIENT TYPE (for Hepatitis Testing only) <input type="checkbox"/> Employee <input type="checkbox"/> Medically Indigent <input type="checkbox"/> Patient <input checked="" type="checkbox"/> Investigation	
PROGRAM TYPE (Select ONE Only):	
<input type="checkbox"/> APC	<input type="checkbox"/> Hospital
<input type="checkbox"/> College / University -FP	<input type="checkbox"/> Jail / Prison
<input type="checkbox"/> College / University -STD	<input type="checkbox"/> Juvenile Detention Center
<input type="checkbox"/> Family Planning	<input type="checkbox"/> Project # _____
<input type="checkbox"/> Fee for Services	<input checked="" type="checkbox"/> STD Clinic/STD Services

OEPS Contact Information

Office of Epidemiology and Prevention Services hepatitis consultation contact information:

(Please contact employees in the order listed below.)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Hepatitis B Epidemiologist | 304-558-2195
800-642-8244 (in WV)

Out of Office Phone 304-549-9589 |
| <ul style="list-style-type: none"> • Viral Hepatitis Prevention Coordinator | 304-558-2195
800-642-8244 (in WV) |
| <ul style="list-style-type: none"> • Director for Division of STD, HIV and Hepatitis | 304-558-2195
800-642-8244 (in WV) |
| <ul style="list-style-type: none"> • State Epidemiologist and Director for the Office of Epidemiology and Prevention Services | 304-558-5358
800-423-1271 (in WV) |

If you leave a message at a phone number, the message will not be picked up until the employee returns to the office or until the employee is capable of retrieving messages while in the field.

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