AN ORDINANCE 2016-06-09-0442

RATIFYING THE EXECUTION OF AN AGREEMENT WITH THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES, INC. WHICH WILL PROVIDE FUNDS OF UP TO \$3,000.00 TO THE SAN ANTONIO METROPOLITAN HEALTH DISTRICT FOR THE PROVISION OF SYPHILIS LABORATORY SPECIMENS TO THE CENTERS FOR DISEASE CONTROL AND PREVENTION FOR A PERIOD BEGINNING ON MAY 23, 2016 AND ENDING ON JUNE 30, 2016.

WHEREAS, relative syphilis rates are seen to be rising in many metropolitan and rural areas in the United States. The San Antonio Metropolitan Health District (Metro Health) has been working to lower/control syphilis rates in our local population for more than fifty years; and

WHEREAS, the Centers for Disease Control and Prevention (CDC) is working on an initiative to develop diagnostic test methods that will aid public health to rapidly identify and diagnose syphilis infections and has solicited public health agencies to provide residual syphilis positive test samples to use in the testing and validation of these new test methods; and

WHEREAS, the San Antonio Metro Health Laboratory has a large repository of residual test samples that meet the criteria for use in CDCs studies; NOW THEREFORE:

BE IT ORDAINED BY THE CITY COUNCIL OF THE CITY OF SAN ANTONIO:

SECTION 1. The execution of an agreement with the Association of Public Health Laboratories, Inc. which will provide funds of up to \$3,000.00 to the San Antonio Metropolitan Health District for the provision of syphilis laboratory specimens to the Centers for Disease Control and Prevention for a period beginning on May 23, 2016 and ending on June 30, 2016 is hereby ratified. A copy of the agreement in substantially final form is attached hereto and incorporated herein for all purposes as **Attachment I**.

SECTION 2. Funds generated by this ordinance shall be appropriated in SAP Fund 29836000, Internal Order 836000000XXX per the table below:

Amount	General Ledger
-\$3,000.00	4502280
\$3,000.00	5304050

SECTION 3. The financial allocations in this Ordinance are subject to approval by the Director of Finance, City of San Antonio. The Director of Finance may, subject to concurrence by the City Manager or the City Manager's designee, correct allocations to specific SAP Fund Numbers, SAP Project Definitions, SAP WBS Elements, SAP Internal Orders, SAP Fund Centers, SAP Cost Centers, SAP Functional Areas, SAP Funds Reservation Document Numbers, and SAP GL Accounts as necessary to carry out the purpose of this Ordinance.

SECTION 4. This ordinance is effective immediately upon the receipt of eight affirmative votes; otherwise, it is effective ten days after passage.

PASSED AND APPROVED this 9th day of June, 2016.

MAYOR

Ivy R. Taylor

APPROVED AS TO FORM:

Martha G. Sepeda, Acting City Attorney

Agenda Item:	17 (in consent v	ote: 5, 6, 7, 8,	9, 10, 11A	, 11B, 13,	14, 15, 17, 18, 20	0, 21, 22, 23)	
Date:	06/09/2016						
Time:	09:38:37 AM						
Vote Type:	Motion to Approv	e					
Description:	An Ordinance rati Laboratories, Inc. \$3,000.00 for the Prevention for a p Vincent R. Nathar	which will prov provision of syp eriod from May	ride funds thilis labora 23, 2016 t	to the San atory speci o June 30,	Antonio Metropo mens to the Cent	olitan Health Dis ters for Disease (trict of up to Control and
Result:	Passed				(0)		
Voter	Group	Not Present	Yea	Nay	Abstain	Motion	Second
Ivy R. Taylor	Mayor		x				
Roberto C. Treviño	District 1		X				х
Alan Warrick	District 2		x				
Rebecca Viagran	District 3		X				
Rey Saldaña	District 4		X			x	
Shirley Gonzales	District 5		x				
Ray Lopez	District 6		x				
Cris Medina	District 7		X				
Ron Nirenberg	District 8	х					
Joe Krier	District 9		x				
Michael Gallagher	District 10		x				



WORK ORDER

Project Specific Terms and Conditions

This Work Order, dated May 17, 2016, is made by and between APHL and the Contractor to authorize and allow the Contractor to work on the Project. All capitalized terms are defined in Section 1 below.

Background

- Under the Cooperative Agreement, APHL has been approved to conduct the Project as part of the overall services to be provided under the terms of the Notice(s) of Award from the Funding Agency for the current Cooperative Agreement funding year.
- II. The Contractor desires to work on the Project and has notified APHL of its interest, and, in accordance with APHL's procurement requirements for a matter of this size, APHL selected the Contractor to provide the services and goods for the Project.
- III. The Parties agree that the Contractor's work on the Project will be subject to the terms and conditions specified in this Work Order.

Agreement on Project Specifics

1. Definitions.

A. The following definitions apply to capitalized terms used in this Work Order:

Capitalized Term	Meaning
"Agreement"	Collectively, this Work Order, the Standard Terms and Conditions and any Cooperative Agreement Funding Conditions, together with any other attachments, exhibits or appendices incorporated into this Work Order by reference
"APHL"	The Association of Public Health Laboratories, Inc., a nonprofit corporation organized under the laws of the District of Columbia
"Contractor"	The City of San Antonio on behalf of the San Antonio Metropolitan Health District, a governmental entity or administrative unit of Texas
"Cooperative Agreement"	Cooperative Agreement Number 1U60OE 00103 (CFDA No. 93.322) with the Centers for Disease Control and I revention (CDC) of DHHS

Capitalized Term	Meaning
"Cooperative Agreement Funding Conditions"	All of the Cooperative Agreement funding conditions imposed by the Funding Agency as specified on Exhibit A to this Work Order
" <u>Deliverables</u> "	All of the deliverables due to APHL (or to the Funding Agency or another party, if applicable) specified in Section 4 of this Work Order
"End Date"	June 30, 2016
" <u>FFATA</u> "	The Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282), as amended
"Final Invoice Due Date"	July 15, 2016
"Funding Agency"	Centers for Disease Control and Prevention (CDC)
"Master Agreement"	As of the Agreement Date, APHL and the Contractor are not party to a Master Agreement and all references to "the Master Agreement" in this Work Order and the Standard Terms and Conditions are inapplicable and of no force or effect.
" <u>Materials</u> "	All articles, reports, and other materials produced by the Contractor pursuant to this Work Order
"Maximum Compensation Amount"	The maximum amount of compensation payable by APHL to the Contractor specified in Section 5.A of this Work Order is \$3,000
"Maximum Travel and Expense Reimbursement Amount"	None. No travel or expense reimbursement is authorized (other than any travel or expenses reimbursement specifically included in the Work and reflected as part of the Maximum Compensation Amount) and APHL will not reimburse the Contractor for any travel or other non-routine expenses.
"Parties" or "Party"	Collectively, APHL and the Contractor, and individually, either APHL or the Contractor
" <u>Project</u> "	The Contractor will support diagnostic test development by shipping residual serum specimens that tested positive for syphilis for a repository hosted at CDC.
"Standard Terms and Conditions"	All of the terms and conditions specified (i), if the Parties have a Master Agreement, in the Master Agreement or (ii), if there is no Master Agreement between the Parties, on Exhibit B to this Work Order
"Start Date"	May 23, 2016

Capitalized Term

Meaning

"Work"

The services to be provided by the Contractor specified in Section 3.A of this Work Order

B. Other capitalized terms used in this Work Order have the meaning given to those terms either (i) in one of the other Sections of this Work Order below or (i) in the Standard Terms and Conditions.

Project Term; Specific Terms and Conditions of the Work.

- A. The term of this Work Order will begin on the Start Date. It will conclude when the Contractor completes its responsibilities. The Contractor will complete its responsibilities no later than the End Date.
- **B.** The Contractor will conduct the Work, and the Parties will fulfill their respective obligations in accordance with the specifications and other terms and conditions contained in the Agreement.
- C. In the event that the component documents that make up the Agreement contain conflicting terms or conditions, the following priority will apply:
 - The terms and conditions specified in the Cooperative Agreement Funding Restrictions will prevail over this Work Order, the Standard Terms and Conditions and any other attachment, exhibit or appendix;
 - ii. The terms and conditions specified in this Work Order will prevail over the Standard Terms and Conditions and any other attachment, exhibit or appendix; and
 - iii. The terms and conditions specified in the Standard Terms and Conditions will prevail over any other attachment, exhibit or appendix.

Services to be Provided by the Contractor.

- A. The Contractor will provide all of the services, materials, equipment, facilities, and personnel required to perform the Work outlined in the statement of work dated April 22, 2016 which is attached to this Work Order as Exhibit C and is incorporated by reference.
- B. [Intentionally omitted.]
- C. The Contractor will provide APHL with the following Deliverables:
 - i. one electronic copy of specimen receipt at CDC

 Schedule of Deliverables. The Contractor will complete the Work according to the schedule in the table below.

Milestone or Deliverable	Completion Date	
Confirmation of Receipt of Specimens at CDC	June 30, 2016	

- A. APHL will review and approve or reject the final version of the Deliverable or the Work within twenty business days after delivery by the Contractor. APHL will notify the Contractor in writing of its (or, if applicable, the Funding Source's) acceptance or rejection. If APHL fails to respond within this timeframe, the Contractor may assume that APHL approves the Deliverable or the Work.
- B. If a Deliverable or the Work is not acceptable, APHL will provide the Contractor with a written explanation. The Contractor will have ten business days to correct the deficiencies to the reasonable satisfaction of APHL (the Contractor acknowledges that if the Funding Source disapproves of any correction, APHL will have reasonable grounds to require further correction). If the Deliverable or the Work remains unacceptable to APHL after two cycles of providing edits and comments to the Contractor, APHL may deem the Contractor to be in default of this Agreement.

Compensation.

- A. As compensation for all services performed pursuant to this Work Order, APHL will pay the Contractor an amount not to exceed the Maximum Compensation Amount specified in Section 1 of this Work Order, allocated as shown in the table(s) in this Section 5 below.
- B. [Intentionally omitted.]

Sample	Rate
Approved Residual Syphilis Specimen	\$50/specimen

C. APHL will pay compensation in response to invoices submitted by the Contractor. The Contractor will ensure that each invoice includes a detailed statement of the services provided. APHL will pay the undisputed portion of each invoice within 30 days after receipt of the invoice by APHL. The Contractor must submit the final invoice to APHL by the Final Invoice Due Date. If the final invoice is not received by the Final Invoice Due Date APHL will have the right, in its sole and arbitrary discretion, not to pay the invoiced amount. The Contractor releases APHL from and waives all claims of any nature for non-payment of the final invoice based upon the

Contractor's failure to submit all reimbursement requests by this date. The Contractor will submit invoices to APHL according to the following schedule:

Payment Amount*	Invoice Date	
As invoiced, up to the remaining balance of the Maximum Compensation Amount	Upon confirmation of receipt of specimens at CDC	

^{* =} The total compensation paid by APHL to the Contractor for the Work may not exceed the Maximum Compensation Amount.

D. The Contractor will send invoices to:

Anne Gaynor, Manager HHST APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910

P: 240.485.2739 F: 240.485.2700

E: anne.gaynor@aphl.org

- **E.** APHL is not responsible for payment of any amount other than those charges specifically set forth in this Agreement, unless the Contractor has obtained APHL's written approval prior to incurring the charge.
- F. In addition to the compensation authorized for the Contractor's services, APHL will reimburse the Contractor for travel and other non-routine direct expenses, up to an amount not to exceed the Maximum Travel and Expense Reimbursement Amount (if the definition of Maximum Travel and Expense Reimbursement Amount in Section 1.A. indicates that no reimbursement is authorized then this Section 5.F. and Sections 5.G. and 5.H. below are inapplicable and of no force and effect). Expenses will be reimbursed at cost. Expense reimbursement requests must be accompanied by receipts or other records of the actual costs incurred. Reimbursement of travel expenses is subject to the following conditions:
 - all travel must be approved in advance by APHL;
 - ii. to the maximum extent possible, the Contractor will utilize APHL's travel agency, EWA Travel to make travel arrangements and to purchase tickets (Marika Delgado serves as APHL's primary contact at EWA Travel and she may be reached by email at marika@ewatravel.com or by telephone at 800.705.8580 (or +1.520.797.0291 if calling from outside of the US));
 - iii. the Contractor must purchase airfare at least 14 days in advance (if feasible) and make other efforts to minimize the costs to APHL;

- iv. travel expenses are paid at the rates and standards authorized for travel by APHL staff; and
- v. if travel is undertaken for APHL business and for the Contractor's other business or personal interests, only a proportionate share of the total expense may be billed to APHL.
- G. The Contractor must submit all invoices and reimbursement requests to APHL the earlier of (i) 30 days after the completion of the authorized travel or (ii) the Final Invoice Due Date, to receive reimbursement for expenses. The Contractor, by its signature to this Agreement, releases APHL from and waives all claims of any nature for non-payment based upon the Contractor's failure to submit all invoices by this date.
- H. The Contractor will not be entitled to any advances for travel expenses without prior express, written authorization from APHL's Grants Department or its Legal Department. If any advance is authorized, the Contractor will have no more than 30 days from the date that the approved travel is completed to provide APHL with the documentation APHL may request to reconcile expenses or charges incurred against the travel advance. In the event that the Contractor does not provide the requested documentation, APHL will have the express right, in its sole discretion, either (i) to offset the amount of the travel advance against authorized payments due to the Contractor under this Work Order or any other work order or agreement that APHL may have with the Contractor at the time or (ii) to request a return of all or a portion of the travel advance to APHL and to charge the Contractor the maximum interest allowed under District of Columbia law should the Contractor fail to return the travel advance within 30 days of APHL's request.
- **Subcontractors**. The Contractor has not identified any subcontractors as of the Agreement Date. The Contractor will comply with the notice and approval requirements set out in the Standard Terms and Conditions prior to authorizing any subcontractor to work on the Project.
- 7. <u>FFATA Reporting Requirements</u>. The Maximum Compensation Amount is less than \$25,000 and/or the Contractor is an individual and, as a result, there are no reporting requirements imposed by FFATA to the Work under this Work Order.

8. Copyright & Intellectual Property Rights.

A. All Materials are a "work made for hire" under United States copyright law. APHL will be the exclusive owner of all copyright and proprietary rights to the Materials. If the Materials do not constitute work made for hire as a matter of law, the Contractor, by its signature to this Agreement, transfers and assigns all rights in the Materials to APHL. The Contractor also hereby assigns to APHL and/or waives any claim that Contractor might now or hereafter have in any jurisdiction to so-called "moral rights" or rights of "droit morale" in connection with the Materials. The Contractor will provide any further documentation of these transfers that APHL

requests. The Contractor will secure the same agreement from all independent contractors performing services in connection with the Contractor's performance under this Work Order.

- B. The Contractor represents and warrants that:
 - the Contractor is solely responsible for the creation of the Materials;
 - ii. the Materials are original and have never been published (except for material subject to copyright for which the Contractor has obtained permission to use);
 - iii. the Materials do not infringe upon any copyright, trademark, or other proprietary right, violate any right of privacy, or contain libelous material; and
 - iv. the Materials contain only information and data that is true and accurate to the best of the Contractor's knowledge, belief, and expertise.
- C. Upon termination of this Work Order, the Contractor will immediately deliver to APHL all print and electronic materials provided or owned by APHL.
- 9. Additional Services. If either Party determines that additional services related to the Project might be desirable, the Contractor will prepare an estimate of the work required to complete the additional services and the projected cost of this work. If this estimate is acceptable to APHL, APHL will prepare a written amendment to this Work Order. The Contractor will not perform the additional, proposed work unless this amendment has been duly signed by both Parties.
- 10. Notices. Any notice or request under this Work Order must be in writing and must reference the APHL Agreement Number identified at the top of each page. A Party may send notices (i) personally, (ii) by mail, with first class postage prepaid, certified and return receipt requested, or (iii) by delivery through a nationally recognized overnight delivery service, with confirmed delivery and charges prepaid or billed to shipper. A notice or request must be sent to addressees shown below, unless a different address or addressee is specified in writing by the receiving Party. On the same day that a notice is

placed in the mail or with an overnight delivery service, a complete copy will also be transmitted by the sending Party to the receiving Party via email or facsimile.

APHL	The Contractor
Scott J. Becker, MS, Executive Director	Vincent Nathan, PhD, MPH, Interim Director of
APHL	Health
8515 Georgia Avenue, Suite 700	San Antonio Metropolitan Health District
Silver Spring, MD 20910	332 W Commerce Street
P: 240.485.2745	San Antonio, TX 78205
F: 240.485.2700	P: 210.207.8730
E: scott.becker@aphl.org	F: 210.207.2159
	E: Vincent.Nathan@sanantonio.gov
With a copy to:	
Troy Willitt, General Counsel	
APHL	
8515 Georgia Avenue, Suite 700	
Silver Spring, MD 20910	
P: 240.485.2716	
F: 240.485.2700	
E: troy.willitt@aphl.org	

11. <u>Work Order Administrators</u>. The following individuals are authorized to administer this Work Order on behalf of the respective Parties:

APHL	The Contractor		
Anne Gaynor, Manager HHST	Vincent Nathan, PhD, MPH Interim Director of		
APHL	Health		
8515 Georgia Avenue, Suite 700	San Antonio Metropolitan Health District		
Silver Spring, MD 20910	332 W Commerce Street		
P: 240.485.2739	San Antonio, TX 78205		
F: 240.485.2700	P: 210.207.8730		
E: anne.gaynor@aphl.org	F: 210.207.2159		
	E: Vincent.Nathan@sanantonio.gov		

- 12. <u>Survival</u>. The obligations and rights of the Parties which by their nature would continue beyond the termination or expiration of this Work Order will so survive and will remain in full force and effect regardless of any termination or expiration of this Work Order. These obligations and rights include those set forth in the Section entitled "Copyright & Intellectual Property Rights" above.
- 13. Other Terms and Conditions. For purposes of this Work Order, the Parties make the following modifications, amendments or substitutions to the Standard Terms and Conditions. Unless expressly modified, amended or replaced in this Section 13.B. below, the Standard Terms and Conditions remain in full force and effect.

i. *Termination.* Subsection 4.A. of the Standard Terms and Conditions is deleted and the following is added as a substitute for that subsection's text:

"Either party may terminate this Agreement or any portion of the Work in progress by written notice to the other party."

- ii. Indemnification. Section 5 of the Standard Terms and Conditions is deleted in its entirety.
- iii. Confidentiality. The following is added as the last sentence to Section 6 of the Standard Terms and Conditions:

"Notwithstanding the above, APHL acknowledges requests for records pertaining to this Agreement shall be responded to by the Contractor in compliance with the Texas Public Information Act."

- iv. Governing Law. Section 12 of the Standard Terms and Conditions is deleted in its entirety.
- v. *Dispute Resolution.* Subsection 14.B. of the Standard Terms and Conditions is deleted in its entirety.

Remainder of page intentionally left blank; signatures on the following page.

Each Party represents to the other Party that the individual signing below has the legal capacity and proper authority to do so and that, once signed on behalf of the Party, this Work Order will be enforceable against the Party in accordance with its terms and conditions.

THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES, INC.

By:

Name: Carol Clark, CPA, MS Title: Chief Operating Officer

SAN ANTONIO METROPOLITAN HEALTH DISTRICT

By:

Name: Vincent R. Nathan, PhD, MPH Title: Intertain Director

Date: 6-7-16

EXHIBIT A

Cooperative Agreement Funding Conditions

See Attached



FUNDING RESTRICTIONS

FOR COOPERATIVE AGREEMENT #1U600E000103 (CFDA NO. 93.322) with the U.S. Centers for Disease Control and Prevention (CDC)

These Cooperative Agreement Funding Restrictions (the "Funding Restrictions") have been attached as Exhibit A to a Project Agreement (as defined in Section 1 of these Funding Restrictions) between APHL (as defined in the Project Agreement) and the Counterparty (as defined in Section 1 of these Funding Restrictions) and have been incorporated into that Project Agreement by reference. These Funding Restriction, together with the Project Agreement and, if the Project Agreement is a Work Order, the Standard Terms and Conditions, make up the entire Agreement (as defined in the Project Agreement) between the Parties (as defined in the Project Agreement).

Definitions.

- A. The term "Counterparty" is used in these Funding Restrictions to refer to either (i) the Contractor under the Work Order or (ii) the Subrecipient under the Subaward Agreement, as applicable.
- B. The term "Maximum Amount" is used in these Funding Restrictions to refer to either (i) the Maximum Compensation Amount under the Work Order or (ii) the Maximum Assistance Amount under the Subaward Agreement, as applicable.
- C. The term "Project Agreement" is used in these Funding Restrictions to refer to either (i) the Work Order or (ii) the Subaward Agreement, as applicable, to which these Funding Restrictions are attached as Exhibit A.
- 2. <u>Compliance with Funding Conditions</u>. This project is funded through the Cooperative Agreement (as defined in the Project Agreement) between APHL and the Centers for Disease Control and Prevention ("<u>CDC</u>"). The Counterparty will comply with the terms and conditions of the Cooperative Agreement.
- 3. <u>Uniform Administrative Requirements</u>. The US Office of Management and Budget's Uniform Administrative Requirements (the "<u>UAR</u>") found at 2 CFR Part 200, as implemented by the US Department of Health and Human Services ("<u>DHHS</u>") at 45 CFR Part 75, apply to the terms of the Agreement. An electronic copy of DHHS' UAR is currently available at http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75 and the Counterparty will ensure that it has reviewed the applicable provision and will conduct the Project (as defined in the Project Agreement) in compliance with the UAR terms.
- 4. HHS Grants Policy Statement. The Cooperative Agreement is subject to the terms of the DHHS Grants Policy Statement (dated January 1, 2007), as supplemented by any addenda in effect as of July 1, 2015. An electronic copy of which is currently available at http://www.hhs.gov/asfr/ogapa/

<u>aboutog/hhsgps107.pdf</u> and the Counterparty will ensure that it has review the applicable provisions and will conduct the Project in compliance with its terms.

- 5. <u>Lower Tier Transactions</u>. The Counterparty will include the provisions of these Funding Restrictions as conditions of any subcontract or sub-subaward (with the subcontractor or sub-subrecipient agreeing to comply with these provisions as if it is the Counterparty). These provisions must be conditions of any subcontract, sub-subcontract, etc., governing a lower tier transaction.
- **6.** <u>Public Policy Requirements</u>. The Counterparty will comply with each of the following laws and regulations as applicable to the Cooperative Agreement:
 - A. Byrd Anti-Lobbying Amendment (31 U.S.C. §1352);
 - B. Debarment and Suspension (Executive Orders 12549 and 12689);
 - C. Equal Employment Opportunity regulations (Executive Order 11246, as amended by Executive Order 11375 and as supplemented by 41 CFR Part 60);
 - **D.** Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended (42 U.S.C. §§201 et seq.);
 - E. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, as amended (USA PATRIOT Act) (Pub. L. 107-56); and
 - F. Non-Discrimination Acts, including: (a) Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. §§2000d et seq.) which prohibits discrimination on the basis of race, color or national origin (not applicable to foreign (non-US) organizations); (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex (not applicable to foreign (non-US) organizations); (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicap (not applicable to foreign (non-US) organizations); (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101 et seq.), which prohibits discrimination on the basis of age (not applicable to foreign (non-US) organizations); (e) the Drug Abuse Office and Treatment Act of 1972 (Pub. L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Pub. L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912, as amended (42 U.S.C. §§290 dd-3 and 290 ee-3), relating to confidentiality of alcohol and drug abuse patient records; and (h) any other nondiscrimination provisions in the specific statute(s) under which the Cooperative Agreement was made, or any other nondiscrimination statute(s) which may otherwise apply to the Cooperative Agreement.

7. <u>Bayh-Dole Act</u>. Inventions conceived or first actually reduced to practice by the Counterparty in the performance of experimental, developmental, or research work under the Agreement are subject to the Bayh-Dole Act (37 CFR Part 401) and the standard patent right clauses (37 CFR Part 401.14).

Equipment & Products.

- A. Purchases of equipment and products under the Agreement are subject to the Buy American Act of 1933, as amended (41 U.S.C. §§8302 et seq.), which requires the purchase of American-made equipment and products to the greatest extent practicable.
- B. The CDC defines "equipment" as tangible non-expendable personal property (including exempt property) charged directly to the Project Agreement having a useful life of more than one year <u>and</u> an acquisition cost of \$5,000 or more per unit but the Counterparty is permitted to have a lower threshold consistent with its policies. The Counterparty will provide APHL with information or documentation regarding its procurement policies if it has established a lower threshold.
- 9. <u>Travel</u>. Travel within and outside the US under the Agreement is subject to the Fly America Act, as amended (49 U.S.C. §40118), which requires utilization of US-flag carriers to the greatest extent practicable (generally regardless of cost, convenience, and personal travel preferences).

10. Publications and Publicity.

A. Any (a) publication, paper or journal article relating to or (b) press release, article, report, or other material publicizing or resulting from the Counterparty's work or services under the Agreement must include an acknowledgment that the Project was supported by CDC. The Counterparty will use the following disclaimer and acknowledgment of support:

"This publication (journal article, etc.) was supported by the Cooperative Agreement Number U60OE000103, funded by the Centers for Disease Control and Prevention through the Association of Public Health Laboratories. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention, the Department of Health and Human Services, or the Association of Public Health Laboratories."

- B. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing the Project (as a project funded in whole or in part with federal money) such documents must clearly state:
 - the percentage of the total costs of the project which will be financed with Federal money;
 - ii. the dollar amount of Federal funds for the project or program; and

- iii. the percentage and dollar amount of the total costs of the project that will be financed by non-governmental sources.
- **C.** Any publication, paper, journal article or any other document published must cite the funding support of all institutes listed below:

Office of Surveillance, Epidemiology and Laboratory Services (OSELS) (OE)
National Center for HIV, STDs and TB Prevention (PS)
National Center for Zoonotic, Vector-Borne, and Enteric Diseases (CK)
National Center for Immunization and Respiratory Diseases (IP)
National Center for Environmental Health (NCEH)

National Center for Birth Defects and Developmental Disabilities (NCBDD)

Coordinating Office of Global Health (GH)

Office of Infectious Diseases (OID) (CH)

Coordinating Office for Terrorism Preparedness and Emergency Response (CTPER)
Office for State, Tribal, Local and Territorial Support (OT)

- D. The US Government has a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, and otherwise use publications, data, and other copyrightable works developed by the Counterparty under the Agreement. The US Government may also grant a sublicense of these rights to others to do so for Federal purposes.
- E. For the purposes of this Section 10 of these Funding Restrictions, "data" means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

11. Copyright Interests.

A. Pursuant applicable federal grant regulations and the CDC's Public Access Policy, the Counterparty will submit into the National Institutes of Health (NIH) Manuscript Submission ("NIHMS") system an electronic version of the final, peer-reviewed manuscript (as defined below) of the work developed under or in connection with the Agreement upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, the Counterparty or the Counterparty's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central ("PMC"). The Counterparty or the Counterparty's submitting author must also post the manuscript to PMC within 12 months of the publisher's official date of final publication; however the Counterparty is strongly encouraged to make the subject manuscript available as soon as possible. The Counterparty must obtain prior written approval from APHL (who, in turn, must obtain prior approval from CDC) for any exception to this provision.

- B. For purposes of this Section 11 of these Funding Restrictions, the "final, peer-reviewed manuscript" is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. The Counterparty and its submitting authorized working under the Agreement are responsible for ensuring that any published or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the licensing reserved by the CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for the Project, the Counterparty must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three months after the publication date and the PMC identification number (PMCID) number thereafter.
- 12. <u>Limitations on an Individual's Salary</u>. The Consolidated Appropriations Act of 2012 (Pub. L. 112-74), as amended, limits the salary amount that may be awarded or charged to the Cooperative Agreement. Cooperative Agreement funds may not be used to pay the salary of an individual at a rate in excess of \$183,300 (the Executive Level II salary in the Federal Executive Pay scale for 2015). Such amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of his or her duties to the Counterparty. Such salary limitation also applies to any subcontracts or sub-subawards issued by the Counterparty for services to or work on the Project under the Project Agreement. The salary limitation does not limit how much salary the Counterparty may pay an individual, but simply limits the amount that may be awarded or charged to Cooperative Agreement funds.
- **13.** <u>Whistleblower Protections</u>. In the event that the Maximum Amount is equal to or greater than \$100,000, the following provisions will apply.
 - A. he Agreement and employees of the Counterparty working on the Agreement will be subject to the whistleblower rights and remedies in the pilot program in the Pilot Program for Enhancement of Contractor Employee Whistleblower Protections established at 41 U.S.C. §4712 by Section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and Federal Acquisition Regulation ("FAR") §3.908.
 - B. The Counterparty will inform its employees in writing, in the predominate language of the workforce, of employee whistleblower rights and protections under 41. U.S.C. §4712, as described in §3.908 of FAR.
 - **C.** The Counterparty will insert the substance of this Section, including this subsection (C), in all subcontracts over the simplified acquisition threshold.
- 14. <u>Examination of Records</u>. The Counterparty will cooperate with APHL in the audit of APHL that is required by the UAR audit requirements found at 2 CFR Part 200 Subpart F or contained in the HHS Grants Policy Statement. The Counterparty acknowledges that the standards set forth in 2 CFR Part 200 Subpart F will apply to audits of fiscal years beginning on or after 26 December 2014. The Comptroller General of the United States, DHHS, CDC, APHL, and their representatives have the right to access and examine any books, documents, papers, and records of the Counterparty that involve transactions

related to the Agreement, for the purpose of audit and making excerpts and transcriptions. The Counterparty will maintain auditable records for at least four years following the close of the Cooperative Agreement (currently expected to end March 31, 2019). Further, the Counterparty will permit these representatives access to its facilities and personnel for the purpose of on-site inspections, and will provide information, as requested, to determine compliance with the Cooperative Agreement terms and conditions.

- **Termination of Cooperative Agreement**. If (i) funds are not appropriated or otherwise made available for the continued performance of the Cooperative Agreement, (ii) the Cooperative Agreement is terminated or (iii) the Cooperative Agreement funds are reduced or eliminated for the Project, APHL may terminate the Agreement without penalty upon written notice to the Counterparty.
- 16. <u>Prohibition on Lobbying</u>. No part of the Cooperative Agreement funds may be used for:
 - A. Publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation, designed to support or defeat the enactment of legislation before the Congress or any state or local legislature or legislative body, except in presentation of the Congress or any state or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government itself.
 - B. Paying the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local or tribal government in policymaking and administrative processes within the executive branch of that government.
 - C. Any activity to advocate or promote any proposed, pending, or future Federal, state or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale of marketing, including, but not limited to the advocacy or promotion of gun control.
 - D. In addition, the Cooperative Agreement is subject to the additional lobbying restrictions and provisions of CDC's Anti-Lobbying Restrictions for CDC Grantees (an electronic copy of which is currently available at http://www.cdc.gov/grants/documents/Anti-Lobbying Restrictions for CDC Grantees July 2012.pdf).
- 17. <u>Federal Information Security Management Act</u>. The Counterparty will ensure that all information systems, electronic or hard copy, that contain federal data are protected from unauthorized access and will comply with the Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002, as amended (Pub. L. 107-347).

- **18. Gun Control Prohibition**. None of the funds made available under the Project Agreement may be used, in whole or in party, to advocate or promote gun control.
- 19. Needle Exchange. No funds made available under the Project Agreement may be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.
- 20. <u>Blocking Access to Pornography</u>. No funds made available under the Project Agreement may be used to maintain or establish a computer network unless this network blocks the viewing, downloading and exchanging of pornography. Nothing in this Section 20 will limit the use of funds necessary for any federal, state, tribal or local law enforcement agency or any other entity carrying out criminal investigations, prosecution or adjudication activities.,
- **21.** <u>Trafficking in Persons</u>. If the Counterparty is either a for-profit organization or a nonprofit organization, including any nonprofit institution of higher education, hospital, or most US tribal organizations then the following provisions apply.
 - A. The Counterparty, its employees, any subcontractors under the Agreement, and any subcontractor's employees may not:
 - Engage in severe forms of trafficking in persons during the period of time that the Agreement is in effect;
 - ii. Procure a commercial sex act during the period of time that the Agreement is in effect; or
 - iii. Use forced labor in the performance of the Project or any work performed by approved subcontractors under the Agreement.
- 22. Meetings and Conferences; Logo Use for Conferences and Other Meetings. If the Project Agreement involves or is related to a meeting, conference or seminar, then the following provisions apply.
 - A. The Counterparty will include the following statement on conference or meeting materials, including promotional materials, agenda and internet sites:

"Funding for this conference was made possible (in part) by the U.S. Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official positions of the U.S. Department of Health and Human Services, nor does the mention of trade names, commercial practices or organizations imply endorsement by the U.S. Government."

B. Neither the DHHS nor the CDC logo may be displayed if such display would cause confusion as to the conference source or give false impression of U.S. Government endorsement. Use of the DHHS logo is governed by U.S.C. §1320b-10, which prohibits misuse of the DHHS name and emblem in written communication. The Counterparty is prohibited from using the DHHS name or logo except as governed by U.S.C. §1320b-10. The appropriate use of the DHHS logo is subject to the review and approval of the DHHS Office of the Assistant Secretary for Public Affairs. Moreover, the Office of the Inspector General has the authority to impose civil monetary penalties for violations (see 42 CFR Part 1003). Neither the DHHS nor the CDC logo can be used on conference materials without the expressed, written consent of APHL (who, in turn, must receive such consent from the CDC). \

- **23.** <u>Certifications</u>. By signing the Project Agreement, the Counterparty certifies the statements listed below. These certifications are material representations of facts upon which APHL relied when it entered into this transaction.
 - A. <u>Debarment, Suspension, Ineligibility and Voluntary Exclusion</u>. The Counterparty certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.
 - B. Lobbying. The Counterparty certifies that:
 - i. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Counterparty, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
 - ii. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the Cooperative Agreement supporting this Agreement, the Counterparty will complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.
 - C. <u>No Delinquency on US Government Debts</u>. The Counterparty certifies that it is not indebted to the US government, and does not have a judgment lien filed against it.
 - D. Recent Felonies. The Counterparty certifies that it has not been convicted (nor has any of its officers or agents acting on behalf of the Counterparty been convicted) of a felony criminal violation under any Federal or State law within the preceding 24 months.
 - **E.** Equal Opportunity Employer. The Counterparty certifies that it is an Equal Opportunity Employer in accordance with US law and regulation in effect as of the date of this Agreement.

EXHIBIT B Standard Terms and Conditions

See Attached



STANDARD TERMS AND CONDITIONS

TO APHL WORK ORDERS

These Standard Terms and Conditions (the "Standard T&C") have been attached as Exhibit B to a Work Order between APHL (as defined in the Work Order) and the Contractor (as defined in the Work Order) and have been incorporated into that Work Order by reference. The Standard T&C, together with the Work Order and any applicable Cooperative Agreement Funding Conditions (as defined in the Work Order) attached to that Work Order, make up the entire Agreement (as defined in the Work Order) between the Parties (as defined in the Work Order).

Responsibilities of the Contractor.

- A. The Contractor will prepare all materials and perform all services required to complete the Work (as defined in the Work Order) using its best skills, efforts and attention.
- B. The Contractor will prepare reports and other final deliverables (each, a "<u>Deliverable</u>") using a format and software programs agreed to in advance by APHL. The Contractor will check the APHL Work Order Administrator identified in the Work Order if the Contractor is unclear as to whether a Deliverable requires a specific formatting or software program. In the event that any Deliverable is prepared in a language other than English, the Contractor will also prepare an English translation of such Deliverable.
- C. Any data provided by the Contractor must be free of identifiers that would permit linkages to individuals and must be free of variables that could lead to deductive disclosure of the identity of the individual subjects.
- D. The Contractor will comply with all applicable laws in the performance of its obligations under the Agreement. The Contractor will comply with federal, state, and local health and safety standards applicable to its operations, and will establish and implement necessary measures to minimize its employees' risk of injury and illness in activities related to the Agreement. If the Contractor is conducting activities outside the United States of America ("US") under the Agreement, the Contractor will coordinate as necessary with appropriate government authorities and will obtain appropriate licenses, permits, and approvals. The Contractor will ensure that it and its officers, directors, employees, agents, and contractors (regardless of nationality) (i) avoid any action that violates or appears to violate any governmental rule relating to ethics and integrity, (ii) avoid any corrupt practice (for example, offering or accepting bribes), and (iii) avoid any fraudulent practice (for example, falsifying financial records). The Contractor will immediately inform APHL of any violation of this provision, and will cooperate with APHL in taking corrective action. APHL will have the express right, in its sole discretion, to require cessation of all Work until these corrective actions have been taken by the Contractor.
- E. If either the Contractor or APHL determines that additional work might be desirable, the Contractor will prepare an estimate of (i) the scope of work required to complete the service

and (ii) the projected cost (a "Quote"). If APHL and, if applicable, the Funding Source (as defined in the Work Order) find the Quote acceptable, APHL will prepare a written amendment to the Agreement. The Contractor will not perform the proposed additional work unless authorized by a written amendment to this Agreement.

- F. APHL may unilaterally order minor changes in the work that are not inconsistent with the intent of the Agreement. The cost or credit to APHL as a result of these changes will be determined by the Parties' (as defined in the Work Order) mutual agreement, and APHL prepare a written amendment or an email modification to reflect this cost or credit. The Contractor will not perform any change in the Work without prior written authorization from APHL.
- G. In the event that the Contractor is an individual (and not a business or nonprofit entity, a governmental agency or unit or a partnership), the Contractor acknowledges and understands each of the following provisions.
 - The Contractor will implement its duties under this Agreement in an efficient, economical, and timely fashion. As an independent contractor, the Contractor has sole responsibility and control of the manner and means of providing the services required, including the right to determine the hours and sequence of its work.
 - ii. APHL neither has a legal or regulatory duty nor a contractual requirement: (a) to carry Workers Compensation insurance covering the Contractor or its employees; or (b) to withhold funds for Social Security, Medicare, income taxes, or Unemployment Insurance. The Contractor and its employees are not entitled to any benefits of employment that are offered to employees of APHL except if explicitly noted in the Work Order.
 - iii. The Contractor is responsible for all indirect expenses connected with the Contractor's services, including the costs of maintaining the Contractor's own office, equipment, and administrative staff.

Subcontracting and Subcontractors.

- A. The Contractor will not subcontract its services under the Agreement without the prior written consent of APHL.
- B. In the event that the Contractor desires to subcontract any portion of its services under this Agreement, the Contractor will make positive efforts to include small businesses and minority- and women-owned businesses as subcontractors. The required efforts include the methods outlined in Office of Management and Budget ("OMB") Circular A-110 §.44(b) (an electronic copy of which is currently available at http://www.whitehouse.gov/omb/circulars/al10/al10.html), and the following methods:
 - Place small, minority, and women-owned business firms on bidders mailing lists;

- Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services;
- iII. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms; and
- iv. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, Department of Health and Human Services ("DHHS"), and similar state and local offices.
- C. The Contractor will contract in its own name with each subcontractor under APHL-approved subcontracts. The Contractor is responsible for (i) coordination and review of its subcontractors' work, (ii) paying any compensation and reimbursing any expenses authorized by subcontracts, and (iii) ensuring that any work performed by subcontractors is performed in accordance with the terms of the Agreement.

3. Project Schedule.

- A. APHL has the right to request revisions to any Deliverable. The Contractor will complete all requested revisions to the satisfaction of APHL prior to the start of the next step of the project.
- B. The Contractor will promptly notify APHL of any situation which might interfere with the Contractor's ability to meet project deadlines.
- C. If a Party (as defined in the Work Order) fails to meet deadlines because of a matter beyond the Party's control, the Parties will work together to adjust the future deadlines accordingly.

4. Termination.

- A. APHL may terminate this Agreement or any portion of the Work in progress by written notice to the Contractor.
- B. Upon receipt of a notice of termination, the Contractor will immediately cease all work and will turn over all work product and work-in-progress to the Representative of APHL.
- C. In the event of early termination, APHL will be obligated to pay the Contractor only for work satisfactorily performed through the date of termination.
- 5. <u>Indemnification</u>. Unless prohibited from doing so pursuant to applicable law or regulation, the Contractor will defend and indemnify APHL against all claims, liabilities, damages, and expenses (including reasonable attorney's fees) arising out of any act, omission, negligence, misconduct, or breach

of the Agreement by the Contractor, its directors, officers, employees, subcontractors, or agents while engaged in the performance of the Agreement.

- Confidentiality. The Contractor will maintain in strict confidence any Confidential Information of APHL that the Contractor reviews, receives, or acquires in the performance of this Agreement. APHL will make efforts to clearly identify, preferably in writing, any Confidential Information. "Confidential Information" means, subject to the limitation set forth below: economic and financial information, information and materials obtained from interviews or surveys, membership and donor lists, business procedures, solicitation or contact methods, and any other information regarding the business of APHL. Confidential Information does not include information that: (i) is or becomes available from public sources through no wrongful act of the Contractor; (ii) is already in the Contractor's possession prior to the date of the Agreement without an obligation of confidentiality, except for information disclosed during discussions related to the Agreement; (iii) is rightfully disclosed to the Contractor by a third party with no obligation of confidentiality; (iv) is independently developed by the Contractor; or (v) is required to be disclosed pursuant to any court or regulatory order served on the Contractor. The Contractor may disclose Confidential Information to its accountants, counsel, and other financial and legal advisors with a need to know. If disclosure to a subcontractor is necessary in order to carry out the Contractor's work, the Contractor must obtain the subcontractor's agreement to abide by this confidentiality provision prior to disclosure.
- 7. Insurance. Unless prohibited from doing so pursuant to applicable law or regulation, the Contractor will maintain with a reputable insurance company policies of insurance providing an adequate level of coverage for all risks which may be incurred by the Contractor as a result of its performance of the Agreement (including death, personal injury or loss of or damage to property). Upon reasonable request from APHL, the Contractor will provide APHL with copies of such insurance policies or other evidence confirming the existence and extent of the coverage given by those policies.
- 8. <u>Conflicts of Interest</u>. The Contractor, to the to the best of its knowledge and belief at this time, certifies that either (i) there no relevant facts or circumstances which could give rise to an organizational conflict of interest ("<u>OCI</u>"), as defined in Federal Acquisition Regulation (FAR) Subpart 9.5 or (ii) the Contractor has disclosed all such relevant information, and that it will disclose any actual or potential OCI that is discovered. During the term of the Agreement, the Contractor will not enter into other contracts or arrangements or otherwise engage in work that will conflict with the Contractor's obligations under the Agreement.
- 9. <u>Survival</u>. The obligations and rights of the Parties which by their nature would continue beyond the termination or expiration of the Agreement will survive beyond the termination or expiration of the Agreement and remain in full force and effect. These obligations and rights include those set forth in the Section entitled "Copyright & Intellectual Property Rights" in the Work Order and "Indemnification" and "Confidentiality" in these Standard T&C.
- 10. <u>Impossibility</u>. Either Party may terminate or suspend its obligations under the Agreement if performance of its obligations is prevented or delayed by an event beyond the Party's control and without its fault or negligence, including acts of war or the public enemy, terrorism, fires, floods,

epidemics, quarantine restrictions, strikes, freight embargoes, unusually severe weather, laws, regulations and orders of governmental authorities, and curtailment of transportation facilities. Upon this circumstance arising, the non-performing Party will promptly notify the other Party in writing and the Parties will negotiate in good faith to reach a resolution. The non-performing Party will not be liable for this delay or failure to perform its obligations, except there will be a pro rata reduction in the consideration that would otherwise be due.

- 11. <u>Non-Discrimination</u>. The Parties will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, national origin, sexual orientation, gender identity, disability, genetic information, citizenship status, veteran status or any other classification protected by applicable law or regulation.
- 12. Governing Law. This Agreement is governed exclusively by the laws of the District of Columbia.
- 13. Governing Language. In the event that all or part of the Agreement is produced in English and one or more foreign languages, this English language version of the Agreement is the official version and will govern if there is a conflict between this English language version and one or more of the foreign translations.

14. Dispute Resolution.

- A. In the event the Maximum Compensation Amount (as defined in the Work Order) is equal to or greater than \$20,000, the Parties agree that the sole jurisdiction and venue for any litigation arising from the Agreement is the appropriate federal or district court located in the District of Columbia. The Parties hereby waive trial by jury in any action arising out of this Agreement. If a dispute arises, the Parties will make a good faith attempt to resolve the dispute through dialogue and negotiation prior to pursuing court action.
- B. In the even the Maximum Compensation Amount is less than \$20,000, the Parties agree that any dispute arising from the Agreement must be settled by arbitration in accordance with either (i) the Commercial Arbitration Rules (if the Work is being conducted in the US) or (ii) the International Arbitration Rules (if the Work is being conducted outside of the US) of the American Arbitration Association. Judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction. Arbitration must be held in Washington, DC. If a dispute arises, the Parties will make a good faith attempt to resolve the dispute through dialogue and negotiation prior to pursuing arbitration.
- 15. <u>Independent Contractors</u>. The relationship between the Parties to the Agreement is that of independent contractors. The Agreement is not intended to create any association, partnership, joint venture, or agency relationship between the Parties. Neither Party has the authorization or ability to legally bind the other Party to any contract, agreement, obligation, commitment or fixed or contingent liability with a third party.

- 16. <u>Assignability</u>. The Contractor will not assign the Agreement, or any interest in the Agreement, without the prior written consent of APHL.
- 17. <u>Successors</u>. The Agreement will be binding upon, and will inure to the benefit of, the Parties and their respective permitted successors and assigns.
- 18. <u>Sole Agreement</u>. This Agreement contains the entire agreement between the Parties concerning the subject matter of the Work Order. It supersedes all prior and contemporaneous oral and written understandings.

Amendment.

- A. Except as provided in Section 19.B. below, no amendment of the Agreement will be valid unless in writing and signed by both Parties.
- B. In the event of a ministerial or non-substantive modification to the Agreement (such as a no-cost change to the Schedule of Deliverables), a Party may send an email to the other Party stating the terms of the proposed modification and, upon receipt of the other Party's email reply confirming the other Party's consent to such modification, the modification will be valid and will be deemed by the Parties to constitute a valid amendment under this Section 19.
- 20. <u>Waiver</u>. A Party's waiver of a breach is not to be deemed a waiver of any subsequent breach of the same term or of any other term. No waiver will be valid unless in writing and signed by the waiving Party.
- 21. <u>Severability</u>. If any provision of the Agreement is held to be invalid, the remaining provisions of the Agreement are not to be affected and will continue in effect. The invalid provision is to be deemed modified to the least degree necessary to remedy the invalidity.
- 22. <u>Interpretation</u>. When used in the Agreement, the terms "include" or "including" are not limiting (such that the terms should be read as if stating "include without limitation" or "including without limitation" as applicable).
- 23. Section Headings. The captions or headings in the Agreement are made for convenience and general reference only and should not be construed to describe or limit the scope or the intent of the provisions of the Agreement.
- 24. <u>Drafting Party</u>. The Parties have participated jointly in the negotiation and drafting of the Agreement and each Party has had the opportunity to consult with, and to get assistance from the counsel and other advisors that Party deemed appropriate. In the event an ambiguity or question of intent or interpretation arises, the Agreement will be construed as jointly drafted by the Parties, and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provision of the Agreement.

- **25.** <u>Counterparts</u>. The Parties may execute the Work Order in counterparts, each of which is deemed an original and all of which taken together constitute one original.
- **26.** <u>Signatures/E-delivery</u>. A manually signed copy of the Work Order delivered by facsimile, email or other means of electronic transmission will be deemed to have the same legal effect as delivery of an original signed copy of the Work Order.

[End of Standard Terms and Conditions to APHL Work Orders]

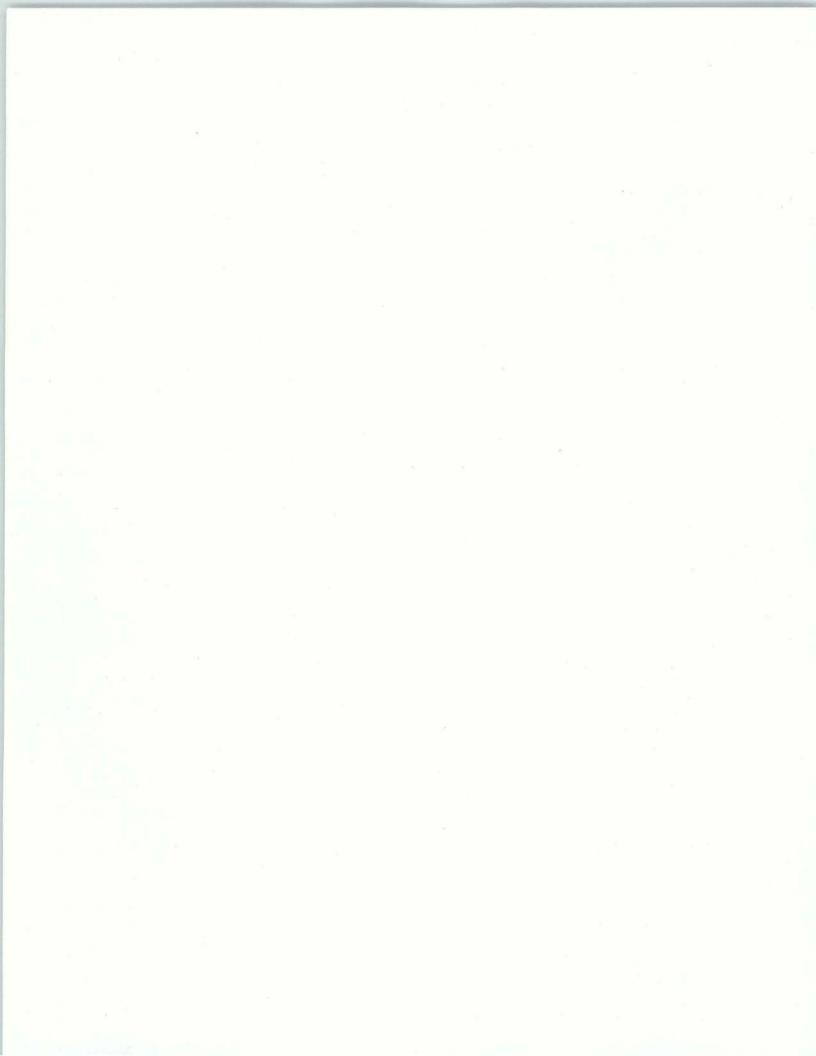


EXHIBIT C

The Contractor's Proposal

See Attached

ASSOCIATION OF PUBLIC HEALTH LABORATORIES



Dear Public Health Laboratory Directors and Member-Associates,

To support diagnostic test development, the Division of STD Prevention (DSTDP) at the Centers for Disease Control and Prevention (CDC) is requesting residual syphilis serum specimens that have been previously tested with a treponemal and a non-treponemal diagnostic assay. Specimens that have been categorized as primary, secondary, early latent, late latent or tertiary syphilis are requested. The Association of Public Health Laboratories (APHL) will compensate each facility for costs associated with pulling and packaging specimens that are identified for shipment. A FedEx account number for direct payment of shipping costs will be provided.

Interested laboratories should complete and submit the Syphilis Specimen Inventory Request Form for specimens that meet the criteria listed below. Once submitted to APHL, DSTDP will review spreadsheets and indicate which specimens will be selected for shipment. APHL will notify laboratories of which specimens were selected for shipment. Compensation will occur after confirmation of specimen receipt at DSTDP.

Use of residual specimens is addressed in FDA guidance Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff issued on April 25, 2006.

Specimen Requirements

- Syphilis serum specimens must have a minimum of 2mL volume available and must have been previously tested with both a treponemal and non-treponemal diagnostic assay.
- Specimens must be classified as one of the following stages of syphilis (all stages should indicate treated or non-treated):
 - o Primary syphilis
 - o Secondary syphilis
 - o Early latent syphilis
 - Late latent syphilis
 - Tertiary syphilis
- The residual specimen must have been stored at -20°C or below.
- The specimen should not have gone through more than 5 freeze/thaw cycles.
- Each specimen should have a unique identifier that does not relate to the patient's identity (e.g., date of birth).
- Required information for each specimen on the attached form should include: gender, age, pregnancy status, date of collection, storage conditions, # of freeze/thaw cycles, volume, state of syphilis, tests performed (including manufacture information) and test results.

Specimen Inventory Request Form

The Specimen Inventory Request Form must be fully complete in the format provided for acceptance. Forms should be submitted to APHL for approval prior to shipment of specimens. Please provide complete information for no more than 25 specimens. However, if your laboratory has additional syphilis specimens, please indicate

that you have additional specimens. Additional specimens may be solicited later depending on total number received from all PHLs. Please email forms to anne.gaynor@aphl.org with the subject line "Syphilis Specimen Inventory Form—<Your Laboratory Name>". APHL will notify labs if specimens were selected for the laboratory and further shipping instructions will be sent at that time.

Please submit Specimen Inventory Forms no later than May 13, 2016.

Compensation for Acceptable Specimens

APHL will compensate submitting laboratories \$50.00 per acceptable specimen with confirmed receipt from CDC. Specimen shipping must follow IATA guidelines and any specified shipping requirements for reimbursement. Specimens that are not packaged or shipped appropriately will not be eligible for reimbursement.

For eligible specimens, APHL will require PHLs to submit an invoice for reimbursement. If your laboratory will require a contract for reimbursement, please ensure to notify APHL in your response so we can start the paperwork as soon as possible. Further instructions will be provided upon approval of the Syphilis Specimen Inventory Request Form.

Specimen De-Identification by Submitting Laboratories

Prior to shipping specimens to CDC, specimens will have to be unlinked from any information that could be linked to a specific patient. Specific instructions will be provided after eligible specimens have been identified. Please include your original unique identifier in the Syphilis Specimen Inventory Request Form that will be returned to APHL.

If you have any questions, please do not hesitate to contact me.

Best regards,

Anne Gaynor, PhD Manager: HIV, Hepatitis, STD and TB Programs Association of Public Health Laboratories 240.485.2739 anne.gaynor@aphl.org

forward TO A FRIEND -

