



April 26, 2019

Carolyn Wester, MD, MPH  
Director, Division of Viral Hepatitis  
Centers for Disease Control and Prevention  
Atlanta, GA

Re: Submission of Patient Specimens to CDC for Hepatitis A Testing

Dear Colleagues:

During the past three years, the United States has been experiencing widespread outbreaks of hepatitis A virus infections among at-risk populations, primarily: people who use drugs, people experiencing homelessness, and men who have sex with men. The Centers for Disease Control and Prevention is collaborating with state public health departments to characterize the genetic relatedness of hepatitis A virus (HAV) strains associated with these outbreaks to inform response efforts. To streamline laboratory testing during these outbreaks, CDC requests that states consider sending *only* those specimens that have tested positive for anti-hepatitis A IgM and meet any of the following criteria:

- Specimen from a case patient in a county that has not yet reported a hepatitis A case in an at-risk population;
- Specimen from a case patient who doesn't report any known risk factors or contact with at-risk populations (e.g., household or sexual contact, volunteering at a homeless shelter);
- Specimen from a case patient suspected to be associated with foodborne transmission;
- Archived/stored specimen from a patient who has died, and whose classification as an outbreak-related death requires nucleic acid testing beyond anti-HAV IgM-positivity; or
- Other patient specimens not meeting the above criteria that require nucleic acid testing or molecular characterization (*to be discussed on a case-by-case basis*).

#### **Specimen Submission**

- State health departments wanting to submit specimens meeting the above criteria to CDC for further testing are requested to contact CDC at [hepaoutbreaklab@cdc.gov](mailto:hepaoutbreaklab@cdc.gov) for prior approval.
- Once approved for submission:
  - Please follow instructions for 'Submitting Specimens to CDC' using test code CDC-10325 at <https://www.cdc.gov/laboratory/specimen-submission/detail.html?CDCTestCode=CDC-10325>, and
  - Complete CDC 50.34 specimen submission form as specified in the example with adding the priority status in the 'Brief Clinic Summary' section along with any additional information the state would normally include.

**Each specimen must receive prior approval based on above criteria. Specimens submitted without prior approval or that fall outside of the priority criteria listed may not be tested at CDC.**

Sincerely,

Carolyn Wester, MD, MPH  
Director, Division of Viral Hepatitis  
CDC

Enclosures

Complete section  
as indicated

Use dropdown listing  
for submitter  
information

Select the Specimen Origin to Begin the Form

HUMAN

CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN

LABORATORY EXAMINATION REQUESTED

Test order name: Hepatitis A Serology, NAT and Genotyping  
Test order code: CDC-10325  
Suspected Agent: Hepatitis A  
Date sent to CDC: MM/DD/YYYY  
At CDC, bring to the attention of:  
Amanda Poe

PATIENT INFORMATION

Patient Name: Last First MI Suffix  
Birth date: MM/DD/YYYY Case ID:   
Sex: Age: Age Units:   
Clinical Diagnosis:   
Date of onset: MM/DD/YYYY Pregnancy Status:   
Fatal: Date of Death: MM/DD/YYYY

Add patient  
information

STATE PHIL / NEW YORK CITY DEPARTMENT OF HEALTH & MENTAL HYGIENE /  
FEDERAL AGENCY / INTERNATIONAL INSTITUTION / PEACE CORPS

Name: (Laboratory Director or designee)

Prof: Last First MI Suffix Degree  
Institution name:   
Street address: Line 1 Line 2  
City ZIP Postal Code  
State Country  
Fax: Country Code Area Code Local Number (e.g. 630000) Institutional e-mail: stateemail@stateemail.st  
Point of Contact: (Person to be contacted if there is a question regarding this order)  
Phone: Country Code Area Code Local Number (e.g. 630000) POC e-mail:   
Patient ID: Alternative Patient ID:   
Specimen ID: Alternative Specimen ID:

SPECIMEN INFORMATION

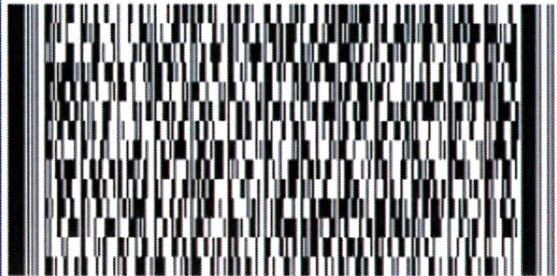
Specimen collected date: MM/DD/YYYY Time:   
Material Submitted: Original material  
Specimen source (type): Serum specimen  
Specimen source modifier:   
Specimen source site:   
Specimen source site modifier:   
Collection method:   
Treatment of specimen:   
Transport medium/Specimen preservative:   
Specimen handling: Frozen (Dry Ice)

CDC USE ONLY

Package ID#:   
Delivered to Unit #:   
Opened By:   
Unit Specimen ID#:   
Date received at CDC: / /   
Date received at STAT: / /   
Date received in testing lab: / / Time:   
Barcode 1

CDC Specimen  
Identification label

Condition	STAT Laboratory	Testing Laboratory
Outer Package		
Specimen Container		
Specimen		



ORIGINAL SUBMITTER (Organization that originally submitted specimen for testing)

Name: (Laboratory Director or designee)  
Prof: Last First MI Suffix Degree  
Institution name:   
Street address: Line 1 Line 2  
City ZIP Postal Code  
State Country  
Fax: Country Code Area Code Local Number (e.g. 630000) Institutional e-mail:   
Point of Contact: (Person to be contacted if there is a question regarding this order)  
Phone: Country Code Area Code Local Number (e.g. 630000) POC e-mail:   
Patient ID: Alternative Patient ID:   
Specimen ID: Alternative Specimen ID:

INTERMEDIATE SUBMITTER (Complete if specimen is submitted to SPHL through an intermediate agency)

Name: (Laboratory Director or designee)  
Prof: Last First MI Suffix Degree  
Institution name:   
Street address: Line 1 Line 2  
City ZIP Postal Code  
State Country  
Fax: Country Code Area Code Local Number (e.g. 630000) Institutional e-mail:   
Point of Contact: (Person to be contacted if there is a question regarding this order)  
Phone: Country Code Area Code Local Number (e.g. 630000) POC e-mail:   
Patient ID: Alternative Patient ID:   
Specimen ID: Alternative Specimen ID:

**CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN**

Patient Name:

\_\_\_\_\_  
Last First

AND/OR Original Patient ID:

\_\_\_\_\_

AND/OR SPHL Specimen ID:

\_\_\_\_\_

**PATIENT HISTORY**

**BRIEF CLINICAL SUMMARY** (include signs, symptoms, and underlying illnesses if known)

1 or 2 or 3 or 4 or 5 or 6

\_\_\_\_\_

**STATE OF ILLNESS**

- ☐ Symptomatic  
☐ Asymptomatic  
☐ Acute  
☐ Chronic  
☐ Convalescent  
☐ Recovered

**TYPE OF INFECTION**

- ☐ Upper respiratory  
☐ Lower respiratory  
☐ Cardiovascular  
☐ Gastrointestinal  
☐ Genital  
☐ Urinary tract  
☐ Other, specify \_\_\_\_\_
- ☒ Sepsis  
☐ Central nervous system  
☐ Skin/soft tissue  
☐ Ocular  
☐ Disseminated

**THERAPEUTIC AGENT(S) DURING ILLNESS**

Agent	Start Date	End Date
1. _____	____/____/____	____/____/____
2. _____	____/____/____	____/____/____
3. _____	____/____/____	____/____/____

**Add the following code for test criteria:**

**"1"** Specimen from a case in a county that has yet reported a hepatitis A case in an at-risk population

**"2"** Specimen from a case patient who doesn't report any known risk factors or contact with at-risk populations (e.g., household or sexual contact, volunteering at a homeless shelter)

**"3"** Specimen from a case patient suspected to be associated with foodborne transmission

**"4"** Archived/stored specimen from a patient who has died, and whose classification as an outbreak-related death requires nucleic acid testing beyond anti-HAV IgM-positivity

**"5"** Other patient specimens not meeting the above criteria that require nucleic acid testing or molecular characterization *(to be discussed on a case-by-case basis).*

**EPIDEMIOLOGICAL DATA**

**EXTENT**

- ☐ Isolated Case  
☐ Carrier  
☐ Contact  
☒ Outbreak  
☐ Family  
☐ Community  
☐ Healthcare-associated  
☐ Epidemic

**TRAVEL HISTORY**

Travel: \_\_\_\_\_ Dates of Travel: \_\_\_\_\_ to \_\_\_\_\_

Travel: Foreign (Country): \_\_\_\_\_ Travel: United States (State): \_\_\_\_\_

Foreign Residence (Country): \_\_\_\_\_ United States Residence (State): \_\_\_\_\_

**EXPOSURE HISTORY**

☐ Animal  
Common name: \_\_\_\_\_  
Scientific name: \_\_\_\_\_

☐ Arthropod  
Type of Exposure: \_\_\_\_\_  
Common name: \_\_\_\_\_  
Scientific name: \_\_\_\_\_

**RELEVANT IMMUNIZATION HISTORY**

Immunization(s)	Date Received
1. _____	____/____/____
2. _____	____/____/____
3. _____	____/____/____
4. _____	____/____/____

**PREVIOUS LABORATORY RESULTS** (Or attach copy of test results or worksheet)

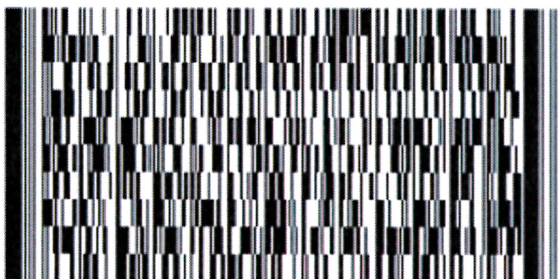
\_\_\_\_\_

**COMMENTS**

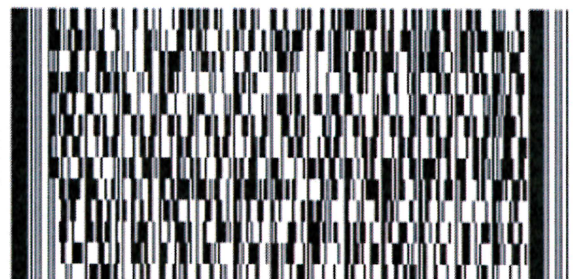
\_\_\_\_\_

CDC USE ONLY

Barcode 2



Barcode 3



The Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services, is authorized to collect this information, including the Social Security number (if applicable), under provisions of the Public Health Service Act, Section 301 (42 U.S.C. 241). Supplying the information is voluntary and there is no penalty for not providing it. The data will be used to increase understanding of disease patterns, develop prevention and control programs, and communicate new knowledge to the health community. Data will become part of CDC Privacy Act system 06-20-0108, "Specimen Handling for Testing and Related Data" and may be disclosed to appropriate State or local public health departments and cooperating medical authorities to deal with conditions of public health significance, to private contractors assisting CDC in analyzing and refining records; to researchers under certain limited circumstances to conduct further investigations; to organizations to carry out audits and reviews on behalf of HHS; to the Department of Justice in the event of litigation, and to a congressional office assisting individuals in obtaining their records. An accounting of the disclosures that have been made by CDC will be made available to the subject individual upon request. Except for permissible disclosures expressly authorized by the Privacy Act, no other disclosure may be made without the subject individual's written consent.

Please refer to the CDC Infectious Diseases Laboratories Test Directory for information on specimen requirements. CDC must maintain and document specific acceptance criteria to perform laboratory tests on samples obtained from humans pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accompanying regulations. 42 U.S.C. § 263a; 42 C.F.R. § 403.1241.

Samples transferred to the CDC for testing or any other purpose will become the legal property of the agency unless otherwise agreed upon in writing. Samples will not be returned to the submitting entity.