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**Vaccine-Preventable Diseases Project  
Prepared: June 2010**

**Request for Proposal (RFP):**

**Pilot Proficiency Testing Panels exercise for US State and Local Public Health Laboratories**

- **Pertussis multi-target PCR**
- **Measles IgM Serology**

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## **INTRODUCTION AND BACKGROUND**

### APHL Background

The Association of Public Health Laboratories (APHL) is the national nonprofit member organization of public health laboratories in the United States, which encompasses state and local institutions that conduct laboratory testing of public health significance. APHL works to provide these laboratories with the resources and infrastructure to protect the health of US residents and to prevent and control diseases globally. APHL also advances the development of laboratory systems and practices, and promotes policies that support healthy communities. The association's members include state and local public health laboratories, state environmental and agricultural laboratories, other government laboratories that conduct testing of public health significance, and individuals with an interest in public health laboratory science and practice. APHL is a non-profit, 501(c)(3) organization with a history of over fifty years.

The stated mission of APHL is to promote the role of public health laboratories in shaping national and global health objectives, and to promote policies, programs, and technologies which assure continuous improvement in the quality of laboratory practice and health outcomes.

### Vaccine-Preventable Diseases (VPD) Project

To address gaps in testing capacity for VPDs, APHL was recently awarded funding through the American Recovery and Reinvestment Act of 2009 (ARRA) to partner with the US Centers for Disease Control and Prevention (CDC) to provide training programs and quality improvement activities for VPD testing in public health laboratories. Timely and accurate diagnosis of VPDs is essential to identify and control outbreaks and to provide the information needed to improve vaccines and vaccination programs. However, the capacity and capability of state and local public health laboratories to perform testing for VPDs has become widely varied, with some labs being extremely proficient while others lack the training and/or equipment to conduct the appropriate testing and investigate outbreaks.

One of the activities of this project has been to evaluate the need for proficiency testing or availability of standardized specimen panels, and to develop, deliver, and evaluate at least one pilot proficiency panel or other exercise to evaluate testing capabilities in selected methods for diagnosis of VPDs. Based on information gathered from a needs assessments survey conducted in February and March 2010, as well as from a 2007 VPD survey and knowledge of subject matter experts, APHL is planning to implement a proficiency testing like panel or validation panel or exercise.

The pilot panel or exercise will be delivered by October 29, 2010 and deliverable reports completed by March 31, 2011, unless otherwise negotiated. The test or exercise will be voluntary, and participants will likely be evaluated for the accuracy of results as well as appropriate methods used. A follow-up lessons-learned teleconference will be conducted by June 30, 2011 after results of the test have been distributed to the participants, and will include a discussion of testing method assessments and the value of standardized testing protocols.

#### Proposal Summary

APHL is seeking to identify and select an outside, independent organization to perform the activities listed above as a subcontracting Vendor to APHL. This Vendor will be a laboratory that can purchase or manufacture specimen panels, package and ship the panels, and evaluate test results by multiple methods. The Vendor will preferably have experience working with public health laboratories and an understanding of their unique roles and responsibilities as diagnostic and reference laboratories.

**APHL would like to solicit an offer to develop, deliver, and evaluate pilot proficiency testing panels for Pertussis multi-target PCR and Measles IgM serology testing.**

The remainder of this document provides additional information that will allow a service provider to understand the scope of the effort and develop a proposal in the format desired by APHL.

## ADMINISTRATIVE INFORMATION

### Contact Information

Any questions concerning technical specifications or Statement of Work (SOW) requirements must be directed to:

Travis Jobe, Senior Specialist  
Association of Public Health Laboratories  
8515 Georgia Avenue, Suite 700  
Silver Spring, MD 20910  
(240) 485-2764  
[Travis.Job@aphl.org](mailto:Travis.Job@aphl.org)

### Due Dates

A verbal or emailed confirmation of the Vendor's intent to respond to this RFP is required by 07/14/10. All proposals are due by Close of Business on 07/30/10. Any proposal received at the designated location after the required time and date specified for receipt shall be considered late and non-responsive. Any late proposals will not be evaluated for award.

### Schedule of Events

| Event                                                             | Date     |
|-------------------------------------------------------------------|----------|
| 1. RFP Distribution to Vendors                                    | 07/07/10 |
| 2. Verbal or Emailed Confirmation from Vendors with Bid Intention | 07/14/10 |
| 3. Questions from Vendors about scope or approach due             | 07/21/10 |
| 4. Responses to Vendors about scope or approach due               | 07/23/10 |
| 5. Electronic Proposal Due Date                                   | 07/30/10 |
| 6. Target Date for Review of Proposals                            | 08/06/10 |
| 7. Final Vendor Selection Discussion(s)--Week of                  | 08/09/10 |
| 8. Anticipated decision and selection of Vendor(s)                | 08/13/10 |

## **GUIDELINES FOR PROPOSAL PREPARATION**

### Proposal Submission

Award of the contract resulting from this RFP will be based upon the most responsive Vendor whose offer will be the most advantageous to APHL in terms of cost, functionality, and other factors as specified elsewhere in this RFP.

APHL reserves the right to:

- Reject any or all offers and discontinue this RFP process without obligation or liability to any potential Vendor,
- Accept other than the lowest priced offer,
- Award a contract on the basis of initial offers received, without discussions or requests for best and final offers, and
- Award more than one contract.

Vendor's proposal shall be submitted in several parts as set forth below. The Vendor will confine its submission to those matters sufficient to define its proposal and to provide an adequate basis for APHL's evaluation of the Vendor's proposal.

Vendor's proposal in response to this RFP will be incorporated into the final Contract agreement between APHL and the selected Vendor(s). The submitted proposals are suggested to include each of the following sections, and be no longer than ten pages total:

1. Executive Summary
2. Scope, Approach, and Methodology
3. Project Deliverables
4. Project Management Approach
5. Detailed and Itemized Budget (not included in page count)
6. Appendix: References
7. Appendix: Company Overview

The detailed requirements for each of the above-mentioned sections are outlined below.

### Detailed Response Requirements

#### **1. EXECUTIVE SUMMARY**

- a. This section will present a synopsis of the Vendor's response to the RFP. The Executive Summary should be a brief overview of the engagement, and should identify the main features and benefits of the proposed work.

## **2. SCOPE, APPROACH, AND METHODOLOGY**

- a. Include detailed implementation procedures and technical expertise by phase. This section should include a description of each major type of work being requested of the vendor. All information that is provided will be held in strict confidence. The proposal should reflect each of the sections listed below (examples of the types of sections that could appear are listed below – select or modify them as appropriate):
  - i. Methods of preparation of viral serology specimens
  - ii. Methods of preparation of bacterial specimens
  - iii. Testing methods used to internally validate correct specimen results. i.e. “gold standards” used.
  - iv. Delivery procedures for specimen shipments
  - v. Instructions given to participating laboratories on testing and reporting procedures
  - vi. Paper and/or online reporting requirements
  - vii. Evaluation of results and methods utilized

## **3. PROJECT DELIVERABLES**

- a. Include descriptions of the types of reports used to summarize the project activities and provide detailed information on technical methodology. Include sample reports as attachments to the proposal to provide an example of the types of reports that will be provided for this engagement.

## **4. PROJECT MANAGEMENT APPROACH**

- a. Include the method and approach used to manage the overall project and client correspondence.
- b. Briefly describe how the engagement proceeds from beginning to end.

## **5. DETAILED AND ITEMIZED BUDGET**

- a. Include a fee breakdown by project phase and estimates of any travel expenses.
- b. Include estimates of pricing for purchase of reagents, supplies, and equipment needed to successfully implement the outlined activities

## **6. APPENDIX: REFERENCES**

- a. Provide three current corporate references for which you have performed similar work.

## **7. APPENDIX: COMPANY OVERVIEW**

Provide the following for your company/organization:

- a. Official registered name, address, main telephone number, and facsimile numbers.

- b. Key contact name, title, address (if different from above address), direct telephone and fax numbers, and email address.
- c. Name of person authorized to contractually bind the company/organization for any proposal against this RFP, including title, address (if different from above address), direct telephone and fax numbers, and email address.
- d. Brief history, including year established and number of years your company has been offering the services stated in your proposal response.

## EVALUATION FACTORS FOR AWARD

### Criteria

Any award to be made pursuant to this RFP will be based upon the proposal with appropriate consideration given to operational, technical, cost, and management requirements. Evaluation of offers will be based upon the Vendor's responsiveness to the RFP and the total price quoted for all items covered by the RFP.

The following elements will be the primary considerations in evaluating all submitted proposals and in the selection of a Vendor or Vendors. Proposal responses elements will be weighted according to the following scale:

|                                                                                                                                      | <u>Score</u> |
|--------------------------------------------------------------------------------------------------------------------------------------|--------------|
| 1. Completion of all required responses in the correct format.                                                                       | 10           |
| 2. The extent to which Vendor's proposed solution fulfills APHL's stated requirements as set out in this RFP.                        | 40           |
| 3. An assessment of the Vendor's ability to deliver the indicated service in accordance with the specifications set out in this RFP. | 30           |
| 4. The Vendor's stability, experiences, and record of past performance in delivering such services.                                  | 20           |
| 5. Detailed budget and justification.                                                                                                | 0            |
| Total:                                                                                                                               | 100          |

APHL may, at their discretion and without explanation to the prospective Vendors, at any time choose to discontinue this RFP without obligation to such prospective Vendors. APHL is not responsible for lost or mis-directed proposals.

## STATEMENT OF WORK

### Scope of Work

The following information should be used to determine the scope of this project and provide pricing for this engagement:

Outline your implementation plan for developing, delivering, and evaluating Pertussis PCR and Measles IgM serology pilot proficiency testing panels or test validation panels for delivery to US state and local public health laboratories. The implementation plan should at a minimum cover the areas listed below and include the information outlined above in the Detailed Response Requirements, including a specific schedule with timeline, costs included and not included in the bid, and the personnel involved in the activities and their roles and responsibilities. Also, please indicate the date(s) you are available to begin delivery of the proficiency testing panels to the participating laboratories.

- Manufacture and/or purchase of specimen panels for Pertussis PCR testing for delivery to approximately 50-70 laboratories. Spiked saline would be an appropriate and simple medium for delivery of the panel specimens. The CDC-developed multiplex PCR method will be used as the “gold standard” for defining the correct assay results. All participating labs will receive one or two panels of twelve specimens, unless otherwise negotiated. Those labs attempting to newly implement Pertussis PCR testing in their labs will receive one panel with the specimens identified for validation purposes, and one panel with the specimens as unknowns. Those labs that are already doing Pertussis PCR testing will receive one or both panels as unknowns. Each panel will contain approximately the following:
  - o Four (4) *Bordetella pertussis* specimens.
  - o Two (2) *Bordetella parapertussis* specimens.
  - o Two (2) *Bordetella holmesii* specimens.
  - o One (1) *Bordetella bronchiseptica*.
  - o Three (3) non-*Bordetella* sp. specimens negative by PCR for any of the above listed organisms.
- Manufacture and/or purchase of serology panel for Measles IgM testing for delivery to approximately 30-40 laboratories. The CDC’s in-house capture EIA method will be used as the “gold standard” for defining the correct assay results. Each panel will contain approximately the following:
  - o Three (3) acute Measles serology IgM positive specimens, including at least one (1) low and one (1) mid-range reactive specimens.
  - o One (1) acute Rubella serology positive specimens negative for Measles IgM; non-MMR vaccinated, never infected with measles.

- o Three (3) serology specimens negative for Measles and/or Rubella IgM; non-MMR vaccinated, never infected with measles. Also negative for: Parvovirus B-19, HHV-6, HHV-7, and Amoxicillin IgE.
- Package and ship panels to the number of laboratories identified above for the Bacterial and Viral Serology panels.
- Write panel information and instructions, which should be included with the specimen shipments.
- Follow-up with any laboratories that may have questions about testing or reporting requirements for the panels.
- Analyze data results submitted from participating laboratories.
- Evaluate results, including an assessment of the testing methods employed by the participating laboratories.
- Issue final reports, to be submitted to APHL for review.

### Implementation Plan Requirements

The following requirements should be followed and addressed in the RFP Response in relation to the Scope of Work:

- All specimens should be shipped to the participating laboratories in a manner appropriate for maintaining specimen integrity, and following all applicable laws and requirement regarding shipment of biological agents.
- Written procedures should be established for:
  - o Handling of samples, i.e. in the same manner as potentially infectious patient/client specimens.
  - o Analysis of samples. (e.g. following regular/routine testing strategies, and by technicians normally responsible for performing the testing)
  - o Specific testing requirements for the panels, including an outline of the required timeframe for testing and results submittal, as well as stating that inter-laboratory discussion of PT specimens or results is not permitted.
  - o Communicating problems between participating labs and PT exercise organizers.
  - o Recording of results on report forms and/or online submission site. This should include what other information is also gathered; such as persons doing the testing, equipment used, assay kits used (including lot numbers and expiration dates), raw data results, etc.
  - o Verification of clerical accuracy or results entry.
  - o Use of statistical tools to evaluate results.
  - o Handling and documentation of corrective actions taken as a result of the exercise.
  - o Sending testing results and performance reports back to participating laboratories.

### Deliverables

At the conclusion of the exercise, APHL requires written documentation of the approach, findings, and recommendations associated with this project. A formal presentation of the findings and recommendations to APHL and CDC subject matter experts may also be required. The documentation should consist of the following:

#### **DETAILED TECHNICAL REPORT**

A document developed for the use of APHL and CDC's technical staff which discusses the methodologies employed to implement this activity, and the results obtained. Due March 31, 2011.

#### **EXECUTIVE SUMMARY REPORT**

A document developed to summarize the scope, approach, findings and recommendations, in a manner suitable to APHL and CDC subject matter experts. This can include any corrective actions taken, objective evidence of laboratory testing quality, indicators of where to direct quality improvement efforts, and/or identification of training needs. Due March 31, 2011.