Request for Applications: Implementation or Expansion of Nucleic Acid Testing for Diagnosis of Hepatitis C Virus Infection

Application Due date: December 18, 2019, 5PM ET
Submit to: Anne Gaynor, Manager of HIV, viral Hepatitis, STD and TB (Anne.Gaynor@aphl.org)

Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention (CDC) Division of Viral Hepatitis (DVH), is seeking to award one-time funding for up to seven state or local public health laboratories (PHLs) for the purpose of establishing and/or enhancing nucleic acid testing (NAT) capacity for detection of hepatitis C virus (HCV) RNA for the diagnosis of current HCV infection according to the recommended CDC HCV Diagnostic Testing Algorithm.

Funds may be used for activities contributing to implementation or expansion of laboratory capacity for HCV RNA testing. Funding may be used for a variety of purposes including performing verification or validations studies to:

1) implement/adapt an FDA-approved HCV RNA method for diagnostic purpose,
2) transition from all or part of a manual protocol to automated method/s,
3) evaluate the feasibility of using alternate sample types such dried blood spots.

Additionally, laboratories may choose to use funds to modify current testing workflows (i.e. aliquoting samples on receipt or setting up automatic reflexing for HCV Ab positive samples directly to HCV RNA testing), update existing laboratory information management systems (LIMS), and add electronic laboratory reporting (ELR) messaging to streamline reporting and improve turnaround time of data to healthcare providers and other stakeholders. Funds may not be used to contract with an outside facility to provide testing services. If you include staff time, provide a clear justification for how their time applies to the proposed work. This one-time funding will be awarded via a contract with APHL.

Background

Following the discovery of HCV approximately 30 years ago, treat-to-cure HCV infection regimens became available in 2014. These treatment regimens based on direct antiviral agents (DAA) have been shown to achieve cure in >90% HCV infected individuals. With the availability of such efficacious DAAs
against hepatitis C, CDC updated its HCV testing guidelines in 2013 “Testing for HCV Infections: an Update of Guidance for Clinicians and Laboratorians” that emphasized the importance of identifying cases of current HCV infections in order to promptly link to and prevent further transmission and provided diagnostic testing recommendations. Specimens that are HCV antibody positive (anti-HCV) should be followed with a nucleic acid test (NAT) to detect HCV RNA. If HCV RNA is detected the person is considered to have current HCV infection and should be linked to care for clinical evaluation and treatment.

While this testing algorithm has been recommended since 2013, a 2017 survey of US public health laboratories (PHLs) about HIV and HCV testing practices indicated that while 95% of PHLs performing HCV testing offered a laboratory based HCV antibody immunoassay, only 43% of those (n=19) performed an HCV RNA method for diagnosis of HCV infection. In an effort to address this gap in HCV RNA testing APHL established an HCV NAT reference center in 2018. The reference center is meant to serve PHLs with a limited volume of samples requiring HCV NAT.

However, there continues to be a steady rise in the number of acute hepatitis C cases in the US based on the most recent 2017 surveillance data. These rises have been partially attributed to both the increased surveillance and the ongoing and increasing injection drug use related to the opioid crisis. Rates have increased rapidly for persons in the age groups most affected by the ongoing opioid crisis, persons aged 20-29 and 30-39 years from 2009-2018. Additional increases have been seen in adults aged 50-59 and >60 years between 2015 to 2017, coinciding with the push for screening this population for HCV infection and potentially reflecting increased surveillance and testing in that population.

In order to address the rising rates of hepatitis C cases and the need for complete diagnostic testing to link persons with current infection to treatment, APHL with CDC-DVH is excited to announce this one-time funding opportunity. The aim of this funding opportunity is to assist PHLs with an aspect of implementation or expansion of HCV RNA testing that is otherwise not feasible at this time.

**Eligibility**
All state or local US public health laboratories are eligible to apply for the one-time funding.

**Award**
Funding will be distributed via a contract administered by APHL. Up to seven laboratories, depending on strength of applications, funding requested, and funds available, will be selected. Award amounts will depend on the scope of the proposed project with an estimated award per site of $10,000-$20,000.

**Term of Project**
From date of contract signing (approximately January 1, 2020) through June 30, 2020. Please note that June 30, 2020 is a firm deadline for the funding; all proposed projects must be feasible to complete by that date. No exceptions can be granted with regards to this deadline. A final progress report will be
required as a final deliverable. We do anticipate funding projects with a small, feasible scope. Up to 80% of the proposed amount will be made available at the start of the project and 20% upon completion.

**Use of Funds**

Use of funds: Below are several examples of the types of activities that may be appropriate. You may also propose other activities as long as they are aimed at improving HCV diagnostics, not listed below.

- Purchase equipment or supplies necessary to implement an HCV RNA testing method
- Perform verification studies to implement new method or transition from one method to another
- Evaluate assays in order to expand testing services to include additional sample types
- Work with program to provide outreach to clinical laboratories and/or physicians on collection of appropriate clinical specimens
- Modify current testing workflows to enable more efficient HCV RNA testing and reporting
- Modify existing laboratory information management systems (LIMS), and electronic laboratory reporting (ELR) messaging to streamline reporting and improve turnaround time of data to healthcare providers and other stakeholders
- Implementation of third-party billing

**Note:** Funds may not be used to contract with an outside facility to provide testing services. If you include staff time, provide a clear justification for how their time applies to the proposed work.

**Request for Application**

In order to be considered for selection, an interested laboratory must submit a proposal that responds to the following questions. Responses should be limited to no more than five (5) double-spaced pages total (font size ≥ 11pt and page margins of ≥ 1 inch).

1. Provide a detailed description of how your laboratory intends to use the one-time funding to establish or improve existing HCV RNA testing capabilities and / or capacities. This should include up to three measurable, specific objectives that describe the intended impact of the funding to laboratory services and address sustainability given the one-time funding. Please limit your response to no more than four (4) single-spaced pages.

2. Provide a brief, line item budget reflecting the requested funding amount as outlined in the Award above. For each budget area (equipment, supplies, travel, training materials, etc.), provide a brief description of the intended procurements necessary to support the proposed activities. Please limit your response to no more than one (1) single-spaced page.