



# Request for Proposals: Expansion of Hepatitis C Virus (HCV) Nucleic Acid Testing (NAT)

Application Due date: May 15, 2017

Submit to: Anne Gaynor, Manager of HIV, viral Hepatitis STD and TB  
([Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org))

## Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention's (CDC) Division of Viral Hepatitis (DVH) is seeking to identify one state or local public health laboratory that will perform HCV NAT testing for public health laboratories in a regional shared service model.

## Background

From 2006-2010 there were around 800 new cases of hepatitis C virus (HCV) infections per year. Since that time the number of HCV infected cases continues to rise each year. The most recent data from 2014 estimated 30, 500 cases of hepatitis C with 2,194 cases being officially reported during that time frame. These numbers are expected to continue to rise as the main route of transmission is through injection drug use, which is also on the rise in the US. In 2013 the CDC published "[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. We are also now in an era that treat-to-cure regimens are available when a current HCV infection is identified.

The recommended testing algorithm for diagnosis of current HCV infection comes from the [2013 Guidance](#). All persons who test positive for an HCV antibody (anti-HCV) test should receive a HCV nucleic acid test (NAT) to detect HCV RNA. If HCV RNA is detected the case is considered to have current HCV infection and should be linked to care. HCV testing in the PHL system is limited according to the most recent [APHL survey](#), with only 61% (45/74) of responding PHLs offering any HCV testing. Of the laboratories performing any HCV testing, 42 (93%) offer conventional anti-HCV test, but only 11 (24%) provide either a qualitative or a quantitative HCV NAT test. For those patients with samples being

tested at PHLs for an anti-HCV test alone, is insufficient to diagnose current HCV infection and access to a cost-effective HCV NAT is necessary.

To determine the best approach to assist laboratories in expanding access to HCV NAT in a cost effective and timely manner, APHL is seeking proposals for test sharing models that would provide HCV NAT on qualified specimens (anti-HCV positive) to PHLs in neighboring jurisdictions.

The applicant must work with the neighboring jurisdictions to identify a feasible plan. It may be difficult to provide HCV NAT on all anti-HCV positive specimens in a certain jurisdiction without limiting it to certain patient populations. Therefore, this should be considered as part of the approach. The proposal may choose to limit qualified specimens based on specific risk factors or patient populations (e.g. corrections) and may explore other approaches to improve cost effectiveness. The applicant will be wholly responsible for identifying partnering jurisdictions, providing HCV NAT and reporting results to the jurisdictional partners throughout the project. The applicant will be responsible for updating APHL on a monthly, basis on testing volumes, turnaround times and any issues or challenges associated with the project execution.

This is a one-time funding mechanism that would provide an opportunity to explore expanded HCV NAT testing for one selected PHL. The selected site is encouraged to save HCV NAT positive specimens for potential future studies including next generation sequencing technology.

## Eligibility

Eligible laboratories include all member public health laboratories with the following capabilities and facilities in place. Specific expectations regarding methodologies to be used by the awardees are outlined in [Appendix A: Expectations for HCV](#). All applicants are required to agree to the following minimum requirements (as also outlined in [Appendix B: Expansion of HCV NAT Minimum Requirements](#)):

- Established capacity for diagnostic HCV NAT;

- Established capacity for providing testing for outside PHLs including data transfer and specimen receipt and processing; and

- Sufficient equipment, laboratory space and workforce capacity for the proposed workload

## Anticipated RFP Schedule

APHL anticipates the following schedule:

March 20, 2017	–	RFP Issued
April 15, 2017	–	Letter of Intent Due to APHL (see below)
<b>May 15, 2017</b>	–	<b>RFP Responses Due</b>
June 2, 2017	–	Proposal review completed

Please send the Letter of Intent (Due 4/15/17) and completed application (Due 5/15/17) to Anne Gaynor, [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org)

- |                 |   |   |
|-----------------|---|---|
| June 5-16, 2017 | – | If needed, follow-up interviews and updated proposals due               |
| June 21, 2017   | – | Final review completed and awardees selected                            |
| June 30, 2017   | – | Draft contracts submitted to APHL Legal Dept. for final internal review |

Any modification to this anticipated schedule will be communicated on APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)) and via an email blast to the public health laboratories (PHLs).

## Response Submittal

### Confirmation of Intent to Respond

APHL requests that prospective applicants submit a brief email statement indicating an intent to submit a proposal. This must be received by **5:00pm EST on April 15, 2017.**

### Final Response

APHL must receive complete responses by **5:00 pm EST, on May 15, 2017.** Please see [Proposal – Required Submissions](#) section for items that must be included in the completed proposal. Applicants may send proposals by the following methods:

Via email to [Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org) or

Via Mail (USPS, FedEx, UPS) addressed to:

Association of Public Health Laboratories

Attn: ANNE GAYNOR

8515 Georgia Avenue. Suite 700

Silver Spring, MD 20910

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, please email the RFP points of contact above to confirm receipt.

## Award

Funding will be distributed via a contract administered by APHL. The award is up to \$75,000.

## Term of Project

The project term will be from the date of notification through June 30, 2018. The contract will be from July 1, 2017 through June 30, 2018. APHL anticipates that from the date of notification to the start date of the contract the selected site will work with APHL to refine the proposal and ensure mechanisms are in place for specimen and data transfer from the submitting site to the testing facility. The potential for annual renewals (with each additional funding year running from July 1 to June 30) may be considered by APHL based on availability of funds and performance of the awardee for a maximum of two additional years. Each of the potential renewals may involve some adjustment to the scope of work in order to address any change in the funding received by APHL

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and to accommodate CDC programmatic needs in that funding year. The awardee would be notified in advance of any modification to the anticipated scope of work in a future funding year.

## Evaluation Team

APHL staff, led by the HHST Program Manager, will conduct an initial review of all proposals for completeness. Any incomplete application on the proposal due date specified in [Anticipated RFP Schedule](#) Section above will not be considered and will not receive a formal evaluation.

Complete proposals will be reviewed by a team of three subject matter experts (SMEs) from CDC DVH and a panel of three APHL members selected from non-applicant public health laboratories. SMEs from CDC will be identified and selected by the Branch Chief of the DVH Laboratory Branch based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant PHLs by the APHL HHST Program Manager and will have expertise in the laboratory testing methods described in this RFP and familiarity with APHL reference center structure.

APHL will ask potential reviewers to disclose any real or perceived conflict of interest prior to the start of the evaluation process or to affirm that they have no conflict of interest that would preclude an unbiased and objective review of the proposals received. APHL will not select reviewers with a perceived conflict of interest.

Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

## Evaluation Criteria

Proposals will be evaluated based on the responses to the questions in the [Proposal – Required Submissions](#) Section and will receive a numeric score of up to 100 maximum points based on the scorecard template in [Appendix C: HCV/GHOST Pilot Site RFP Score Card](#).

Laboratories will also be given preference based on more extensive experience with the test methods, ability to handle increased test volume for HCV, past experience with shared services, a more comprehensive shared service approach with multiple jurisdictions, ability to comply with expectations laid out in [Appendix A: Expectations for HCV](#) and ability to meet the minimum expectations outlined in [Appendix B: Expansion of HCV NAT Minimum Requirements](#).

## Evaluation Process

The entire review will be conducted via a combination of email communication between APHL's HHST Program Manager and the members of the evaluation team or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL's HHST Program Manager will coordinate the review process and the evaluation sessions.

The reviewers may request follow-up interviews with all or some of the applicant laboratories and, following these interviews, may request supplemental information on an applicant's proposal. These interviews and any supplemental information would clarify a laboratory's capacity or

experience in one or more of the evaluation criteria or to explain other information contained in an applicant's proposal.

There will be no formal evaluation performed by a member of APHL staff. In cases where all other evaluation criteria are substantially similar, APHL will have the ability to advise the evaluation team on selections that would provide geographical spread or otherwise diversify APHL's funding allocations. In addition, the evaluation team may receive documentation from APHL staff on an applicant's past performance in other capacities noted in this RFP as part of the evaluation criteria.

## Post-Evaluation Procedures

The selected laboratories will be notified by APHL staff within ten business days of the completion of the evaluation and the names of the three recipients will be posted to APHL's procurement website, [www.aphl.org/rfp](http://www.aphl.org/rfp) on the same day. Unsuccessful applicants will receive notification of these results by e-mail or by U.S. mail within 30 days of the date the name of the winning vendor is posted.

All applicant laboratories will be entitled to utilize APHL's RFP Appeals Process to formulate a protest regarding alleged irregularities or improprieties during the procurement process. Specific details of this policy are located on the procurement website.

## Conditions of Award Acceptance

The eligible laboratory must be able to contract directly with APHL or have an existing relationship with a third-party organization that can contract directly with APHL on behalf of the laboratory. Laboratories must agree to comply with expectations outlined in [Appendix A: Expectations for HCV](#).

The eligible laboratory must be able to receive specimens and report results to all submitting partners in the proposal.

Prior to making the official award, a group of individuals from CDC and APHL will be entitled to elect to tour the facilities to assess compliance with requirements for testing and/or have a teleconference with applicant laboratories. Post award, monitoring site visits may be conducted to include an assessment of continued compliance.

## Proposal – Required Submissions

To submit a proposal for consideration please respond to the following questions. Responses should be limited to no more than four (4) double-spaced pages (font size  $\geq$  11pt and page margins of  $\geq$  1 inch) and must comply with submission requirements set out in Additional Information and Deadlines for Application Submission Below.

1. **Please describe the laboratory’s current HCV testing practices including methodologies, algorithms, and average monthly volume.**
  - a. Provide the methods and algorithms in use and how long they have been used in the PHL
  - b. How often testing is performed and the average turnaround time from specimen receipt to reporting
  - c. Amount of experience laboratory staff have using the methodology described
  - d. Current average monthly volume and maximum volume that could be achieved for this project
2. **Please describe your proposal to provide HCV NAT testing using a shared service model including the following:**
  - a. Provide an overall summary of the approach
  - b. A list of all jurisdictional PHLs that would be included in the project and their estimated submission volume. Please also include documentation of their willingness to participate. **Note: A letter of support from the jurisdiction(s) would be the ideal documentation and can be included in an appendix to application and will not count against the page limit.**
  - c. A description of the process for sample receipt and delivery of results back to the submitting laboratory including estimated turnaround times including information about the test request form and potential reporting format.
  - d. A description of the requirements for a qualified specimen to be tested under the proposed model (e.g. specific patient risk factors, specimen storage requirements, specimen volume requirements, etc.).
3. **Please provide a budget for execution of the proposal**
  - a. The contract will be setup as a deliverable based contract with an initial payment, mid-term payment and final payment and will not be fee-based
  - b. If the applicant has discussed cost-sharing with other jurisdictional PHLs that will also contribute to the budget of this project this should be included as an additional source of income for the project

4. **Include a completed and signed copy of [Appendix B: Expansion of HCV NAT Minimum Requirements](#) as an attachment.**

## Additional Information and Deadlines for Application Submission

All questions should be directed to Anne Gaynor at [anne.gaynor@aphl.org](mailto:anne.gaynor@aphl.org). Questions received from interested PHLs, together with the answers provided by APHL or CDC staff will be posted to APHL's procurement website ([www.aphl.org/rfp](http://www.aphl.org/rfp)).

Applications should be submitted to Anne Gaynor at APHL ([Anne.Gaynor@aphl.org](mailto:Anne.Gaynor@aphl.org); 8515 Georgia Ave Suite 700, Silver Spring, MD, 20910; telephone: 240-485-2739; fax: 240-485-2700).

**Applications must be received at APHL, attention Anne Gaynor by close of business (5:00pm ET) May 15, 2017.** Either electronic or physical submission is acceptable. APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within 48 hours, call 240-485-2739 to confirm receipt.

## Appendix A: Expectations for HCV NAT Testing

### Methods

A Hepatitis C Virus Nucleic Acid Test FDA approved or CLIA-validated for use as a diagnostic assay to detect HCV RNA.

### Procurement

Supplies, Reagents and Equipment can be procured using the funding for this project. Each site will only be funded up to \$75,000 and allocation of those funds is at the discretion of the awarded sites.

### Data Management

The selected laboratory will maintain all diagnostic records for the testing and report results to the submitting laboratory in a timely manner.

### Performance Management and Evaluation

Performance will be monitored by timeliness of responses to CDC and APHL requests and successful transfer of a monthly summary of testing performed

### *Reports*

The laboratory will submit to APHL and CDC a monthly line listing of the samples tested and the following variables: unique identifier not linked to patient, date of shipment, date of receipt, NAT result, submitting jurisdiction and anti-HCV test used.

A mid-term and final report submitted to APHL discussing successes, challenges, impact and suggested approaches for sustainability will also be required.

### *Site visits and teleconferences*

APHL, CDC and the selected site will participate in monthly teleconferences to review monthly reports, assess successes and challenges and discuss potential resolutions.

## Appendix B: Expansion of HCV NAT Minimum Requirements

YES	NO	MINIMUM REQUIREMENT
		Does your laboratory have established capacity to perform HCV NAT?
		Does your laboratory have the established capacity for providing testing for outside PHIs including specimen receipt and processing and data transfer to report results?
		Does your laboratory have sufficient laboratory space and equipment for the testing volume proposed?
		Does your laboratory have sufficient workforce capacity for the testing volume proposed?

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name:

## Appendix C: HCV/GHOST Pilot Site RFP Score Card

The following table is a copy of the score card that will be used to evaluate RFP responses.

Category	Maximum Value	Score	Comments (REQUIRED)
<p>1. Does the applicant have sufficient capacity and experience to perform diagnostic HCV NAT testing?  <i>Excellent: Has performed HCV NAT testing for &gt;3 years, performs HCV NAT testing at least 1x per week, all staff is highly experienced in method (16-20); High: Has performed HCV NAT testing for 1-3 years, and performs HCV NAT testing at least 1x per week, most staff is experienced in method, (11-15); Moderate: Has performed HCV NAT testing for 1-3 years, and performs HCV NAT testing less than 1x per week, some staff is experienced in method (6-10); Limited: has performed HCV NAT testing &lt;1 year and/or performs HCV NAT testing less than 1x per week, staff has limited experience (1-5); No experience = 0</i></p>	20		Type comments here. (REQUIRED)
<p>2. Does the applicant provide sufficient information and an appropriate approach to provide HCV NAT testing as a shared service model?  <i>Evaluate overall proposed approach for the project including the number of jurisdictional partners and scope of the project. Consider if the sample receipt and delivery of results and specimen criteria are appropriate. Excellent = 16-20; High = 11-15 ; Moderate = 6-10; Limited = 1-5; No experience = 0</i></p>	20		Type comments here. (REQUIRED)
<p>3. Does the applicant provide sufficient information and an appropriate method for sample receipt and delivery of results?  <i>Consider approach for sample receipt including potential test request and reporting formats and estimated turnaround time. Excellent = 16-20; High = 11-15 ; Moderate = 6-10; Limited = 1-5; No experience = 0</i></p>	20		Type comments here. (REQUIRED)
<p>4. Does the applicant provide sufficient information and appropriate requirements for a qualified specimen?  <i>Consider specific patient risk factors, specimen storage requirements and specimen volume requirements. Excellent = 16-20; High = 11-15 ; Moderate = 6-10; Limited = 1-5; No experience = 0</i></p>	20		Type comments here. (REQUIRED)
<p>5. Does the applicant provide an appropriate budget for the requested funding and proposed workload?  <i>Consider estimated cost per sample vs cost per kit and any potential cost-sharing amongst jurisdictional partners. Excellent = 16-20; High = 11-15 ; Moderate = 6-10; Limited = 1-5; No experience = 0</i></p>	20		Type comments here. (REQUIRED)
<b>TOTAL SCORE</b>	<b>100</b>		