



Protocol for Hepatitis A Genotyping

Specimen Collection and Storage and Transport

Background: In response to an increasing number of outbreaks of hepatitis A occurring in different at-risk groups in the U.S. and Europe, the CDC has requested the submission of specimens from confirmed cases for genotyping. The Tennessee Department of Health (TDH) requests that clinical laboratories **hold all anti-HAV IgM+ specimens for at least 14 days** to prevent disposal prior to case investigation by public health. Upon confirmation of a case of hepatitis A, local public health investigators will work with facilities to forward the specimen to TDH Laboratory Services. All submissions should be accompanied by appropriate documentation to ensure they can be tracked and results provided to local and regional health departments.

Blood (venous) specimen: *The preferred specimen is the initial anti-HAV IgM+ clinical specimen collected during the patient's acute illness.* The regional or state liaison should take quick action as soon as the case is confirmed to ensure that:

- The initial collected specimen from the hospital or healthcare provider is held at the clinical laboratory to prevent disposal.
- If initial specimen is unavailable or insufficient, another should be drawn within 14 days of the onset of acute symptoms. Collection instructions:
 - Acceptable specimens should be collected in either a serum separator tube (SST) or red top plain tube with no additive.
 - The specimen is centrifuged according to the laboratory's requirements and **serum** is transferred to a leak proof vial with a screw cap.
 - Minimum volume of 1.5 mL (*if possible, an additional vial can be collected to make sure the appropriate volume is collected for genotyping*).
 - Label leak proof vial with patient identifiers such as (*name, DOB*).
 - Complete documentation:
 - Clinical lab: TDH PH-4182 Clinical Submission Requisition Form
 - [PH-4182](#)
 - Regional public health and TDH Laboratory Services: CDC 50.34 Specimen Submission Form (*download and fill out electronically*)
 - [CDC 50.34 Specimen Submission Form](#)

Specimen Storage and Shipping Temperatures:

- Most clinical laboratories keep specimens for 7 days before disposing of them.
- Specimen can be refrigerated or frozen on site for 7-14 days (*will depend on reference lab*)
- Shipping temperature requirements:
 - If the specimen will arrive at the TDH Laboratory Services within 24 hours of collection, the specimen can be sent cold but unfrozen at 4°C.
 - If the specimen will arrive at TDH Laboratory Services more than 24 hours after collection, the specimen should be sent frozen to the State lab on dry ice (-70°C).

Specimen packaging and shipment:

- Ship specimens on Monday-Thursday to avoid weekend delivery to TDH Laboratory Services. Specimens can be shipped with required specimens for other reportable conditions: <https://www.tn.gov/health/cedep/reportable-diseases.html>
- A separate PH-4182 requisition should accompany each specimen sent to TDH Laboratory Services.
- The CDC 50.34 Specimen Submission Form is filled out electronically, printed and sent electronically to TDH Laboratory Services personnel: Linda Thomas (Linda.Thomas@tn.gov). A separate 50.34 specimen form should be completed and a hard copy printed and sent along with each submitted specimen (*include as much information as possible in the event a specimen is routed inappropriately*)
- Laboratories can send specimens alone or with a batch of other specimens to TDH Laboratory Services (*these specimens are not urgent because they are for genotyping, not clinical diagnosis*)
- Pack and submit specimens in accordance with shipping requirements for laboratories: Category 6.2-infectious substances <https://www.mass.gov/files/documents/2016/07/oe/div-6-2-infectious-substance-shipping-guide.pdf>
- Ship to the state lab via United States Postal Service (USPS) or FedEx, UPS, or courier delivery
- The shipping address is:

Tennessee Department of Health
Laboratory Services
c/o Immunoserology
630 Hart Lane
Nashville, TN 37216

CDC HAV genotype results:

TDH laboratory Immunoserology section will receive HAV genotype results which will be forwarded to Vaccine Preventable Disease staff in the TDH Immunization Program (Janice Johnson and Cassie Jones) with a copy to Dr. Fiscus. These central office staff will enter the results into REDCap.