Request for Proposals: National HIV and HCV Nucleic Acid Test (NAT) Reference Centers

Application Due date: May 26, 2020

Submit to: Anne Gaynor, Manager of HIV, Viral Hepatitis, STD and TB (Anne.Gaynor@aphl.org)

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Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention (CDC) Division of HIV/AIDS Prevention and Division of Viral Hepatitis are seeking to recompete the National HIV and HCV Nucleic Acid Test (NAT) Reference Centers. APHL is seeking to identify one or two state or local public health laboratories (PHL) to serve as the HIV NAT Reference Center(s) and one state or local PHL to serve as the HCV NAT Reference Center. These Reference Centers will perform testing validated according to jurisdictionally appropriate regulatory criteria (CLIA/CAP/CLEP etc.).

- The **National HIV NAT Reference Center(s)** will perform an HIV-1 NAT and HIV-2 NAT or an HIV-1/HIV-2 NAT that is either Food and Drug Administration (FDA)-approved for use as a diagnostic, an a modified FDA-approved method that has been validated for off-label use as a diagnostic test, or a laboratory developed test that has been validated according to jurisdictionally appropriate regulatory criteria (CLIA/CAP/CLEP etc.) for serum or plasma specimens from US PHLs that meet specimen submission requirements.
    - If two Reference Centers are chosen, only one will be required to offer an HIV-2 NAT Method.
- The **National HCV NAT Reference Center** will perform an HCV NAT that is either FDA-approved, or a modified FDA-approved, method that has been validated according to jurisdictionally appropriate regulatory criteria (CLIA/CAP/CLEP etc.) as a diagnostic method for serum or plasma specimens from US PHLs that are reactive for HCV antibody on an FDA-approved anti-HCV assay.

Background

In March 2019 a National plan to "End the HIV Epidemic" was announced that features four key strategies: diagnosis, treat, prevent and respond. The goal of the first strategy is to "diagnose all individuals with HIV as early as possible," which requires not only testing the appropriate populations, but also using the most effective testing technology to detect infections as early as possible.

In 2017, The National Viral Hepatitis Action Plan for 2017—2020 was published. This Action Plan outlines goals to prevent new infections, improve the lives of people living with viral hepatitis, and a move towards a future without viral Hepatitis.

In the most recent CDC progress report, the CDC highlighted concerns about the ongoing and large increases in the incidence of acute HCV infection and suggested that increasing the proportion of persons receiving recommended testing for Hepatitis C would improve efforts to achieve the outlined goals in the National Action Plan.

Diagnosis of HIV and HCV infection requires conducting multiple tests following a testing algorithm. Completion of the entire testing algorithm is imperative for a complete and accurate diagnosis. The CDC

recommends the HIV Laboratory Diagnostic Testing Algorithm[1,2] for the diagnosis of HIV infection testing which begins with an FDA-approved antigen/antibody immunoassay (HIV-1/2 Ag/Ab IA) that detects HIV-1 and HIV-2 antibodies and HIV-1 p24 antigen. If the sample is reactive, the next test in the algorithm is an FDA-approved supplemental antibody immunoassay (HIV-1/HIV-2 Ab differentiation IA) that differentiates HIV-1 antibodies from HIV-2 antibodies. If the HIV-1/HIV-2 Ab differentiation IA is nonreactive or indeterminate, the specimen should be tested with an FDA-approved HIV-1 NAT. The HIV-1 NAT test is critical to identify potentially acute HIV-1 infections but is only necessary for a small number of specimens and is prohibitively expensive for all PHLs to have available for in-house testing.

However, based on a recent survey of US PHLs, only 21 perform HIV-1 NAT in-house while the majority 65% (41 of 65 respondents) submit specimens to the current National HIV NAT Reference Centers operated by APHL.[3] Therefore, access to HIV-1 NAT testing through the National HIV NAT Reference Centers remains integral to timely testing and diagnosis of HIV infection in the US.

As of July 2016, the HIV NAT Reference Center started offering a laboratory developed, validated qualitative HIV-2 NAT to address the need to confirm HIV-2 reactivity detected in either the FDA-approved HIV-1/2 Ag/Ab IA that differentiates analytes (BioPlex® 2200 HIV Ag-Ab) or in the FDA-approved HIV-1/HIV-2 antibody differentiation IA on the market (Geenius™ HIV1/2 Supplemental Assay) has become a reality that PHLs must face. Specimen criteria for submission has evolved slightly over time; the current specimen criteria are: 1) a repeatedly reactive result on a HIV-1/2 Ag/Ab IA, Geenius Final Assay Interpretation of HIV Indeterminate or HIV-2 Indeterminate and HIV-1 NAT Nonreactive or 2) BioPlex Repeatedly Reactive for HIV Ag-Ab—Reactive for HIV-2 Ab Only, Geenius result of HIV Indeterminate or HIV-2 Indeterminate or HIV Ab Negative and HIV-1 NAT Nonreactive or 3) BioPlex Repeatedly Reactive for HIV Ag-Ab—Reactive Undifferentiated, Geenius result of HIV Indeterminate or HIV-2 Indeterminate or HIV Ab Negative and HIV-1 NAT Nonreactive. In all cases an HIV-1 NAT is performed to rule out an acute HIV-1 infection before testing for HIV-2 RNA is performed. An HIV-2 NAT testing service is currently included in the National HIV NAT Reference Center and at least one of the selected applicants must be able to offer this testing.

In 2013, the CDC published guidelines on the recommended testing for HCV infection. These guidelines stated that testing begin with an HCV antibody (Ab) test. If this test resulted in a positive, the result should be followed by a NAT to detect HCV RNA.[4] Detection of HCV RNA in addition to an antibody to HCV indicates a current infection. The completion of the diagnostic testing algorithm enables providers to distinguish between current infection and past resolved infection, and provides the impetus to link a patient to care. As of 2017, 54% of US PHLs perform HCV testing, compared with 81% that perform HIV testing.[3] Of the PHLs that perform HCV testing, 95% (n=42) offer a laboratory based HCV antibody immunoassay, but only 19 of those PHLs offer HCV RNA testing for diagnosis and only 9 offer HCV RNA testing for monitoring/viral load. To address this lack of access to HCV NAT testing, APHL established a National Reference Center for HCV NAT testing in 2018. A total of 12 PHLs have enrolled, with six

actively submitting specimens and two PHLs that have discontinued participation once these PHLs brought testing in-house.

In addition to performing quality assured testing, it is imperative that testing and reporting of results are performed in a timely manner to ensure the greatest impact on clinical management. The goal of the reference center is to offer these test methods and results within two days of receipt at the reference center. To meet the stated turnaround time (TAT) requirements for testing and reporting, laboratory information systems (LIMS) and infrastructure must be available or adopted to support testing and resulting workflows. In addition to a LIMS to support analytical data capture during testing, careful consideration must be placed on the ability to electronically capture orders and report results to external submitters. Furthermore, Electronic Test Order and Result (ETOR) allows a public health laboratory to offer a higher level of service to its submitters, reduces the impact of manual data entry and reporting methods, and increases communication efficiencies across a network of clinical and public health partners.

To address the gap in access to quality assured and cost-effective NAT testing for HIV and HCV, APHL and CDC established these Reference Centers and plans to continue their operations and services to US PHLs as funding allows.

Eligibility

Eligible laboratories include all public health laboratories with the following capabilities, resources, and facilities in place:

1. Established capacity to perform an FDA-approved or modified FDA-approved NAT method that detects HIV-1 RNA and is validated to provide results to aid in diagnosis for serum and plasma specimens for HIV-1 (HIV NAT Reference Center Only), see *Appendix A: Expectations for National HIV NAT Reference Center for complete details* ***AND/OR***
2. Established capacity to perform an FDA-approved or modified FDA-approved NAT method that detects HCV RNA and is validated to provide results to aid in diagnosis for serum and plasma specimens for HCV (HCV NAT Reference Center Only), see *Appendix B: Expectations for National HCV NAT Reference Center for complete details*
3. Availability of adequate laboratory space and necessary equipment (including infrastructure for unidirectional workflow for molecular testing);
4. Sufficient workforce capacity for testing volume or the ability to hire additional qualified staff;
5. Ability to receive and test specimens from other laboratories;
6. Willingness to increase frequency of performing certain methods (if required) to meet expected turnaround times;

7. Willingness to use provided specimen submission form(s) for samples submitted to the Reference Center;
8. Willingness to alter existing reporting language to a standardized reporting language with input from APHL/CDC;
9. Willingness to share copies of quality assurance (QA) or biosafety documentation associated with relevant procedures to APHL and CDC upon request;
10. Ability to report results to submitter in a timely manner, ideally electronically.

Specific expectations regarding the methodologies to be used by the Reference Center are outlined in Appendix A: *Expectations for National HIV NAT Reference Center* and Appendix B: *Expectations for National HCV NAT Reference Center*. All applicants are required to agree to the minimum requirements for the Reference Center they are applying to, which are outlined in Appendix C: Minimum Requirements for National HIV NAT Reference Center and/or National HCV NAT Reference Center. Applicants may apply for either the **National HIV NAT Reference Center**, the **National HCV NAT Reference Center** or both.

Anticipated RFP Schedule

March 9, 2020	–	RFP Issued
April 27, 2020	–	Informational Teleconference (Q&A)
May 1, 2020	**–**	**Letter of Intent Due to APHL (see below)**
May 26, 2020	–	**RFP Responses Due**
June 17, 2020	–	Proposal review completed
June 18-26, 2020	–	If needed, follow-up interviews and updated proposals due
June 29, 2020	–	Final review completed and awardees selected
January 1, 2021	–	First year contract awarded

APHL will communicate any modification to this anticipated schedule on APHL's procurement website (www.aphl.org/rfp) and via an email blast to the public health laboratories (PHLs).

Response Submittal

Confirmation of Intent to Respond

APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal. APHL must receive this email by no later than **5:00pm EST on May 1, 2020.** To allow for appropriate review process planning, **a letter of intent is required** for consideration.

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020) to Anne Gaynor, anne.gaynor@aphl.org

Final Response

APHL must receive complete responses by **5:00 pm EST on May 26, 2020**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to Anne.Gaynor@aphl.org

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 point of contact above to confirm receipt.

Award

At least one laboratory will be selected for each of the Reference Centers, although up to 2 may be selected for the National HIV NAT Reference Center. The amount of the award will be based on submitted budgets and may vary year to year based on testing performed and volume of specimens submitted. The maximum compensation for the National HIV NAT Reference Center is estimated at $75,000/year which could either be awarded to one laboratory or divided between two laboratories. For the HIV NAT Reference Center the anticipated specimen volume is approximately 500-600 specimens per year for HIV-1 NAT with a very small subset potentially requiring HIV-2 NAT.

The HCV NAT Reference Center specimen volume in 2018 – 2019 was 374 and for the first half of 2019 – 2020, approximately 450 specimens have been tested. The maximum compensation for the HCV NAT Reference Center is approximately $75,000/year. Funding is distributed through an annual contract with APHL based on per specimen rates. By accepting this award, the laboratory agrees to the agreed upon rate for up to a five (5) year time span barring substantive changes in scope or material expenses at APHL's discretion.

Use of funds: The awarded laboratory should use the funding for testing of referred specimens (including retesting due to laboratory/personnel error), reagents and consumables and personnel time required to conduct these activities. Funding may also be used for necessary equipment upgrades or expansions, equipment maintenance and service agreements, or validation of new testing services.

Term of Project

The project term will be from January 1, 2020 through June 30, 2021 for the first year. Additional activities may precede this start term if needed to establish testing capacity, data transmissions, and proficiency demonstrations to ensure operational expectations are in place for the contracted period.

The potential for annual renewals (with each additional funding year running from July 1 to June 30) may be considered by APHL based on the availability of funds and performance of the awardee for a maximum of 4 additional years (through June 30, 2025). 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

and to accommodate CDC programmatic needs in that funding year. The awardee will 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 HIV, Viral Hepatitis, STD and TB (HHST) Program Manager, will conduct an initial review of all proposals for completeness. Any application that is incomplete as of the proposal due date specified in the 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's National Center for HIV, Viral Hepatitis, STD and TB Prevention (NCHHSTP) that are familiar with the laboratory techniques and project requirements (i.e. SMEs from the Division of HIV/AIDS Prevention and/or Division of Viral Hepatitis or within the Center itself) and a panel of three APHL members selected from non-applicant public health laboratories. SMEs from CDC will be identified and selected based on their familiarity with laboratory techniques and project requirements in consultation with the Associate Director of Laboratory Science of NCHHSTP. APHL member experts will be identified from among the non-applicant laboratories 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. Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

Conflict of Interest

APHL will ask potential reviewers to complete and sign APHL's **Conflict of Interest Disclosure Statement** in order to disclose any real or perceived conflict of interest prior to the start of the evaluation process. Reviewers will have to affirm that they have no conflict of interest that would preclude an unbiased and objective review of the proposals received. A copy of the disclosure statement and the related Fiduciary Responsibility and Conflict of Interest Policy is attached as **Appendix F**: Conflict of Interest Disclosure Statement and Policy. APHL will not select reviewers with a perceived or potential conflict of interest. This Conflict of Interest Disclosure Statement is provided in the RFP for Applicant review only. **Applicants should not complete the Conflict of Interest Disclosure Statement unless instructed by APHL.**

Evaluation Criteria

The evaluation team will evaluate proposals based on responses to the questions in the Proposal – Required Submissions section and will give a numeric score of up to 100 maximum points based on the scorecard template in Appendix D or Appendix E .

Laboratories meeting the following criteria have preference in the evaluation:

1. Extensive experience with the test methods;

2. Ability to handle increased volume;
3. Existing in-house subject matter expertise to provide consultation as needed;
4. Experience and past performance serving as a Reference Center;
5. Ability to report results electronically;
5. Ability to comply with expectations laid out in Appendix A and/or Appendix B and

Evaluation Process

The evaluation team will conduct the review 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. The evaluation team will use these interviews and any supplemental information to 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 as part of the evaluation criteria.

Post-Evaluation Procedures

APHL staff will notify the selected laboratories within ten business days of the completion of the evaluation and will post the names of the recipient(s) to APHL's procurement website, www.aphl.org/rfp, within three (3) business days of the laboratory's acceptance of the award. Unsuccessful applicants will receive notification of these results by e-mail within 30 days after the name of the selected awardee 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 and/or Appendix B. Acceptance of the award means agreement to the compensation structure and amounts agreed upon with the awardee and APHL.

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020)
to Anne Gaynor, anne.gaynor@aphl.org

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

An interested laboratory must submit both a letter of intent to apply (**due May 1, 2020**) and a proposal (**due May 26, 2020**). Applications must comply with submission requirements set out in the Additional Information and Deadlines for Application Submission below. A complete proposal will include the following items:

- **A completed and signed copy of Appendix C,**

  Note: If your laboratory cannot respond "yes" to each of the minimum requirements for the Reference Center(s) that you are applying for, your laboratory does not meet the minimum qualifications required to apply for this award.

- **Responses to Questions (below)**
  - Responses should be limited to no more than ten (10) single spaced pages (font size ≥ 11pt, 1 inch margins)
  - The proposal should include responses to the questions below, including each aspect of the question. The proposal should clearly indicate what question is being answered.

Response to Questions

Please review carefully to ensure you respond to the correct questions for your application.
There are seven questions that must be answered by all applicants and for each Reference Center there are two unique questions. If you want to be considered for both Reference Centers please answer all questions (1-11) and address each question individually as the review for the two Reference Centers will be separate.

- Applicants for the National HIV NAT Reference Center respond to questions 1-7 and 8-9
- Applicants for the National HCV NAT Reference Center respond to questions 1-7 and 10-11

Physical Environment

1. Describe your laboratory's space and equipment, including infrastructure for unidirectional workflow for molecular testing, to accommodate Reference Center testing. Please also address how the space and equipment will be used to handle the additional workload. If your laboratory cannot immediately handle the increased workload please include timelines and plans for scaling up.
   a. National HIV Reference Center Applicants: ensure you address anything available for HIV-1 NAT methods, and if applicable, HIV-2 NAT methods.

b. National HCV Reference Center Applicants: ensure you address everything available for the HCV NAT method.

Workforce

2. Does your laboratory have sufficient workforce capacity to perform the testing as outlined?
    a. Please describe the qualifications and experience staff have in performing the method(s) proposed.
    b. If submitting an application for both Reference Centers clearly delineate the staff for HIV and HCV testing.
3. Does your laboratory have staff with the appropriate subject matter expertise to provide guidance to submitting laboratories on appropriate specimen submission and interpretation of test results including discordant results?
    a. Please describe the qualifications and experience staff have in providing consultative services.
    b. If submitting an application for both Reference Centers, clearly delineate the staff for HIV and HCV consultation(s)

Reference Center/Shared Service Testing

4. Briefly describe your laboratory's experience, if any, in providing reference testing for other public health laboratories in a shared service model including, but not limited to, temporary service coverage to assure continuity of operations.
    a. Please describe your ability to receive, test and report results to external (outside of your state) submitters.

Reporting Results/Information Technology

5. Please describe the current workflow/process for submitting orders to your public health laboratory including if appropriate any LIMS, tools, and infrastructure. Please also describe your ability to use a test requisition form that is unique to the Reference Center testing and how this would be incorporated to meet the expectations outlined in Appendix A and Appendix B.
    a. If you are able to report electronically please detail your ETOR capability available to support the reporting requirements of the Reference Centers including ability to modify LIMS if needed to agreed upon test requisition form and capacity to onboard submitting sites to the ordering system and any/all back-up ordering mechanisms.
6. Please describe the current workflow/process for reporting results from your public health laboratory including, if appropriate any LIMS, tools, and infrastructure. If you have more than one mechanism, please identify the potential options and highlight the method most likely to be used for the Reference Center testing. Please also describe your ability to use the agreed upon reporting

language as outlined in Appendix A and Appendix B and any steps that would need to be taken to incorporate the new reporting language into your workflow/process.

a. If you are able to report electronically please provide details of your laboratory's available ETOR capability to support the reporting requirements of the Reference Centers, including the ability to modify LIMS, if needed, to an agreed upon test requisition form and capacity to onboard submitting sites to the reporting solution and any/all back-up reporting mechanisms.

Budget

7. Provide a per specimen cost based on the estimated specimen volume included in the award section above. This cost should incorporate all aspects of testing including staff time, test reagents, ancillary reagents and anticipated fringe/overhead charges. You may justify the budget explaining how you derived your cost but MUST supply a cost per specimen and a total estimated cost to support the Reference Center testing.

    a. If you are applying for the HIV NAT Reference Center and only offering HIV-1 NAT, please submit a cost per specimen and the total estimated cost based on half of the estimated testing volume.

National HIV NAT Reference Center

8. Please describe the current methodology used in your laboratory for qualitative HIV-1 NAT. Include information on the following:
    a. Is the method performed according to the FDA-approved instructions for use? If not, please describe the modifications that are currently used and summarize the validation study performed for the above mentioned modifications including the number of specimens analyzed.
    b. How long has the methodology been in use in your laboratory?
    c. How often is the methodology performed and what is the average TAT (from diagnostic specimen receipt to result reported)?
        i. If you were selected for this award, would you be able to meet the TAT goals in Appendix A?
    d. Provide information on testing algorithm(s) and reflex testing in your laboratory.
    e. Describe the following specimen requirements: does your laboratory have any additional requirements beyond the package insert, have you validated additional specimen types, or other aspects for the method?
    f. Provide annual HIV-1 NAT volume for samples tested within your jurisdiction (for the 2018 and 2019 Calendar Years)

g. Provide your current reporting language and method for reporting positive and negative results (i.e. Do you call with positives within a certain time? Do you only mail negative results?)
    i. If you were selected for this award, what adjustments could you make to the reporting method to improve the average TAT?
h. What contingency plans do you have if the method or instrument were to become unavailable?

9. Please describe the current methodology used in your laboratory for qualitative HIV-2 NAT (if applicable). Include information on:
    a. Summarize the validation study including the number of specimens analyzed.
    b. How long has the methodology has been in use in your laboratory?
    c. How often is the methodology performed and what is the average TAT (from diagnostic specimen receipt to result reported)?
        i. If you were selected for this award, would you be able to meet the TAT goals in Appendix A?
    d. Provide information on testing algorithm(s) and reflex testing in your laboratory.
    e. Describe specimen requirements: does your laboratory have any additional requirements beyond the package insert, have you validated additional specimen types, or other aspects for the method?
    f. Provide annual HIV-2 NAT volume for samples tested within your jurisdiction (for the 2018 and 2019 Calendar Years).
    g. Provide your current reporting language and method for reporting positive and negative results (i.e. Do you call with positives within a certain time? Do you only mail negative results?)
        i. If you were selected for this award, what adjustments could you make to the reporting method to improve the average TAT?
    h. What contingency plans do you have if the method or instrument were to become unavailable?

National HCV NAT Reference Center

10. Please describe the current methodology used in your laboratory for HCV NAT. Include information on:
    a. Is the method performed according to the FDA-approved instructions for use? If not, please describe the modifications that are currently used and summarize the validation study performed for the above mentioned modifications including the number of specimens analyzed.
    b. How long has the methodology been in use in your laboratory?

c. How often is the methodology performed and what is the average TAT (from diagnostic specimen receipt to result reported)?
    i. If you were selected for this award, would you be able to meet the TAT goals in Appendix B?
d. Provide information on testing algorithm(s) and reflex testing in your laboratory.
e. Describe specimen requirements: does your laboratory have any additional requirements beyond the package insert, have you validated additional specimen types, or other aspects for the method?
f. Provide annual HCV NAT volume for samples tested within your jurisdiction (for the 2018 and 2019 Calendar Years).
g. Provide your current reporting language and method for reporting positive and negative results (i.e. Do you call with positives within a certain time? Do you only mail negative results?)
    i. If you were selected for this award, what adjustments could you make to the reporting method to improve the average TAT?
h. What contingency plans do you have if the method or instrument were to become unavailable?

11. Many HCV NAT methods are FDA-approved for providing both qualitative and quantitative results. Would your laboratory be able to provide a quantitative result in addition to the qualitative result? Please describe any additional information about providing a quantitative result including:

    a. Is the method performed according to the FDA-approved instructions for use? If not, please describe the modifications that are currently in use and summarize the validation study performed for the above mentioned modifications including the number of specimens analyzed.
    b. Describe specimen requirements: does your laboratory have any additional requirements beyond the package insert, have you validated additional specimen types, or other aspects for the method?
    c. Would there be any change in the average TAT (from diagnostic specimen receipt to result reported) from what was described in Question 9.
    d. Provide your current reporting language and method for reporting positive and negative results (i.e. Do you call with positives within a certain time? Do you only mail negative results?) (if different from Question 9)
        i. If you were selected for this award, what adjustments could you make to the reporting method to improve the average TAT?
    e. What contingency plans do you have if the method or instrument were to become unavailable?

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Anne Gaynor (anne.gaynor@aphl.org). APHL will post questions received from interested PHLs, together with the answers provided by APHL or CDC staff to APHL's procurement website associated with the specific RFP (www.aphl.org/rfp).

To allow for appropriate review process planning, a **letter of intent is required for consideration**. Applicants should submit letters by email to Anne Gaynor at APHL (anne.gaynor@aphl.org) no later than **5:00 pm ET on Friday May 1, 2020.**

Applications are due to Anne Gaynor at APHL (anne.gaynor@aphl.org) by **5:00 pm ET on Tuesday May 26, 2020.** APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-2739 to confirm receipt.

APHL will hold an optional teleconference on Monday April 27, 2020 at 2:00pm ET. The purpose of this call will be to provide a brief overview of the project and to allow potential applicants to ask CDC and APHL questions. Please come with questions prepared.

Teleconference Call-in Information is below, or please contact anne.gaynor@aphl.org or infectious.diseases@aphl.org no later than 3:00pm ET on Friday April 24, 2020 to receive the calendar invitation.

Join Zoom Meeting
https://aphl.zoom.us/j/564449328

Call-in Information
1-646-876-9923 OR 1-669-900-6833
Meeting ID: 564 449 328

References:

1. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. 2014. Available from: http://stacks.cdc.gov/view/cdc/23447
2. Centers for Disease Control and Prevention. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. Available from: https://stacks.cdc.gov/view/cdc/50872
3. Association of Public Health Laboratories. Public Health Laboratory Issues in Brief: 2017 HIV and HCV Diagnostics Survey Report. 2019. Available from: https://www.aphl.org/aboutAPHL/publications/Documents/ID-2019Mar-HIV-HCV-Survey-Report.pdf
4. Centers for Disease Control and Prevention. Testing for HCV infection: an update of guidance for clinicians and laboratorians. MMWR Morb Mortal Wkly Rep. 2013 May 10;62(18):362–5.

Appendix A: Expectations for National HIV NAT Reference Center(s)

Identifying Submitting Laboratories for Participation

APHL will manage enrollment for the Reference Center(s) including explaining the minimum requirements for participation, maintaining points of contact, assisting with communications between the submitting PHLs and Reference Center(s). Minimum requirements for participation as a submitting laboratory include: active APHL membership and use of the recommended or alternate HIV Diagnostic Testing Algorithm.[1] To enroll, laboratories must provide the specific tests currently being used in their diagnostic algorithm, an estimate of their annual HIV testing volume, and two primary points of contact for this project. Upon enrollment, APHL will assign the submitting laboratories to a Reference Center(s) and provide the specimen requirements and specimen submission protocol. Each submitting laboratory will also be assigned a unique identifier for submission to the Reference Center(s).

Specimen Requirements for Submitting Laboratories (HIV-1 NAT)

Specimens that are repeatedly reactive by a HIV-1/ HIV-2 Ag/Ab IA or HIV-1/HIV-2 Ab IA and nonreactive or indeterminate by an HIV-1/HIV-2 differentiation IA should be submitted to the assigned Reference Center(s) for testing with an FDA-approved CLIA-validated method for detecting HIV-1 RNA. Additionally, submitting laboratories that are performing the BioPlex 2200 HIV Ag-Ab Assay are allowed to submit specimens that have HIV-1 antigen reactivity only with no HIV-1 or HIV-2 antibody reactivity (Reactive for HIV Ag-Ab, Reactive for HIV-1 Ag (only) and the HIV-1/HIV-2 Ab differentiation IA has not been performed.

Prior to shipment the submitting laboratory should notify the point of contact at the Reference Center(s) that they will be a submitting a specimen. The submitting laboratory will fill out the appropriate requisition form, provided by APHL, for inclusion with the shipment. The following information will be included on the requisition form and must be collected and recorded by the Reference Center:

- Submitting Laboratory ID
- Unique patient identifier(s);
- Date of collection;
- Date and time of receipt in the laboratory;
- Conditions and specimen type received;
- Specimen storage conditions from point of specimen receipt;
- Manufacture name of initial immunoassay;
- Result(s) of initial immunoassay (only for BioPlex);
- Manufacture name of supplemental test performed;
- Results of supplemental antibody assays;

Specimen Storage and Volume Requirements:

Submitting laboratories will be provided with specific submission instructions which state that submitted specimens comply with the package insert/ validation and are of sufficient volume. The Reference Center must be able to perform a qualitative HIV-1 NAT on plasma and serum specimens. If the Reference Center has modified an FDA-approved method and performed the appropriate validation

the specimen storage requirements should be no more stringent than the package insert for the FDA-approved version of the assay. Additionally, specimen volume requirements will depend on the exact method that is being employed but the information will be conveyed to the submitting laboratories by APHL and should use the minimum volume necessary for performing appropriate testing. It is the responsibility of the Reference Center to ensure that all specimens received meet the minimum requirements prior to testing and inform submitting laboratories if a specimen does not meet the requirements. If a submitting laboratory has repeated issues, APHL can help address the issue with the Reference Center.

Specimen Handling at Reference Center

Upon receipt of the specimens, the Reference Center will ensure the test requisition form is complete and specimens meet the specimen criteria. They will also assign the specimen with a unique identifier for de-identifying the specimen to share data with APHL. The Reference Center will check the temperature and condition of the specimen and record the temperature, along with the date and time of receipt, on the data collection form.

Specimens should be thawed according to the package insert/validated protocol on the day of testing with an effort to maintain the integrity of samples by minimize the time specimens are stored at 2 to 8^{o}C. Upon completion of all testing, remnant specimen should be stored at ≤ -20 degrees centigrade as soon as possible.

Specimen Testing and Reporting Procedures for Reference Laboratories to Submitters

The Reference Center will perform the FDA-approved CLIA-validated qualitative HIV-1 NAT in accordance with the package insert or validated protocol. If HIV-2 NAT testing is needed (see Procedures for HIV-2 NAT Testing) and there is sufficient specimen volume an HIV-2 NAT will also be performed. Final specimen volume will be recorded for the bi-monthly report. The Reference Center will perform testing as needed to meet an average TAT of 2 days after specimen receipt in the laboratory and no more than 2 business days. All positive results should be reported immediately (within 24 hours) to the submitting laboratory, ideally by telephone and electronic laboratory reporting. Results that are not positive, may also be reported by telephone, but should be reported by electronic laboratory reporting. If electronic laboratory reporting is not possible, a less ideal solution would be through a secure fax. Results should also be recorded in the APHL reporting form using the unique identifier.

Procedures for HIV-2 NAT Testing

As of January 2020, there are two FDA-approved methods that can lead to identification of HIV-2 seroreactivity (BioPlex® 2200 HIV Ag-Ab or Geenius™ HIV1/2 Supplemental Assay), either at the first or second step of the recommended testing algorithm but there is currently no FDA-approved method for detecting HIV-2 RNA. Therefore, at least one Reference Center must have a qualitative HIV-2 NAT method validated following jurisdictionally appropriate regulatory criteria. There are three scenarios (outlined in Table 1) that may require that an HIV-2 NAT is performed to assess HIV-2 infection.

Table 1: HIV Laboratory Diagnostic Testing Algorithm Results that would be eligible for HIV-2 NAT

	Initial IA Result	HIV-1/HIV-2 Ab Differentiation Result	HIV-1 NAT Result	Actions
1	Repeatedly Reactive	HIV Indeterminate, or HIV-2 Indeterminate (repeatedly)	Not Detected/ Nonreactive	Reflex to HIV-2 NAT
2	Repeatedly Reactive for HIV Ag-Ab, Reactive HIV-2 Ab Only (BioPlex HIV Ag-Ab)	HIV Indeterminate, or HIV-2 Indeterminate (repeatedly), or HIV Ab Negative	Not Detected/ Nonreactive	Reflex to HIV-2 NAT
3	Repeatedly Reactive for HIV Ag-Ab, Reactive Undifferentiated (BioPlex HIV Ag-Ab)	HIV Indeterminate, or HIV-2 Indeterminate (repeatedly), or HIV Ab Negative	Not Detected/ Nonreactive	Reflex to HIV-2 NAT

Requirements for HIV-2 NAT

Specimens meeting one of the criteria (1-3)of Table 1 (above) may be submitted to their designated Reference Center for testing with the FDA-approved, CLIA-validated qualitative HIV-1 NAT method.

The Reference Center should receive notification of sample submission prior to shipment. The submitting laboratory will fill out the provided requisition form for inclusion with the shipment. The following information MUST be recorded on the requisition form and is consistent with data routinely collected by reference laboratories: Unique patient identifier(s); date of collection; date and time of receipt in the laboratory; specimen handling conditions from collection to receipt; date IA and supplemental testing performed; results of IA and supplemental antibody assays; specimen storage conditions from point of specimen receipt; and date of shipment.

Reporting Procedures for APHL

The Reference Center is responsible for recording all of the requested data for each specimen and using only the unique identifier to identify the specimen. The Reference Center must not disclose to APHL and CDC the key that links the patient identifier(s) to the unique project identifier. All files that include the key will be destroyed by the Reference Center at the end of the project period. APHL currently collects data on the following variables:

- Unlinked Specimen Identifier
- Submitting Laboratory ID Number
- Date of Specimen Collection
- Date of Specimen Receipt in Submitting Laboratory
- Conditions of Specimen Receipt in Submitting Laboratory
- Specimen Storage Conditions in Submitting Laboratory

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- Specimen Type
- Screening Immunoassay Manufacturer
- Screening Immunoassay Result
- Supplemental Antibody Test Manufacturer
- Supplemental Antibody Result
- Supplemental Antibody Result (if repeated)
- Specimen Shipping Conditions
- Date of Shipment to Reference Center
- Date of Specimen Receipt in Reference Center
- Conditions of Specimen Receipt in Reference Center
- Specimen Storage Conditions in Reference Center Prior to Testing
- Specimen Volume Received (estimated)
- Date Test Performed
- Test Result
- Date Result Reported to Submitting Laboratory
- Remaining Specimen Volume
- Note Specimen Rejection and Reason
- Date Test Performed-HIV-2 NAT
- Test Result -HIV-2 NAT
- Date Result Reported to Submitting Laboratory-HIV-2 NAT
- Remaining Specimen Volume-HIV-2 NAT
- Note Specimen Rejection and Reason-HIV-2 NAT

Data will be compiled and submitted to APHL on a bi-monthly basis. The data submitted to APHL will NOT contain unique patient identifiers or personally identifying information. Specimens will only be identified by the assigned unique demonstration project identifier. The submitting laboratory test requisition form will remain with the Reference Center and will never be transmitted to APHL. The retention policy for requisition forms will be determined based on discussions with the selected Reference Centers, APHL, and CDC.

Test Order and Resulting

- Laboratory Information Management System or other data structure in place and able to be enhanced or modified to meet submission requirements (capture additional fields beyond normal testing), testing needs, workflows and reporting language.
- The capacity to report results in a timely manner, ideally through an electronic/ETOR portal.
    - If using an electronic portal or standardized messaging, the ability to on-board all submitters within 2 months of the award.
- Back-up reporting mechanisms in place to ensure reporting requirements are met.

Performance Management and Evaluation

APHL will monitor workload, reasons for submission to reference center, data quality, transport times, TAT times, data anomalies and outliers, discordant results, appropriate use of reporting language, appropriate use of reflex testing algorithms, effective consultative services, customer satisfaction, referrals to CDC, and service costs on a bi-monthly basis through the following mechanisms:

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020) to Anne Gaynor, anne.gaynor@aphl.org

Data Review

The Reference Center is responsible for recording all of the requested data (outlined above) for each specimen and submitted to APHL on a bi-monthly basis. The data submitted to APHL will NOT contain unique patient identifiers. Specimens will only be identified by the assigned unique demonstration project identifier. The submitting laboratory test requisition form will remain with the Reference Center and will never be transmitted to APHL.

The Reference Center may develop additional QA monitors, in conjunction with CDC, for their own performance and that of submitting laboratories. Data will be analyzed with feedback provided to the Reference Center within 1 month of receipt either by email or during a teleconference, if necessary.

On a yearly basis, the data will be analyzed to characterize the overall performance of the HIV Diagnostic Testing Algorithm, median TAT for a number of parameters (i.e. specimen collection to final qualitative HIV-1 NAT result reported), calculate the proportion of specimens with resolved infection status, and to determine whether any special testing situations resulted in useful, actionable data to guide changes to the HIV diagnostic testing algorithm or to encourage other PHL practices. The Reference Center(s) will have the option to collaborate on publications in the peer reviewed literature or presented at national conferences using the data compiled.

Site visits and teleconferences

- APHL in collaboration with CDC will perform site visits as needed. Additional monitoring visits may be needed based on data review and any ongoing challenges mutually identified. Site visits could include data review, review of laboratory workflow, procedural observation and quality control (QC) information.
- APHL, CDC and the Reference Center will participate in teleconferences as needed to review reports, assess successes and challenges and discuss potential resolutions.

Customer satisfaction

APHL may perform customer satisfaction surveys that may include key informant interviews with select submitters to assess satisfaction with service, TAT, reporting format, expert consultation, and continued use of reference laboratory.

Reporting Language

Reporting language and disclaimers will be reviewed and if more than one Reference Center is chosen, the reporting language will be harmonized between the two laboratories to ensure consistency.

Consultation

- Subject matter expertise within the National HIV NAT Reference Center(s) should be available for consultation by phone or dedicated email address.
- The Reference Centers will provide points of contact for APHL and the submitters to maintain dedicated lines of communication for submitters (i.e. phone number(s), email(s)).

Archiving Specimens

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020) to Anne Gaynor, anne.gaynor@aphl.org

- Specimens will be stored frozen by the Reference Center and may be used for future studies either at the Reference Center(s) or in collaboration with/at the CDC. Further instructions will be provided for archiving specimens as needed.

Appendix B: Expectations for the National HCV NAT Reference Center

Identifying Submitting Laboratories for Participation

APHL will manage enrollment for the Reference Center(s) including explaining the minimum requirements for participation, maintaining points of contact, assisting with communications between the submitting PHLs and Reference Center(s). Minimum requirements for participation as a submitting laboratory include: active APHL membership and use of an FDA-approved HCV antibody immunoassay. To enroll, laboratories must provide the specific test they are currently using, an estimate of their monthly need for HCV NAT and two primary points of contact for this project. Upon enrollment, APHL will assign the submitting laboratories to the Reference Center and provide the specimen requirements and specimen submission protocol.

Specimen Requirements for Submitting Laboratories

Specimens that are reactive for HCV Ab by an FDA-approved anti-HCV Ab immunoassay should be submitted to the assigned Reference Center for testing with a FDA-approved CLIA-validated method for detecting HCV RNA. Additionally, specimens are allowed to be submitted that are nonreactive for HCV Ab but from a person at high-risk for acute HCV infection that would not be detected by an HCV Ab IA. While all specimens that are reactive for HCV Ab should be tested by an HCV NAT, funding for the Reference Center is limited. Therefore, submitting laboratories are asked to be cognizant of this and request that they target high-risk populations (i.e. persons who inject drugs, persons that are HIV-positive, persons with known recent exposure to a known HCV positive individual).

Prior to shipment the submitting laboratory should notify the point of contact at the Reference Center. That they will be a submitting a specimen. The submitting laboratory will fill out the appropriate requisition form, provided by APHL, for inclusion with the shipment. The following information will be included on the requisition form and must be collected and recorded by the Reference Center:

- Submitting Laboratory Information
- Two unique identifiers (two from below)
    - Patient name;
    - Unique patient identifier(s);
    - Date of Birth
- Date of collection;
- Date of receipt in the laboratory;
- Specimen type received;
- Name of immunoassay test performed;
- Results of immunoassay test;
- Date of shipment

Specimen Storage and Volume Requirements:

Submitting laboratories will be provided with specific submission instructions such that submitted specimens comply with the package insert/CLIA-validation and are of sufficient volume. The Reference Center must be able to perform an HCV NAT that detects HCV RNA from plasma and serum specimens. If the Reference Center has modified an FDA-approved method and performed the appropriate validation

the specimen storage requirements should be no more stringent than the package insert for the FDA-approved version of the assay. Additionally, specimen volume requirements will depend on the exact method that is being employed but the information will be conveyed to the submitting laboratories by APHL and should use the minimum volume necessary for performing appropriate testing. It is the responsibility of the Reference Center to ensure that all specimens received meet the minimum requirements prior to testing and to let submitting laboratories know if a specimen does not meet the requirements. If there are repeated issues with a submitting laboratory APHL can help address the issue with the Reference Center.

Specimen Handling at Reference Center

Upon receipt of the specimens, the Reference Center will ensure the test requisition form is complete and specimens meet the specimen criteria. The Reference Center will check the temperature and condition of the specimen to ensure it meets testing requirements.

Unless specimens will be tested on the day of receipt, the Reference Center will store specimens at an appropriate storage condition until the day of testing in accordance with the package insert or validated protocol. Specimens should be thawed according to the package insert/validated protocol on the day of testing. Testing laboratories should ensure that specimens are stored at 2 to 8^{o}C for the minimum time possible to complete all testing. Upon completion of all testing, remnant specimen should be stored at ≤ -20 degrees centigrade as soon as possible.

Specimen Testing and Reporting Procedures for Reference Laboratories to Submitters

The Reference Center will perform the qualitative HCV NAT that is either FDA-approved, or a modified FDA-approved, method that has been validated according to jurisdictionally appropriate regulatory criteria (CLIA/CAP/CLEP etc.) in accordance with the package insert or validated protocol. The Reference Center will perform testing as needed to meet an average TAT of two calendar days after specimen receipt in the laboratory and no more than two business days. All positive results should be reported immediately (within 24 hours) to the submitting laboratory, ideally by telephone and electronic laboratory reporting. Results that are not positive, may also be reported by telephone, but should be reported by electronic laboratory reporting. If electronic laboratory reporting is not possible, a less ideal solution would be through a secure fax. Results should also be recorded in the APHL reporting form using the unique identifier.

Reporting Procedures for APHL

The Reference Center is responsible for providing APHL aggregate data on a bi-monthly basis. The aggregate data will include the number of specimens received per public health laboratory, the number of specimens that were rejected, the number of specimens that were previously HCV Ab reactive, the number of specimens that were sent based on risk factors alone (HCV Ab nonreactive), the number of specimens that are HCV RNA positive, the number of specimens that are HCV RNA negative, the number of specimens that had invalid results, the average TAT for the testing period, the range of TAT for the testing period and any non-conforming events, description of any non-conforming events, challenges or issues. Data will be compiled and submitted to APHL on a bi-monthly basis. The data submitted to APHL

will not contain unique patient identifiers. The test requisition form will remain with the Reference Center and will never be transmitted to APHL.

Test Order and Resulting

- Laboratory Information Management System (LIMS) or other data structure in place and able to be enhanced or modified to meet submission requirements (capture additional fields beyond normal testing), testing needs, workflows and reporting language.
- The capacity to report results in a timely manner, ideally through an electronic/ETOR portal.
    - If using an electronic portal or standardized messaging, the ability to on-board all submitters within 2 months of the award.
- Back-up reporting mechanisms in place to ensure reporting requirements are met.

Performance Management and Evaluation

APHL will monitor workload, reasons for submission to reference center, data quality, TAT, data anomalies and outliers, discordant results, appropriate use of reporting language, effective consultative services, customer satisfaction, referrals to CDC, and service costs on a bi-monthly basis through the following mechanisms:

Data Review

The Reference Center is responsible for recording all of the requested data (outlined above) and submitted to APHL on a bi-monthly basis. The data submitted to APHL will NOT contain unique patient identifiers. Specimens will only be identified by the assigned unique demonstration project identifier. The submitting laboratory test requisition form will remain with the Reference Center and will never be transmitted to APHL.

The reference center may develop additional quality assurance monitors, in conjunction with CDC, for their own performance and that of submitting laboratories. Data will be analyzed with feedback provided to the reference center within 1 month of receipt either by email or during a teleconference, if necessary.

On a yearly basis, the data will be analyzed to characterize the overall performance of the Reference Center to determine whether there is any actionable data to guide needed changes or improvements to QC. The Reference Center will have the option to collaborate on publications in the peer reviewed literature or presented at national conferences using the data compiled.

Site visits and teleconferences

- APHL in collaboration with CDC will perform site visits as needed. Additional monitoring visits may be needed based on data review and any ongoing challenges mutually identified. Site visits could include data review, review of laboratory workflow, procedural observation and quality control information.
- APHL, CDC and the Reference Center will participate in teleconferences as needed to review reports, assess successes and challenges and discuss potential resolutions.

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020) to Anne Gaynor, anne.gaynor@aphl.org

Customer satisfaction

APHL may perform customer satisfaction surveys that may include key informant interviews with select submitters to assess satisfaction with service, TAT, reporting format, expert consultation, and continued use of reference laboratory.

Reporting Language

Reporting language and disclaimers will be reviewed prior to approval and usage for the Reference Center

Consultation

- Subject matter expertise within the National HCV NAT Reference Center(s) should be available for consultation by phone or dedicated email address.
- The Reference Centers will provide points of contact for APHL and the submitters to maintain dedicated lines of communication for submitters (i.e. phone number(s), email(s)).

Archiving Specimens

- Specimens will be stored frozen by the Reference Center and may be used for future studies either at the Reference Center(s) or in collaboration with/at the CDC. Further instructions will be provided for archiving specimens as needed.

Appendix C: Minimum Requirements for National HIV NAT Reference Center and/or National HCV NAT Reference Center

Please review and respond to each of the minimum requirements below. By signing this agreement you are affirming that your laboratory can meet each of the minimum requirements described.

YES	NO	N/A	MINIMUM REQUIREMENT
			Does your laboratory currently perform a CLIA validated qualitative HIV-1 NAT on serum and plasma? **(Required for National HIV NAT Reference Center)**
			Does your laboratory currently perform a CLIA validated HCV NAT that detects HCV RNA on serum and plasma? **(Required for National HCV NAT Reference Center)**
			Does your laboratory have adequate laboratory space and equipment (including infrastructure for unidirectional workflow for molecular testing)?
			Does your laboratory have sufficient workforce capacity for expanded testing volume or the ability to hire additional qualified staff?
			Is your laboratory able to receive and test specimens from other laboratories?
			Is your laboratory willing to increase the frequency of performing certain methods (if required) to meet expected TAT?
			Is your laboratory willing to use APHL provided specimen submission form(s)?
			Is your laboratory willing to amend specimen submission form(s) to include additional variables?
			Is your laboratory willing to alter existing reporting language to a standardized reporting language with input from APHL/CDC?
			Is your laboratory willing to provide copies of QA or biosafety documentation to APHL and CDC upon request?
			Is your laboratory able to report results in a timely manner?

On behalf of the applicant laboratory, I agree that the applicant laboratory is able to meet the minimum requirements necessary to apply for this award as outlined above.

Signature: _____ Date: _____

Printed Name: _____

Submit the Letter of Intent (Due 3/23/2020) and completed application (Due 4/20/2020) to Anne Gaynor, anne.gaynor@aphl.org

Appendix D: Score Card-National HIV NAT Reference Center

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

Category/Question	Maximum Value	Score	Comments (REQUIRED)
Physical Environment 1. Does the applicant demonstrate the ability to handle the testing volume for the required methods? Consider the availability of equipment, space and workflows and timelines to scale up if applicable. **Ideal** (12-15 points): Describes ability to handle testing volume for all activities; describes appropriate equipment, space and can currently handle the volume. **Adequate** (7-11 points): Describes ability to meet most testing requirements but may have to adjust workflow or has some deficiencies in their equipment or ability to immediately handle the volume. **Limited** (1-6 points): Applicant describes limited ability to meet testing requirements; has many deficiencies in their equipment or ability to handle the workload in a timely manner. **Inadequate** (0 points): Applicant does not demonstrate the ability to handle the testing volume and/or perform necessary methods and neither has the equipment or ability to scale up in a timely manner and/or does not demonstrate a clear understanding of the requirements.	15		Type comments here. (REQUIRED)
Workforce 2. Does the applicant describe sufficient workforce capacity and in-house subject matter expertise to provide consultation to submitting jurisdictions? **High** (16-20 points): Applicant has sufficient staffing with a strong history of relevant experience, subject matter expertise: at least 1.0 FTE with > 5 years or 2.0 FTEs with > 3 years of experience providing consultation to submitters on interpretation of results including discordant results. **Moderate** (8-15 points): Applicant has some staff with relevant experience but will require additional training, guidance or technical assistance in others, subject matter expertise: >1.0 FTE with ≥ 3 years of experience providing consultation to submitters on interpretation of results including discordant results. **Low** (1-7 points): Deficiencies in staffing in this area, subject matter expertise: ≤ 1 FTE with <3 years of experience providing consultation to submitters on interpretation of results including discordant results.	20		Type comments here. (REQUIRED)

No Experience (0 points): Applicant does not demonstrate internal subject matter expertise is this area.			
Reference Center Testing 3. Rate the applicant's level of experience in providing reference testing services for other public health laboratories in a shared service model. **Rate on a scale of 0-10 points** (10 = Applicant has served as a reference center for other PHL on an ongoing basis with submissions from and reporting to multiple out-of-jurisdiction submitters; 0 = Applicant has no experience serving as a Reference Center for other PHLs)	10		Type comments here. (REQUIRED
Reporting 4. What is the applicants' ability to offer timely ordering and reporting of results? **Ideal** (12-15 points): Applicant already has mechanism to electronically order and report with ability to modify for Reference Center Testing and onboarding of submitters in <2 months **Adequate** (7-11 points): Applicant has a mechanism to receive orders and report results in a timely manner to meet expectations in Appendix A and/or Appendix B which could include an electronic system. **Limited** (1-6 points): Applicant has a mechanism to receive orders and report results but there are concerns that it may not be as timely as possible and could cause delays in timely reporting and/or is overly burdensome for the Reference Center or submitters. **Inadequate** (0 points): Applicant does not have an acceptable solution in place for reporting results and/or the timeline to put one in place exceeds the timeline outlined in Appendix A and/or Appendix B.	15		Type comments here. (REQUIRED
Budget 5. Rate the appropriateness of the applicants budget **Rate on a scale of 0-5 points** (5=most cost-effective budget; 0=budget is inappropriate)	5		Type comments here. (REQUIRED
HIV-1 6. Does the applicant have sufficient capacity and experience performing HIV-1 NAT? Consider experience with described method(s), whether the method is being used appropriately (and appropriately validated) experience of existing staff? **High** (18-25 points): Describes extensive experience performing an appropriate method, sufficient capacity and staff experience to handle additional volume, describes	25		Type comments here. (REQUIRED)

appropriate staffing and equipment, and regularly meets expectations outlined in Appendix A, especially turnaround time. If modified from FDA-approved assay the validation study is appropriate and sufficient. **Moderate** (9-17 points): Describes sufficient experience performing method, some concerns about appropriate capacity to handle additional volume and/or does not regularly meet expectations outlined in Appendix A, especially turnaround time. If modified from FDA-approved assay there are some shortcomings of the validation study. **Low** (1-8 points): Describes minimal experience performing method, deficiencies in workforce experience and/or ability to meet expectations in Appendix A, especially turnaround time and/or handle additional volume. If modified from FDA-approved assay the validation study is not sufficient. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.			
HIV-2 NAT 7. Does the applicant have sufficient capacity and experience performing HIV-2 NAT? Consider experience with described method(s), whether the method is being used appropriately (and appropriately validated) experience of existing staff. **High** (9-10 points): Describes extensive experience performing an appropriate method and validation study is appropriate and sufficient, sufficient capacity and staff experience to handle additional volume, describes appropriate staffing and equipment, and regularly meets expectations outlined in Appendix A, especially turnaround time. **Moderate** (5-8 points): Describes sufficient experience performing method, some concerns about appropriate capacity to handle additional volume and/or does not regularly meet expectations outlined in Appendix A. If modified from FDA-approved assay there are some shortcomings of the validation study. **Low** (1-4 points): Describes minimal experience performing method, deficiencies in workforce experience and/or ability to meet expectations in Appendix A and/or handle additional volume. If modified from FDA-approved assay the validation study is not sufficient. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.	10		Type comments here. (REQUIRED
TOTAL SCORE	**100**	**____**	

Appendix E: Score Card-National HCV NAT Reference Center

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

Category/Question	Maximum Value	Score	Comments (REQUIRED)
Physical Environment 1. Does the applicant demonstrate the ability to handle the testing volume for the required methods? Consider the availability of equipment, space and workflows and timelines to scale up if applicable. **Ideal** (12-15 points): Describes ability to handle testing volume for all activities; describes appropriate equipment, space and can currently handle the volume. **Adequate** (7-11 points): Describes ability to meet most testing requirements but may have to adjust workflow or has some deficiencies in their equipment or ability to immediately handle the volume. **Limited** (1-6 points): Applicant describes limited ability to meet testing requirements; has many deficiencies in their equipment or ability to handle the workload in a timely manner. **Inadequate** (0 points): Applicant does not demonstrate the ability to handle the testing volume and/or perform necessary methods and neither has the equipment or ability to scale up in a timely manner and/or does not demonstrate a clear understanding of the requirements.	15		Type comments here. (REQUIRED)
Workforce 2. Does the applicant describe sufficient workforce capacity and in-house subject matter expertise to provide consultation to submitting jurisdictions? **High** (16-20 points): Applicant has sufficient staffing with a strong history of relevant experience, subject matter expertise: at least 1.0 FTE with > 5 years or 2.0 FTEs with > 3 years of experience providing consultation to submitters on interpretation of results including discordant results. **Moderate** (8-15 points): Applicant has some staff with relevant experience but will require additional training, guidance or technical assistance in others, subject matter expertise: >1.0 FTE with ≥ 3 years of experience providing consultation to submitters on interpretation of results including discordant results. **Low** (1-7 points): Deficiencies in staffing in this area, subject matter expertise: ≤ 1 FTE with <3 years of experience providing consultation to submitters on interpretation of results including discordant results.	20		Type comments here. (REQUIRED)

No Experience (0 points): Applicant does not demonstrate internal subject matter expertise is this area.			
Reference Center Testing 3. Rate the applicant's level of experience in providing reference testing services for other public health laboratories in a shared service model. **Rate on a scale of 0-10 points** (10= Applicant has served as a reference center for other PHL on an ongoing basis with submissions from and reporting to multiple out-of-jurisdiction submitters; 0=Applicant has no experience serving as a Reference Center for other PHLs)	10		Type comments here. (REQUIRED
Reporting 4. What is the applicants' ability to offer timely ordering and reporting of results? **Ideal** (9-10 points): Applicant already has mechanism to electronically order and report with ability to modify for Reference Center Testing and onboarding of submitters in <2 months **High** (5-8 points): Applicant has a mechanism to receive orders and report results in a timely manner to meet expectations in Appendix A and/or Appendix B which could include an electronic system. **Adequate** (1-4 points): Applicant has a mechanism to receive orders and report results but there are concerns that it may not be as timely as possible and could cause delays in timely reporting and/or is overly burdensome for the Reference Center or submitters. **Inadequate** (0 points): Applicant does not have an acceptable solution in place for reporting results and/or the timeline to put one in place exceeds the timeline outlined in Appendix A and/or Appendix B.	10		Type comments here. (REQUIRED
Budget 5. Rate the appropriateness of the applicants budget **Rate on a scale of 0-5 points** (5=most cost-effective budget; 0=budget is inappropriate)	5		Type comments here. (REQUIRED
HCV NAT (qualitative) 6. Does the applicant have sufficient capacity and experience performing a HCV NAT? Consider experience with described method(s), whether the method is being used appropriately (and appropriately validated) experience of existing staff? **High** (18-25 points): Describes extensive experience performing an appropriate method, sufficient capacity and staff experience to handle additional volume, describes appropriate staffing and equipment, and regularly meets	25		Type comments here. (REQUIRED)

expectations outlined in Appendix B, especially turnaround time. If modified from FDA-approved assay the validation study is appropriate and sufficient. **Moderate** (9-17 points): Describes sufficient experience performing method, some concerns about appropriate capacity to handle additional volume and/or does not regularly meet expectations outlined in Appendix B, especially turnaround time. If modified from FDA-approved assay there are some shortcomings of the validation study. **Low** (1-8 points): Describes minimal experience performing method, deficiencies in workforce experience and/or ability to meet expectations in Appendix B, especially turnaround time and/or handle additional volume. If modified from FDA-approved assay the validation study is not sufficient. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.			
HCV NAT (quantitative) 7. Does the applicant have sufficient capacity and experience performing quantitative HCV NAT? Consider experience with described method(s), experience of existing staff? **High** (9-10 points): Describes extensive experience performing an appropriate method, sufficient capacity and staff experience to handle additional volume, describes appropriate staffing and equipment, and regularly meets expectations outlined in Appendix B, especially turnaround time. If modified from FDA-approved assay the validation study is appropriate and sufficient. **Moderate** (5-8 points): Describes sufficient experience performing method, some concerns about appropriate capacity to handle additional volume and/or does not regularly meet expectations outlined in Appendix B, especially turnaround time. If modified from FDA-approved assay there are some shortcomings of the validation study **Low** (1-4 points): Describes minimal experience performing method, deficiencies in workforce experience and/or ability to meet expectations in Appendix B, especially turnaround time and/or handle additional volume. If modified from FDA-approved assay the validation study is not sufficient. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.	10		Type comments here. (REQUIRED
TOTAL SCORE	**100**	**____**	

Appendix F: Conflict of Interest Disclosure Statement and Policy

Association of Public Health Laboratories
Conflict of Interest Disclosure Statement

Applicability: Disclosure of the following information is required of all Officers, Directors, committee members, staff members and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel"). Please answer the following questions and, where indicated, include the same information for your immediate family members (your parents, your spouse or partner, your children and your spouse/partner's parents).

APHL will keep your completed disclosure statement in the corporate records of the association.

1. Please list the name, address, phone number, email address and type of business of your current employer. If you are self-employed, please note that below and provide us with the address, phone number, email address and type of business you operate.

_____

_____

_____

2. Do you, or does any family member, currently serve as an officer, director, committee member, or other volunteer (or work as an employee of or a paid consultant to) any organization serving the interest of laboratory science or public health laboratories other than APHL or your state or local laboratory?

☐ **Yes** ☐ **No**

If yes, please list the organization(s) and provide detail on your or your family member's interest or position in the organization(s).

_____

_____

_____

3. Do you, or any family member, have an existing or potential interest in, or compensation arrangement with, any third party providing goods or services to APHL, or with which APHL is currently negotiating?

☐ **Yes** ☐ **No**

If the answer is yes, please provide the name of the organization below and describe in detail the nature of the position held.

4. Please note any other financial or business interest you may have with any organization serving the interests of public health laboratories.

If you have none, please check this box: ☐

5. Do you, or does any family member, have any other interest or affiliation that is likely to compromise your ability to provide unbiased and undivided loyalty to APHL, or that could come in conflict with your official duties as an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL?

☐ **Yes** ☐ **No**

If you answered yes, please describe in detail below the nature of each such interest or affiliation.

6. If you are currently aware of any actual or possible conflict of interest that might otherwise hamper your ability to serve APHL to your best ability and with the highest degree of care, loyalty and obedience – ***including any potential conflict you or a family member may have with one or more of the RFP applicants*** – please describe them in detail below.

_____

_____

_____

_____

_____

7. Do you agree that so long as you are an Officer, Director, committee member, staff member or other volunteer who has been designated and who has accepted responsibility to act on behalf of APHL you will immediately disclose to the other Directors and/or Officers or, for staff members, the Executive Director and/or General Counsel the nature of any interest or affiliation which you may hereafter acquire, which is in or is likely to become in conflict with your official duties with APHL?

☐ **Yes** ☐ **No**

YOU MUST READ THIS SECTION AND THEN SIGN BELOW

I acknowledge that I have received and read APHL's Fiduciary Responsibility and Conflict of Interest Policy (the Policy). I have listed all my relevant fiduciary responsibilities and affiliations, and I have identified any actual or potential conflict of interest on this Disclosure Statement and I agree to abide by the Policy. I understand that it is my responsibility to inform APHL in writing of any change in circumstances relating to the Policy and this Disclosure Statement.

Signature: _____ Date: _____

Printed Name: _____

APHL Fiduciary Responsibility and
Conflict of Interest Policy

1. Policy Statement and Purpose

The members of the APHL Board of Directors understand the importance of serving APHL to the best of their ability and with the highest degree of obedience, loyalty and care. Accordingly, the Board adopts the following policy for APHL Officers and Directors, all staff, committee members, and other volunteers who have been designated and who have accepted responsibility to act on behalf of APHL ("APHL Personnel").

2. Individual Duty and Annual Disclosure

APHL Personnel will avoid any conflict of interest with APHL. APHL Personnel will not profit personally from their affiliation with APHL, or favor the interests of themselves, relatives, friends or other affiliated organizations over the interests of APHL. As used in this Policy, "Conflict of interest" includes any actual, apparent, and potential conflict of interest.

Upon commencing service with APHL, each APHL Personnel will file with the Board an annual statement disclosing all material business, financial, and organizational interests and affiliations they or persons close to them have which could be construed as related to the interests of APHL or the profession of public health laboratory science. Each APHL Personnel has an obligation to make an additional disclosure if a conflict of interest arises in the course of the individual's service to APHL, whether arising out of his/her employment, consulting, investments, or any other activity. These disclosures will be documented promptly in writing and recorded in the Board minutes and corporate records.

3. Procedure

Whenever APHL considers a matter, which presents an actual, apparent, or potential conflict of interest for APHL Personnel, the interested individual will fully disclose his/her interest in the matter, including the nature, type, and extent of the transaction or situation and the interest of the individual or that individual's relatives, friends or other affiliated organizations. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, what is the appropriate course of action under this policy and the Board vote will be recorded in the minutes.

Any Board member having a conflict of interest must either (i) voluntarily abstain from and be disqualified from participation in all deliberation and voting on all Board actions relating to the situation or matter that gives rise to the conflict of interest, or (ii) ask the Board to determine whether an apparent or potential conflict of interest is considered by the Board to be an actual and material conflict. In the event that the Board member in question requests that the Board evaluate the apparent or potential conflict, that Board member will abstain and be disqualified from participating in (and voting on) the determination of whether the issue presents an actual and material conflict. If the Board determines that an actual and material conflict exists, the Board member in question will abstain from all voting on, and will be disqualified from participation in all deliberation concerning all Board actions relating to the conflict of interest. The vote will be recorded in the minutes.

These procedures will neither prevent the interested individual from briefly stating his/her position on the matter, nor preclude him/her from answering pertinent questions of Board members, since his/her knowledge may be of assistance to the Board's deliberations.

APHL Personnel must be cautious and protective of the assets of APHL and insure that they are used in the pursuit of the mission of APHL. The association's policy requires APHL Personnel to avoid transactions in which APHL personnel may have a significant financial interest in any property which

APHL purchases, or a direct or indirect interest in a supplier, contractor, consultant, or other entity with which APHL does business. The Board, after consultation with counsel as appropriate, will determine whether an actual and material conflict exists and, if so, determine whether the transaction is nonetheless favorable to APHL before considering whether to approve it.

4. Other Duties and Obligations

Whenever any APHL Personnel discovers an opportunity for business advantage which is relevant to the activities of APHL, the opportunity belongs to APHL and the individual must present this opportunity to the Board. Only once the Board determines not to pursue the matter and relinquishes the opportunity may the individual consider it a matter of possible personal benefit.

APHL Personnel may not accept favors or gifts exceeding $75.00 from anyone who does business with APHL.

All APHL Personnel will keep confidential those APHL matters designated confidential. APHL Personnel are prohibited from disclosing information about APHL to those who do not have a need to know or whose interest may be adverse to APHL, either inside or outside APHL, and are prohibited from using in any way such information for personal advantage to the detriment of APHL.

All APHL Personnel who participate in APHL activities, including committee activities and international consultation activities, must be adequately prepared to fully participate as their position descriptions require and will do so in accordance with the applicable laws and regulations of their respective state or territory and APHL's Articles of Incorporation, Bylaws, and corporate policies. The APHL Board will read and understand the association's Articles of Incorporation, Bylaws, corporate policies and financial statements, and routinely verify that all state, federal, and local tax payments, registrations and reports have been filed in a timely and accurate manner.

Board members will never exercise authority on behalf of APHL except when acting in meetings with the full Board or the Executive Committee or as authorized by the Board. If any member of the Board has significant doubts about a course of action of the Board, he or she must clearly raise the concern with the Executive Director and the Board and, when appropriate, seek independent expert advice.