



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2025-0321]

Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) announces a two-day convening hosted and facilitated by the Association of Public Health Laboratories (APHL) to discuss hepatitis C diagnostics. Leaders from public health, laboratory, medical, academic, and industry sectors will have the opportunity to provide individual input, without building a consensus, on accelerating the diagnosis of current hepatitis C virus (HCV) infection. Members of the public with interest and expertise in diagnosing HCV infection are also invited to provide individual input. Specifically, the convening will focus on how to leverage the following hepatitis C diagnostic methods: same-day diagnosis and treatment, and viral-first testing.

DATES: Written comments must be received on or before September 24, 2025.

Times: September 16, 2025, 2:00–5:30 p.m. EDT and September 17, 2025, 1:00–4:45 p.m. EDT.

To register for this virtual meeting on the public line (listen-only access), please use the following link: <https://webster.eventsair.com/hepatitis-2025-meeting/hcvattendee/Site/Register>.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2025-0321 by either of the methods listed below. **Do not submit comments by email. CDC does not accept comments by email.**

- Federal eRulemaking Portal: <http://www.regulations.gov> . Follow the instructions for submitting comments.
- Mail: Office of Policy and Communications, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS US12-3 Atlanta, GA 30329-4018.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> .

FOR FURTHER INFORMATION CONTACT: D’Angela T. Green, Office of Policy and Communications, Division of Viral Hepatitis, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, MS US12-3 Atlanta, GA 30329-4018, phone: 1 (404) 718-8539, email: dvhpolicy@cdc.gov.

SUPPLEMENTARY INFORMATION:

CDC announces a convening to discuss hepatitis C diagnostics. Interested parties are invited to provide public comment on regulations.gov in docket CDC-2025-0321 on or before September 24, 2025. The goal of the convening will be for each person to give their individual input, and not to build consensus. No discussions, recommendations, or advice to CDC will occur or be provided at the meeting. Day 1 will focus on the utility of point-of-care (POC) testing for accelerating same-day HCV diagnosis and rapid treatment initiation. Day 2 will focus on the utility of viral-first testing strategies for accelerating HCV diagnosis and treatment initiation in the United States. Following the meeting, APHL will prepare a meeting report summarizing the discussion and public comment received through regulations.gov, developed and documented as individual input to ensure thorough and complete input from partners. CDC and APHL will disseminate the APHL-prepared report as a reference for partners and industry to follow in

developing and implementing future hepatitis C testing strategies. The final report will be added to docket CDC-2025-0321 once it is available.

Background

More than 2.4 million adults in the United States are estimated to have hepatitis C virus (HCV) infection [Eric H, Hepatology 2024]. New infections continue to increase, primarily in association with injection drug use; nearly 69,000 cases of acute hepatitis C are estimated to have occurred in 2023 [CDC 2023 VH Surv Rpt]. More than half of new infections progress to chronic infection [Seo S, Clin Gastro Hepatol 2020]. Without treatment, HCV infection can lead to advanced liver disease, liver cancer, and death [Liang TF, Ann Intern Med 2000]. Since 2013, safe and effective treatment has been available that cures more than 95% of all treated persons, prevents future health complications, stops further transmission, and allows for the possibility of hepatitis C elimination [Falade-Nwulia O, Ann Intern Med 2017].

Testing is the first step to accessing life-saving treatment; however, about one-third of people with hepatitis C in the United States are unaware of their infection [Lewis KC, CID 2024]. The Centers for Disease Control and Prevention (CDC) recommends hepatitis C screening for all adults at least once, all pregnant women during every pregnancy, and all persons with risk for HCV infection, including periodic testing if risk persists [Schillie S, MMWR Recomm Rep 2020]. Current testing guidance for clinicians and laboratorians begins with a hepatitis C antibody (anti-HCV) test followed, when reactive, by a nucleic acid test to detect HCV RNA to diagnose current infection [CDC MMWR 2013]. Updated operational guidance was provided to ensure completion of the two-step approach using specimens collected during a single patient encounter. (Cartwright EJ, MMWR 2023)

A limitation of the antibody-first hepatitis C testing approach is that it takes an average of 7 to 8 weeks after HCV infection to develop a reactive HCV antibody (Abdel-Hamid M, Clin Micro 2002). Therefore, the current testing sequence fails to diagnose HCV infection in the window-

phase/early acute phase, within the initial months following infection, and among immunocompromised people who may have delayed seroconversion. Fortunately, advancements in the diagnostic and regulatory landscape have created an opportunity to improve hepatitis C testing. Currently, there are two tests for viral markers that identify current HCV infection: (1) real-time (RT) polymerase chain reaction (PCR) testing of HCV ribonucleic acid (RNA) detects virus within 1 to 2 weeks of infection (Gowda C, Clin Infect Dis 2020); and (2) HCV core antigen (HCVcAg) testing, currently approved outside of the United States, that uses an immunoassay to detect HCV core antigen within 2 to 3 weeks of infection (Sepulveda-Crespo D, Rev Med Virol 2023). Such virologic tests have become faster to perform and more accessible in a variety of care settings including closer to the point-of-care.

With CDC support, the Association of Public Health Laboratories (APHL) held a 2-day convening of key stakeholders and subject matter experts in October 2021 to identify high-priority diagnostic tools needed to advance diagnosis of current HCV infection and linkage to treatment in a range of clinical and nonclinical settings. The published meeting report called for the U.S. Food and Drug Administration (FDA) to reclassify HCV diagnostic tests from class III to class II, supported the availability of an FDA-cleared rapid CLIA-waived point-of-care (POC) HCV viral detection test, and encouraged CDC to review and update recommendations for HCV testing to identify current HCV infection, including testing sequences that detect HCV viral markers in the first step. (<https://www.aphl.org/aboutAPHL/publications/Documents/ID-HCV-2021-Meeting-Report.pdf>).

Subsequent to the APHL-led meeting:

In November 2021, the FDA reclassified hepatitis C diagnostic tests from class III devices to class II devices with special controls (510k). This action provided a new, lower-barrier opportunity for manufacturers to introduce new hepatitis C diagnostic tools for FDA review,

including tests that were available at that time outside of the United States, such as a nucleic acid test for HCV RNA detection in a point-of-care format and an assay for HCVcAg.

In January 2024, CDC affirmed existing viral-first testing recommendations among people with recent HCV exposure ().

In January 2024, CDC began the process of updating HCV testing guidance for clinicians and laboratorians, including evaluating testing strategies for the general population that include tests for viral markers in the first testing step (e.g., “viral-first”).

In June 2024, the FDA authorized an HCV RNA CLIA-waived near point-of-care test for the diagnosis of current HCV infection.

Public Participation

Public engagement will entail listen-only observation of information shared on day 1 and day 2. If members of the public have input on the questions asked during the meeting, those public comments can be submitted through *regulations.gov* using docket CDC-2025-0321 on or before September 24, 2025, and will be included in the final meeting report.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on <https://www.regulations.gov>. Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

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