1.0 Purpose

1.1 This procedure provides instructions on how to ship non-clinical (non-CLIA) specimens collected as part of hepatitis outbreak and surveillance activities to the Division of Viral Hepatitis (DVH) Laboratory Branch for Global Hepatitis Outbreak and Surveillance Technology (GHOST) testing.

2.0 Scope

2.1.1 This procedure applies to senders of samples from local public health laboratories, state public health laboratories, healthcare facilities, and other federal agencies for analysis.

3.0 Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVH</td>
<td>Division of Viral Hepatitis</td>
</tr>
<tr>
<td>GHOST</td>
<td>Global Hepatitis Outbreak and Surveillance Technology used for genetic testing of specimens from Hepatitis A, Hepatitis B, and Hepatitis C outbreaks and surveillance</td>
</tr>
<tr>
<td>Personally identifiable information (PII)</td>
<td>Patient name, date of birth, medical identification record, or any other information that can link the patient to the sample submitted to CDC</td>
</tr>
<tr>
<td>Form 50.34</td>
<td>Form Required for submission of outbreak and surveillance specimens to CDC - DVH without any personally identifiable information (PII)</td>
</tr>
<tr>
<td>GFAT</td>
<td>Global File Accessioning Template for submission of outbreak and surveillance specimens to CDC - DVH without any personally identifiable information (PII). This form can be provided by the Laboratory Point of Contact upon request.</td>
</tr>
<tr>
<td>CSTOR</td>
<td>CDC Specimen Test Order and Reporting Web Portal - Specimen Submission Form</td>
</tr>
<tr>
<td>CDC Test Directory</td>
<td>Test Directory</td>
</tr>
</tbody>
</table>
### 4.0 Responsibility

<table>
<thead>
<tr>
<th>Position</th>
<th>Responsibility</th>
</tr>
</thead>
</table>
| **External Submitter** | • Email [hepatitislabrequest@cdc.gov](mailto:hepatitislabrequest@cdc.gov) to request viral hepatitis laboratory testing. Please include diagnosis, summary of clinical and epidemiological data about the patient in the email request to enable DVH staff to evaluate the appropriateness of laboratory testing for the public health investigation. Wait to receive approval from DVH laboratory staff via [hepatitislabrequest@cdc.gov](mailto:hepatitislabrequest@cdc.gov) prior to submitting specimens.  
• Follow procedures for proper storage and shipment of specimens according to CDC Test Directory Instructions for Test Order CDC-10531: [Test Order | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC](https://www.cdc.gov/vhf/hepatitis/lab/manuals/submitting-specimens.html)  
• Complete and submit CDC Specimen Submission Form 50.34 (for biological specimens), or GFAT, or through CSTOR for each clinical specimen submitted to CDC with NO PII information.  
• Include a copy of 50.34 or GFAT with shipment  

**NOTE:** Specimens submitted with personally identifiable information (PII) in the accompanying 50.34 form or GFAT will be rejected as outlined in section 5.1. Only specimen ID and demographic information outlined in 5.1.3.2 and 5.1.3.3 is required  |
| **DVH Epi Staff** | • Provides epidemiological consultation to the submitter, and if appropriate, refers the investigation for laboratory evaluation.  
• Any additional follow-up after test reports are shared with the specimen submitter  |
| **DVH LB Staff** | • Provide shipping guidelines to submitters  
• Provide customer support for specimen shipment (as needed) |
• Update the instructions for specimen shipment as needed to meet regulatory criteria, and notify the external submitters of any changes
• Determine final approval of specimens received to be accepted or rejected based on criteria detailed in section 5.1 and 5.2
• Reject specimens that do not meet shipment criteria outlined in the CDC Test Directory CDC-10531 and notify the submitter of the reason for rejection of specimens
• If appropriate, approves the investigation for laboratory evaluation and assigns an investigation code of the accepted specimen. Shares the approval and investigation code with DVH Epi and the submitter.
• Assign CDC specimen ID to accepted specimens, accessions and dispatches specimens submitted for NGS testing
• Test results disseminated to submitter, DVH Epi copied in the communication

5.0 Specimen Submission Procedure

5.1 Specimen Acceptance Criteria

5.1.1 CDC accepts submission of specimens from individuals previously diagnosed with viral hepatitis for non-CLIA testing from local public health laboratories, state public health laboratories (SPHL), Organ Procurement Organizations (OPO) facilities, healthcare facilities, and other federal agencies for analysis after the investigation is initiated through the appropriate epidemiologist.

5.1.2 The 50.34 or GFAT specimen submission forms* must include

5.1.2.1 Unique Laboratory Specimen ID assigned by the submitter (not Patient ID). This identifier can consist of any variation of numerical or alphanumeric characters

5.1.2.2 Information including – state/county, date of symptom onset, date of collection of specimen, age, sex, race, ethnicity, travel history, immunization status

5.1.2.3 In the comments section – include any associated risk factors (Food-borne, homelessness, healthcare associated,
Person who use drugs (PWUD), Men having sex with men (MSM, etc.)

5.1.2.4 If such data listed above are not available, this needs to be stated in the form as “Not Available”.

* Attachment of a sample 50.34 and GFAT is included for reference

Areas to be filled are highlighted in yellow on the 50.34 form, and areas that may contain PII that should not be filled are crossed through with a red line. The GFAT form has a screenshot of the information to be populated.

5.1.3 Specimen submitting laboratory has to ship samples in cryovials with the appropriate shipping documents (50.34 or GFAT). Ensure samples are stored at the appropriate temperature listed in the CDC Test Directory.

5.1.4 Ensure that frozen samples are shipped with enough dry ice to maintain -20°C or below until receipt at CDC.

5.2 Specimen Rejection Criteria

5.2.1 Specimen submitted with PII (patient name, date of birth, medical identification record) in the 50.34 or GFAT does not meet the acceptance criteria and will be rejected.

5.3 Shipping of Specimens to CDC

5.3.1 Please ONLY ship specimens on Mondays, Tuesdays or Wednesdays. Include enough dry ice to maintain a temperature of -20°C or below for at least 48 hours.

5.3.2 Follow CDC Test Directory instructions: Specimen Submission Form | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDCShipment should be by overnight express, on dry ice as “Clinical Specimens Category B”. Enough dry ice should be included to assure the specimens arrive at -20°C or colder. Include the paperwork with your samples: CDC Form 50.34 or GFAT

a) Shipping Address
   Attn: Unit 90
   Centers for Disease Control and Prevention
   1600 Clifton Road NE
   Atlanta, GA 30329
   404-639-3931; dsrstat@cdc.gov
5.4 Packaging Guidance

5.4.1 Determine the mode of transport for the package.
   a) Specimens should be shipped with overnight shipping
   b) Pack the specimen(s):
      The mode of transport and specimen classification determine the packing requirements. Submitters may reference IATA’s packing instructions.
   c) Regardless of classification, all specimen submissions must include:
      i) primary receptacle
      ii) secondary packaging
      iii) secondary container
      iv) rigid, outer packaging

6. Results interpretation and Reporting

6.1 CDC DVH LAB will provide test results from previously diagnosed individuals as a non-CLIA report to the point of contact from the external submitter for outbreak and surveillance activities only. Results cannot be used as a diagnostic result or for patient management.

6.2 Disclaimer:

   Test Order CDC-10531 – Hepatitis Surveillance – Surveillance report:
   The reported non-CLIA test results from previously diagnosed individuals are obtained using research-use only assays that have not been approved by FDA for clinical use and used for surveillance and outbreak purposes only and not as a diagnostic result. Results from these assays may only be used for surveillance and outbreak purposes. The results of these non-CLIA test should not be used for the clinical diagnosis, treatment, or assessment of patient health or management. This report is not diagnostic, and cannot used for clinical management purposes.

7.0 Attachments

7.1 Specimen submission form 50.34 for non-CLIA testing (sample template provided for reference)

7.2 Specimen submission GFAT for non-CLIA testing (sample template provided for reference)

Product Change History (Please include a summary of changes applied)

<table>
<thead>
<tr>
<th>Ver</th>
<th>Description</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>New Document. Drafted by: S. Ramachandran and T. Hayden</td>
<td>20April2023</td>
</tr>
</tbody>
</table>
Select the Specimen Origin to Begin the Form

LABORATORY EXAMINATION REQUESTED

Test order name: Hepatitis Surveillance
Test order code: CDC-10531
Suspected Agent: 
Date sent to CDC: 
At CDC, bring to the attention of: 

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

Name: (Laboratory Director or designee)
Dr Gilbert Leah MD
Institution name: CDC Occupational Health Clinic
Street Address: 1600 Clifton Rd
Building 16, Room 1105, Mailstop A-29
Atlanta, GA 30329
Zip 202 Postal Code
Georgia United States
Fax: 404 639-3166 DutyNurse@cdc.gov

PATIENT INFORMATION

Patient Name: ____________________________
Last Name: ____________________________
First Name: ____________________________
MI: ____________________________
Suffix: ____________________________
Birth date: ____________________________
Case ID: ____________________________
Sex: ____________________________
Age: ____________________________
Age Units: ____________________________
Race: ____________________________
White Black or African American Asian
American Indian and Alaska Native Native Hawaiian and Other Pacific Islander
Clinical Diagnosis: ____________________________
Date of onset: ____________________________
Pregnancy Status: ____________________________
Fatal: ____________________________
Date of Death: ____________________________

SPECIMEN INFORMATION

Specimen collected date: 04/11/2023
Time: ____________________________
Material Submitted: ____________________________
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: ____________________________

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: ____________________________
Condition STAT Laboratory Testing Laboratory
Barcode: ____________________________
Outer Package ____________________________
Specimen Container ____________________________
Specimen ____________________________

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

Name: (Laboratory Director or designee)
Prefix Last First MI Suffix Degree
Institution name: ____________________________
Street Address: ____________________________
Zip 202 Postal Code
State Country
Fax: ____________________________

Point of Contact: (Person to be contacted if there is a question regarding this order)
Prefix Last First MI Suffix Degree
Phone: ____________________________

ORIGINAL SUBMITTER (Organization that originally submitted specimen for testing)

Name: (Laboratory Director or designee)
Prefix Last First MI Suffix Degree
Institution name: CDC Occupational Health Clinic
Street Address: 1600 Clifton Rd
Building 16, Room 1105, Mailstop A-29
Atlanta, GA 30329
Zip 202 Postal Code
Georgia United States
Fax: 404 639-3166 DutyNurse@cdc.gov

Point of Contact: (Person to be contacted if there is a question regarding this order)
Prefix Last First MI Suffix Degree
Phone: ____________________________

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

Name: (Laboratory Director or designee)
Prefix Last First MI Suffix Degree
Institution name: ____________________________
Street Address: ____________________________
Zip 202 Postal Code
State Country
Fax: ____________________________

Point of Contact: (Person to be contacted if there is a question regarding this order)
Prefix Last First MI Suffix Degree
Phone: ____________________________

ORIGINAL SUBMITTER (Organization that originally submitted specimen for testing)

Name: (Laboratory Director or designee)
Prefix Last First MI Suffix Degree
Institution name: CDC Occupational Health Clinic
Street Address: 1600 Clifton Rd
Building 16, Room 1105, Mailstop A-29
Atlanta, GA 30329
Zip 202 Postal Code
Georgia United States
Fax: 404 639-3166 DutyNurse@cdc.gov

Point of Contact: (Person to be contacted if there is a question regarding this order)
Prefix Last First MI Suffix Degree
Phone: ____________________________

CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN
Version 4.2.21-e - Expiration Date 12/8/2023

Public reporting burden of this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, looking for and assembling the data needed, and completing and submitting the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB Control Number. Send comments regarding this burden estimate or any other aspect of this form, including suggestions for reducing this burden, to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333: ATTN: PRA 0920-1309.
**Patient Name:**

<table>
<thead>
<tr>
<th>Last</th>
<th>First</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AND/OR Original Patient ID</th>
<th>AND/OR SPHL Specimen ID</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**PATIENT HISTORY**

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

**STATE OF ILLNESS**

- [ ] Symptomatic
- [ ] Asymptomatic
- [ ] Acute
- [ ] Chronic
- [ ] Convalescent
- [ ] Recovered

**TYPE OF INFECTION**

<table>
<thead>
<tr>
<th>Upper respiratory</th>
<th>Lower respiratory</th>
<th>Cardiac/muscular</th>
<th>Gastrointestinal</th>
<th>Genital</th>
<th>Urinary tract</th>
<th>Skin/soft tissue</th>
<th>Ocular</th>
<th>Joint/bone</th>
<th>Disseminated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**THERAPEUTIC AGENT(S) DURING ILLNESS**

<table>
<thead>
<tr>
<th>Agent</th>
<th>Start Date</th>
<th>End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EPIDEMIOLOGICAL DATA**

**EXTENT**

- [ ] Isolated Case
- [ ] Carrier
- [ ] Contact
- [ ] Outbreak
  - [ ] Family
  - [ ] Community
  - [ ] Healthcare-associated
  - [ ] Epidemic

**TRAVEL HISTORY**

- Travel: Foreign (Countries)
- Travel: United States (States)
- Foreign Residence (Country)
- United States Residence (State)

**EXPOSURE HISTORY**

<table>
<thead>
<tr>
<th>Exposure:</th>
<th>Date of Exposure</th>
<th>Type of Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthropod</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**RELEVANT IMMUNIZATION HISTORY**

<table>
<thead>
<tr>
<th>Immunization(s)</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**COMMENTS**

Include risk factors - food-borne, homelessness, healthcare associated, Person who use drugs (PWUD), Men having sex with men (MSM, etc.).

*PII (patient name, date of birth, case ID, patient ID, medical identification record) details are not to be entered.*
GFAT for GHOST sequencing submission (non-CLIA testing):
Specimens submitted with PII (patient name, date of birth, medical identification record) in GFAT does not meet the acceptance criteria and will be rejected.

Information in the GFAT columns are required by All entities submitting specimens for sequencing of cases that are previously diagnosed with hepatitis.
Risk factors if available include - food-borne, homelessness, healthcare-associated factors, Person who use drugs (PWUD), men having sex with men (MSM).

<table>
<thead>
<tr>
<th>Lab Name</th>
<th>Sample name</th>
<th>Date of sample collection</th>
<th>Date of symptom onset</th>
<th>Age</th>
<th>Gender</th>
<th>Race</th>
<th>Ethnicity</th>
<th>Travel History</th>
<th>Immunosatation status</th>
<th>other clinical reports</th>
<th>Previous diagnosis of hepatitis</th>
<th>Exposure history</th>
<th>Sample setting</th>
<th>Sample type</th>
<th>Risk factor</th>
<th>Other comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>