

ADDENDUM

Contract #000000000000000000071962

This Addendum is entered into by and between Indiana Department of Health (the "State") and the entity designated below. In consideration of those mutual undertakings and covenants, the parties agree as follows:

The purpose of this Addendum is to modify, delete, or amend certain terms and conditions set forth in the attached Form Contract prepared by the entity designated below (the "Form Contract"). This Addendum and the Form Contract are incorporated into each other and, when read together, shall constitute one integrated document (this "Contract"). Any inconsistency, conflict, or ambiguity between this Addendum and the Form Contract shall be resolved by giving precedence and effect to this Addendum.

Name: Association of Public Laboratories Inc (APHL)

Address: 8515 Georgia Avenue, Suite 700
Silver Spring, Maryland 20910

Title of Form Contract: Work Order

1. By mutual agreement of the parties, the following terms and conditions are deleted from the Form Contract:
 - A. Any provision requiring the State of Indiana to provide insurance
 - B. Any provision requiring the State of Indiana to provide indemnity
 - C. Any provision providing that the Contract be construed in accordance with laws other than those of the State of Indiana
 - D. Any provision providing that suit be brought in any state other than Indiana
 - E. Any provision providing for resolution of contract disputes
 - F. Any provision requiring the State of Indiana to pay any taxes
 - G. Any provision requiring the State of Indiana to pay penalties, liquidated damages, interest or attorney's fees
 - H. Any provision modifying the applicable Indiana statute of limitations
 - I. Any provision relating to the time within which a claim must be made.
 - J. Any provision requiring payment of consideration in advance unless authorized by an exception listed in IC § 4-13-2-20
 - K. Any provision limiting disclosure of the contract in violation of the Access to Public Records Act, IC § 5-14-3. This is a Public Contract and will be posted on the transparency portal as required by Executive Order 05-07 and IC § 5-14-3.5-2.
 - L. Any provision requiring payment in less than 35 days
 - M. Any provision providing for automatic renewal
 - N. Any provision giving the Form Contract precedence over this Addendum

2. **Form Contract/Duties of Contractor.** The Contractor shall provide the Services or Products described in the Form Contract.
3. **Term.** This Contract begins on **March 01, 2023** and ends **June 30, 2023**.
4. **Consideration.** Total consideration for term of this Contract is **\$24,965.00**. This is a revenue generating contract. APHL is paying the State for providing services.
5. **Access to Records.** Deleted
6. **Assignment; Successors.** APHL binds its successors and assignees to all the terms and conditions of this Contract. APHL shall not assign nor subcontract the whole or any part of this Contract without the State's prior written consent.
7. **Assignment of Antitrust Claims.** Deleted
8. **Audits.** Deleted
9. **Authority to Bind Contractor.** The signatory for the Contractor represents that he/she has been duly authorized to execute this Contract on behalf of the Contractor and has obtained all necessary or applicable approvals to make this Contract fully binding upon the Contractor when his/her signature is affixed, and accepted by the State.
10. **Changes in Work.** Deleted
11. **Compliance with Laws.**
 - A. The Contractor shall comply with all applicable federal, state, and local laws, rules, regulations, and ordinances, and all provisions required thereby to be included herein are hereby incorporated by reference. The enactment or modification of any applicable state or federal statute or the promulgation of rules or regulations thereunder after execution of this Contract shall be reviewed by the State and the Contractor to determine whether the provisions of this Contract require formal modification.
 - B. The Contractor and its agents shall abide by all ethical requirements that apply to persons who have a business relationship with the State as set forth in IC § 4-2-6, et seq., IC § 4-2-7, et seq. and the regulations promulgated thereunder. **If the Contractor has knowledge, or would have acquired knowledge with reasonable inquiry, that a state officer, employee, or special state appointee, as those terms are defined in IC § 4-2-6-1, has a financial interest in the Contract, the Contractor shall ensure compliance with the disclosure requirements in IC § 4-2-6-10.5 prior to the execution of this Contract.** If the Contractor is not familiar with these ethical requirements, the Contractor should refer any questions to the Indiana State Ethics Commission, or visit the Inspector General's website at <http://www.in.gov/ig/>. If the Contractor or its agents violate any applicable ethical standards, the State may, in its sole discretion, terminate this Contract immediately upon notice to the Contractor. In addition, the Contractor may be subject to penalties under IC §§ 4-2-6, 4-2-7, 35-44.1-1-4, and under any other applicable laws.
 - C. Deleted

- D. The Contractor warrants that it has no current, pending or outstanding criminal, civil, or enforcement actions initiated by the State, and agrees that it will immediately notify the State of any such actions. During the term of such actions, the Contractor agrees that the State may delay, withhold, or deny work under any supplement, amendment, change order or other contractual device issued pursuant to this Contract.
- E. If a valid dispute exists as to the Contractor's liability or guilt in any action initiated by the State or its agencies, and the State decides to delay, withhold, or deny work to the Contractor, the Contractor may request that it be allowed to continue, or receive work, without delay. The Contractor must submit, in writing, a request for review to the Indiana Department of Administration (IDOA) following the procedures for disputes outlined herein. A determination by IDOA shall be binding on the parties. Any payments that the State may delay, withhold, deny, or apply under this section shall not be subject to penalty or interest, except as permitted by IC § 5-17-5.
- F. Deleted
- G. Deleted
- H. Deleted

12. Condition of Payment. Deleted

13. Confidentiality of State Information. The Contractor understands and agrees that data, materials, and information disclosed to the Contractor may contain confidential and protected information. The Contractor covenants that data, material, and information gathered, based upon or disclosed to the Contractor for the purpose of this Contract will not be disclosed to or discussed with third parties without the prior written consent of the State.

The parties acknowledge that the services to be performed by Contractor for the State under this Contract may require or allow access to data, materials, and information containing Social Security numbers maintained by the State in its computer system or other records. In addition to the covenant made above in this section and pursuant to 10 IAC 5-3-1(4), the Contractor and the State agree to comply with the provisions of IC § 4-1-10 and IC § 4-1-11. If any Social Security number(s) is/are disclosed by Contractor, Contractor agrees to pay the cost of the notice of disclosure of a breach of the security of the system in addition to any other claims and expenses for which it is liable under the terms of this contract.

14. Continuity of Services. Deleted

15. Debarment and Suspension. APHL certifies by entering into this Contract that neither it nor its principals nor any of its subcontractors are presently debarred, suspended, proposed for debarment, or declared ineligible or voluntarily excluded from entering into this Contract by any federal agency or by any department, agency, or political subdivision of the State of Indiana. The term "principal" for purposes of this Contract means an officer, director, owner, partner, key employee or other person with primary management or supervisory responsibilities, or a person who has a critical influence on or substantive control over the operations of APHL.

16. Default by State. If the State, sixty (60) days after receipt of written notice, fails to correct or cure any material breach of this Contract, the Contractor may cancel and terminate this Contract and institute measures to collect monies due up to and including the date of termination.

17. Disputes. Deleted

18. Drug-Free Workplace Certification. Executive Order No. 90-5 is not applicable because the State is the recipient of funds pursuant to this Contract.

19. Employment Eligibility Verification. Deleted

20. Employment Option. Deleted

21. Force Majeure. In the event that either party is unable to perform any of its obligations under this Contract or to enjoy any of its benefits because of natural disaster or decrees of governmental bodies not the fault of the affected party (hereinafter referred to as a "Force Majeure Event"), the party who has been so affected shall immediately or as soon as is reasonably possible under the circumstances give notice to the other party and shall do everything possible to resume performance. Upon receipt of such notice, all obligations under this Contract shall be immediately suspended. If the period of nonperformance exceeds thirty (30) days from the receipt of notice of the Force Majeure Event, the party whose ability to perform has not been so affected may, by giving written notice, terminate this Contract.

22. Funding Cancellation. As required by Financial Management Circular 3.3 and IC § 5-22-17-5, when the Director of the State Budget Agency makes a written determination that funds are not appropriated or otherwise available to support continuation of performance of this Contract, this Contract shall be canceled. A determination by the Director of State Budget Agency that funds are not appropriated or otherwise available to support continuation of performance shall be final and conclusive.

23. Governing Law. This Contract shall be governed, construed, and enforced in accordance with the laws of the State of Indiana, without regard to its conflict of laws rules. Suit, if any, must be brought in the State of Indiana.

24. HIPAA Compliance. If this Contract involves services, activities or products subject to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Contractor covenants that it will appropriately safeguard Protected Health Information (defined in 45 CFR 160.103), and agrees that it is subject to, and shall comply with, the provisions of 45 CFR 164 Subpart E regarding use and disclosure of Protected Health Information.

25. Indemnification. The State shall not provide such indemnification to APHL.

26. Independent Contractor; Workers' Compensation Insurance. Deleted

27. Indiana Veteran Owned Small Business Enterprise Compliance. Deleted

28. Information Technology Enterprise Architecture Requirements. Deleted

29. Insurance. Deleted

30. Key Person(s). Deleted

31. Licensing Standards. Deleted

32. Merger & Modification. This Contract constitutes the entire agreement between the parties. No understandings, agreements, or representations, oral or written, not specified within this Contract will be valid provisions of this Contract. This Contract may not be modified, supplemented, or amended, except by written agreement signed by all necessary parties.

33. Minority and Women's Business Enterprises Compliance. Deleted

34. Nondiscrimination. Pursuant to the Indiana Civil Rights Law, specifically IC § 22-9-1-10, and in keeping with the purposes of the federal Civil Rights Act of 1964, the Age Discrimination in Employment Act, and the Americans with Disabilities Act, the Contractor covenants that it shall not discriminate against any employee or applicant for employment relating to this Contract with respect to the hire, tenure, terms, conditions or privileges of employment or any matter directly or indirectly related to employment, because of the employee's or applicant's race, color, national origin, religion, sex, age, disability, ancestry, status as a veteran, or any other characteristic protected by federal, state, or local law ("Protected Characteristics"). Contractor certifies compliance with applicable federal laws, regulations, and executive orders prohibiting discrimination based on the Protected Characteristics in the provision of services. Breach of this paragraph may be regarded as a material breach of this Contract, but nothing in this paragraph shall be construed to imply or establish an employment relationship between the State and any applicant or employee of the Contractor or any subcontractor.

The State is a recipient of federal funds, and therefore, where applicable, Contractor and any subcontractors shall comply with requisite affirmative action requirements, including reporting, pursuant to 41 CFR Chapter 60, as amended, and Section 202 of Executive Order 11246 as amended by Executive Order 13672.

35. Notice to Parties. Whenever any notice, statement or other communication is required under this Contract, it will be sent by E-mail or first class U.S. mail service to the following addresses, unless otherwise specifically advised.

A. Notices to the State shall be sent to:

Indiana Department of Health
ATTN: Contract and Audit Section
2 North Meridian Street, Section 2-C
Indianapolis, Indiana 46204
E-mail: isdhcontracts@isdh.in.gov

B. Notices to the Contractor shall be sent to:

Scott J Becker, MS, Chief Executive Officer
Association of Public Health Laboratories Inc
8515 Georgia Avenue, Suite 700
Silver Spring, Maryland 20910
Email: scott.becker@aphl.org

36. Order of Precedence; Incorporation by Reference. Any inconsistency or ambiguity in this Contract shall be resolved by giving precedence in the following order: (1) this Addendum, (2) the State's cloud terms, if applicable, (3) the Form Contract, (4) other attachments prepared by the State, and (5) attachments prepared by the Contractor. All attachments, and all documents referred to in this paragraph, are hereby incorporated fully by reference.

37. Ownership of Documents and Materials. Deleted

38. Payments. Deleted

39. Penalties/Interest/Attorney's Fees. The State will in good faith perform its required obligations hereunder and does not agree to pay any penalties, liquidated damages, interest or attorney's

fees, except as permitted by Indiana law, in part, IC § 5-17-5, IC § 34-54-8, IC § 34-13-1 and IC § 34-52-2-3.

Notwithstanding the provisions contained in IC § 5-17-5, any liability resulting from the State's failure to make prompt payment shall be based solely on the amount of funding originating from the State and shall not be based on funding from federal or other sources.

40. Progress Reports. Deleted

41. Public Record. The Contractor acknowledges that the State will not treat this Contract as containing confidential information, and the State will post this Contract on the transparency portal as required by Executive Order 05-07 and IC § 5-14-3.5-2. Use by the public of the information contained in this Contract shall not be considered an act of the State.

42. Renewal Option. This Contract may be renewed under the same terms and conditions, subject to the approval of the Commissioner of the Department of Administration and the State Budget Director in compliance with IC § 5-22-17-4. The term of the renewed contract may not be longer than the term of the original contract.

43. Severability. The invalidity of any section, subsection, clause or provision of this Contract shall not affect the validity of the remaining sections, subsections, clauses or provisions of this Contract.

44. Substantial Performance. This Contract shall be deemed to be substantially performed only when fully performed according to its terms and conditions and any written amendments or supplements.

45. Taxes. The State is exempt from most state and local taxes and many federal taxes. The State will not be responsible for any taxes levied on the Contractor as a result of this Contract.

46. Termination for Convenience. This Contract may be terminated, in whole or in part, by the State, which shall include and is not limited to the Indiana Department of Administration (IDOA) and the State Budget Agency whenever, for any reason, the State determines that such termination is in its best interest. Termination of services shall be effected by delivery to the Contractor of a Termination Notice at least thirty (30) days prior to the termination effective date, specifying the extent to which performance of services under such termination becomes effective. For the purposes of this paragraph, the parties stipulate and agree that IDOA shall be deemed to be a party to this Contract with authority to terminate the same for convenience when such termination is determined by the Commissioner of IDOA to be in the best interest of the State.

47. Termination for Default Deleted

48. Travel. Deleted

49. Waiver of Rights. No right conferred on either party under this Contract shall be deemed waived, and no breach of this Contract excused, unless such waiver is in writing and signed by the party claimed to have waived such right.

50. Work Standards. Deleted

51. Amendments. No alteration or variation of the terms of this Contract shall be valid unless made in writing and signed by the parties hereto. No oral understanding or agreement not incorporated herein shall be binding on any of the parties hereto. Any alterations or amendments, except a change between budget categories which requires the prior written consent of a duly authorized representative of the State, shall be subject to the contract approval procedure of the State.

52. State Boilerplate Affirmation Clause. I swear or affirm under the penalties of perjury that I have not altered, modified, changed or deleted the State's standard contract clauses (as contained in the 2022 SCM Template) in any way except as follows:

Access to Records
Amendments
Assignment: Successors
Assignment of Antitrust Claims
Audits
Changes in Work
Compliance with Laws
Condition of Payments
Continuity of Services
Debarment and Suspension
Disputes
Drug-Free Workplace Certification
Employment Eligibility Verification
Employment Option
Forms Contract/Duties of Contractor
Indemnification
Independent Contractor; Workers' Compensation insurance
Indiana Veteran's Business Enterprise Compliance
Information Technology Enterprise Architecture Requirements
Insurance
Key Person(s)
Licensing Standard
Minority and Women's Business Enterprise Compliance
Nondiscrimination
Notice to Parties
Ownership of Documents and Materials
Payments
Progress Reports
Termination for Convenience
Termination for Default
Travel
Waiver of Rights
Work Standard

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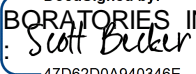
Non-Collusion and Acceptance

The undersigned attests, subject to the penalties for perjury, that the undersigned is the Contractor, or that the undersigned is the properly authorized representative, agent, member or officer of the Contractor. Further, to the undersigned's knowledge, neither the undersigned nor any other member, employee, representative, agent or officer of the Contractor, directly or indirectly, has entered into or been offered any sum of money or other consideration for the execution of this Contract other than that which appears upon the face hereof. **Furthermore, if the undersigned has knowledge that a state officer, employee, or special state appointee, as those terms are defined in IC § 4-2-6-1, has a financial interest in the Contract, the Contractor attests to compliance with the disclosure requirements in IC § 4-2-6-10.5.**

Agreement to Use Electronic Signatures

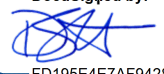
I agree, and it is my intent, to sign this Contract by accessing State of Indiana Supplier Portal using the secure password assigned to me and by electronically submitting this Contract to the State of Indiana. I understand that my signing and submitting this Contract in this fashion is the legal equivalent of having placed my handwritten signature on the submitted Contract and this affirmation. I understand and agree that by electronically signing and submitting this Contract in this fashion I am affirming to the truth of the information contained therein. I understand that this Contract will not become binding on the State until it has been approved by the Department of Administration, the State Budget Agency, and the Office of the Attorney General, which approvals will be posted on the Active Contracts Database: <https://secure.in.gov/apps/idoa/contractsearch/>

In Witness Whereof, the Contractor and the State have, through their duly authorized representatives, entered into this Contract. The parties, having read and understood the foregoing terms of this Contract, do by their respective signatures dated below agree to the terms thereof.

ASSOCIATION OF PUBLIC HEALTH
LABORATORIES INC
By: 
47D62D0A940346E...

Title: Chief Executive Officer

Date: 5/10/2023 | 15:20 EDT

Indiana Department of Health
By: 
FD195E4E7AF9428...

Title: IDOH Chief of Staff

Date: 5/10/2023 | 17:14 EDT

Electronically Approved by: Department of Administration By: _____ (for) Rebecca Holwerda, Commissioner	
Electronically Approved by: State Budget Agency By: _____ (for) Zachary Q. Jackson, Director	Electronically Approved as to Form and Legality by: Office of the Attorney General By: _____ (for) Theodore E Rokita, Attorney General

APHL Agreement #56401-250-451-23-05

WORK ORDER

Project Specific Terms and Conditions

This Work Order, dated February 21, 2023, 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

- I. 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:

<u>Capitalized Term</u>	<u>Meaning</u>
<u>"Agreement"</u>	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
<u>"APHL"</u>	The Association of Public Health Laboratories, Inc., a nonprofit corporation organized under the laws of the District of Columbia
<u>"Contractor"</u>	Indiana Department of Health Laboratories, a governmental entity or administrative unit of Indiana
<u>"Cooperative Agreement"</u>	Cooperative Agreement Number NU600E000104 (CFDA No. 93.322) with the Centers for Disease Control and Prevention (CDC) of DHHS

<u>Capitalized Term</u>	<u>Meaning</u>
<u>“Agreement”</u>	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
<u>“APHL”</u>	The Association of Public Health Laboratories, Inc., a nonprofit corporation organized under the laws of the District of Columbia
<u>“Contractor”</u>	Indiana Department of Health Laboratories, a governmental entity or administrative unit of Indiana
<u>“Cooperative Agreement”</u>	Cooperative Agreement Number NU60OE000104 (CFDA No. 93.322) with the Centers for Disease Control and Prevention (CDC) of DHHS
<u>“Cooperative Agreement Funding Conditions”</u>	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
<u>“End Date”</u>	June 30, 2023
<u>“FFATA”</u>	The Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282), as amended
<u>“Final Invoice Due Date”</u>	July 14, 2023
<u>“Funding Agency”</u>	Centers for Disease Control and Prevention (CDC)
<u>“Master Agreement”</u>	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
<u>“Maximum Compensation Amount”</u>	The maximum amount of compensation payable by APHL to the Contractor specified in Section 5.A of this Work Order is \$24,965
<u>“Maximum Travel and Expense Reimbursement Amount”</u>	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

<u>“Parties” or “Party”</u>	Collectively, APHL and the Contractor, and individually, either APHL or the Contractor
<u>“Project”</u>	Implementation or Expansion of Nucleic Acid Testing for Diagnosis of Hepatitis C Virus Infection.
<u>“Standard Terms and Conditions”</u>	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
<u>“Start Date”</u>	March 1, 2023
<u>“Work”</u>	The services to be provided by the Contractor specified in Section 3.A of this Work Order

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 (ii) in the Standard Terms and Conditions

2. 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:
 - i.** 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.

3. 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 its proposal 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 and, at the request of APHL, one bound paper copy or unbound copy of a final report for the Project. The Contractor will base the final report on a template provided by APHL and will include the following information:

- a.** supplies, equipment and reagents procured;
- b.** staff trained;
- c.** outcome of validation studies, including performance characteristics;
- d.** LIMS updates implemented; and
- e.** Overall successes and challenges.

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

<u>Milestone or Deliverable</u>	<u>Completion Date</u>
Final Report	June 30, 2023

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.

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.

5. 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]

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 of receipt. **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
\$12,482	Upon ratification of this Work Order
\$12,483	Upon completion of the Work and APHL's receipt of all Deliverables

* = 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:

Sarah Buss
 APHL
 8515 Georgia Avenue, Suite 700
 Silver Spring, MD 20910
 P: 240.485.3901
 F: 240.485.2700
 E: sarah.buss@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:

- i. all travel must be approved in advance by APHL;
- ii. to the maximum extent possible, the Contractor will utilize APHL's travel agency, Global Travel Associates (GTA) to make travel arrangements and to purchase tickets (please contact the APHL Work Order Administrator identified in Section 11 below via email and they will assist with setting up the Contractor's account in APHL's travel software) ;
- 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.

6. 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. **FFATA Reporting Requirements.** The Maximum Compensation Amount is less than \$30,000 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:

- i. 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.

<u>APHL</u>	<u>The Contractor</u>
Scott J. Becker, MS, Chief Executive Officer APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.2745 F: 240.485.2700 E: scott.becker@aphl.org <i>With a copy to:</i> 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	Shane Hatchett Deputy Commissioner & Chief of Staff Office of the State Health Commissioner P: 317-233-7877 E: shatchett@health.in.gov <i>With a copy to:</i> Michael Mendyk Director of Grants and Contracts P: 317-234-6874 E: MMendyk@health.in.gov

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

<u>APHL</u>	<u>The Contractor</u>
Sarah Buss PhD, D(ABMM) Manager HHST APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.3901 F: 240.485.2700 E: sarah.buss@aphl.org	Brian Pope Director, Virology and Serology Division Indiana Department of Health Laboratories 550 W 16th Street, Suite B Indianapolis, IN 46202 P: 317-921-5555 F: 317-927-7804 E: bpope1@isdh.in.gov

12. Survival. 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.

[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: Scott J. Becker, MS
Title: Chief Executive Officer

INDIANA DEPARTMENT OF HEALTH LABORATORIES

By: _____ Date: _____
Name: Shane Hatchett
Title: Deputy Commissioner & Chief of Staff

EXHIBIT A
Cooperative Agreement Funding Conditions

COOPERATIVE AGREEMENT

FUNDING CONDITIONS

FOR COOPERATIVE AGREEMENT #NU60OE000104 (CFDA NO. 93.322)

with the U.S. Centers for Disease Control and Prevention (CDC)

These Cooperative Agreement Funding Conditions (the "Funding Conditions") have been attached as Exhibit A to a Project Agreement (as defined in Section 1 of these Funding Conditions) between APHL (as defined in the Project Agreement) and the Counterparty (as defined in Section 1 of these Funding Conditions) and have been incorporated into that Project Agreement by reference. These Funding Conditions, 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).

1. Definitions.

A. The term "Counterparty" is used in these Funding Conditions 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 Conditions 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 Conditions to refer to either (i) the Work Order or (ii) the Subaward Agreement, as applicable, to which these Funding Conditions are attached as Exhibit A.

2. Compliance with Funding Conditions. This project is funded through the Cooperative Agreement (as defined in the Project Agreement) between APHL and the Centers for Disease Control and Prevention ("CDC"). The Counterparty will comply with the terms and conditions of the Cooperative Agreement.

3. Uniform Administrative Requirements. The US Office of Management and Budget's Uniform Administrative Requirements (the "UAR") found at 2 CFR Part 200, as implemented by the US Department of Health and Human Services ("DHHS") 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, 2020. An electronic copy of which is currently available at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf> and the Counterparty will ensure that it has reviewed the applicable provisions and will conduct the Project in compliance with its terms.

5. **CDC General Terms and Conditions for Non-research Awards**. The Cooperative Agreement is subject to the CDC's General Terms and Conditions for Non-research Awards (an electronic copy of which is currently available at <https://www.cdc.gov/grants/documents/General-Terms-and-Conditions-Non-Research-Awards.pdf>). The Counterparty will ensure that it has reviewed the applicable provisions of these General Terms and Conditions for Non-research Awards and will conduct the Project in compliance with its terms.

6. **Lower Tier Transactions**. The Counterparty will include the provisions of these Funding Conditions 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.

7. **Public Policy Requirements**. 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.

8. Bayh-Dole Act. 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).

9. 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 and 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.

10. Travel. 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).

11. 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 NU60OE000104, 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:

- i. 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. 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.

D. For the purposes of this Section 10 of these Funding Conditions, “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.

12. Required Disclosures for Federal Awardee Performance and Integrity Information Systems (FAPIIS).

A. In order to allow APHL to meet its obligations under 45 CFR 75.113, the Counterparty must disclose in a timely manner, in writing to APHL, with a copy to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Project or the Cooperative Agreement.

The Counterparty’s failure to make any required disclosure may result in any of the remedies described in 45 CFR 75.371, including suspension or debarment (see 2 CFR parts 180 and 376, and 31 U.S.C. §3321). The Counterparty must send any required disclosure in writing to APHL and the HHS OIG at the following addresses:

APHL
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

ATTN: Legal Department
Fax: 240.485.2700 (include APHL Agreement number in subject line) or
Email: legal@aphl.org

AND

U.S. Department of Health and Human Services
Office of the Inspector General
ATTN: Mandatory Grant Disclosures, Intake Coordinator
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Fax: (202)-205-0604 (Include "Mandatory Grant Disclosures" in subject line) or
Email: MandatoryGranteeDisclosures@oig.hhs.gov

13. Limitations on an Individual's Salary. 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 \$203,700 (the Executive Level II salary in the Federal Executive Pay scale in effect at the time the Cooperative Agreement funds were awarded to APHL). 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.

14. Whistleblower Protections. In the event that the Maximum Amount is equal to or greater than \$100,000, the following provisions will apply.

A. The 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.

15. Examination of Records. 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 December 26, 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. 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.

16. 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.

17. 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).

18. Certifications. 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. Debarment, Suspension, Ineligibility and Voluntary Exclusion. 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. No Delinquency on US Government Debts. 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.

[End of Cooperative Agreement Funding Conditions]

EXHIBIT B
Standard Terms and Conditions

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, any applicable Cooperative Agreement Funding Conditions (as defined in the Work Order) attached to that Work Order and any other exhibit, attachment or annex to the Work Order, make up the entire Agreement (as defined in the Work Order) between the Parties (as defined in the Work Order).

1. 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 “Deliverable”) 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.

i. 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.

2. Subcontracting and Subcontractors. The Contractor will not subcontract its services under the Agreement without the prior written consent of APHL.

A. 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 https://obamawhitehouse.archives.gov/omb/circulars_a110/), and the following methods:

- i. Place small, minority, and women-owned business firms on bidders mailing lists;
- ii. 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.

B. 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. Indemnification. 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.

6. Confidentiality.

A. 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 fits any of the following criteria:

- i. the information is or becomes available from public sources through no wrongful act of the Contractor;
- ii. the information 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. the information is rightfully disclosed to the Contractor by a third party with no obligation of confidentiality;
- iv. the information is independently developed by the Contractor; or
- v. the information is required to be disclosed pursuant to any court or regulatory order served on the Contractor.

B. 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. Conflicts of Interest. 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 (“OCI”), 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. Survival. 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. Impossibility. 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. Non-Discrimination. 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. Independent Contractors. The Parties have an independent contractor relationship under this Agreement. The Parties do not intend for this Agreement 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. Assignability. The Contractor will not assign the Agreement, or any interest in the Agreement, without the prior written consent of APHL.

17. Successors. The Agreement will be binding upon, and will inure to the benefit of, the Parties and their respective permitted successors and assigns.

18. Sole Agreement. 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.

19. Amendment. Except as provided in the following sentence, no amendment of the Agreement will be valid unless in writing and signed by both Parties. 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. Waiver. 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. Severability. 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 and the invalid provision will be deemed modified to the least degree necessary to remedy the invalidity.

22. Interpretation. 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). Any reference to a plural item in this Agreement includes, when appropriate, a reference to the singular form of such item and vice versa. Any gender reference in this Agreement should be read to refer to the opposite gender or as a gender neutral reference as the text or context may require.

23. Section Headings. The captions or headings in the Agreement are made for convenience and general reference only and may not be construed to describe or limit the scope or the intent of the provisions of the Agreement.

24. Drafting Party. 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. Counterparts. 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. Signatures/E-delivery. 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.

27. Prohibition on Contracting with Entities Using Certain Telecommunications and Video Surveillance Services or Equipment. Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 prohibits contracting and using award funds with certain telecommunications equipment and services produced or provided by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of those entities). More information about this prohibition can be found at <https://www.federalregister.gov/documents/2020/07/14/2020-15293/federal-acquisition-regulation-prohibition-on-contracting-with-entities-using-certain>.

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

EXHIBIT C

The Contractor's Proposal

The Contractor's Proposal

Application for Funding: Implementation or Expansion of Nucleic Acid Testing for Diagnosis of Hepatitis C Virus Infection

Submitted by Indiana Department of Health Laboratories

Project Lead: Brian Pope

Project description

The serology laboratory at the Indiana Department of Health Laboratories (IDOHL) currently performs testing for HCV antibodies using Abbott Alinity *i* instrumentation with the Alinity anti-HCV reagents, controls, and calibrators manufactured by Abbott. IDOHL has validated serum for testing on this instrument in house. For HCV NAAT testing, IDOHL currently utilizes the Hologic Panther Fusion instrument and has validated serum specimens using the Hologic® Aptima® HCV Quant Dx Assay.

The IDOHL follows this current testing algorithm: Serum specimens submitted for HCV testing are tested on the Abbott Alinity *i* per the manufacturer's guidelines. If the results are non-reactive, the results are reported out as non-reactive. If the results are grayzone, the specimen is automatically reflexed for HCV NAAT testing at IDOHL. If the result has an initial reactive result, IDOHL reports the results out to the submitter as reactive with no additional testing being performed. However, two submitters have arranged with IDOHL that specimens with a reactive result will be automatically reflexed to HCV NAAT testing.

IDOHL receives an average of 11,400 specimens annually for HCV screening. Of those, approximately 21% or 2,400 specimens screen as reactive by the Alinity anti-HCV assay. Currently, IDOHL tests 84 specimens annually on the Hologic Panther Fusion instrument for HCV NAAT testing. Funding and transit time are the main challenges to expand NAAT testing at IDOHL. Current manufacturer instructions allow for a 24 hour transit time at room temperature. At this time, IDOHL is unable to test 2,316 or 96.5% of reactive specimens for HCV NAAT testing due funding limitations. Of the 2,400 reactive specimens we test annually, 50.5% or 1,212 would meet the manufacturers guidelines by being received at IDOHL within 24 hours of specimen collection. An additional 510 specimens are received at IDOHL within 2 days of specimen collection and 383 are received at IDOHL within 3 days of specimen collection. By extending the transit time for HCV NAAT testing to 3 days at room temperature, IDOHL would be able to test

an additional 893 specimens annually. Upon the successful implementation of this transit study, 88% or 2,105 reactive specimens would be eligible for confirmatory testing at IDOHL annually.

Most specimens are currently tested due to being a grayzone on the Abbott Alinity *i* instrument. Those two submitters with an agreement with IDOHL to do NAAT testing on reactive screens account for 8.3% of all NAAT tests. Specimens for HCV screening and NAAT testing have a turn-around-time (TAT) of 5 business days. The screening assay is typically run daily at IDOHL with the NAAT test being run at least weekly.

Currently, the HCV screen assay allows for a transit time of 7 days at room temperature, per an approved and validated IDOHL transit study. The HCV NAAT assay allows for a 24-hour transit at room temperature and 5 days at 2-8°C per the manufacturer's instructions. This manufacturer requirement for HCV NAAT transit times severely hinders the number of specimens that qualify for HCV NAAT testing at IDOHL as most facilities currently ship specimens at room temperature.

To ensure fiscal responsibility at IDOHL, the serology supervisor generates monthly financial reports and invoices concerning all facets of HCV testing; only a fraction of our services is reimbursed.

The serology laboratory at IDOHL has the following competent staff with over 50 years of combined experience: 5 microbiologist analysts, all but one are competent in the HCV screening assay. Of those 5 microbiologist, 2 are also competent in HCV NAAT testing. Each of these analysts qualifies as testing personnel per CLIA regulation § 493.1489 Standard: Testing personnel qualifications. Among the testing personnel- 3 of these microbiologists have significant experience at IDOHL – with two having over 20 years of experience and the other having 5 years of experience at IDOHL. The other 2 microbiologists have been working at IDOHL for less than 1 year but are quickly expanding their base of competencies and knowledge. The 3 senior microbiologists have been involved in multiple method validations, verifications, and studies at IDOHL- including, but not limited to the validation for HCV NAAT testing on the Hologic Panther, transit studies for the Abbott Alinity *i*, and the validation of HIV confirmatory testing on the Geenius platform.

Stephanie Sweets is the supervisor over the serology laboratory at IDOHL and has been since 2015. Stephanie started at the IDOHL in 2011 and worked in both the rabies laboratory and the virology laboratory. Stephanie has lead the serology laboratory through several different validations, verifications, studies, and outbreaks- in addition to those mentioned above, she expertly lead the team in fully validating the new method of testing for SARS-CoV-2 antibodies in serological specimens in coordination with the Fairbanks School of Public Health, the IDOHL response to Operation Allies Welcome in 2021, as well as responding to several serological outbreaks throughout Indiana, including but not limited to Hepatitis A and

Syphilis.

The serology group reports to the virology and serology division director, Brian Pope, who has been at IDOHL since 2014 working first as an analyst, then as a supervisor before becoming the division director. Ultimately, the entire organization reports to the laboratory director, Dr. Lixia Liu. The QA Director, Chris Grimes will be involved in the transit study validation at IDOHL. Chris has served as the QA director at IDOHL since 2007.

The IDOHL plans to use these funds to extend the transit time and to expand NAAT testing on all HCV specimens screening reactive or grayzone on the initial screening test at the IDOHL. These results will be analyzed by IDOH to assess the impact on missing the active cases without fully implementing CDC's recommended HCV testing algorithm and to provide funding justification for expanding the NAAT testing to all submitters. Reactive HCV specimens which have been screened at IDOHL will be used for the transit study. The specimens will be from a broad base of submitters to ensure a diverse population are included in the study, these populations include the Department of Corrections (DOC) as well as those submitted from across Indiana via Health Departments (HD), Counseling and Testing sites (CTS), and various clinics.

Upon review of the specimens tested as part of this study, all specimens which meet the manufacturers guidelines for HCV testing would be initially screened on the Abbott Alinity *i* instrument, any reactive specimens would automatically be reflexed to the Hologic Panther instrument for NAAT testing, with the requirement that the specimens meet manufacturers guidelines on specimen integrity or the IDOH validated transit study, pending final results and approval. Each patient will submit only 1 specimen to complete testing on both platforms, a regular specimen submission will have ample volume to complete both tests. If it is determined that additional specimen is needed, the serology laboratory will request additional specimens to be collected and submitted.

Due to the known restrictive nature of the manufacturer's guidelines for transit on the Hologic Aptima NAAT test, many specimens do not qualify for HCV NAAT testing at IDOHL. The IDOHL will also perform a transit study to extend the room temperature transit up to 3 days. The final data produced by the transit study will determine the final allowable transit time for room temperature specimens. To determine the final allowable room temperature shipping conditions a panel of 50 pooled specimens will be created.

These specimens will cover a wide range of the Hologic® Aptima® HCV Quant Dx Assay potential results. IDOH will also work to procure controls that can be utilized to read at the lower 1 – 10 IU/mL level. The IDOHL will work with the in-house LIMS team to modify our STARLIMS algorithm to reflect the automated reflexing of reactive screened specimens for NAAT testing.

Any changes to the process, involving algorithm changes as well as transit changes will

be communicated to submitters via all of the following methods.

1. Our LIMSNet portal, where submitters enter in specimens for testing at IDOHL will be updated to include a message that will be read upon logging in communicating the change.
2. An email will be sent out to submitters communicating the changes implemented with the opportunity for them to ask questions.
3. The HIV/STD Program area at IDOH will be formally notified of said changes via email with a meeting if desired by the program area. They have already been notified of our involvement in this RFP.
4. The IDOHL hosts a monthly webinar where laboratory updates are shared, the IDOHL will share this information through this means.

To measure success, the IDOHL will implement the following goals:

1. The IDOHL will test a number of specimens in a pilot study for HCV NAAT on the Hologic® Aptima® HCV Quant Dx Assay, in accordance to the amount of money awarded. These specimens will be HCV antibody reactive on the Alinity platform and the data will be analyzed to determine if a change in algorithm for Indiana is necessary.
2. The IDOHL will conduct a transit study to extend the transit time for HCV NAAT testing on the Hologic Panther for room temperature specimens. Specimens will be evaluated on a daily basis through day 3 to determine the allowable transit time for room temperature specimens.

These onetime funds will allow the IDOHL to extend the transit time for HCV NAAT specimens up to 3 days at room temperature, which permits an increase up to 88% of specimens to be tested due to most specimens being shipped to IDOHL from across Indiana. These funds will also allow for IDOHL to gather data to address any additional funding necessary to enhance HCV confirmatory testing on the Hologic Aptima platform at IDOHL.

Budget

Budget for APHL Request for Proposals: Implementation or Expansion of Nucleic Acid Testing for Diagnosis of Hepatitis C Virus Infection				
Supplies/Reagents				
Quantity	Line Item	Costs/ Unit	Total Costs	Comments
550	Hologic® Aptima® HCV Quant Dx Assay	\$45	\$24,750	IDOHL will purchase reagents at \$45/specimen from Hologic. IDOHL will test as many specimens as able, pending the final \$\$ amount awarded. To perform the transit study, \$9,900 will be required. The rest of the funds will be used in the pilot study to evaluate the difference in between antibody tests results and NAAT results to present to state officials.
Supplies/Reagents				
No requests			-	
5	Zeptomatrix Human Hepatitis C Virus (HCV) (200 IU/mL) (1 mL) (Low Concentration Control) Catalog# NATHCV-0001	\$43	\$215	These controls will function as a low concentration test- specimens submitted to IDOHL often exceed the lowest concentration detected by the Hologic Assay (1 - 10 IU/mL). These controls will be diluted out to the proper concentration of 1 - 10 IU/mL.
		Total	\$24,965	