COLLEGE of AMERICAN PATHOLOGISTS

September 24, 2025

Jim O'Neill
Acting CDC Director
Centers for Disease Control and Prevention
1600 Clifton Road MS US12-3
Atlanta, GA 30329-4018

Re: Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States [Docket No. CDC-2025-0321]

Dear Mr. O'Neill,

The College of American Pathologists (CAP) appreciates the opportunity to submit comments on **Establishing a Road Map for Accelerated Diagnosis and Treatment of HCV Infection in the United States** and looks forward to continuing engagement with the CDC on multiple aspects of diagnostics and public health to ensure sensible guidance for pathologists and the safety of patients. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, healthcare providers, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

After reviewing the request, the CAP has identified multiple aspects of Hepatitis C Virus (HCV) testing that should be considered when establishing a roadmap for accelerated diagnosis. The CAP applauds the CDC in working with the Association of Public Health Laboratories (APHL) to develop an accelerated timeline for diagnosis to reduce infections and transmission of HCV, as well as promote timely treatment.

Testing Landscape

Currently, approved hepatitis C antibody (anti-HCV) tests are reasonably priced and widely available allowing for patient access with rapid turnaround time (TAT). These tests are particularly crucial for diagnosing chronic infection, screening in a situation of exposure, or in high-risk individuals such as intravenous drug users. There is not an FDA-approved HCV core antigen (cAg) test which limits the type of testing available to Americans. There is a single FDA-approved point-of-care (POC) HCV ribonucleic acid (RNA) test on the market; however, it is not as widely available as anti-HCV tests.

Real-time polymerase chain reaction (PCR) testing of HCV RNA requires a laboratory equipped for molecular diagnostics; now the POC RNA test can be run in a more settings. When HCV RNA testing is indicated but not locally available, the samples must be sent to a reference laboratory for analysis. This mode of diagnostics can limit access for patients, delay results, and increase costs for testing. However, with the PCR testing of HCV RNA, the ability to catch an HCV infection earlier than with anti-HCV tests can also allow for more timely diagnosis and treatment of patients. Ultimately, the treating clinician should determine which test to use first depending on the patient's location and clinical history.

Self-collect Samples

Self-collection of samples for HCV testing may improve the number of individuals who are tested for HCV including those who live in underserved areas. This may allow for more testing to be available for individuals who have a difficult time accessing care. Self-collection of samples could increase the number of individuals tested and would not require staff with expertise in sample collection. Availability of FDA-cleared self-collect collection devices that collect samples compatible with validated laboratory test methods would be necessary to enable a self-collection strategy. The CAP believes that further studies to demonstrate the efficacy of self-collection for HCV testing and FDA approved medical devices to enable this strategy could improve access to HCV testing.

Necessary Confirmatory Testing

Currently, the CDC recommends a confirmatory HCV RNA test if an anti-HCV test is run first and is reactive. If only an anti-HCV test is completed and the result is reactive, then this is considered incomplete testing for HCV if there is no known history of HCV infection or prior test results to explain the reactive anti-HCV result. If the FDA approves an HCV cAg test, the CDC could consider eliminating confirmatory HCV RNA testing, as it would only be needed if the anti-HCV and HCV cAg test were discrepant. This combination of testing would raise confidence in the results and may reduce the need for further testing. While collecting and potentially testing additional samples is more costly, it is important to note that obtaining all necessary samples from a patient in a single visit reduces the need for patients to return to provide a second sample at a specimen collection site.

Conclusion

Overall, the CAP believes that accelerated testing for HCV will be beneficial to implement. However, further research on capabilities for molecular testing in laboratories should be conducted. In addition, access to approved POC HCV RNA tests should improve. Additionally, the CDC should develop guidance on self-collect samples if suitable collection devices and compatible test systems become available. Finally, if the FDA would approve an HCV cAg test, the CDC could eliminate confirmatory testing needs. This change could eliminate unnecessary, additional tests and specimen collections which would lower overall costs for patients and laboratories.

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The CAP appreciates the opportunity to comment and provide the pathologist's perspective regarding the acceleration of HCV diagnostics. Please contact Andrew Jackson, CAP Senior Policy Analyst, Scientific Regulatory Affairs Policy, at ajackso@cap.org if you have any questions on these comments.