Request for Proposals (RFP): Tuberculosis (TB) Testing Reference Center for the US-Affiliated Pacific Islands (USAPI)

Submit to: Sarah Buss, Manager of Infectious Disease (sarah.buss@aphl.org) with a copy to infectious.diseases@aphl.org

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 Tuberculosis Elimination (DTBE), is seeking to identify one clinical, commercial, or state/local public health laboratory, to serve as the Tuberculosis (TB) Testing Reference Center for the US-Affiliated Pacific Islands (USAPI). This Reference Center will provide TB laboratory services, coordinate external quality assessment, and support laboratory quality improvement through workforce development and laboratory evaluations to improve TB diagnosis, surveillance, and treatment monitoring for ten USAPI locations: 1) American Samoa; 2) Commonwealth of the Northern Mariana Islands; 3) Guam; 4) Chuuk State, 5) Kosrae State, 6) Pohnpei State, and 7) Yap State in the Federated States of Micronesia; 8) Ebeye and 9) Majuro in the Republic of the Marshall Islands; and in the 10) Republic of Palau. Up to 3,500 specimens will be received and processed per year. Services will include:

1) specimen transport from USAPI locations, inclusive of provision and shipping for specimen collection and packaging supplies
2) smear microscopy and culture for acid-fast bacilli (AFB)
3) identification and direct detection of *M. tuberculosis* complex (MTBC)
4) minimally phenotypic and if performed, molecular, first-line drug susceptibility testing (DST), and as applicable, reflex (in-house or to a different laboratory) for Molecular Detection of Drug Resistance testing and second-line DST when drug resistance is suspected or detected
5) Submission of MTBC isolates for genotyping to a designated laboratory, as applicable
6) Efficient results reporting to USAPI locations to include use of a laboratory web portal

Background

The CDC domestic portfolio for TB control and prevention includes the 50 states, Washington DC, Puerto Rico, US Virgin Islands, and the USAPI. The USAPI includes three US territories with Clinical Laboratory Improvement Amendments (CLIA) regulated laboratories – American Samoa, the Commonwealth of the Northern Mariana Islands (CNMI) Guam, and three freely associated states (FAS) – the Federated States of Micronesia (FSM), the Republic of the Marshall Islands (RMI), and the Republic of Palau. The FAS have a Compact of Free Association with the US, which allows citizens of these jurisdictions to migrate to the US to live, study, and work as nonimmigrants without visa and they are not required to complete a medical examination to screen for TB prior to arrival. Laboratories in the FAS are not subject to CLIA regulations.

During 2023, a total of 501 TB cases were reported by the USAPI, representing an increase of 252 cases (101%) as compared with 2022 *(1)*. The USAPI TB incidence rate in 2023 was 114.1 per 100,000 persons, which was 39 times greater than the US rate of 2.9 per 100,000 persons.

A core component of effective TB control programs is the delivery of laboratory and diagnostic services, as well as the need to collect and analyze data *(2)*. Laboratories in the USAPI are unable to fulfill this essential program activity as they conduct limited local TB testing and lack the capacity to provide comprehensive laboratory services needed to detect and identify MTBC.

Provision of these services will improve CDC's ability to detect TB rapidly so that medical consultation and technical assistance can be provided to reduce the high burden of TB disease in the USAPI. This contract will support the CDC mission to fight disease before it reaches our border to increase our national security.

Eligibility

Eligible laboratories include any clinical, commercial, or public health laboratory located within the United States including Puerto Rico, the US Virgin Islands, and the USAPI that can meet the requirements below and the specific expectations regarding the methodologies to be used by the Reference Center outlined in Appendix A: Expectations for the TB Testing Reference Center for the USAPI. All applicants are required to agree to the minimum requirements outlined in Appendix B: Minimum Requirements for the TB Testing Reference Center for the USAPI. Eligible laboratories must have the following capabilities, resources, and facilities in place:

1. CLIA certification for high complexity testing;
2. International Air Transportation Association (IATA) certification;
3. Availability of adequate laboratory space or space to accommodate additional equipment if necessary, anticipating up to 3500 samples per year;
4. Availability of necessary equipment or ability to purchase additional equipment if necessary, anticipating testing for up to 3500 samples per year;
5. Sufficient workforce capacity for expected testing scope and volume or ability to hire additional qualified staff;
6. Ability to maintain an approved permit from the CDC Import Permit Program, as applicable;
7. Biosafety infrastructure (https://www.cdc.gov/labs/BMBL.html), practices, safety equipment, facilities, and training in handling infectious agents and associated procedures;
8. Willingness to share copies of quality assurance (QA) or biosafety documentation associated with relevant procedures to APHL and CDC upon request;
9. Compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and HIPAA Privacy & Security Rules to ensure the protection and confidentiality of individually identifiable health information;
10. Informatics capabilities including:
    a. **Laboratory Information Management System** in place and able to be enhanced or modified to meet expectations outlined in Appendix A.
    AND
    b. Proven capability to support **Electronic Test Order and Results (ETOR)** through an existing web portal
    AND
    c. Ability to establish and/or maintain ETOR connectivity to the 10 USAPI locations;
11. An infection control and surveillance program that monitors the possibility of laboratory acquired infection;
12. Participation in laboratory external quality assessment, ideally CDC's Model Performance Evaluation Program (MPEP);
13. Ability to coordinate airline and land courier logistics to ensure the timely shipping, transport,

and processing of specimens.

14. Familiarity with the MTBC laboratory infrastructure in the USAPI is preferred.

Anticipated RFP Schedule

June 24, 2025	–	RFP Issued
July 9, 2025	**–**	**Letter of Intent Due to APHL (see below)**
July 11, 2025	–	Informational Teleconference, if necessary (Q&A)
July 28, 2025	**–**	**RFP Responses Due**
August 6, 2025	–	Proposal Reviews Completed
August 7-8, 2025	–	Follow-up Interviews and Updated Proposals Due (as needed)
August 13, 2025	–	Final Review Completed and Awardee Selected
Summer, 2025	–	Site visit, Harmonization, Validations, and Other Pre-Planning (as needed)
September 25, 2025	–	First Year Contract Awarded

APHL will communicate any modification to this anticipated schedule on APHL's procurement website (www.aphl.org/rfp) and via email blast to 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 due date**.** 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 due date**.** 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 copy to infectious.diseases@aphl.org.

APHL will send an email acknowledging 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

One laboratory will be selected. The amount of the award will be based on submitted budgets and the anticipated specimen volume of approximately 3,500 specimens per year, although not all test methods will be performed on all specimens. The maximum compensation could be up to $601,500, to be

distributed on a monthly basis. Funding is distributed through an annual contract with APHL and is contingent upon APHL's receipt of funds from the funding agency. By accepting this award, the laboratory agrees 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 specimen collection and transport supplies, shipping, testing of referred samples (including retesting due to laboratory/personnel error), reagents, 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. Additionally, the awardee may use funds to prepare and ship external quality assessment materials, conduct workforce development and evaluation activities or to subcontract with another US-based entity to perform any of these tasks.

Term of Project

The project term will be from September 25, 2025 through June 30, 2030, with the first annual contract established for the period of September 25, 2025, through June 30, 2025. 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) will be considered by APHL based on availability of funds and performance of the awardee for a maximum of four additional years (to end June 30, 2030). Each of the potential renewals may involve some adjustment to the scope of work, including the potential for test volume fluctuations, 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 for a future funding year.

Evaluation Team

APHL staff, led by the Infectious Diseases Program Manager, will conduct an initial review of all proposals for completeness. Any application that is incomplete as of the proposal due date specified in the Anticipated RFP Schedule section above will not be considered and will not receive a formal evaluation.

Complete proposals will be reviewed by a team of three subject matter experts (SMEs) from CDC's DTBE and a panel of three APHL members selected from non-applicant PHLs. SMEs from CDC will be identified and selected by the DTBE Laboratory Branch Chief based on their familiarity with laboratory techniques and project requirements. APHL member experts will be identified from among the non-applicant laboratories by the APHL Infectious Diseases Program Manager and will have expertise in laboratory testing methods described in this RFP and familiarity with APHL's Reference Center structure. Once potential reviewers have been identified, APHL's Director of Infectious Disease Programs will have final approval over the review team's composition.

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 C.

Laboratories meeting the following criteria have preference in the evaluation:

1. Ability to facilitate shipping of supplies to and specimens from the 10 USAPI locations;
2. Extensive experience with the test methods;
3. Ability to handle anticipated test volume;
4. Existing in-house subject matter expertise;
5. Experience and past performance serving as a reference laboratory, especially if experienced with provision of testing for the USAPI;
6. Experience with preparation or coordination of external quality assessment programs;
7. Experience conducting laboratory workforce development and laboratory evaluations;
8. Experience working with non-CLIA regulated laboratories;
9. Current usage of web-based electronic laboratory information system for ETOR;
10. Ability to comply with expectations laid out in Appendix A; and
11. Ability to meet minimum expectations outlined in Appendix B.

Evaluation Process

The evaluation team will conduct the review via a combination of email communication between APHL's Infectious Diseases Program Manager and members of the evaluation team, or among evaluation team members and teleconference and/or webinar evaluation sessions. APHL's Infectious Diseases Program Manager will coordinate the review process and the evaluation sessions.

The reviewers may request follow-up interviews with all or some of the applicant laboratories and, following these interviews, may request supplemental information on an applicant's proposal. The evaluation team will use these interviews and any supplemental information to clarify a laboratory's capacity or experience in one or more of the evaluation criteria, or to explain other information contained in an applicant's proposal.

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

Post-Evaluation Procedures

APHL staff will notify the selected laboratory within ten business days of the completion of the evaluation and will post the name of the recipient 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. The laboratory must agree to comply with expectations outlined in Appendix A. 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 the applicant laboratory. Post award, monitoring site visits may be conducted to include an assessment of continued compliance.

Following selection and prior to making the official award, APHL will require the finalist to submit a letter of support from the LIMS vendor confirming the following items as applicable: Confirming the respondents capability to modify and maintain the relevant testing algorithms, and reporting language within the LIMS, and confirming the applicants ability and willingness to extend any current electronic test ordering and reporting (ETOR) capabilities to support the requirements of this project.

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 B,**

  Note: If your laboratory cannot respond "yes" to each of the minimum requirements, your laboratory does not meet the minimum qualifications required to apply for this award.

- **A letter of support from your institution's IT department:**
  a. **Current USAPI Reference Laboratory Only:** Confirming your commitment to maintain ETOR connectivity to the 10 USAPI locations with the support of a designated IT staff member **OR**

  b. Confirming your ability to establish ETOR connectivity to the 10 USAPI locations **OR**

  d. Confirming your current ETOR capability using an existing web portal and confirming that there is the capacity to onboard 10 USAPI locations to the system including any costs associated with such onboarding **AND**

e. Confirming that the applicant will have the support of a designated IT staff member to support this work.

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

Response to Questions

Physical Environment

1. Describe your laboratory's space and the equipment available to accommodate Reference Center testing at the anticipated workload (3,500 samples / year) for coordinating shipping and receiving of specimens and related materials, performing smear microscopy, direct detection, culture, identification, phenotypic and, if applicable, molecular drug susceptibility testing at current staffing levels. Please address how the space and equipment will be used to handle the workload. If your laboratory cannot immediately handle the anticipated workload, please include timelines and plans for scaling up.
    a. Please describe the existing space, equipment and staff to handle testing volume(s) for all aspects of shipping and receiving and testing as well as ability to expand, as applicable. Does the facility have laboratory space available for additional instrumentation or staff, if needed, to accommodate anticipated workload?
    b. Please describe the biosafety infrastructure, practices, safety equipment.

Workforce

2. Does your laboratory have staff with the subject matter expertise to provide testing as well as technical guidance and assistance with interpretation of results (including discordant results) to submitting laboratories?
    a. Please describe the qualifications and experience staff have in providing related testing activities, including relevant experience with MTBC, and comment on your laboratory staff's ability or experience with providing training to both CLIA and non-CLIA regulated laboratories, development and maintenance of a QA plan for monitoring of submitting sites, providing consultative services.
    b. Does the laboratory have sufficient staffing or the ability to hire additional staff if necessary to accommodate workload? If hiring would be required, please describe approximate timelines associated with posting and hiring new positions.

Methodology

3. Please describe the current methodology and algorithms used in your laboratory for TB testing and the approach that will be used to complete the tasks/subtasks outlined in Appendix A. Include information on:
    a. For AFB smear microscopy, direct detection, culture, identification and drug susceptibility testing, please describe:
        i. testing algorithm and workflow (figures are acceptable supplements)
        ii. methods and platform(s) used, including whether methods are FDA-cleared or laboratory developed
        iii. annual testing volume (2023 and 2024 Calendar Year, if available)
        iv. how often testing performed
        v. how long the methodology has been used
        vi. specimen types accepted / tested
        vii. average turnaround times
        viii. any tasks that are performed by subcontractors or referral laboratories as applicable
    b. drugs included on first-line phenotypic and, if applicable, molecular DST panels, and as applicable,
        i. which genetic loci are evaluated
        ii. how interpretations are determined
        iii. names of referral laboratories used
    c. drugs included on second-line DST panels
    d. number of laboratory staff and their experience with the test method(s) including years of experience of each trained staff member
    e. any training staff has received
    f. any planned changes to current testing procedures
    g. approach towards quality management including participation in external quality assessments

Reporting Results/Information Technology

4. Please describe all LIMS, tools, and infrastructure available to support the work outlined in Appendix A including current processes for submitting orders to your laboratory, and current processes for reporting results (e.g., LIMS, ETOR HL7, ETOR web portal, or secure fax, etc.). Respondents must identify any ETOR capability available to support the reporting requirements of TB Testing Reference Center for the USAPI including ability to modify LIMS, capacity to onboard submitting sites to the ETOR solution and any/all back-up reporting mechanisms. Please also include the process and estimated timeline to onboard new submitters.

Specimen Transport

5. If selected, how would your laboratory approach the requirement to provide specimen collection and shipping supplies to USAPI laboratories on a regular schedule? What would your general plan be to assist USAPI locations with efficient and timely specimen shipping? What would the timeline be for the development of procedures related to requesting supplies, specimen collection, packaging

and shipping? If you have remarkable relationships with relevant vendors or experience coordinating the shipment of laboratory specimens from remote international locations, please provide detail.

Reference Center Testing

6. Briefly describe your laboratory's experience, if any, in providing reference testing for other laboratories, including experience providing testing for the USAPI.

Non-CLIA Regulated Laboratories

7. Diagnostic laboratories in FAS are not subject to CLIA regulations. Describe your laboratory's experience working with non-CLIA regulated laboratories.

External Quality Assessment

8. Describe your laboratory's experience preparing or coordinating external quality assessment programs.

Capacity Building

9. Describe your laboratory's experience conducting laboratory workforce development activities and laboratory evaluations.

Risk Management

10. Please describe potential problems that may be encountered while performing the work requirements and risks to sustained capability. Provide plans for overcoming these difficulties and ensuring client satisfaction.

Budget

11. Provide a one-year budget outlining at least the following line items: staff time; charge per specimen/isolate tested by each method; travel expenses and anticipated overhead charges if any.

Surge Support

12. Please state whether you are able to provide surge support as needed. This activity could require contract amendments and additions to the budget which would require further approval from both parties. Briefly detail experience with surge volume testing and addition of new testing methodologies or alteration of workflows in response to emergent situations.

Additional Information and Deadlines for Application Submission

Applicants must direct all questions to Sarah Buss (sarah.buss@aphl.org). APHL will post questions received from interested laboratories, 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 Sarah Buss at APHL (sarah.buss@aphl.org) with copy to infectious.diseases@aphl.org no later than **11:59 pm EST** on the due date**.**

Applications are due to Sarah Buss at APHL (sarah.buss@aphl.org) with copy to infectious.diseases@aphl.org **by close of business (11:59pm ET)** on the due date**.** 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.

If necessary, APHL will hold an optional teleconference at 4:00pm ET on the date listed in the schedule above. 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 Registration Information is below, or please contact sarah.buss@aphl.org or infectious.diseases@aphl.org no later than 8:00 am ET on July 11, 2025 to receive registration instructions.

Register in Advance for this Zoom Meeting:
https://aphl.zoom.us/meeting/register/i6EoajrDTLiqf_Hb6kay6g

References:

1. CDC. Reported Tuberculosis in the United States, 2023. Atlanta, GA: US Department of Health and Human Services, CDC; 2023. https://www.cdc.gov/tb-data/index.html
2. CDC. Essential components of a tuberculosis prevention and control program. Recommendations of the Advisory Council for the Elimination of Tuberculosis. MMWR 1995;44(No. RR-11):1–16. Available at http://www.cdc.gov/mmwr/pdf/rr/rr4411.pdf
3. Clinical and Laboratory Standards Institute (CLSI). Laboratory Detection and Identification of Mycobacteria; 2nd Ed. CLSI guideline M48. 2018, Wayne, Pennsylvania.
4. Kent, P.T. and G. P. Kubica, 1985. Public Health Mycobacteriology: A guide for the level III laboratory. Atlanta: Department of Health and Human Services.
5. World Health Organization. Quality Assurance of Sputum Microscopy in DOTS Programmes. Manila, Philippines: Regional Office for the Western Pacific, WHO; 2003. Available at: http://www.who.int/ihr/training/laboratory_quality/11_cd_rom_tb_eqa_wpro.pdf
6. CDC. Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis. Atlanta, GA: US Department of Health and Human Services, CDC; 2009. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5801a3.htm
7. CDC. Availability of an Assay for Detecting Mycobacterium tuberculosis, Including Rifampin-Resistant Strains, and Considerations for Its Use—United States, 2013. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at https://www.cdc.gov/mmwr/pdf/wk/mm6241.pdf
8. Clinical and Laboratory Standards Institute (CLSI). Susceptibility Testing of Mycobacteria, Norcardiae spp, and Other Aerobic Actinomycetes, in 3rd Ed. CLSI Standard M24. 2018, Wayne, Pennsylvania.

9. CDC. National Plan for Reliable Tuberculosis Laboratory Services Using a Systems Approach. Atlanta, GA: US Department of Health and Human Services, CDC; 2002. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5406a1.htm
10. Association of Public Health Laboratories. Mycobacterium tuberculosis: Assessing Your Laboratory. 2019. Silver Spring, MD. Available at https://www.aphl.org/aboutAPHL/publications/Documents/ID-2019Apr-TB-Toolkit.pdf

Appendix A: Expectations for the TB Testing Reference Center for the USAPI

Activities

1.0 Specimen Transport

Establish and implement an airline and land courier logistical process to pack, ship, and receive TB specimens from the ten USAPI TB laboratories to the Reference Center on a schedule that allows for timely processing.

Subtask 1.1 – Provision of Specimen Collection and Packaging Supplies

Provide all specimen collection and packaging supplies which include, but are not limited to, collection containers, Sputocol™ sputum collection system, substances for neutralization of gastric aspirates, leak-proof specimen bags, absorbent material, Styrofoam containers, United Nations (UN) approved boxes, packaging tape, mailing labels, and shippers declaration forms. Fulfill requests for supplies within five business days of receipt. Develop and provide written procedures for the following:

- Requesting specimen collection and packaging supplies
- Using the Sputocol™ sputum collection system
- Using substances for neutralization of gastric aspirates
- Packaging specimens for shipment that includes appropriate illustrations for various packaging steps

Subtask 1.2 – Shipping of Specimens

Develop and provide written procedures for shipping specimens from each of the ten USAPI TB laboratories to the Reference Center. The procedures shall adhere to all regulations and/or guidelines established by the U.S. Department of Transportation (DOT), Federal Aviation Administration (FAA), and International Air Transportation Association (IATA). The procedures shall outline steps for delivering shipment to the local carrier in the USAPI site, ensuring appropriate temperature controls based on flight duration, obtaining clearance at the destination airport, ensuring appropriate temperature controls at the destination airport if timely delivery to the Reference Center cannot be made, and transportation from the destination airport to the Reference Center. In the event of changes to regulations, guidelines, and/or procedures, the Reference Center shall provide written notification to the USAPI sites and CDC and APHL within 48 hours and shall provide an updated written procedure within five business days.

2.0 Laboratory Testing

Provide smear microscopy and culture for acid-fast bacilli (AFB), identification of *M. tuberculosis*, direct detection, and drug susceptibility testing on samples submitted from the USAPI sites. Ensure that testing algorithms for the USAPI established by CDC are followed. The Reference Center shall process up to 3,500 specimens each contract period.

Subtask 2.1 – Smear Microscopy and Culture for AFB and Identification

Perform AFB smear microscopy, culture, and identification of *M. tuberculosis* complex by using conventional, molecular, and rapid methodologies described in published guidelines cited in

Section: Additional Information and Deadlines for Application Submission - Reference Materials (*3,4,5,6,10*). Report identification of non-tuberculous mycobacteria (NTM) if testing methods include these results.

Subtask 2.2 – Direct Detection

Perform nucleic acid amplification (NAA) testing, molecular testing, or other rapid tests for direct detection of *M. tuberculosis* using validated and established procedures described in published guidelines cited in Section: Additional Information and Deadlines for Application Submission - Reference Materials (*3,6,7,10)*.

Subtask 2.3 – Drug Susceptibility Testing

- Perform phenotypic (i.e., growth-based) or molecular drug susceptibility testing (DST), as applicable, on MTBC isolates using validated and established procedures described in published guidelines cited in Section: Additional Information and Deadlines for Application Submission - Reference Materials (*4,7,8,10)*. The DST panel shall include at least the four first-line anti-tuberculosis drugs: 1) isoniazid, 2) rifampin, 3) pyrazinamide, and 4) ethambutol.
- Perform reflex Molecular Detection of Drug Resistance testing when resistance to rifampin is detected, or suspected, by either molecular or phenotypic methods, in accordance with testing algorithms established by CDC.
- Perform or ensure reflex DST of second-line anti-tuberculosis drugs and molecular drug susceptibility testing in accordance with testing algorithms established by CDC.
- Use of a reference laboratory for DST is acceptable and may be necessary to obtain DST for new and repurposed drugs that might be used as part of treatment regimens, especially for drug resistant cases. The Reference Center shall describe the criteria to determine which isolates will be sent to the reference laboratory, the name of the reference laboratory, testing methods, DST panel, and anticipated turnaround times. Consideration should be given to use of the CDC Division of TB Elimination Reference Laboratory for samples from the USAPI that require expanded DST.

Subtask 2.4 – Submission for Genotyping

Ship at least one *M. tuberculosis* isolate from each culture-positive TB patient in coordination with the public health laboratory in the state of the Reference Center for submission to a laboratory contracted by CDC to conduct genotyping.

3.0 Reporting and Storing Results

Follow the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and HIPAA Privacy & Security Rules to ensure the protection and confidentiality of individually identifiable health information while completing the following subtasks:

Subtask 3.1 – Reporting and Storing Results

Results shall be securely maintained and reported through a web-based electronic laboratory information system within 24 hours after results are known. Provide USAPI sites, and CDC designees with access to the system to retrieve results and written instructions on how to operate the system. Provide APHL and CDC with a list of all users who have access to the system.

Verify this list annually and add or remove user access when requested by the USAPI sites, APHL and CDC designees.

Subtask 3.2 – Reporting of Critical Value Test Results

Notify specimen submitters of critical value test results via e-mail within 24 hours after results are known. Critical value test results include AFB smear-positive, culture identification of *M. tuberculosis* complex, direct detection of *M. tuberculosis* complex, and detection of any drug resistance.

Subtask 3.3 – Line List Report

Submit a monthly line list report that includes, at a minimum, the following variables for all specimens received and processed from each of the ten USAPI TB laboratories:

- Patient identification number.
- Specimen accession number, collection date, receiving date, days between collection and receipt, specimen source or type (e.g., sputum, gastric lavage, or pleural fluid), number in series collected (e.g., 1 of 3), specimen category (diagnostic or follow-up), volume (milliliter), and consistency (mucoid or salivary).
- USAPI local laboratory direct smear result (WHO grading scale), smear count, and local Xpert MTB/RIF (or equivalent) results.
- Reference Center laboratory smear result, smear count, culture, DST, overgrowth, and any molecular results, as applicable.

Subtask 3.4 – Monthly Workload Report

Submit a monthly quantitative workload report that includes:

- Number of specimens processed for each of the ten USAPI TB laboratories.
- Cumulative number of specimens processed during the base and option periods.

Subtask 3.5 – Monthly Specimen Transport and Contamination Report

Submit a monthly quantitative report that includes the following measures for each of the ten USAPI TB laboratories and cumulatively:

- Longest time from specimen collection to receipt.
- Shortest time from specimen collection to receipt.
- Median turnaround time from specimen collection to Reference Center receipt.
- Total number of specimens that are contaminated with overgrowth.
- Total number of specimens cultured.
- Percent of specimens that are contaminated with overgrowth (contamination rate).
- Include a bar and/or line chart that illustrates trends.

Subtask 3.6 – Monthly Quality Report

Submit a monthly quantitative report that includes data on the following performance measures:

- Percentage of fluorescent AFB smear results reported within one day of specimen receipt.
- Percentage of TB identifications performed by NAA testing, molecular testing, or other rapid tests for direct detection (and resulted within 48 hours of receipt) that are later confirmed by culture.

- Percentage of TB isolates identified by initial diagnostic specimens within 21 calendar days of specimen receipt.
- Percentage of TB susceptibility results reported within 17 days of culture identification.
- Include a bar and/or line chart that illustrates trends.

Subtask 3.7 – Final Workload Report

Submit a final quantitative workload report that includes:

- Number of specimens processed for each of the ten USAPI TB laboratories by base and option periods.
- Total number of specimens processed for all USAPI TB laboratories by base and option periods.
- Total number of specimens processed during the entire period of performance.

Subtask 3.8 – Final Specimen Transport and Contamination Report

Submit a final quantitative report that summarizes data from Subtask 3.5 by base and option year, and for the entire period of performance.

Subtask 3.9 – Final Quality Report

Submit a final quantitative report that summarizes data from Subtask 3.6 by base and option year, and for the entire period of performance.

4.0 Laboratory Consultation

The Reference Center shall be available for consultation by phone and email to the ten USAPI TB laboratory and TB control program staff for technical assistance and interpretation of results.

- CDC DTBE Reference Laboratory may be consulted when needed.
- Reference Center will maintain dedicated lines of communication for submitters (i.e., telephone number, email, website).
- APHL will host a dedicated website available to submitting laboratories to include appropriate contact information and documents.

5.0 Specimen Storage

Archive isolates in appropriate refrigerated storage areas for the duration of this contract. Safely and legally destroy isolates at the expiration of this contract only after verifying that at least one isolate from each culture-positive TB patient has been submitted for genotyping.

6.0 Coordination and Facilitation of Conference Calls

Coordinate and facilitate conference calls to share information, develop plans, provide clarity, discuss issues, identify solutions, and make decisions in conjunction with APHL and CDC. There shall be monthly conference calls that include the Reference Center, APHL and CDC. There shall be quarterly conference calls that include the Contractor, CDC, and the laboratory managers and technicians from the ten USAPI TB laboratories. The Reference Center shall provide the conference call line that will be used, develop the agendas, take notes during the calls, and email minutes to all participants within 3 business days after the calls.

7.0 Laboratory Quality Assurance

The following subtasks shall be completed by the Reference Center :

Subtask 7.1 – Development of a TB Laboratory Quality Assurance Plan
Develop a laboratory quality assurance (QA) plan as described in published guidelines cited in Section: Additional Information and Deadlines for Application Submission - Reference Materials *(3,4,5,9,10)* that will be used to monitor the ten USAPI TB laboratories to ensure consistency and measure improvement in delivering accurate local AFB-smear microscopy results and molecular results, as applicable. The plan shall include laboratory external quality assessment (EQA) protocols for using proficiency testing panels, blinded slide rechecking, and nucleic acid amplification testing (e.g., Xpert MTB/RIF Assay). Disseminate the laboratory QA plan and EQA protocol to the APHL, CDC, and the ten USAPI TB laboratories.

Subtask 7.2 – Implementation and Monitoring
Implement the laboratory QA plan within 60 calendar days after contract award and conduct EQA during the base period and each option period. The Reference Center shall provide or ensure provision of all materials needed for the ten USAPI TB laboratories to complete the EQA.

Subtask 7.3 – Reporting Outcomes
Develop and submit a report that summarizes the results of all activities that are part of the laboratory QA plan within 10 business days of completing the EQA to APHL and CDC. Laboratory-specific results should be provided to each of the ten USAPI TB laboratories.

8.0 Site Visits to USAPI TB Laboratories

Conduct a site visit to five USAPI TB laboratories each performance period to evaluate staff capabilities, provide technical assistance, and assess operations, equipment, and safety. Site visit activities shall be conducted over 1–2 days. Use a laboratory assessment tool comparable to the resource published by the Association of Public Health Laboratories and cited in Section Additional Information and Deadlines for Application Submission - Reference Materials *(10)*. Awardee may work with APHL and CDC to finalize assessment tool.

The Reference Center and APHL/CDC shall agree on the USAPI TB laboratories that will receive a site visit within 30 days from the start of each performance period. The Reference Center shall communicate directly with each USAPI TB laboratory to coordinate site visits and provide APHL/CDC with a list of the dates and locations of scheduled site visits.

Submit a written report containing the following elements within 30 days of returning from a site visit:

- Location, dates, and times of site visit
- Site visit objectives
- Name and position title of key persons met
- Key findings
- Recommendations
- Action items and timelines for completion
- Method for measuring completion of action items

9.0 Training of USAPI TB Laboratory Staff

Deliver web-based trainings to address knowledge gaps when a need is identified. In-person trainings shall only be delivered during site visits. The Reference Center shall provide all training materials (e.g., PowerPoint slides and handouts) to APHL/CDC for review 3 weeks before the training takes place. Create a training record that includes the jurisdiction name, training date, topic, names of training participants, test scores (pre and post), and training evaluation results. Training records shall be submitted to the APHL/CDC within 30 calendar days after the training.

10.0 Participate in the Pacific Islands TB Controllers Association (PITCA) Conference

Starting in 2026, serve on the planning committee for the annual PITCA conference to help inform laboratory topics for the plenary session agenda. Lead the coordination and development of the agenda for the laboratory breakout session agenda. Serve as conference faculty during the PITCA Conference, present a summary of the services the Reference Center provides, present on TB laboratory topics, and facilitate the laboratory breakout session.

The laboratory breakout session shall focus on addressing training and education needs identified during site visits and include some of the following topics:

- Direct AFB smear microscopy with Ziehl-Neelsen (ZN) stain (i.e., preparing, staining, and reading AFB slides)
- GeneXpert MTB/RIF and Xpert MTB/RIF Ultra or MTB/XDR direct detection or equivalent molecular assay
- Collecting quality specimens (i.e., sputum vs. saliva) of sufficient quantity
- Recording results and submitting complete documentation with specimen to the Reference Center
- Updates on packing and shipping procedures based on current DOT, FAA, and IATA guidelines
- Feedback on results of laboratory testing from jurisdictional samples and EQA
- Developing TB laboratory testing manuals that align with principles of a functioning quality management system

11.0 Post-Award Kickoff Meeting

Host a one-day post-award kickoff meeting at the Reference Center's facility, or virtually, within 2 weeks after contract award that will be attended by subject matter experts from the CDC Division of TB Elimination. The meeting shall include a discussion of the contract requirements and if conducted in-person, shall include a tour of the Reference Center's facility. The Reference Center shall develop the agenda with input from CDC, take notes during the meeting, and email a summary of the notes to all participants within 3 business days after the meeting.

(Optional) Task 12.0 – Surge Support

"Surge support" may be needed in response to public health emergencies (e.g., outbreaks), special projects, or unknown federal mandates which are unpredictable and may result in a significant workload increase for the Reference Center. The scope of surge support shall be based on the number of additional specimens that require processing.

The need for surge support may be realized during any year of the contract. Surge requirements are subject to the availability of funds during the period of performance. Surge support may be exercised

multiple times and will not exceed the 25% of the ceiling amount of the services line item for each period of performance.

A preliminary notification of the exercise of this surge will be provided by APHL. This notification will state the performance requirements that are to be increased under the terms of the contract. The preliminary notice will be followed by a contract amendment for a firm-fixed price based on the number of additional samples that require processing and price per sample. Once the option is exercised, the Reference Center is expected to have the resourcing ability to very quickly bring on and assign the needed resources to begin the work. In certain rare situations, an event response may quickly be dis-banded. APHL reserves the right not to exercise the optional task of surge support if no surge requirements are needed during the entire performance of this contract.

Performance Management and Evaluation

APHL in collaboration with CDC DTBE Laboratory Branch will monitor monthly reports and evaluate workload, data quality, transport times, TATs, data anomalies and outliers, discordant results, trends and quality metrics.

Appendix B: Minimum Requirements for the TB Testing Reference Center for the USAPI

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	MINIMUM REQUIREMENT
		Does your laboratory have Clinical Laboratory Improvement Amendments (CLIA) certification that enables you to perform high complexity testing?
		Does your laboratory assure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and HIPAA Privacy & Security Rules to ensure the protection and confidentiality of individually identifiable health information?
		Does your laboratory have International Air Transportation Association (IATA) certification?
		Does your laboratory have adequate equipment for the work or the ability to purchase additional equipment if necessary?
		Does your laboratory have adequate laboratory space for the work and the ability to accommodate additional equipment if necessary?
		Does your laboratory have sufficient workforce capacity for anticipated testing volume (up to 3500 specimens per year) or the ability to hire additional qualified staff?
		Does your laboratory have Biosafety infrastructure, practices, safety equipment, facilities, and training in handling infectious agents and associated procedures?
		Does your laboratory have established capacity for MTBC culture and first-line DST for TB?
		Does your laboratory participate in an external quality assessment program?
		Do you have or have the ability to establish an infection control and surveillance program that monitors the possibility of laboratory acquired infection?
		Is your laboratory willing and able to provide specimen collection and transport materials to submitting sites in USAPI locations?
		Is your laboratory willing to coordinate airline and land courier logistics to ensure the timely shipping, transport, and processing of specimens from USAPI locations?
		Is your laboratory willing to provide copies of QA or biosafety documentation to APHL and CDC upon request?
		Does your laboratory have the necessary informatics capabilities including a LIMS and either proven capability to support ETOR and onboard new submitters?

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

Signature: _____ Date: _____

Printed Name:

_____

Appendix C: Score Card

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)
Testing Environment (question 1 along with 2 & 3) 1. Does the applicant demonstrate the ability to handle the testing volume for all required methods? Consider the availability of existing staff, equipment and space and ability of the laboratory to purchase additional equipment or hire additional staff as needed. **Ideal** (11-15 points): Describes ability to handle testing volume for all activities; describes appropriate staffing, equipment and space or ability to obtain additional equipment or staffing in a timely manner. **Adequate** (6-10 points): Describes ability to meet most testing volume requirements but may have to adjust workflow and/or staffing to accommodate work; has some deficiencies in their staffing, equipment or ability to obtain additional resources. **Limited** (1-5 points): Applicant describes limited ability to meet testing volume requirements; has many deficiencies in their staffing, equipment or ability to obtain additional resources. **Inadequate** (0 points): Applicant does not demonstrate the ability to handle the testing volume for all methods and neither has the current staffing or equipment or ability to obtain the unmet needs and/or does not demonstrate a clear understanding of the requirements.	15		Type comments here. (REQUIRED)
Staff Subject Matter Expertise (question 2 along with 3) 2. Does the applicant describe in-house subject matter expertise that is sufficient to provide relevant consultation to submitting laboratories on specimen collection, discordant results or other issues? **High** (11-15 points): Applicant has 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** (6-10 points): Applicant has some relevant experience, but will require additional training, guidance or technical assistance from others, subject matter expertise: >1.0 FTE with ≥ 3 years of experience providing consultation to submitters on interpretation of results including discordant results.	15		Type comments here. (REQUIRED)

Low (1-5 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.			
Methodology (question 3 along with 1 and 2) 3. Does the applicant have sufficient capacity and experience performing all required methods? Consider experience with described method(s), experience of existing staff? **High** (11-15 points): Describes extensive experience performing all relevant methods, sufficient capacity and staff experience to handle additional volume, describes appropriate staffing and equipment, and regularly provides testing with clinically relevant TATs. **Moderate** (6-10 points): Describes sufficient experience performing methods, some concerns about appropriate capacity to handle additional volume and/or does not regularly meet target TATs as recommended in the CDC Tuberculosis Elimination and Laboratory Cooperative. **Low** (1-6 points): Describes experience performing some methods, but deficiencies in workforce experience and/or ability to meet target TATs and/or handle additional volume. **No Experience** (0 points): Applicant does not demonstrate internal subject matter expertise is this area.	15		Type comments here. (REQUIRED)
Reporting (question 4) 4. What is the applicants' ability to offer electronic test ordering and reporting? **Ideal** (10 points): Applicant already provides electronic test ordering and reporting to external submitters and describes ability to maintain or establish connections with new submitters. **Adequate** (5 points): Applicant has a LIMS in plave with ETOR capability but lacks experience in onboarding new submitters or requires extensive time to complete the process. **Inadequate** (0 points): Applicant does not have an ETOR capability.	10		Type comments here. (REQUIRED)
Specimen Transport (question 5) 5. Does the applicant have sufficient capacity and experience to establish and implement an airline and land courier logistical process to pack, ship, and receive TB specimens from USAPI locations? Consider experience and described plans. **High** (11-15 points): Details a sound plan for providing specimen collection and packaging supplies to 10 sites, with ability to quickly deliver related procedures; outlines a	15		Type comments here. (REQUIRED

sufficient shipping plan; describes relevant experience and staff expertise, with higher points awarded for international ventures. **Moderate** (6-10 points): Details sufficient plans for shipping and providing specimen collection and packaging supplies to 10 sites and development and delivery of related procedures; but some concerns about appropriate capacity to handle the task at the international level. **Low** (1-6 points): Describes plans, but deficiencies in workforce experience and/or ability to meet deliverables. **No /Unclear** (0 points): Applicant does not demonstrate internal subject matter expertise or capabilities is this area.			
Reference Center Testing and Non-CLIA lab Experience (questions 6 and 7) 6. Rate the applicant's level of experience in providing reference testing services for other laboratories, including experience providing testing for the USAPI, and experience working with non-CLIA regulated laboratories. **Rate on a scale of 0-5 points** (5= Applicant has served as a reference center for other laboratories on an ongoing basis with submissions from and reporting to multiple out-of-jurisdiction submitters, some of these have been non-CLIA regulated laboratories; 0=applicant has no experience serving as a reference center for other PHLs and has not worked with non-CLIA regulated laboratories)	5		Type comments here. (REQUIRED)
External Quality Assessment and Capacity Building (questions 8 and 9) 7. Rate the applicant's level of experience in preparing or coordinating external quality assessment programs, conducting laboratory workforce development activities and conducting laboratory evaluations. **High** (8-10 points): Applicant has experience with coordination of external quality assessment programs and has conducted both workforce development activities and evaluations of other laboratories. **Moderate** (4-7 points): Applicant has limited direct experience with the coordination of external quality assessment programs and/or orchestration of workforce development activities and evaluations of other laboratories, but has enough subject matter expertise to execute the tasks. **Low** (1-3 points): Applicant describes some relevant experience, but concerns remain regarding their ability to execute the tasks. **No /Unclear** (0 points): Applicant has no relevant experience.	10		Type comments here. (REQUIRED)

Risk Management (question 10) 8. Does the applicant understand the factors that could jeopardize the successful execution of the work and describe effective risk management strategies reflective of unique challenges that may be encountered? **High** (5 points): Identifies risks and provides a well-thought-out mitigation plan. **Moderate** (4 points): Identifies risks; but some concerns about ability to mitigate the problems. **Low** (3 points): Describes plans, but deficiencies in risk identification or mitigation strategies. **No /Unclear** (0 points): Applicant does not demonstrate an understanding of associated risks.	5		Type comments here. (REQUIRED)
Budget (question 11) 10. Rate the appropriateness of the applicants budget. **Rate on a scale of 0-5 points** (5=most cost-effective budget; 0=budget is inappropriate)	5		Type comments here. (REQUIRED)
Surge Support (question 12) 9. Does the laboratory demonstrate a willingness and ability to evaluate additional specimens or alter terms of the contract to address emergent needs? **High** (4-5 points); Applicant has experience with surge volume testing, bringing on new test technology or otherwise responding to emergent situations and expresses a willingness to consider unexpected needs from submitting jurisdictions. **Moderate** (1-3 points); Applicant has limited experience with surge volume testing or bringing on new test technology, but is willing to consider emergent needs from the submitting laboratories. **No experience** (0 points); Applicant is not willing to consider provision of surge support.	5		Type comments here. (REQUIRED)
TOTAL SCORE	**100**	____	

Appendix D: Federal Funding Accountability & Transparency Act (FFATA)

Applicability: The awarded entity must disclose the information below when the award is over $30,000 and the contracting entity is not an individual person.

APHL will collect this information during the contracting phase and will keep your completed statement in the corporate records of the Association.

Contractor/Award Recipient's Name:	
Amount of Compensation (obligated amount):	
Funding Agency:	
CFDA Number: See the definition of the "Cooperative Agreement" in the Work Order.	
Award Title Descriptive of the Purpose of the Funding Action (See definition of the "Project" in the Work Order):	
Contractor/Award Recipient's Location:	
Contractor/Award Recipient's Congressional District:	
Contractor/Award Recipient's Place of Performance:	
Contractor/Award Recipient's Place of Performance Congressional District:	
Contractor/Award Recipient's Unique Entity ID (SAM UEI):	
Contractor/Award Recipient's Unique Entity ID of Parent Organization, if applicable (SAM UEI): In order to determine whether you are required to provide executive compensation data, answer the following question(s):	
1. In your business or organization's preceding completed fiscal year, did your business or organization (the legal entity to which this specific CCR record, represented by a SAM UEI, belongs) receive:	
a) 80 percent or more of your annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?	☐ Yes ☐ No

b) $25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?		☐ Yes ☐No	
If you selected 'Yes' for both a) and b) in question 1 please go to question 2. If you selected 'No' for either or both a) and b) in question 1 you are done completing the form.			
2. Does the public have access to information about the compensation of the executives in your business or organization (the legal entity to which this specific CCR record, represented by a SAM UEI, belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (15 U.S.C. §§78m(a), 78o(d)), or section 6104 of the Internal Revenue Code of 1986, as amended (26 U.S.C. §6104)?		☐ Yes ☐No	
If you selected 'Yes' to question 2 you are done completing the form. **If you selected 'No' to question 2 please provide the names and total compensation for your five highest compensated executives** (i.e. officers, managing partners, or any other employees in management positions):			
Name:		Total Compensation:	
Name:		Total Compensation:	
Name:		Total Compensation:	
Name:		Total Compensation:	
Name:		Total Compensation:	