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

Table of Contents

Summary

The Association of Public Health Laboratories (APHL), in cooperation with the US Centers for Disease Control and Prevention (CDC) Division of HIV 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, 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.
    - For HIV-1 testing, there is a preference for use of an FDA approved test.
- 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 December 2021 a National HIV/AIDS Strategy was announced that focuses on four goals. The first goal is to prevent new HIV infections and the strategy asserts that, “The most effective ways to reduce new HIV infections are to ensure timely diagnosis and engagement in care and treatment for people with HIV so that they achieve and maintain viral suppression and therefore cannot transmit the virus.” This requires not only testing the appropriate populations but also using the most effective testing technology to detect infections as early as possible.

In 2020, The Viral Hepatitis National Strategic Plan: A Roadmap to Elimination 2021—2025 was published. This Action Plan outlines goals to prevent new infections, improve the lives of people living with viral hepatitis, and eliminate viral hepatitis as a public health threat in this nation by 2030. The most recent Viral Hepatitis National Progress Report shows that the estimated number of new HCV infections declined in 2022 for the first time in over a decade. While the rate decreased, the incidence of new cases remained higher than the 2022 target. Improving testing and access to testing remains critical to ensuring equitable treatment for people living with HCV.

Diagnosis of both HIV and HCV infection relies upon a multi-step testing algorithm. Completion of the entire testing algorithm is imperative for a complete and accurate diagnosis. CDC recommends the HIV

Laboratory Diagnostic Testing Algorithm[1,2,3] 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 or HIV-1/-2 NAT[3].

The HIV NAT test is critical to identify potentially acute HIV 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 the most recent survey of US PHLs, only 22 perform HIV-1 NAT in-house while the majority 45% (30 of 66 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-1 infection in the US. Additionally, 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 detected HIV-2 reactivity). HIV-1 NAT is performed to rule out an acute HIV-1 infection before testing for HIV-2 RNA is performed. At least one of the selected applicants must be able to offer HIV-2 testing.

In 2023, the CDC published Updated Operational Guidance for Implementing CDC's Recommendations on Testing for Hepatitis C Virus Infection. This guidance supports collecting samples to enable the completion of the two step testing algorithm in a single visit. Testing begins 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] Having a sample available for automatic reflex to HCV RNA testing when HCV Ab is reactive, eliminates the need for multiple patient visits. 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 2020, 62% of US PHLs perform HCV testing, compared with 80.5% that perform HIV testing.[3] Of the PHLs that perform HCV testing, 92% (n=50) offer a laboratory based HCV antibody immunoassay, but only 30 of those PHLs offer HCV RNA testing for diagnosis and only 14 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.

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

November 18, 2024	–	RFP Issued
December 6, 2024	–	Informational Teleconference (Q&A)
December 16, 2024	**–**	**Letter of Intent Due to APHL (see below)**
January 17, 2025	–	**RFP Responses Due**
February 10, 2025	–	Proposal review completed
February 11-16, 2025	–	If needed, follow-up interviews and updated proposals due
February 21, 2025	–	Final review completed and awardees selected
July 1, 2025	–	First year contract awarded

Send Letter of Intent, Applications and Questions to Erin Estes (erin.estes@aphl.org) and infectious.diseases@aphl.org.

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 **11:59pm EST on the date indicated in the RFP Schedule above.** To allow for appropriate review process planning, **a letter of intent is required** for consideration.

Final Response

APHL must receive complete responses by **11:59 pm EST on the date indicated in the RFP Schedule above**. Please see Proposal-Required Submissions section for items that must be included in the completed proposal. Applicants may send proposals via email to the email addresses provided in the RFP Schedule above.

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 may vary year to year based on testing performed and volume of specimens submitted. Reimbursement will be based on a mixed model consisting of a flat rate of $15,000.00 upon contract ratification to cover costs associated with maintaining testing, and a per specimen reimbursement of $60.00. The maximum compensation

for the National HIV NAT Reference Center is estimated at $75,000 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 in2023 – 2024 was 365 and for the first half of 2024 – 2025, approximately 301 specimens have been tested. The maximum compensation for the HCV NAT Reference Center is approximately $75,000. Funding for the HIV and HCV Reference Centers is distributed through an annual contract with APHL based on a one-time flat rate and per specimen rates. By accepting this award, the laboratories agree to the negotiated 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 July 1, 2025 through June 30, 2026. 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, 2030). 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) Specialist, 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 Infectious Disease 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 Senior Director of Infectious Diseases Programs will have final approval over the review team's composition.

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;
6. Ability to comply with expectations laid out in Appendix A and/or Appendix B, and Appendix C.

Evaluation Process

The evaluation team will conduct the review via a combination of email communication between APHL's HHST Specialist and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL's HHST Specialist 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.

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 and a proposal. 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 six 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 (1-10) 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 1-6 and 7-8
- Applicants for the National HCV NAT Reference Center respond to questions 1-6 and 9-10

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.

National HIV NAT Reference Center

7. 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 (e.g.: discuss alternative specimen types validated including off-label age groups, alternative stability conditions, etc.).
    b. A few HIV NAT methods are FDA-approved for both diagnosis (qualitative) and viral load monitoring (quantitative) using plasma specimens. 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:
        i. 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.
        ii. 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?
        iii. Would there be any change in the average TAT (from diagnostic specimen receipt to result reported) ?
    c. 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?) How long has the methodology been in use in your laboratory?
        i. If you were selected for this award, what adjustments could you make to the reporting method to improve the average TAT?
    d. 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?
e. Provide information on testing algorithm(s) and reflex testing in your laboratory. Please discuss all available order types including those used for routine diagnostic testing and those used when testing for purposes related to HIV pre-exposure prophylaxis (PrEP), if applicable.
f. 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?
g. Provide annual HIV-1 NAT volume for samples tested within your jurisdiction (for the 2022 and 2023 Calendar Years)
h. What contingency plans do you have if the method or instrument were to become unavailable?

8. 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 2022 and 2023 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

9. 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. (e.g.: discuss alternative specimen types validated including off-label age groups, alternative stability conditions, etc.).

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 2022 and 2023 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?

10. 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. (e.g.: discuss alternative specimen types validated including off-label age groups, alternative stability conditions, etc.).
    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) ?
    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?)
        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 the email provided in the RFP Schedule. 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 the addresses provided in the RFP Schedule by the due date indicated in the RFP Schedule**.**

Applications are due by the dates indicated in the RFP Schedule**.** APHL will send an email acknowledging the receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-3916 to confirm receipt.

APHL will hold an optional teleconference on the date and time indicated in the RFP Schedule. 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 the emails indicated in the RFP Schedule **no later than 8:00am ET on the day prior to the call to receive registration instructions.**

Join Zoom Meeting
https://aphl.zoom.us/meeting/register/tZItde2vqT8iHtaYWEIkB-8ImYQxEQu9tqzy

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. Centers for Disease Control and Prevention. Technical Update for HIV Nucleic Acid Tests Approved for Diagnostic Purposes. 2023. Available from: https://www.cdc.gov/hiv/guidelines/recommendations/technical-update-for-hiv.html
4. Association of Public Health Laboratories. Public Health Laboratory Issues in Brief: 2019-2020 HIV and HCV Diagnostics Survey Report. 2022. Available from: https://www.aphl.org/aboutAPHL/publications/Documents/ID-2022March-HIV-and-HCV-Survey-Report.pdf
5. 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.
6. Centers for Disease Control and Prevention. Updated Operational Guidance for Implementing CDC's Recommendations on Testing for Hepatitis C Virus Infection. MMWR Morb Wkly Rep. 2023 July 14; 72(28);766-768

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[1,2,3] 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;
- Manufacturer name of initial immunoassay;
- Result(s) of initial immunoassay (only for BioPlex);
- Manufacturer 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 must comply with the package insert/ validation and be of sufficient volume. The Reference Center must be able to perform an HIV-1 NAT on plasma and serum specimens and provide a qualitative result, providing quantitative results for plasma specimens is optional. 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 (both ideal and minimum) will depend on the exact method that is being employed, but the information will be conveyed to the submitting laboratories by APHL. 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 minimizing the time specimens are stored at 2 to 8°C. Upon completion of all testing, remnant specimens 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 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 October 2024, there are three FDA-approved methods that can lead to identification of HIV-2 seroreactivity (BioPlex® 2200 HIV Ag-Ab, Geenius™ HIV1/2 Supplemental Assay, or VioOne HIV Profile Supplemental Assay), either at the first or second step of the recommended testing algorithm and one FDA-approved method for detecting and differentiating HIV-1 and HIV-2 RNA (cobas HIV-1/HIV-2 Qualitative). At least one Reference Center must have a qualitative HIV-2 NAT method using either and FDA approved assay or a laboratory developed test 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 HIV-1 NAT method. If HIV-1 RNA is not detected by the Reference Center, the specimen should be automatically reflexed to an HIV-2 NAT. This reflex testing will be conducted by the reference center that performs HIV-2 testing, whether or not that reference center is the original recipient of the specimen.

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
- 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:

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

- 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 (ideal and minimum volume) will be conveyed to the submitting laboratories by APHL. 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.

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 HIV-1 NAT that is FDA authorized for diagnostic use on serum and plasma (i.e. either a qualitative assay or quantitative assay that has a diagnostic claim)? **(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 accordance with turnaround times as outlined in Appendix A and/or B?

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

Signature: _____ Date: _____

Printed Name: _____

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 (Question 1) 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 (Questions 2-3) 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. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.	20		Type comments here. (REQUIRED)

Reference Center Testing (Question 4) 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 0-15 points** (5 = 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)	5		
Reporting (Questions 5-6) 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		
HIV-1 (Question 7) 5. Does the applicant have sufficient capacity and experience performing HIV-1 NAT? Consider experience with described method(s), reported turnaround times, 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 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.	25		Type comments here. (REQUIRED)

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 (Question 8) 6. 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
Additional Comments (Question 7 parts a, bii and f) 7.Does the applicant have any unique aspects/services to contribute and or does the laboratory demonstrate the ability to incorporate new technologies and methodologies? **Rate on a scale of 0-10 points** (10 = Applicant has unique aspects/services to contribute and has demonstrated the ability to incorporate new technologies and methodologies through validation of off-label age groups and alternative stability conditions. Applicant also has a discrete orderable for HIV testing being performed for the purpose of PrEP testing 0 = Applicant does not have any unique aspects/service to contribute and has not demonstrated the ability to incorporate new technologies and methodologies)	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 (Question 1) 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 (Questions 2 and 3) 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. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.	20		Type comments here. (REQUIRED)

Reference Center Testing (Question 4) 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 0-5 points** (5= 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)	5		
Reporting (Questions 5-6) 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 **High** (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. **Adequate** (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		
HCV NAT (qualitative) (Question 9) 5. 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 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.	25		Type comments here. (REQUIRED)

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) (Question 10) 6. 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
Additional Comments (Questions 9 and 10) 7.Does the applicant have any unique aspects/services to contribute and or does the laboratory demonstrate the ability to incorporate new technologies and methodologies? **Rate on a scale of 0-5 points** (10 = Applicant has unique aspects/services to contribute and has demonstrated the ability to incorporate new technologies and methodologies through validation of off-label age groups and alternative stability conditions. 0 = Applicant does not have any unique aspects/service to contribute and has not demonstrated the ability to incorporate new technologies and methodologies)	10		Type comments here. (Required)
TOTAL SCORE	**100**	**____**	