Request for Proposals (RFP): Evaluation of Molecular Detection Methods for *Treponema pallidum* or Genital Ulcer Disease

Submit to: Sarah Buss, Program Manager of Infectious Diseases (sarah.buss@aphl.org) with a copy to infectious.diseases@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 Sexually Transmitted Disease Prevention (DSTDP), is seeking to award one-time funding for up to 15 state or local public health laboratories (PHLs) for the purpose of developing capacity for molecular detection of *Treponema pallidum* either as a standalone test or as part of a multiplex genital ulcer disease panel. Funding will be awarded via a contract with APHL.

Background

Serologic testing for syphilis has been standard practice for many years, but the practice has several limitations. Serology can be negative early in primary infection, remain positive after successful treatment and sometimes yields discordant results that require further clarification[1]. Detecting *T. pallidum* DNA directly from primary ulcers or lesion exudate can lead to a faster diagnosis, confirm current infection at the lesion site, and ultimately improve detection of early syphilis so treatment can be rapidly provided, preventing complications and transmission.

While genital ulcers are common with syphilis, they are also hallmarks of other diseases including herpes, mpox, lymphogranuloma venereum (LGV), chancroid, Varicella Zoster Virus (VZV), and granuloma inguinale (Donovanosis)[2]. In the US, swabs from genital ulcers are commonly tested for HSV 1 and 2, however these specimens are less frequently tested for *T. pallidum* DNA. Studies show that a relatively high number of specimens that test negative for HSV 1 and 2 test positive for *T. pallidum*[3]. Syndromic testing of swabs from genital ulcers using multiplex panels could lead to detection of more syphilis cases but given the lack of FDA authorized tests for direct detection of *T. pallidum*, capacity for panel-based genital ulcer disease testing is lacking in the US and must be built.

APHL in collaboration with CDC DSTDP is happy to announce this one-time funding opportunity to advance molecular methods for *T. pallidum* detection in public health laboratories. The aim of this funding opportunity is to support development and evaluation of nucleic acid amplification tests (NAATs) for *T. pallidum* in public health laboratories, either as a single-plex assay or as part of a genital ulcer disease (GUD) panel that also targets HSV 1/2 at minimum.

APHL is a non-profit, 501(c)(3) organization that works to safeguard the public's health by strengthening public health laboratories in the United States and globally. The Association's members include state and local laboratories, state environmental and agricultural laboratories, and other government laboratories that conduct testing of public health significance. To obtain more information about APHL, please visit http://www.aphl.org.

Eligibility

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

Anticipated RFP Schedule

January 12, 2026	RFP Issued
January 26, 2026	Informational Teleconference
February 2, 2026	Required Letter of Intent Due to APHL (see below)
February 27, 2026	RFP Responses Due
Multiple Dates	Follow-Up Interviews and Updated Proposals Due (if needed)
May 1, 2026	Estimated Contract Start Date

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

Response Submittal

Confirmation of Intent to Respond

To allow for appropriate review process planning, a letter of intent is required for consideration. APHL requires that prospective applicants submit a brief email statement indicating an intent to submit a proposal to Sarah.Buss@aphl.org with a copy to infectious.diseases@aphl.org. APHL must receive this email by no later than **11:59pm EDT on the date listed in the Anticipated RFP Schedule above**.

Final Response

APHL must receive complete responses by **11:59 pm EDT on the date listed in the Anticipated 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 Sarah.buss@aphl.org with a copy to infectious.diseases@aphl.org.

APHL will send an email acknowledging the receipt of your application; if you do not receive an acknowledgement within two business days, please email the RFP point of contact above to confirm receipt.

Award

Funding will be distributed via a contract administered by APHL. Up to 15 laboratories, depending on strength of applications, funding requested, and funds available, will be selected. Award amounts will depend on the scope of the proposed project with an estimated award per site of $10,000-$40,000.

Use of funds: Funds may be used for activities contributing to development and/or evaluation of a NAAT for detection of *T. pallidum,* either as a standalone test or as part of a multiplex panel that also targets HSV1/2, at minimum. Projects that include multiplex panel evaluation will be prioritized and may target additional pathogens. Beyond the required targets (*T. pallidum* and HSV 1/2), additional priority targets for multiplex panels include mpox and VZV. All activities should be conducted on molecular platforms and with reagents that are expected to be supported long-term. The activities may rely upon test kits or analyte specific reagents available commercially or developed specifically for this project. Publication of final protocols is encouraged.

Funds may not be used to contract with an outside facility to provide testing services. The activities listed below (singularly or in any combination) are examples of expenditures appropriate for the scope of the RFP. You may also propose other activities that are in-line with the scope of this funding opportunity.

1. Purchasing reagents or supplies for evaluation and potential validation of:
    a. a NAAT for *T. pallidum*
    OR
    b. a multiplex GUD NAAT targeting *T. pallidum* and HSV 1/2 at minimum (Additional targets will be supported but will not be required.)
2. Procuring specimens for evaluation of *T. pallidum* or GUD NAAT
3. Updates to existing laboratory information management systems (LIMS) for electronic ordering and reporting of new laboratory orders and results, or instrument interfaced ordering and reporting
4. Providing training for laboratory staff

Term of Project

From date of contract signing (approximately April 1, 2026) through March 31, 2027. A final progress report will be required as a final deliverable. Up to 20% of the proposed amount will be made available at the start of the project, with the remainder disbursed throughout the contract period.

Evaluation Team

APHL staff, led by the Program Manager of Infectious Diseases 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 six subject matter experts (SMEs) selected from non-applicant public health laboratories and / or CDC's Division of Sexually Transmitted Disease Prevention. SMEs from CDC will be identified and selected by the Chief of the Laboratory Branch of the Division of Sexually Transmitted Disease Prevention based on their familiarity with project requirements. APHL member experts will be identified from among the non-applicant laboratories by the APHL Program Manager of Infectious Diseases and will have expertise in the laboratory testing methods described in this RFP. Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

Evaluation Criteria

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 B.

Evaluation Process

The evaluation team will conduct the review via a combination of email communication between APHL's Program Manager of Infectious Diseases and the members of the evaluation team, or among the evaluation team members and teleconference and/or webinar evaluation sessions. APHL's Program Manager of Infectious Diseases 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 budgetary expectations outlined in Appendix A. Acceptance of the award means agreement to the compensation structure and amounts agreed upon with the awardee and APHL.

* Laboratories must be legally able to contract within the United States and not disbarred or prohibited from contracting with businesses or the federal government.

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:

Responses to Questions (below)

o Responses should be limited to no more than six (6) single spaced pages (font size > 11pt, > 1-inch margins) inclusive of one (1) page for the budget.

o Proposal should include responses to the questions below, including each aspect of the question and should clearly indicate what question is being answered.

Response to Proposal Questions

Please review and respond to every question unless otherwise indicated.

1. **Problem Statement:** Please provide a brief explanation (3-5 sentences) of why these one-time funds are needed and, if relevant, briefly document challenges you've encountered with syphilis serology, darkfield microscopy or requests for molecular syphilis or panel based GUD testing, as applicable. Explain how development of the proposed NAAT will improve and positively impact the STI program in your jurisdiction.
2. **Current Testing Capability and Capacity:** Please describe your STI testing program to include a brief description of tests offered, population and clients served, and volume and type of specimens received. Please also describe the test method(s) performed and testing volume for each relevant method. Relevant methods include tests performed on the molecular platform that will be utilized for this work, NAATs for HSV or *T. pallidum*, and NAATs that utilize the same specimen type(s) that will be accepted for this work (e.g.: swabs from lesions), as applicable.
3. **Staffing:** Describe the qualifications and experience of existing laboratory staff that will be involved with the project, including familiarity with development, evaluation and implementation of laboratory developed molecular test methods. Describe any relevant staff training that will be required to evaluate the new protocols or testing capacity.
4. **Detailed Description of Approach**: Provide a description of how your laboratory intends to use the one-time funding to develop and evaluate a *Treponema pallidum* or GUD NAAT. Please address:
    a. **Test Method:** Please describe the testing method(s) that will be evaluated including targeted organism(s) and loci (if known), currently available equipment that will be leveraged and/or if new equipment is required and describe your ability to procure such equipment in a timely manner.
    b. **Evaluation Plans**: Please describe your plans for evaluation of the new NAAT including the estimated timeline, plans for validation, reference/comparator method,

how discrepancies will be resolved, and criteria that will be used to determine if the assay will be implemented in the laboratory. When estimating the timeline, please consider the time required for approvals and LIMS modifications, should the evaluation and validation be successful.

c. **Specimens:** Describe the types of specimens you will use in these studies and how they will be obtained.
d. **Sustainability:** Please provide a brief description of how these one-time funds will be leveraged to generate sustainable testing capacity in your laboratory and be sure to address how testing will be funded in the future. Please also comment on how implemented changes will be communicated to clients and partners and how you envision the test being used.

5. **Measuring Success:** Please describe at least one, and up to three, specific and measurable objectives that allow for assessment of impact and sustainability of the project.
6. **Budget:** Provide a line-item budget reflecting the requested funding amount. Refer to Appendix A for more details. For each category of funding requested (supplies, travel, training materials, etc.), include a brief description of how the requested items support the proposed activities. Please limit your response to no more than one (1) single-spaced page.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to APHL at (infectious.diseases@aphl.org). Questions received from interested PHLs, together with the answers provided by APHL or CDC staff will be posted to APHL's procurement website associated with the specific RFP (www.aphl.org/rfp). APHL will try to post responses on a rolling basis, within 1 business day of receipt of the question.

To allow for appropriate review process planning, a letter of intent is required for consideration. Applicants should submit letters by email to Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org no later than **11:59 pm EDT on the date listed in the Anticipated RFP Schedule above**. Applications are due to Sarah Buss at APHL (sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org by **11:59 pm EDT on the date listed in the Anticipated RFP Schedule above**. APHL will send an email acknowledging receipt of your application. If you do not receive an acknowledgement within two (2) business days, call 240-485-3901 to confirm receipt.

Appendix A: Budget Guidance

Budgets should be prepared to reflect costs through March 31, 2027. Budgets should be divided into the line items shown below. A guideline for each line item is described for preparation of the budget and justifications. It is not appropriate to include staff time on this one-time funding award.

Supplies/Reagents

Provide a total supply budget and list each item included in that budget. Listing the cost of individual items is appreciated. Provide justification for each item and describe how it will be used to develop or evaluate a *Treponema pallidum* or GUD NAAT. General laboratory or safety supplies not specifically used for this work, such as gloves, pipettes, lab coats, etc., are not appropriate for this award.

Equipment/Instrumentation

Equipment/Instrumentation should be listed in priority order, with the first item being of highest priority. Provide justification for the use of each item and describe how the item will be used to develop or evaluate the NAAT. Maintenance costs for equipment should be shown in the "Other" category.

* Given the size of each award, it is unlikely we will be able to cover the total cost of a piece of equipment. However, we are open to providing funding for a portion of equipment, offsetting costs associated with leasing equipment and/or service agreements.

* If durable equipment that costs > $5,000 is purchased using these funds, the cost must be reported to APHL as part of our cooperative agreement reporting.

Other

This category contains items not included in the previous budget categories. Appropriate items for inclusion include, but are not limited to, specimens, relevant IT expenses, maintenance contracts, shipping expenses for validation specimens, and training costs. Individually list each item and the amount requested and provide justification for how the item will be used to develop or evaluate the NAAT.

Additional Costs Budget (optional)

Laboratories may include an additional costs budget reflecting additional funds needed (above the anticipated amount of this award) to fully develop and evaluate NAAT for *Treponema pallidum* or GUD assay methods in their laboratory and or jurisdiction, to meet jurisdictional needs. This budget should also include a brief description of how the funds would be used and should be prepared using the instructions found above.

* This information will assist APHL and DSTDP in determining the allocation of additional funds should they become available.

Appendix B: Scorecard

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

Category/Question	Maximum Value	Score	Comments
1. Considering the proposed approach (Question 4) --does the applicant demonstrate the capacity, capability (Question 2), and appropriate staffing (Question 3) to evaluate the *Treponema pallidum* or GUD NAAT or mechanisms to obtain additional resources to perform the testing? *Consider the following: Does the applicant have appropriate expertise and programmatic infrastructure and/or the ability to obtain additional equipment, supplies, or training required to perform the testing method? Does the applicant provide a timeline for evaluation of the new method that aligns with the project period?* **No issues or concerns:** Applicant has the required expertise and programmatic infrastructure or will build capacity and capability to execute their proposed plans within established timelines (25 points). **Minor concerns:** There are minor concerns about the applicant's ability to execute the proposal within the proposed timeline (20-24 points). **Moderate concerns:** There is missing information and/or there are moderate concerns about the applicant's ability to execute the proposal within the proposed timeline (10-19 points). **Major concerns:** There are major concerns about the applicant's capacity and capability to execute the proposal within the proposed timeline (1-9 points).	25		

Applicant will not be able to evaluate plans based on the information provided (0 points).			
2. Does the applicant provide a sufficiently detailed and achievable plan for evaluation and validation of the *Treponema pallidum* or GUD NAAT? (Question 4) **No issues or concerns:** Sufficient information and appropriate approach (30 points). **Minor concerns:** Some information missing to fully assess and/or some minor concerns with approach (20-29 points). **Moderate concerns:** Information missing to fully assess plan and/or moderate concerns with the approach (10-19 points). **Major concerns:** Significant information missing to fully assess plan and/or major concerns with the approach (1-9 points). **Insufficient information to assess plan and/or inappropriate approach** (0 points)	30		
3. Does the applicant provide a clear explanation and justification for how evaluating a *Treponema pallidum* or GUD NAAT will improve syphilis testing in their jurisdiction and positively impact their STI program? (Question 1 and 2) **Applicant expresses significant and appropriate need**: Jurisdiction has not evaluated direct syphilis or GUD testing, demonstrates how funds would improve the testing program, and serves an STI program(s) that would benefit from addition of the test (20-25 points). **Applicant expresses appropriate and moderate need:** Jurisdiction demonstrates how funds would improve current STI testing yet may have already implemented a *Treponema pallidum* or GUD NAAT. Receives moderate STI testing volume (11-19 points); reasonable request. **Applicant expresses minimal need**: Jurisdiction receives minimal STI requests each year or fails to demonstrate why funds are needed to	25		

evaluate the *Treponema pallidum* or GUD NAAT but has reasonable request to utilize funds (1-10 points). **Insufficient information to assess need** (0 points).			
4. Does the applicant provide at least one and up to three specific, measurable objective(s) that will enable them to assess the impact of the funding (Question 5)? **No concerns with stated objective(s):** Objective(s) are appropriate, clear, specific, and measurable, with a well thought out plan for sustainability of testing (10 points). **Minor to moderate concerns with objective(s):** Slight concern with plan for sustainability or defined objective(s) but displays an ability to measure impact (5-9 points). **Major concerns:** Project likely lacks sustainability and / or objective(s) are not entirely appropriate, clear, specific, or measurable and would be difficult to use for measuring success/impact (1-4 points). **Sustainability not addressed and / or objective(s) not provided and/or don't address impact** (0 points).	10		
6. Does the applicant provide an appropriate budget for the requested funding? (Question 6) **No concerns with budget** (10 points). **Minor to moderate concerns with budget** (5-9 points). **Major Concerns with budget** (1-4 points). **Budget not appropriate for proposal** (0 points).	10		
TOTAL SCORE	100	_____	