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

Term	Definition
DVH	Division of Viral Hepatitis
GHOST	Global Hepatitis Outbreak and Surveillance Technology used for genetic testing of specimens from Hepatitis A, Hepatitis B, and Hepatitis C outbreaks and surveillance
Personally identifiable information (PII)	Patient name, date of birth, medical identification record, or any other information that can link the patient to the sample submitted to CDC
Form 50.34	Form Required for submission of outbreak and surveillance specimens to CDC - DVH **without any personally identifiable information (PII)** Specimen Submission Form | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC
GFAT	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.
CSTOR	CDC Specimen Test Order and Reporting Web Portal -Specimen Submission Form | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC
CDC Test Directory	Test Directory | Submitting Specimens to CDC | Infectious Diseases Laboratories | CDC

4.0 Responsibility

Position	Responsibility
External Submitter	• Email 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 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 • 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)

Ver	Description	Effective Date
	New Document. Drafted by: S. Ramachandran and T. Hayden	20April2023

Select the Specimen Origin to Begin the Form

HUMAN

Form Approved | OMB Control No.: 0920-1309 | Expiration Date: 11/30/2023

CDC SPECIMEN SUBMISSION FORM: SPECIMENS OF HUMAN ORIGIN

LABORATORY EXAMINATION REQUESTED

Additional form(s)/Info required

Test order name: Hepatitis Surveillance

Test order code: CDC-10531

Suspected Agent:

Date sent to CDC:

At CDC, bring to the attention of:

PATIENT INFORMATION

~~Patient Name:~~

~~Last~~ | ~~First~~ | ~~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: _____

CDC Specimen Identification label

Barcode 1	Condition	STAT Laboratory	Testing Laboratory
	Outer Package		
	Specimen Container		
	Specimen		

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

Name: (Laboratory Director or designee)

Prefix: Dr | Last: Gilbert | First: Leah | MI: | Suffix: | Degree: MD

Institution name: CDC Occupational Health Clinic

Street Address: Line 1: 1600 Clifton Rd

Line 2: Building 16, Room 1105, Mailstop A-29

City: Atlanta | ZIP Postal Code: 30329

State: Georgia | Country: United States

Fax: Country Code: 1 | Area Code: 404 | Local Number (e.g. 6390000): 639-3166 | Institutional e-mail: 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: Country Code | Area Code | Local Number (e.g. 6390000) | POC e-mail

~~Patient ID:~~ ~~Alternative Patient ID:~~

Specimen ID: Alternative Specimen ID:

ORIGINAL SUBMITTER (Organization that originally submitted specimen for testing)

Name: (Laboratory Director or designee)

Prefix | 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. 6390000) | Institutional e-mail

Point of Contact: (Person to be contacted if there is a question regarding this order)

Prefix | Last | First | MI | Suffix | Degree

Phone: Country Code | Area Code | Local Number (e.g. 6390000) | 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)

Prefix | 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. 6390000) | Institutional e-mail

Point of Contact: (Person to be contacted if there is a question regarding this order)

Prefix | Last | First | MI | Suffix | Degree

Phone: Country Code | Area Code | Local Number (e.g. 6390000) | 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)

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
- ☐ Joint/bone
- ☐ Disseminated

THERAPEUTIC AGENT(S) DURING ILLNESS

	Agent	Start Date	End Date
1			
2			
3			

EPIDEMIOLOGICAL DATA

EXTENT

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

TRAVEL HISTORY

Travel: | Dates of Travel: | to

Travel: Foreign (Countries) | Travel: United States (States)

Foreign Residence (Country) | United States Residence (State)

Note: Additional states or countries of residence or travel should be entered in the Brief Clinical Summary field.

EXPOSURE HISTORY

Exposure:

Date of Exposure:

☐ Animal — Type of Exposure:

Common Name:

Scientific Name:

☐ Arthropod — Type of Exposure:

Common Name:

Scientific Name:

RELEVANT IMMUNIZATION HISTORY

	Immunization(s)	Date Received
1		
2		
3		
4		

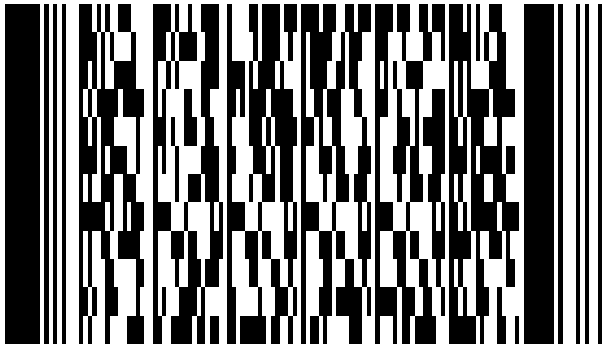
PREVIOUS LABORATORY RESULTS (Or attach copy of test results or worksheet)

COMMENTS

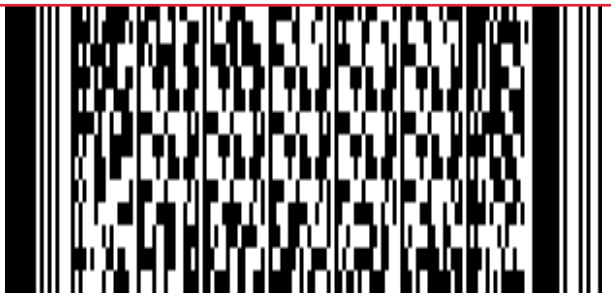
Include risk factors - food-borne, homelessness, healthcare associated, Person who use drugs (PWUD), Men having sex with men (MSM, etc.).
***PII (patient name, date of birth, case ID, patient ID, medical identification record)** details are not to be entered.

CDC USE ONLY

Barcode 2



Barcode 3



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)

Lab Name	Sample name	Date of sample collection	Date of symptom onset	Age	Gender	Race	Ethnicity	Travel History	Immnuziation status	other clinical reports	Previous diagnosis of hepatitis	Exposure history	Sample setting	Sample type	Risk factor	Other comments
	(assigned by testing lab)	(mm/dd/yyyy)		(mm/dd/yyyy)									(Outbeak/Surveillance)	(Acute/Chronic)		