



September 1, 2023

Department of Health and Human Services  
Food and Drug Administration  
The Center for Devices and Radiological Health (CDRH)  
Attn: Microbiology Devices Panel of the Medical Devices Advisory Committee

**Re: Evaluation of the current classification of hepatitis B testing and screening**

Dear Committee Members,

The members of Hep B United and other organizations listed below, are pleased to submit comments on how receiving a timely diagnosis positively impacts the trajectory and health outcomes of those impacted by the hepatitis B virus (HBV). This opportunity is exceptionally well-timed as numerous recent U.S. policy changes and action/elimination plans require improved access to hepatitis B diagnostic testing.

Hep B United is a national coalition of 54 organizations across 39 cities, 27 states, and Washington, D.C. We are dedicated to reducing the health disparities associated with HBV by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the United States. Most Hep B United partners are community-based organizations and local community coalitions providing culturally competent hepatitis B education, screening, vaccination, and linkage to care in underserved communities. We serve Asian American, Pacific Islander, Native Hawaiian, African immigrant communities as well as People Who Inject Drugs (PWID). In 2022 alone, Hep B United partners across the U.S. hosted over 400 educational events, reaching at least 22,000 people – and hosted 230 screening events, screening almost 6,700 people.

Currently, HBV screening involves a blood draw and laboratory-based diagnostics. This means multiple visits are needed to diagnose the disease. The communities we serve are difficult to reach and face numerous systemic and financial challenges to accessing hepatitis B services. Having a multi-step screening process that involves phlebotomy and returning to testing sites for results are significant barriers to screening high-risk individuals in the communities we serve, and often result in loss to follow-up. Additionally, the need for phlebotomy increases the cost of screening – paid for largely by grants – limiting the number of people our community partners can screen each year. Having access to point-of-care (POC) rapid diagnostic tests (RDT) would allow our partners to test more people each year in a much more cost-effective way. POC diagnostics would allow partners to provide screening and test results in one visit and simplify and improve navigation to follow-up care for those who need vaccines or are identified as infected. Ultimately, this will help more people with HBV access care and treatment to save their lives and make it so those at risk can access vaccination and prevent infection.

There are also specific situations in which POC rapid diagnostic tests would improve health outcomes at the intersection of current policies and national disease elimination strategies. Testing for hepatitis B is mandatory before starting someone on medication to treat or prevent HIV (PrEP), or to treat hepatitis C infection. On the ground, we unfortunately see gaps in screening for hepatitis B within the HIV and hepatitis C realms, and the lack of POC rapid diagnostic tests plays a role. As elimination plans progress in the U.S. for HIV and hepatitis C, POC rapid diagnostic tests will be critical for ensuring that people who are co-infected with hepatitis B are diagnosed and managed. There is a national goal for “one-stop” testing and initiation of treatment for HIV and hepatitis C, and this cannot be effectively implemented without rapid POC diagnostics for HBV.

Of the 2.4 million people in the U.S. living with chronic hepatitis B, only 25%-30% have been diagnosed. Diagnosis is the first critical step to ensuring that people with hepatitis B access care and treatment to reduce their risk of hepatitis B-associated cirrhosis and liver cancer<sup>1,2,3,4</sup>. There are no FDA-approved hepatitis B surface antigen (HBsAg) tests available in the U.S., which we believe has added to the current low diagnosis rates.

Recently, the Centers for Disease Control and Prevention (CDC) published [universal adult hepatitis B screening recommendations](#), which aligns with the [U.S. Department of Health and Human Services plan to eliminate hepatitis B in the U.S.](#) This new recommendation provides an ideal opportunity to improve hepatitis B diagnosis rates in the U.S., and *we strongly believe that hepatitis B POC rapid diagnostic tests are necessary to implement these recommendations*. POC RDTs will allow us to address current challenges and improve hepatitis B diagnosis across the U.S., to move infected people into life-saving care and treatment and play a critical role in reaching the goals of disease elimination plans.

To this end, we respectfully request that the Food and Drug Administration (FDA) consider the re-classification of hepatitis B testing and screening from the current class III to class II. This would encourage manufacturers of POC hepatitis B test kits to apply for approval in the U.S.

We thank you for the opportunity to provide these comments, and we look forward to hearing your thoughts and feedback.

Sincerely,

Chari Cohen, DrPH, MPH  
Co-Chair, Hep B United

Jeffrey Caballero, MPH  
Co-Chair, Hep B United

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<sup>1</sup>() Lim JK, Nguyen MH, Kim WR, Gish R, Perumalswami P, et al. (2020) Prevalence of chronic hepatitis B virus infection in the United States. *Am J Gastroenterol* 115: 1429-1438.

<sup>2</sup>() Wong RJ, Brosgart CL, Welch S, Block T, Chen M, Cohen C, Kim WR, Kowdley KV, Lok AS, Tsai N, Ward J, Wong SS, Gish RG. An Updated Assessment of Chronic Hepatitis B Prevalence Among Foreign-Born Persons Living in the United States. *Hepatology*. 2021 Mar 3. doi: 10.1002/hep.31782. Epub ahead of print.

<sup>3</sup>() Terrault NA, Lok ASF, McMahon BJ et al. Update on Prevention, Diagnosis, and Treatment of Chronic Hepatitis B: AASLD 2018 Hepatitis B Guidance. *Hepatology*. 2018; 67(4):1560-1599. doi:10.1002/hep.29800

<sup>4</sup>() Lok, A. S., & McMahon, B. J. (2001). Chronic hepatitis B. *Hepatology*, 34(6), 1225-1241. doi: S027091390141617X [pii] 10.1053/jhep.2001.29401.

## **On behalf of the following partners**

### **Hep B United Partners:**

African Health Coalition, IL  
American Liver Foundation, National  
Asian & Pacific Islander American Health Forum, National  
Asian American Community Services, OH  
Asian American Health Coalition (AAHC)/HOPE Clinic, TX  
Asian American Health Initiative, MD  
Asian American Network for Cancer Awareness, Research and Training, National  
Asian Center – Southeast Michigan  
Asian Health Coalition, IL  
Asian Pacific American Medical Student Association, National  
Asian Pacific Community in Action, AZ  
Asian Pacific Health Foundation, San Diego, CA  
Asian Pacific Partners for Empowerment, Advocacy and Leadership, National  
Asian Services in Action, Inc., OH  
Asian Women for Health, MA  
Association of Asian Pacific Community Health Organizations, National  
Center for Pan Asian Community Services, GA  
Charles B Wang Community Health Center, NY  
Community Welfare Services of Metro Detroit  
Dallas-Fort Worth Hep B Free  
HBI-Minnesota  
Hep B Free Las Vegas  
Hep B Free Los Angeles  
Hep B United - Philadelphia  
Hep B United Twin Cities/Lao Assistance Center of MN  
Hep Free Hawaii  
Hepatitis B Coalition of WA/International Community Health Services  
Hepatitis B Foundation, National  
Hepatitis B Initiative of Washington, DC  
Hepatitis Education Project, National  
HepAware Coalition, DE  
Illinois Public Health Association  
Immunization Action Coalition, National  
Immunize Colorado  
Intercultural Center for Health, Research & Wellness, TX  
Mercy Housing and Human Development, MS  
Midwest Asian Health Association, IL  
Minnesota Health Dept.  
Mongolian Community Health Network, IL  
NASTAD  
National Associations of Pasifika Organizations, AR  
National Foundation for Infectious Diseases, National  
National Task Force on Hepatitis B, national  
National Viral Hepatitis Roundtable, National  
New Jersey Hepatitis B Coalition/Robert Wood Johnson Barnabas Health

New York City Hepatitis B Coalition  
Northeast Medical Services, CA  
NYU Center for the Study of Asian American Health  
Ohio Asian American Health Coalition  
San Francisco Hep B Free – Bay Area  
Team HBV, national  
The Hep B Project Alameda County  
The University of Oklahoma Health Science Center  
Utah Hepatitis Coalition  
Vietnamese American Cancer Foundation, CA  
Virginia Tech APAMSA

**Others:**

AIDS United, national  
Asian Liver Center at Stanford University, CA  
Caring Ambassadors Program, National  
Center for Disease Analysis Foundation, CO  
Community Liver Alliance, National  
Community Vision Group  
Congoese Health Board of the Congoese Community of Washington State  
Great Lakes Peace Center, MI  
Hawai'i Health & Harm Reduction Center  
HIV+Hepatitis Policy Institute, National  
Kumukahi Health + Wellness, HI  
Mission Gastroenterology and Hepatology, CA  
Philadelphia Department of Public Health  
The Hepatitis C Allies of Philadelphia (HepCAP)  
Virginia Pharmacy Association

Literature Cited:

([1]) Lim JK, Nguyen MH, Kim WR, Gish R, Perumalswami P, et al. (2020) Prevalence of chronic hepatitis B virus infection in the United States. *Am J Gastroenterol* 115: 1429-1438.

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[doi:10.1002/hep.29800](https://doi.org/10.1002/hep.29800)

([1]) Lok, A. S., & McMahon, B. J. (2001). Chronic hepatitis B. *Hepatology*, 34(6), 1225-1241. doi: S027091390141617X [pii] 10.1053/jhep.2001.29401.