

STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES

STANDARD AGREEMENT

STD 213 (Rev. 04/2020)

AGREEMENT NUMBER

20-10648

PURCHASING AUTHORITY NUMBER (If Applicable)

1. This Agreement is entered into between the Contracting Agency and the Contractor named below:

CONTRACTING AGENCY NAME

California Department of Public Health

CONTRACTOR NAME

PerkinElmer Health Sciences, Inc.

2. The term of this Agreement is:

START DATE

8/26/2020

THROUGH END DATE

10/31/2021

3. The maximum amount of this Agreement is:

\$1,700,000,000.00

One Billion Seven Hundred Million Dollars and Zero Cents

4. The parties agree to comply with the terms and conditions of the following exhibits, which are by this reference made a part of the Agreement.

Exhibits	Title	Pages
Exhibit A	Statement of Work	9
	Attachment 1 - Equipment	1
	Attachment 2 - FDA EUA	8
+ - Exhibit B	Budget Detail & Provisions	7
+ -	Attachment 1 - Cost Breakdown Spreadsheet	1
+ - Exhibit C	General Terms & Conditions	4
+ - Exhibit D	Special Terms & Conditions	7
+ - Exhibit E	HIPAA BAA	14
+ - Exhibit F	FEMA Provisions	6

Items shown with an asterisk (*), are hereby incorporated by reference and made part of this agreement as if attached hereto.

These documents can be viewed at <https://www.dgs.ca.gov/OLS/Resources>

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES HERETO.

CONTRACTOR

CONTRACTOR NAME (if other than an individual, state whether a corporation, partnership, etc.)

PerkinElmer Health Sciences, Inc.

CONTRACTOR BUSINESS ADDRESS

940 Winter Street

CITY

Waltham

STATE

MA

ZIP

02451

PRINTED NAME OF PERSON SIGNING

LeeAnn L. Dennewitz

TITLE

VP/GM Global Commercial Excellence

CONTRACTOR AUTHORIZED SIGNATURE

DATE SIGNED

8/26/2020

STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES

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20-10648

PURCHASING AUTHORITY NUMBER (If Applicable)

STATE OF CALIFORNIA

CONTRACTING AGENCY NAME

California Department of Public Health

CONTRACTING AGENCY ADDRESS

1615 Capitol Ave

CITY

Sacramento

STATE

CA

ZIP

95814

PRINTED NAME OF PERSON SIGNING

Tim Bow

TITLE

Procurement Officer

CONTRACTING AGENCY AUTHORIZED SIGNATURE

Timothy BowDigitally signed by Timothy Bow
Date: 2020.08.26 10:13:28 -07'00'

DATE SIGNED

CALIFORNIA DEPARTMENT OF GENERAL SERVICES APPROVAL

EXEMPTION (If Applicable)

EO-N-25-20-COVID19

PCC 1102

LLD

Exhibit A
Statement of Work

This Agreement is entered into by and between the California Department of Public Health (“CDPH”) and PerkinElmer Health Sciences, Inc. (“Contractor”) to procure certain laboratory testing and reporting services in response to the SARS-CoV-2 pandemic.

RECITALS

WHEREAS, in 2020, the State of California, the United States, and multiple key continents around the world are combating the rapid spread of the pandemic known as the Novel Coronavirus or COVID-19 (the “Pandemic”);

WHEREAS, despite the current state of the Pandemic around the world as of August, 2020, the parties agree they are capable of performing all obligations under this Agreement;

WHEREAS, CDPH determined that grounds exist to contract with an operator to provide critical and “essential” laboratory testing services, pursuant to the Governor’s Proclamation of a State of Emergency dated March 4, 2020, Executive Order N-25-20 dated March 12, 2020, and Executive Order N-39-20 dated March 30, 2020, all as amended or supplemented subsequently (collectively, the “Executive Orders”);

WHEREAS, all agencies of the state government shall perform any and all activities consistent with the direction of the State, pursuant to the Executive Orders;

WHEREAS, Contractor is a manufacturer of instrumentation and reagents for SARS-CoV-2 diagnostic testing, is a provider of diagnostic testing services, and is willing to supply personnel, equipment and reagents as identified herein to stand up a high through-put SARS-CoV-2 testing program for the State of California and provide SARS-CoV-2 diagnostic testing services on behalf of CDPH in response to the novel coronavirus-related health emergency;

WHEREAS, CDPH desires that Contractor should stand up a SARS-CoV-2 diagnostic testing program and perform SARS-CoV-2 diagnostic testing on behalf of CDPH as provided herein;

NOW, THEREFORE, in consideration of the promises and agreements contained herein, the parties mutually agree as follows:

1. Service Location

The services provided by Contractor shall be performed at up to three (3) laboratories as determined by CDPH following consultation with Contractor.

2. Project Representatives

A. The project representatives during the term of this Agreement will be:

California Department of Public Health Timothy Bow Telephone: (916) 552-8388 E-mail: tim.bow@cdph.ca.gov	PerkinElmer Health Sciences LeeAnn L. Dennewitz Telephone: (302) 598-0261 Fax: (781) 669-5984 E-mail: leeann.dennewitz@perkinelmer.com
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Exhibit A
Statement of Work

B. Direct all inquiries to:

California Department of Public Health CDPH / PSB Attention: Tim Bow 1616 Capitol Avenue Sacramento, CA 95814 Telephone: (916) 552-8388 E-mail: tim.bow@cdph.ca.gov	PerkinElmer Health Sciences Project Manager Attention: Joe Mendoza Telephone: (650) 740-1538 Fax: (510) 237-9492 Remittance Address 13633 Collections Center Dr. Chicago, IL 60693 E-mail: joe.mendoza@perkinelmer.com
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C. Either party may make changes to the information above by giving written notice to the other party. Said changes shall not require an amendment to this Agreement.

3. Services to be Performed

A. Contractor Responsibilities

Contractor will be responsible for providing SARS CoV-2 diagnostic testing services (the "Services") at CDPH approved laboratories (the "Facilities") under the guidance of and in collaboration with the California Novel Coronavirus Testing Task Force. The Services shall consist of:

1. Delivery and installation of equipment necessary for SARS CoV-2 diagnostic testing, as itemized in Attachment 1 (the "Equipment").
2. Supply of all consumables, reagents and Personal Protective Equipment ("PPE") necessary for performing the Services.
3. Supply furniture and all equipment necessary for performance of the Services at the Facilities.
4. Supply of all personnel, duly licensed as required by, and in compliance with, applicable federal and state law and regulations to operate at the Facilities (the "Personnel"), including, as needed:
 - Logistics and Supply Chain Management
 - Quality Assurance / Quality Control
 - Lab Testing Personnel
 - Information Technology Professionals
 - Specimen Processors
 - Service Engineers
 - Human Resources
 - Laboratory Management (except CA State accredited Medical and Laboratory Directors)
 - A designated project manager to collaborate with CDPH with respect to Facility maintenance.
5. Performance of all necessary service for proper installation and maintenance of the Equipment (the "Maintenance Services").
6. Supply and installation of PerkinElmer Genomics' proprietary laboratory information management system (the "LIMS") at the Facilities. Contractor shall implement an interface to the LIMS enabling collecting healthcare providers to enter required demographic information and sample identification, and CDPH shall require collection sites to enter all such information through the interface, unless otherwise agreed for specific, remote collection sites as may be

Exhibit A
Statement of Work

agreed by the Parties from time to time. All reports from the testing Services will be generated through the LIMS and CDPH's assigned laboratory director will be able to sign out reports through the LIMS. Notwithstanding anything else in the foregoing, Contractor shall have no liability for errors or delays resulting from any sample collection site's failure to submit timely and accurate information.

7. Reporting of the results of the Services in a mutually agreed upon format and medium.
8. Facilities operations management, including cleaning, and biohazard disposal at the Facilities.
9. Reporting of the testing results within twenty-four (24) to forty-eight (48) hours after the receipt of the specimen. Contractor will make every effort to resume the process by which testing is completed within forty-eight (48) hours once the delay has been corrected.
10. Specimen samples will be tested (including samples submitted for Backup Services, as defined below) in compliance with the requirements set forth in the FDA Emergency Use Authorization (the "EUA") described in Attachment 2.

Contractor shall bring each Facility online for testing after receiving access to the Facility from CDPH. Contractor shall notify CDPH weekly about the Facilities' then-current testing capacity until reaching up to 100,000 samples received cumulatively by Facilities per day, seven days per week. The parties anticipate that the Services will begin at 40,000 samples per day, but shall use best efforts to communicate in real time the anticipated testing capacity and volume. CDPH shall notify Contractor as soon as practicable of any need to increase testing volume, and Contractor shall notify CDPH of the timeline to meet such requested testing capacity. Contractor reserves the right to extend turnaround time or increase its fee for testing samples above the then-current required testing capacity.

B. CDPH Responsibilities

CDPH will be responsible for:

1. Providing the Facilities, together with any landlord or related consents, permits, and/or California licenses required for Contractor to perform and complete the Services at the Facilities.
2. Providing such supplies of electricity, energy and water necessary for Contractor's ability to perform the Services at the Facilities and the availability of any telephone, facsimile, and internal intranet, and external internet and communication services.
3. Providing uninterruptible power and backup generator power that supply the mutually agreed portions of each Facility.
4. Providing sufficient storage and refrigeration for performance of the Services at each Facility.
5. Arrangement for the collection and transportation of specimens to the Facilities on predetermined, mutually agreed upon schedules, with the quantity of specimens to each Facility to be determined collaboratively by the parties in real time, and accompanied by any completed electronic test requisition form or informed consent required by applicable laws and/or regulations (collectively, "Documentation"), ensuring that such specimens have the appropriate Sample ID and are transported in accordance with the Clinical Laboratory Improvement Amendments ("CLIA") and all applicable California laws and regulations pertaining to the specimens for testing.
6. Making the best effort to provide that each Facility be of satisfactory quality, fit for its intended

Exhibit A
Statement of Work

purpose, and maintain landscaping and physical repair.

7. Ensuring up-to-date maintenance of all rights, consents, authorizations, licenses and/or accreditations required from the State of California for each Facility.
8. In addition and without prejudice to any specific notification requirements set out in this Agreement, promptly notifying Contractor of any health and safety hazard which CDPH is aware may arise or has arisen in connection with the Facilities, and taking such steps as are reasonably necessary to ensure the health and safety of persons likely to be affected by such hazards.
9. Installing and maintaining card key access control at each Facility.
10. Retaining or otherwise supplying medical directors and laboratory directors as needed to sign out results of the testing.
11. Providing Contractor with copies or citations to any and all local, state and federal reporting requirements.
12. Obtaining any and all necessary licenses and/or permits for oversight and result reporting during this state of emergency.
13. Ensure collection sites and healthcare providers submitting samples for testing submit timely and accurate information through the LIMS.

C. Instrument Loan

- 1) All Equipment is provided by Contractor on a no-cost loan basis. CDPH, in the capacity of bailee, will take possession of any Equipment provided by Contractor only as provided in this Agreement. The continued bailment of the Equipment to CDPH is contingent upon CDPH purchasing the Services as provided in this Agreement.
- 2) With two (2) weeks prior notification and agreement with CDPH, Contractor may move Equipment among Facilities or add or remove Equipment as necessary or prudent for providing the Services, provided that the Contractor shall ensure that sufficient Equipment is present at each Facility for performance of the Services. On a monthly basis, Contractor shall provide CDPH with an updated listing of Equipment provided by Contractor on a no-cost loan basis under this Agreement.
- 3) All Equipment shall remain the property of Contractor, shall be used only by Contractor, and Contractor shall use Equipment solely with consumables provided by Contractor under this Agreement or as otherwise provided in the specifications for the applicable Equipment. CDPH shall not use, and shall not allow any third-party to use, any Equipment.
- 4) Title to the Equipment shall remain in Contractor. CDPH agrees that the Equipment are and shall remain personal property and shall not be attached to or become part of any realty; that they shall be installed and used at the Facilities only and not be removed therefrom; and that CDPH shall not sell, assign, transfer, lease, part with possession of, or encumber any Equipment, or permit any liens or charges to become effective thereon. CDPH will comply with all laws relating in any way to taking possession of the Equipment and Contractor may attach such labels as Contractor wishes to show that such Equipment is owned by Contractor. CDPH hereby grants Contractor the right to inspect the Equipment upon prior arrangement and scheduling with CDPH, and shall not make any alterations or improvements to the Equipment without the prior written consent of Contractor.

Exhibit A
Statement of Work

- 5) Upon termination or expiration of this Agreement, Contractor shall remove all Equipment. CDPH shall exercise due care as bailee to protect the Equipment from damage. CDPH shall not be responsible for Contractor's failure to provide Maintenance Services or for Equipment wear and tear resulting from the Contractor's delivery of the Services.

4. PerkinElmer Genomics Testing Option

- 1) PerkinElmer Genomics located at 250 Industry Drive, Pittsburgh, PA 15275 is available to function as a bridge, overflow or backup laboratory to the Services ("Backup Services"), for volumes to be agreed by the parties in writing from time to time. Upon execution of this Agreement, the maximum capacity for Backup Services is 4,000 specimens testing per day.
- 2) For specimen samples submitted for Backup Services, CDPH shall be responsible for:
 - a. providing orders electronically in a mutually agreed upon format prior to sending specimen samples;
 - b. sending samples via a trackable courier;
 - c. paying for all costs related to shipping samples to PerkinElmer Genomics
 - d. sending the samples to PerkinElmer Genomics in accordance with a predetermined, mutually agreed upon schedule accompanied by Documentation, ensuring that such samples have the appropriate Sample ID and are transported in accordance with CLIA and any applicable law or regulation for testing or as otherwise may be defined under any applicable laws and/or regulations;
- 3) The parties will take all reasonable steps to ensure prompt implementation of an interface between PerkinElmer Genomics LIMS and CalREDIE eCR, or any later version thereof or successor system, for reporting of testing results from Backup Services.

5. Force Majeure

- 1) The failure of either party to this Agreement to perform its obligations hereunder, if caused by "force majeure" as hereinafter defined, shall not constitute a default hereunder nor subject the party so failing to any liability to the other; provided, however, the party affected by such force majeure shall promptly notify the other of (1) the existence hereof, (2) its expected duration, (3) the estimated effect such force majeure will have on its ability to perform its obligations hereunder, and (4) when such force majeure circumstance has ceased to affect its ability to perform its obligations hereunder.
- 2) As used herein, the term "force majeure" shall mean and include any circumstances beyond the reasonable control of the affected party, including without limitation, the following: any act of God or the public enemy, accident, explosion, fire, storm, earthquake, flood, drought, perils of the sea, the elements, casualty, strikes, lockouts, labor troubles, riots, sabotage, embargo, war (whether or not declared and whether or not the United States is a participant), pandemic, the imposition of any law, regulation or order by or the imposition of restrictions by any Federal, State or municipal government, or any agency or subdivision thereof, governmental priority, seizure, requisition or allocation, failure or delay of transportation, shortage of or inability to obtain supplies, equipment, fuel or labor.
- 3) In the event that performance of the affected party is suspended under the terms hereof for a period of more than thirty (30) days, either party shall thereafter have the option to terminate this Agreement upon fifteen (15) days' prior written notice to the other party, provided that the force majeure conditions then continue to exist.
- 4) Contractor and CDPH each covenants that it will use its best efforts to eliminate any circumstances

Exhibit A
Statement of Work

of force majeure which affects its ability to carry out its responsibilities under this Agreement.

- 5) In the event of termination for Force Majeure, Section 8(4) shall apply.

6. Warranty and Limitation of Remedy

- 1) Contractor warrants that testing of properly collected and shipped specimen samples under this Agreement with all required Documentation, up to the testing volume as agreed upon between the parties and specified herein, will be completed and the testing results reported within forty-eight (48) hours of receipt at the Facility.
- 2) Contractor shall maintain Equipment during the term of the loan of such Equipment.
- 3) Contractor's sole responsibility to CDPH in the event of any breach of warranty in the performance of any of its obligations hereunder shall be to repair or replace any defective Equipment, replace any defective or deficient materials supplied by Contractor, or re-perform any defective testing Services. This section shall not be construed to require CDPH to reimburse Contractor for any damages to third parties to the extent such damages are caused by Contractor.
- 4) Contractor warrants that the testing shall be performed with the EUA assay, and in accordance with the requirements of the EUA, and CLIA. Contractor warrants further that the testing services will detect as few as twenty (20) copies per milliliter. The foregoing warranty applies only to all known versions of SARS-CoV-2 as of the Effective Date.
- 5) Contractor makes no representation or warranty with regard to materials made by or to the order of CDPH and used by any third-party or CDPH in conjunction with Contractor's materials or the Equipment.
- 6) Contractor makes no representation or warranty with regard to any Equipment manufactured by any third-party, but Contractor will use commercially reasonable efforts to pass through such third-parties' warranties for CDPH's benefit, and to obtain prompt warranty service from such third-parties on CDPH's behalf.
- 7) Contractor warrants that the results of the Services will be consistent with the technical capabilities of the EUA.

7. Miscellaneous

- 1) If Contractor receives approval/clearance from the Food and Drug Administration, including EUA, for a pooling assay for initial screening, in which multiple patient samples are determined by validation procedure for SARS-CoV-2, the parties shall meet and confer regarding amendment of this Agreement to implement the pooling assay. In any amendment to implement a pooling assay, the pricing will treat a) each pooled test as one test rather than a test of each sample in the pool, and b) retest of each specimen in a positive pool as an individual test. The parties understand and agree that implementation of a pooling assay is expected to reduce the overall workflow requirements and cost of the Services, but that such reductions will not be pro-rata with the number of samples in each pool, and that the pricing for each instance of a pooling test will be higher than the current single-specimen EUA assay.
- 2) After commencement of the Services at the Facilities, the parties will meet and confer regarding the possibility of Contractor sourcing collection kits for samples.
- 3) This Agreement constitutes the full understanding of the parties and a complete and exclusive

Exhibit A
Statement of Work

statement of the terms.

- 4) No delay or omission on the part of Contractor or CDPH in the exercise of any right or remedy hereunder shall operate as a waiver thereof.
- 5) Contractor, and the agents and employees of Contractor, in the provision of services and materials under this Agreement, shall act in an independent capacity and not as officers or employees or agents of the State of California.
- 6) No alteration or variation of the terms of this Agreement shall be valid unless made in writing and signed by the parties hereto, and no oral understanding or agreement not incorporated herein, shall be binding on any of the parties hereto.
- 7) CDPH agrees and acknowledges that use of the Equipment represents proprietary processes, which are owned by Contractor. This Agreement shall not be considered to confer upon CDPH any right or license to use the Equipment except as expressly set forth in the instructions, manuals and specifications of this Agreement.
- 8) CDPH or the Contractor shall not release or otherwise distribute any abstract, manuscript, or document describing work performed that reference the name of either entity or the Equipment without giving one another prior written notice.
- 9) Upon execution this Agreement is a public document, and parties may disclose this Agreement as required by applicable law, regulation, or stock exchanges rules.

8. Termination

- 1) Unless otherwise stated in this section, this Agreement may be canceled by CDPH without cause upon at least forty-five (45) calendar days advance written notice to the Contractor.
- 2) This Agreement may be terminated by CDPH upon thirty (30) calendar days advance written notice to the Contractor, in the event CDPH reasonably determines that (1) new and superior SARS CoV-2 diagnostic testing technology has become commercially available, or (2) comparable SARS CoV-2 diagnostic testing has become commercially available at lower cost, if in either case Contractor is unable, on mutually agreeable commercial terms, to implement a solution comparable to the new and superior technology or achieve comparable cost reduction as applicable.
- 3) This Agreement may be terminated by either party for material breach of the Agreement upon thirty (30) days prior written notice of such breach provided that such breach is not rectified to the non-breaching party's reasonable satisfaction within the thirty (30) day period.
- 4) If because of the actions of any governmental agency, it is impossible for the parties to perform their obligations under this Agreement, other than CDPH's payment obligations that are otherwise unaffected hereunder, such failure to perform shall not be deemed a breach of this Agreement.

9. Authority to Bind.

Each person signing this Agreement represents and warrants that he or she is duly authorized and has legal capacity to execute and deliver this Agreement and to bind the party for which he or she is signing. Each party represents and warrants to the other that the execution and delivery of the Agreement and the performance of such party's obligations hereunder have been duly authorized and that the Agreement is a valid and legal agreement binding on such party and enforceable in accordance with its terms.

Exhibit A
Statement of Work

10. Term

The term of the Agreement is fourteen (14) months. This Agreement shall automatically renew for two (2) successive terms of one (1) year each, unless CDPH notifies Contractor of non-renewal no later than ninety (90) days prior to expiration of the then-current contract year.

On each anniversary of this Agreement, Contractor may increase all prices by the lesser of Consumer Price Index (CPI) or 3%.

11. Changes to Scope of Work

The parties acknowledge that this Agreement is intended to provide immediate testing of SARS CoV-2 samples using the currently available testing technology and methodology. However, recognizing that SARS CoV-2 diagnostic testing technology and methodology is continually evolving, the current SOW and/or cost may be subject to changes and/or modification as needed and upon mutual agreement of the parties.

The parties will maintain continuous contact about testing solutions for SARS CoV-2, and whether and what additional infectious diseases may be tested at the Facilities by Contractor. In the event that CDPH desires to add to and/or modify the Services as needed to provide testing of other infectious diseases, i.e. influenza, the parties will negotiate in good faith the terms under which the Contractor will perform such modified services.

12. Labor Standards

- A. **ADA compliance.** The Contractor warrants that it is in compliance with the Americans with Disabilities Act (ADA) and all regulations issued thereunder and that it will comply in all respects with the provisions of the ADA and regulations thereunder. The Contractor shall advise CDPH of any exemptions, exceptions to or waivers from this statutory requirement; the Contractor shall notify CDPH of the Contractor's ADA-related accessibility and other accommodating ADA-related arrangements. CDPH shall notify Contractor in advance of any special accommodations needed, when such needs are known by CDPH. Contractor agrees to hold harmless CDPH, and its volunteers and employees from any and all claims arising from ADA violations within the scope and responsibility of the Contractor and its activities under this Agreement.
- B. **High-Road Labor Standards.** The Contractor warrants that it and any subcontractors it may use to fulfill this Agreement will satisfy the following high-road labor standards:
- a. **Fair wages.** All employees performing work to fulfill this Agreement shall be paid no less than the minimum Trainee Wage set by the Employment Training Panel for the county in which the work is performed, or the applicable federal, state, or local minimum wage, whichever is greater. Healthcare benefits valued at up to \$2.50 per hour can be used to meet this wage requirement.
 - b. **Fringe benefits.** Fringe benefit contributions shall be made on behalf of each employee performing work to fulfill this Agreement in an amount no less than the fringe benefit contributions required by the most recent Service Contract Act area-wide wage determination issued by the United States Secretary of Labor for the locality in which the work is performed.
 - c. **No misclassification.** Individuals performing work to fulfill this Agreement shall not be misclassified as independent contractors.
 - d. **Paid sick leave.** The Contractor and any subcontractors performing work to fulfill this Agreement shall comply with all applicable federal, state, and local laws pertaining to paid sick leave, including any anti-retaliation provisions contained in such laws.

Exhibit A
Statement of Work

- e. Workplace safety and health. The Contractor and any subcontractors performing work to fulfill this Agreement shall comply with all applicable safety and health requirements, including those identified in Cal/OSHA's Interim Guidelines for General Industry on 2019 Novel Coronavirus Disease (COVID-19), including requirements applicable to worksites where COVID-19 exposure is a known hazard. The Contractor and any subcontractors shall comply with Labor Code sections 6310 and 6311 pertaining to protection of employees who file complaints or refuse to work in the face of hazardous conditions.
- f. Priority for unemployed workers. When hiring any new employees to perform work to fulfill this Agreement, the Contractor and any subcontractor shall give preference to any applicant who is currently unemployed and who is qualified for the position over applicants who are qualified but not currently unemployed.

Exhibit A
Statement of Work

Attachment 1

**SARS CoV-2 Instruments &
Kits***

<u>Item</u>		
<u>#</u>	<u>Part #</u>	<u>Description</u>
1	CJL8002	JANUS G3 Primary Sample Reformatter
2	2024-0020	chemagic 360
3	CJM8M01	JANUS G3 Standard, 8-tip + MDT, IVD
4	CMG-1033-S	chemagic Viral DNA/RNA 300 kit H96
5	2019-NCOV-PCR-AUS	PerkinElmer New Coronavirus NA Kit AUS
6	010MISC	qPCR Instrument

*Items may be substituted depending on new technology or need for increased efficiencies



March 24, 2020

Brian Ciccariello, RAC
Head of Regulatory & Medical Affairs - Americas
PerkinElmer, Inc.
940 Winter Street,
Waltham, MA 02451 US

Device: PerkinElmer New Coronavirus Nucleic Acid Detection Kit

Company: PerkinElmer, Inc.

Indication: Qualitative detection of nucleic acid from the SARS-CoV-2 virus in human oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Dear Mr. Ciccariello:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.³ Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.⁴

¹ For ease of reference, this letter will use the term “you” and related terms to refer to the PerkinElmer, Inc.

² For ease of reference, this letter will use the term “your product” to refer to the PerkinElmer New Coronavirus Nucleic Acid Detection Kit used for the indication identified above.

³ On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.

⁴ U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and*

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the scope Section of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and
3. There is no adequate, approved, and available alternative to the emergency use of your product.⁵

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in human oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 nucleic acid is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from human oropharyngeal swab and nasopharyngeal swab specimens, using authorized extraction methods. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time PCR instrument. The PerkinElmer New Coronavirus Nucleic Acid Detection Kit includes the following materials and control materials or other authorized materials: nCoV reagent A, nCoV reagent B, nCoV enzyme mix, nCoV internal control, nCoV positive control, and nCoV negative control.

Your product requires the following control materials, or other authorized control materials, that

Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

are to be run as outlined in the instructions for use. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the instructions for use:

- nCoV Internal Control - bacteriophage MS2 added clinical samples and controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.
- nCoV Negative Control - buffer used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product, when labeled consistently with the labeling authorized by FDA, entitled “PerkinElmer New Coronavirus Nucleic Acid Detection Kit” instructions for use (available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>), which may be revised in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

Your product is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: PerkinElmer New Coronavirus Nucleic Acid Detection Kit
- Fact Sheet for Patients: PerkinElmer New Coronavirus Nucleic Acid Detection Kit

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your authorized product, when used for the qualitative detection of SARS-CoV-2 and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective for the indication above, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as

described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), your product is authorized for the indication above.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

PerkinElmer, Inc. (You) and Authorized Distributor(s)⁶

- A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).
- B. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- C. You and authorized distributor(s) will provide to authorized laboratories the Fact Sheet

⁶ “Authorized Distributor(s)” are identified by you, PerkinElmer, Inc., in your EUA submission as an entity allowed to distribute your device.

for Healthcare Providers and the authorized Fact Sheet for Patients. You may request changes to the authorized Fact Sheets. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- D. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- E. You and authorized distributor(s) will inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, authorized labeling and authorized Fact Sheets.
- F. Through a process of inventory control, you and authorized distributor(s) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- G. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

PerkinElmer, Inc. (You)

- I. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You will provide its authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.
- L. You may request the addition of other instruments and associated software for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- M. You may request the addition of other extraction methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

- N. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You may request the addition and/or substitution of primers or probes for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You may request the addition and/or substitution of other ancillary reagents and materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You will evaluate the analytical limit of detection and assess traceability⁷ of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, You will update its labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- S. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

Authorized Laboratories

- T. Authorized laboratories using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- U. Authorized laboratories using your product will use your product as outlined in the instructions for use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- V. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- W. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

⁷ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- X. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and You (via email: COVID-19.TechnicalSupport@PerkinElmer.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- Y. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

PerkinElmer, Inc. (You), Authorized Distributors and Authorized Laboratories

- Z. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Advertising and Promotion

- AA. All advertising and promotional descriptive printed matter relating to the use of your product shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- BB. All advertising and promotional descriptive printed matter relating to the use of your product shall clearly and conspicuously state that:
- This test has not been FDA cleared or approved;
 - This test has been authorized by FDA under an EUA for use by authorized laboratories;
 - This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
 - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

No advertising or promotional descriptive printed matter relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures

Exhibit B
Payment Provisions

1. Invoicing and Payment

- A. In no event shall the Contractor request reimbursement from CDPH for obligations entered into or for costs incurred prior to the commencement date or after the expiration of this Agreement.
- B. CDPH agrees to compensate the Contractor for expenditures incurred in accordance with the cost breakdown stated section E “Amounts Payable” below and Exhibit B Attachment 1.
- C. Invoices shall include the Agreement Number and shall be submitted in triplicate not more frequently than monthly to:

Phebe Lapinig
Emergency Preparedness Office
California Department of Public Health
P.O. Box 997377, MS 0500
Sacramento, CA 95899-7377

- D. Invoice shall:
 - 1) Be prepared on Contractor letterhead. If invoices are not on produced letterhead invoices must be signed by an authorized official, employee, or agent certifying that the expenditures claimed represent activities performed and are in accordance with Attachment 1.
 - 2) Invoices must be submitted to CDPH either electronically or in hard copies.
 - 3) Identify the billing and/or performance period covered by the invoice.
 - 4) Itemize costs for the billing period in the same or greater level of detail as indicated in this Agreement. Subject to the terms of this Agreement, reimbursement may only be sought for those costs and/or cost categories expressly identified as allowable in this Agreement and approved by CDPH.

E. Amounts Payable

- 1) CDPH shall pay Contractor costs associated with Facility setup (“Startup Payments”) as follows:
 - 1st payment in the amount of \$100,223,600 will be made upon notification by Contractor of the completion of the following:
 - Ordered all Equipment required to be provided by Contractor for the Services at a Facility;
 - Hired recruiting agency for hiring personnel for performance of the Services at a Facility;
 - Completed EUA for the test to be used to perform the Services; and
 - Obtained all accreditations necessary for performance of the Services at a Facility.

Exhibit B
Payment Provisions

- 2nd payment of \$100,223,600 will be made upon delivery to CDPH the first reportable result of the Services performed at the Facilities as provided in this Agreement.
- 2) 3rd payment of up to \$74,814,800 will be made upon request by CDPH that Contractor implement capacity for Services in excess of 120,000 samples per day. The 3rd payment shall be for actual or anticipated costs, including Services performed implementing capacity for 150,000 tests per day. Prior to requesting that Contractor implement capacity for Services in excess of 120,000 samples per day, CDPH may request, and Contractor shall provide, an itemized estimate for implementing capacity for 150,000 tests per day. If Contractor's estimate is less than \$74,814,800, then Contractor shall notify CDPH and i) the 3rd payment shall be reduced by such identified savings, and ii) the Balancing Credit for samples in excess of 120,000 will be revised commensurately to maintain current proposed pricing.
- 3) CDPH shall pay Contractor a monthly fee for testing (the "Monthly Fee"), which shall be the lesser of: (a) a fee comprised of a fixed fee for maintenance of Contractor's testing carrying capacity (the "Monthly Fixed Fee") based on Contractor's declared average testing capacity for the following month, plus a price per reported result in the prior month (the "Variable Fee") as provided below, or (b) Contractor's Best Price. "Best Price" means the lowest price, on a per test basis, accepted by Contractor from any purchaser for SARS CoV-2 diagnostic testing under substantially similar commercial terms and circumstances, including, but not limited to, labor, utilities, taxes, insurance and other third-party costs, testing volume, technology used, personnel requirements, and facilities as under this Agreement. For the purpose of determining Best Price, Contractor shall divide the Monthly Fee by the total number of reported results for that month, excluding any credits or penalties other than as provided in Section 1(E)(4). Upon ten (10) days written notice, CDPH may audit Contractor's books and records as reasonably applicable to services rendered that meet the prerequisites for a Best Price in the foregoing sentence. A detailed cost breakdown for the Services is attached to this Exhibit as Attachment 1.

If Contractor implements daily testing capacity of 150,000 or more tests, and if CDPH requests daily testing capacity of 160,000 or more tests, the parties will establish pricing for such tests on mutually agreeable commercial terms.

Exhibit B
Payment Provisions

Contractor's Daily Testing Capacity	Monthly Fixed Fee (\$)	Average Daily Tests Performed	Variable Fee per Test Performed (\$)
40,000	24,000,000	40,000= \leq X<50,000	\$19.95
50,000	30,000,000	50,000= \leq X<60,000	\$20.63
60,000	36,000,000	60,000= \leq X<70,000	\$19.59
70,000	42,000,000	70,000= \leq X<80,000	\$19.91
80,000	48,000,000	80,000= \leq X<90,000	\$18.66
90,000	54,000,000	90,000= \leq X<100,000	\$18.85
100,000	60,000,000	100,000= \leq X<110,000	\$18.00
110,000	65,000,000	110,000= \leq X<120,000	\$17.12
120,000	70,000,000	120,000= \leq X<130,000	\$16.24
130,000	75,000,000	130,000= \leq X<140,000	\$15.33
140,000	80,000,000	140,000= \leq X<150,000	\$14.40
150,000	85,000,000	X \geq 150,000	\$13.47

- 4) Each Monthly Fee shall be credited as follows:
- Startup Payments: \$5.51 per reported result up to 120,000 samples per day each day of the applicable month, until the aggregate of all such credits equals the sum of the first two Startup Payments; and b) if CDPH has made the 3rd payment, \$5.04 per reported result in excess of 120,000 samples each day of the applicable month (subject to reduction to maintain overall per-sample cost pursuant to Section 1(E)(2), until the aggregate of all such credits equals the amount of the 3rd Startup Payment.
 - Balancing Credits: For purposes of this Section "Contract Month" means each successive thirty (30) day period following the effective date of this Agreement.

Beginning the first Contract Month in which CDPH sends an average of 125,000 samples per day to Contractor for testing under this Agreement (the "Full Run Rate Month"), in each Contract Month that CDPH sends an average of greater than 115,000 samples per day to Contractor for testing, Contractor shall credit CDPH pro rata on a per sample basis until the average of all Variable Fees paid on all samples sent to Contractor for testing under this Agreement reaches \$16.24 (the "Balancing Credit"). The total amount of the Balancing Credit under this Section 1(E)(4)(b) will be an amount equal to the difference between: i) the total Variable Fees actually paid or payable by CDPH for testing performed by Contractor under this Agreement before reaching the Full Run Rate Month, less ii) the product of a) \$16.24 and b) the total number of tests actually performed prior to the Full Run Rate Month. The Balancing Credit shall be credited pro rata against amounts payable for the reportable results beginning in the Full Run Rate Month equal to: i) the difference between the product of a) 125,000, b) the number of Contract Months before the Full Run Rate Month, and c) 30, and ii) the number of tests actually performed by Contractor under this agreement prior to the Full Run Rate Month.

Beginning the Contract Month in which CDPH sends an average of 130,000 samples per day to Contractor for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, in each Contract

Exhibit B**Payment Provisions**

Month that CDPH sends an average of greater than 120,000 samples per day to Contractor for testing, Contractor shall provide a Balancing Credit with a Variable Fee per test of \$15.33.

Beginning the Contract Month in which CDPH sends an average of 140,000 samples per day to Contractor for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, in each Contract Month that CDPH sends an average of greater than 130,000 samples per day to Contractor for testing, Contractor shall provide a Balancing Credit with a Variable Fee per test of \$14.40.

Beginning the Contract Month in which CDPH sends an average of 150,000 samples per day to Contractor for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, in each Contract Month that CDPH sends an average of greater than 140,000 samples per day to Contractor for testing, Contractor shall provide a Balancing Credit with a Variable Fee per test of \$13.47.

By way of example, if CDPH sends averages of 47,000, 73,000, and 122,000 in the first three (3) months of testing (each assumed to be thirty-day months) preceding the Full Run Rate Month, the credit would be as follows:

Total amount of Variable Fees paid or payable by CDPH =
 $(47,000 \times 30 \times 20.95) + (73,000 \times 30 \times 20.91) + (122,000 \times 30 \times 17.24) =$
\$138,430,800

Total number of tests performed =
 $(47,000 \times 30) + (73,000 \times 30) + (122,000 \times 30) =$ **7,260,000**

Number of Contract Months before reaching the Full Run Rate Month = **3**

Total Balancing Credit Value = $\$138,430,800 - (\$13.47 \times 7,260,000) =$
\$33,378,600

Number of samples credited = $(150,000 \times 3 \times 30) - 7,260,000 =$ **6,240,000**

Credit per sample = $\$33,378,600 / 6,240,000 =$ **\$5.349**

- 5) The Variable Fee shall be reduced as follows based on the percentage of test results not returned within forty-eight (48) hours of receipt of the sample by Contractor:

Exhibit B
Payment Provisions

Percentage (%) within 48 hours	Impact
>=95	None
90=<X<95	Meet and confer re improvement plan
80=<X<90	5% reduction in the Variable Fee for the second consecutive contract month in or below this range
70<X<80	15% reduction in the Variable Fee for the second consecutive contract month in or below this range

Any samples in excess of the then-current testing capacity received within any rolling twenty-four (24) hour period shall be excluded from this calculation. Contractor's failure to return 70% or more of test results within 48 hours in any month shall be a material breach of this Agreement, which Contractor shall have an opportunity to cure within 30 days in accordance with Exhibit A, Section 8.

- 6) On a monthly basis, CDPH shall reimburse Contractor for Facility management and maintenance, including, but not limited to, personnel costs, actual third-party service provider expenses including cleaning and biohazard disposal, and associated overhead. Total estimated costs under this provision depend on the details of Facility size, location and accessibility, and third-party provider expenses, and the single Facility expenses are estimated to be in the range of:

Supplier Testing Capacity (samples per day)	Estimated Cost Range per year (\$)
<=40,000	1,800,000 – 2,200,000
40,000<100,000	2,600,000 – 3,600,000
100,000	4,000,000 – 4,500,000

- 7) The cost per specimen sample for Backup Services is \$40.00.

2. Budget Contingency Clause

- A. It is mutually agreed that if the Budget Act of the current year and/or any subsequent years covered under this Agreement does not appropriate or allocate sufficient funds for the program, this Agreement shall be of no further force and effect. In this event, CDPH shall have no liability to pay any funds to Contractor or to furnish any other considerations under this Agreement, and Contractor shall not be obligated to perform any provisions of this Agreement.
- B. If funding for any fiscal year is reduced or deleted by the Budget Act or otherwise not allocated for purposes of this program, CDPH shall have the option to either cancel this Agreement with no liability occurring to CDPH, or offer an agreement amendment to Contractor to reflect the reduced amount.

3. Prompt Payment Clause

Exhibit B
Payment Provisions

Payment will be made in accordance with, and within the time specified in, Government Code Chapter 4.5, commencing with Section 927.

4. Timely Submission of Final Invoice

A final undisputed invoice shall be submitted for payment no more than sixty (60) calendar days following the expiration or termination date of this Agreement, unless a later or alternate deadline is agreed to in writing by the program contract manager. Said invoice should be clearly marked "Final Invoice," indicating that all payment obligations of CDPH under this Agreement have ceased and that no further payments are due or outstanding. CDPH may, at its discretion, choose not to honor any delinquent final invoice if the Contractor fails to obtain prior written CDPH approval of an alternate final invoice submission deadline.

5. Expense Allowability/Fiscal Documentation

- A. Invoices, received from the Contractor and accepted for payment by CDPH, shall not be deemed evidence of allowable agreement costs.
- B. For five years, Contractor shall maintain for review and audit and supply to CDPH upon request, adequate documentation of all expenses claimed pursuant to this Agreement to permit a determination of expense allowability.
- C. If the allowability of an expense cannot be determined by CDPH because invoice detail, fiscal records, or backup documentation is nonexistent or inadequate according to generally accepted accounting principles or practices, all questionable costs may be disallowed and payment may be withheld by CDPH. Upon receipt of adequate documentation supporting a disallowed or questionable expense, reimbursement may resume for the amount substantiated and deemed allowable.

6. Recovery of Overpayments

- A. Contractor agrees that claims based upon the terms of this Agreement or an audit finding and/or an audit finding that is appealed and upheld, will be recovered by CDPH by one of the following options:
 - 1) Contractor's remittance to CDPH of the full amount of the audit exception within 30 days following CDPH's request for repayment; or
 - 2) A repayment schedule agreeable between CDPH and the Contractor.
- B. CDPH reserves the right to select which option as indicated above in paragraph A will be employed and the Contractor will be notified by CDPH in writing of the claim procedure to be utilized.
- C. Interest on the unpaid balance of the audit finding or debt will accrue at a rate equal to the monthly average of the rate received on investments in California's Pooled Money Investment Fund commencing on the date that an audit or examination

Exhibit B
Payment Provisions

finding is mailed to the Contractor, beginning 30 days after Contractor's receipt of CDPH's demand for repayment.

- D. If the Contractor has filed a valid appeal regarding the report of audit findings, recovery of the overpayments will be deferred until a final administrative decision on the appeal has been reached. If the Contractor loses the final administrative appeal, Contractor shall repay, to CDPH, the over-claimed or disallowed expenses, plus accrued interest. Interest accrues from the Contractor's first receipt of CDPH's notice requesting reimbursement of questioned audit costs or disallowed expenses.

Exhibit B Attachment 1

Fixed Monthly Fee		Variable Fee						Total Cost				
Contractor's Daily Testing Capacity	Monthly Fixed Fee	Average Tests Per Month	Average Tests Per Year	Variable Fee/Test Performed	Sample Cost (Including Credit)	Monthly Cost	Monthly	Yearly	Cost Per Test (Excluding Startup)	Total Cost (Including Startup)	Total Cost Per Test (Including Startup)	
40,000	\$24,000,000	1,213,333	14,560,000	\$19.95	\$14.44	\$17,524,427	\$41,524,427	\$498,293,120	\$34.22	\$698,740,320	\$ 47.99	
50,000	\$30,000,000	1,516,667	18,200,000	\$20.63	\$15.12	\$22,936,867	\$52,936,867	\$635,242,400	\$34.90	\$835,689,600	\$ 45.92	
60,000	\$36,000,000	1,820,000	21,840,000	\$19.59	\$14.08	\$25,631,440	\$61,631,440	\$739,577,280	\$33.86	\$940,024,480	\$ 43.04	
70,000	\$42,000,000	2,123,333	25,480,000	\$19.91	\$14.40	\$30,582,813	\$72,582,813	\$870,993,760	\$34.18	\$1,071,440,960	\$ 42.05	
80,000	\$48,000,000	2,426,667	29,120,000	\$18.66	\$13.15	\$31,918,453	\$79,918,453	\$959,021,440	\$32.93	\$1,159,468,640	\$ 39.82	
90,000	\$54,000,000	2,730,000	32,760,000	\$18.85	\$13.34	\$36,426,960	\$90,426,960	\$1,085,123,520	\$33.12	\$1,285,570,720	\$ 39.24	
100,000	\$60,000,000	3,033,333	36,400,000	\$18.00	\$12.49	\$37,896,067	\$97,896,067	\$1,174,752,800	\$32.27	\$1,375,200,000	\$ 37.78	
110,000	\$65,000,000	3,336,667	40,040,000	\$17.12	\$11.61	\$38,749,407	\$103,749,407	\$1,244,992,880	\$31.09	\$1,445,440,080	\$ 36.10	
120,000	\$70,000,000	3,640,000	43,680,000	\$16.24	\$11.20	\$40,762,800	\$110,762,800	\$1,329,153,600	\$30.43	\$1,529,600,800	\$ 35.02	
130,000	\$75,000,000	3,943,333	47,320,000	\$15.33	\$10.29	\$40,571,267	\$115,571,267	\$1,386,855,200	\$29.31	\$1,587,302,400	\$ 33.54	
140,000	\$80,000,000	4,246,667	50,960,000	\$14.40	\$9.36	\$39,742,733	\$119,742,733	\$1,436,912,800	\$28.20	\$1,637,360,000	\$ 32.13	
150,000	\$85,000,000	4,550,000	54,600,000	\$13.47	\$8.43	\$38,350,000	\$123,350,000	\$1,480,200,000	\$27.11	\$1,680,647,200	\$ 30.78	

Start-up Payments (up to 120,000)	
7.3%	\$ 100,223,600
7.3%	\$ 100,223,600
Total (14.6%)	\$ 200,447,200
Estimated Annual Volume	36,400,000
Credit Monthly Payments	\$ 5.51

Additional Start-up Payment (120,000+)	
7.1%	\$ 100,223,600
7.1%	\$ 100,223,600
5.4%	\$ 74,814,800
Total (20%)	\$ 275,262,000
Estimated Annual Volume	54,600,000
Credit Monthly Payments	\$ 5.04

Exhibit C

General Terms and Conditions (GTC 04/2017)

1. APPROVAL: This Agreement is of no force or effect until signed by both parties and approved by the Department of General Services, if required. Contractor may not commence performance until such approval has been obtained.
2. AMENDMENT: No amendment or variation of the terms of this Agreement shall be valid unless made in writing, signed by the parties and approved as required. No oral understanding or Agreement not incorporated in the Agreement is binding on any of the parties.
3. ASSIGNMENT: This Agreement is not assignable by the Contractor, either in whole or in part, without the consent of the State in the form of a formal written amendment.
4. AUDIT: Contractor agrees that the awarding department, the Department of General Services, the Bureau of State Audits, or their designated representative shall have the right to review and to copy any records and supporting documentation pertaining to the performance of this Agreement. Contractor agrees to maintain such records for possible audit for a minimum of three (3) years after final payment, unless a longer period of records retention is stipulated. Contractor agrees to allow the auditor(s) access to such records during normal business hours and to allow interviews of any employees who might reasonably have information related to such records. Further, Contractor agrees to include a similar right of the State to audit records and interview staff in any subcontract related to performance of this Agreement. (Gov. Code §8546.7, Pub. Contract Code §10115 et seq., CCR Title 2, Section 1896).
5. INDEMNIFICATION: Contractor agrees to indemnify, defend and save harmless the State, its officers, agents and employees from any and all claims and losses accruing or resulting to any and all contractors, subcontractors, suppliers, laborers, and any other person, firm or corporation furnishing or supplying work services, materials, or supplies in connection with the Contractor's performance of this Agreement, and from any and all claims and losses accruing or resulting to any person, firm or corporation who may be injured or damaged by Contractor in the performance of this Agreement.
6. DISPUTES: Contractor shall continue with the responsibilities under this Agreement during any dispute.
7. TERMINATION FOR MATERIAL BREACH: Should the State terminate this Agreement for material breach, Contractor agrees to refund to the State, within thirty (30) days of termination: i) if such termination is due to Contractor's bad faith, intentional misconduct, or fraud, then the amount of the Startup Payments made by the State, less any portion of the Startup Payments that has already been credited back to the State pursuant to Exhibit B, Section 1(E) on a per-reported-result basis, or ii) if such termination is not due to Contractor's bad faith, intentional misconduct, or fraud, then the lesser of a) \$100,223,600 and b) the amount of the Startup Payments made by the State, less any portion of the Startup Payments that has already been credited back to the State pursuant to Exhibit B, Section 1(E) on a per-reported-result basis. Any sum due the Contractor under this Agreement shall be paid as provided in the Agreement and the Contractor may offset any refund due to the State under this Section with any sum due from the State to the Contractor under this Agreement, if any. If Contractor still owes a refund to the State after that offset, it shall be paid to the State.
8. RECYCLING CERTIFICATION: The Contractor shall certify in writing under penalty of perjury, the minimum, if not exact, percentage of post-consumer material as defined in the Public Contract Code Section 12200, in products, materials, goods, or supplies offered or sold to the State regardless of

whether the product meets the requirements of Public Contract Code Section 12209. With respect to printer or duplication cartridges that comply with the requirements of Section 12156(e), the certification required by this subdivision shall specify that the cartridges so comply (Pub. Contract Code §12205).

9. NON-DISCRIMINATION CLAUSE: During the performance of this Agreement, Contractor and its subcontractors shall not deny the contract's benefits to any person on the basis of race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, sexual orientation, or military and veteran status, nor shall they discriminate unlawfully against any employee or applicant for employment because of race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, sexual orientation, or military and veteran status. Contractor shall insure that the evaluation and treatment of employees and applicants for employment are free of such discrimination. Contractor and subcontractors shall comply with the provisions of the Fair Employment and Housing Act (Gov. Code §12900 et seq.), the regulations promulgated thereunder (Cal. Code Regs., tit. 2, §11000 et seq.), the provisions of Article 9.5, Chapter 1, Part 1, Division 3, Title 2 of the Government Code (Gov. Code §§11135-11139.5), and the regulations or standards adopted by the awarding state agency to implement such article. Contractor shall permit access by representatives of the Department of Fair Employment and Housing and the awarding state agency upon reasonable notice at any time during the normal business hours, but in no case less than 24 hours' notice, to such of its books, records, accounts, and all other sources of information and its facilities as said Department or Agency shall require to ascertain compliance with this clause. Contractor and its subcontractors shall give written notice of their obligations under this clause to labor organizations with which they have a collective bargaining or other agreement. (See Cal. Code Regs., tit. 2, §11105.)

Contractor shall include the nondiscrimination and compliance provisions of this clause in all subcontracts to perform work under the Agreement.

10. CERTIFICATION CLAUSES: The CONTRACTOR CERTIFICATION CLAUSES contained in the document CCC 04/2017 are hereby incorporated by reference and made a part of this Agreement by this reference as if attached hereto.

11. TIMELINESS: Time is of the essence in this Agreement.

12. COMPENSATION: The consideration to be paid Contractor, as provided herein, shall be in compensation for all of Contractor's expenses incurred in the performance hereof, including travel, per diem, and taxes, unless otherwise expressly so provided.

13. GOVERNING LAW: This contract is governed by and shall be interpreted in accordance with the laws of the State of California.

14. ANTITRUST CLAIMS: The Contractor by signing this agreement hereby certifies that if these services or goods are obtained by means of a competitive bid, the Contractor shall comply with the requirements of the Government Codes Sections set out below.

a. The Government Code Chapter on Antitrust claims contains the following definitions:

1) "Public purchase" means a purchase by means of competitive bids of goods, services, or materials by the State or any of its political subdivisions or public agencies on whose behalf the Attorney General may bring an action pursuant to subdivision (c) of Section 16750 of the Business and Professions Code.

2) "Public purchasing body" means the State or the subdivision or agency making a public purchase. Government Code Section 4550.

b. In submitting a bid to a public purchasing body, the bidder offers and agrees that if the bid is accepted, it will assign to the purchasing body all rights, title, and interest in and to all causes of action it may have under Section 4 of the Clayton Act (15 U.S.C. Sec. 15) or under the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), arising from purchases of goods, materials, or services by the bidder for sale to the purchasing body pursuant to the bid. Such assignment shall be made and become effective at the time the purchasing body tenders final payment to the bidder. Government Code Section 4552.

c. If an awarding body or public purchasing body receives, either through judgment or settlement, a monetary recovery for a cause of action assigned under this chapter, the assignor shall be entitled to receive reimbursement for actual legal costs incurred and may, upon demand, recover from the public body any portion of the recovery, including treble damages, attributable to overcharges that were paid by the assignor but were not paid by the public body as part of the bid price, less the expenses incurred in obtaining that portion of the recovery. Government Code Section 4553.

d. Upon demand in writing by the assignor, the assignee shall, within one year from such demand, reassign the cause of action assigned under this part if the assignor has been or may have been injured by the violation of law for which the cause of action arose and (a) the assignee has not been injured thereby, or (b) the assignee declines to file a court action for the cause of action. See Government Code Section 4554.

15. CHILD SUPPORT COMPLIANCE ACT: For any Agreement in excess of \$100,000, the contractor acknowledges in accordance with Public Contract Code 7110, that:

a. The contractor recognizes the importance of child and family support obligations and shall fully comply with all applicable state and federal laws relating to child and family support enforcement, including, but not limited to, disclosure of information and compliance with earnings assignment orders, as provided in Chapter 8 (commencing with section 5200) of Part 5 of Division 9 of the Family Code; and

b. The contractor, to the best of its knowledge is fully complying with the earnings assignment orders of all employees and is providing the names of all new employees to the New Hire Registry maintained by the California Employment Development Department.

16. UNENFORCEABLE PROVISION: In the event that any provision of this Agreement is unenforceable or held to be unenforceable, then the parties agree that all other provisions of this Agreement have force and effect and shall not be affected thereby.

17. PRIORITY HIRING CONSIDERATIONS: If this Contract includes services in excess of \$200,000, the Contractor shall give priority consideration in filling vacancies in positions funded by the Contract to qualified recipients of aid under Welfare and Institutions Code Section 11200 in accordance with Pub. Contract Code §10353.

18. SMALL BUSINESS PARTICIPATION AND DVBE PARTICIPATION REPORTING REQUIREMENTS:

a. If for this Contract Contractor made a commitment to achieve small business

participation, then Contractor must within 60 days of receiving final payment under this Contract (or within such other time period as may be specified elsewhere in this Contract) report to the awarding department the actual percentage of small business participation that was achieved. (Govt. Code § 14841.)

b. If for this Contract Contractor made a commitment to achieve disabled veteran business enterprise (DVBE) participation, then Contractor must within 60 days of receiving final payment under this Contract (or within such other time period as may be specified elsewhere in this Contract) certify in a report to the awarding department: (1) the total amount the prime Contractor received under the Contract; (2) the name and address of the DVBE(s) that participated in the performance of the Contract; (3) the amount each DVBE received from the prime Contractor; (4) that all payments under the Contract have been made to the DVBE; and (5) the actual percentage of DVBE participation that was achieved. A person or entity that knowingly provides false information shall be subject to a civil penalty for each violation. (Mil. & Vets. Code § 999.5(d); Govt. Code § 14841.)

19. LOSS LEADER: If this contract involves the furnishing of equipment, materials, or supplies then the following statement is incorporated: It is unlawful for any person engaged in business within this state to sell or use any article or product as a "loss leader" as defined in Section 17030 of the Business and Professions Code. (PCC 10344(e).)

20. LIMITATION OF LIABILITY: **IN NO EVENT SHALL CONTRACTOR BE LIABLE FOR ANY LOSS OF USE, REVENUE OR PROFIT, LOSS OF DATA OR DIMINUTION IN VALUE, OR FOR ANY CONSEQUENTIAL, INDIRECT, INCIDENTAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGES WERE FORESEEABLE AND WHETHER OR NOT CONTRACTOR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND NOTWITHSTANDING THE FAILURE OF ANY AGREED OR OTHER REMEDY OF ITS ESSENTIAL PURPOSE. IN NO EVENT SHALL CONTRACTOR'S AGGREGATE LIABILITY ARISING OUT OF OR RELATED TO THIS AGREEMENT, WHETHER ARISING OUT OF OR RELATED TO BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, EXCEED THE TOTAL OF THE AMOUNTS PAID TO CONTRACTOR (AND NOT OTHERWISE REFUNDED) FOR THE PRODUCTS AND SERVICES SOLD HEREUNDER.** The aforementioned limitation of liability shall not apply to liability resulting from Contractor's gross negligence or willful misconduct.

Exhibit D
Additional Provisions

1. Insurance Requirements

Contractor shall comply with the following insurance requirements:

A. General Provisions Applying to All Policies

- 1) Coverage Term – Coverage needs to be in force for the complete term of the Agreement. If insurance expires during the term of the Agreement, a new certificate and required endorsements must be received by the State at least ten (10) days prior to the expiration of this insurance. Any new insurance must comply with the original Agreement terms.
- 2) Policy Cancellation or Termination and Notice of Non-Renewal – Contractor shall provide to the CDPH within five (5) business days following receipt by Contractor a copy of any cancellation or non-renewal of insurance required by this Contract. In the event Contractor fails to keep in effect at all times the specified insurance coverage, the CDPH may, in addition to any other remedies it may have, terminate this Contract upon the occurrence of such event, subject to the provisions of this Contract.
- 3) Premiums, Assessments and Deductibles – Contractor is responsible for any premiums, policy assessments, deductibles or self-insured retentions contained within their insurance program.
- 4) Primary Clause – Any required insurance contained in this Agreement shall be primary and not excess or contributory to any other insurance carried by the CDPH.
- 5) Insurance Carrier Required Rating – All insurance companies must carry an AM Best rating of at least “A–” with a financial category rating of no lower than VI. If Contractor is self-insured for a portion or all of its insurance, review of financial information including a letter of credit may be required.
- 6) Endorsements – Any required endorsements requested by the CDPH must be physically attached to all requested certificates of insurance and not substituted by referring to such coverage on the certificate of insurance.
- 7) Inadequate Insurance – Inadequate or lack of insurance does not negate Contractor’s obligations under the Agreement.
- 8) Use of Subcontractors - In the case of Contractor’s utilization of Subcontractors to complete the contracted scope of work, Contractor shall include all Subcontractors as insured under Contractor’s insurance or supply evidence of the Subcontractor’s insurance to the CDPH equal to policies, coverages, and limits required of Contractor.

B. Insurance Coverage Requirements

Contractor shall display evidence of certificate of insurance evidencing the following coverage:

- 1) Commercial General Liability – Contractor shall maintain general liability with limits not less than \$1,000,000 per occurrence for bodily injury and property damage combined with a \$2,000,000 annual policy aggregate. The policy shall include coverage for liabilities arising out of premises, operations, independent Contractors, products, completed operations, personal, and advertising injury, and liability assumed under an insured Agreement. This insurance shall apply separately to each insured against whom claim is made or suit is brought subject to Contractor's limit of liability. The policy shall be endorsed to include, "The State of California, its officers, agents, employees, and servants as additional insured, but only insofar as the operations under this Agreement are concerned." This endorsement must be supplied under form acceptable to the Office of Risk and Insurance Management.
- 2) Automobile Liability (when required) – Contractor shall maintain motor vehicle liability insurance with limits not less than \$1,000,000 combined single limit per accident. Such insurance shall cover liability arising out of a motor vehicle including owned, hired, and non-owned motor vehicles. Should the scope of the Agreement involve transportation of hazardous materials, evidence of an MCS-90 endorsement is required. The policy shall be endorsed to include, "The State of California, its officers, agents, employees, and servants as additional insured, but only insofar as the operations under this Agreement are concerned." This endorsement must be supplied under form acceptable to the Office of Risk and Insurance Management.
- 3) Worker's Compensation and Employer's Liability (when required) – Contractor shall maintain statutory worker's compensation and employer's liability coverage for all its employees who will be engaged in the performance of the Agreement. Employer's liability limits of \$1,000,000 are required. When work is performed on State owned or controlled property the policy shall contain a waiver of subrogation endorsement in favor of the State. This endorsement must be supplied under form acceptable to the Office of Risk and Insurance Management.
- 4) Professional Liability (when required) – Contractor shall maintain professional liability covering any damages caused by a negligent error; act or omission with limits not less than \$1,000,000 per occurrence and \$1,000,000 policy aggregate. The policy's retroactive date must be displayed on the certificate of insurance and must be before the date this Agreement was executed or before the beginning of Agreement work.
- 5) Environmental/Pollution Liability (when required) – Contractor shall maintain pollution liability for limits not less than \$1,000,000 per claim covering Contractor's liability for bodily injury, property damage and environmental damage resulting from pollution and related cleanup costs incurred arising out of the work or services to be performed under this Agreement. Coverage shall be provided for both work performed on site as well as transportation and proper disposal of hazardous materials. The policy shall be endorsed to include, "The

State of California, its officers, agents, employees, and servants as additional insured, but only insofar as the operations under this Agreement are concerned." This endorsement must be supplied under form acceptable to the Office of Risk and Insurance Management.

- 6) Aircraft Liability (when required) - Contractor shall maintain aircraft liability with a limit not less than \$3,000,000. The policy shall be endorsed to include, "The State of California, its officers, agents, employees and servants as additional insured, but only insofar as the operations under this Agreement." This endorsement must be supplied under form acceptable to the Office of Risk and Insurance Management.

2. Site Inspection

CDPH, through any authorized representatives, has the right at all reasonable times to inspect or otherwise evaluate the work performed or being performed hereunder including subcontract supported activities and the premises in which it is being performed. If any inspection or evaluation is made of the premises of the Contractor or Subcontractor, the Contractor shall provide and shall require Subcontractors to provide all reasonable facilities and assistance for the safety and convenience of the authorized representatives in the performance of their duties. All inspections and evaluations shall be performed in such a manner as will not unduly delay the work.

3. Intellectual Property

A. Third-Party Intellectual Property

Except as provided herein, Contractor agrees that its performance of this Agreement shall not be dependent upon or include any Intellectual Property of Contractor or third party without first: (i) obtaining CDPH's prior written approval; and (ii) granting to or obtaining for CDPH, without additional compensation, a license, for any of Contractor's or third- party's Intellectual Property in existence prior to the effective date of this Agreement. If such a license upon the these terms is unattainable, and CDPH determines that the Intellectual Property should be included in or is required for Contractor's performance of this Agreement, Contractor shall obtain a license under terms acceptable to CDPH.

B. Warranties

- 1) Contractor represents and warrants that:
 - a. It is free to enter into and fully perform this Agreement.
 - b. It has secured and will secure all rights and licenses necessary for its performance of this Agreement.
 - c. Neither Contractor's performance of this Agreement, nor the exercise by either Party of the rights granted in this Agreement, nor any use, reproduction, manufacture, sale, offer to sell, import, export, modification, public and private display/performance, distribution, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly from this

Agreement will infringe upon or violate any Intellectual Property right, non-disclosure obligation, or other proprietary right or interest of any third-party or entity now existing under the laws of, or hereafter existing or issued by, any state, the United States, or any foreign country. There is currently no actual or threatened claim by any such third party based on an alleged violation of any such right by Contractor.

- d. Neither Contractor's performance nor any part of its performance will violate the right of privacy of, or constitute a libel or slander against any person or entity.
- e. It has secured and will secure all rights and licenses necessary for Intellectual Property including, but not limited to, consents, waivers or releases from all authors of music or performances used, and talent (radio, television and motion picture talent), owners of any interest in and to real estate, sites, locations, property or props that may be used or shown.
- f. It has not granted and shall not grant to any person or entity any right that would or might derogate, encumber, or interfere with any of the rights granted to CDPH in this Agreement.
- g. It has appropriate systems and controls in place to ensure that state funds will not be used in the performance of this Agreement for the acquisition, operation or maintenance of computer software in violation of copyright laws.
- h. It has no knowledge of any outstanding claims, licenses or other charges, liens, or encumbrances of any kind or nature whatsoever that could affect in any way Contractor's performance of this Agreement.

C. Intellectual Property Indemnity

- 1) Contractor shall indemnify, defend and hold harmless CDPH and its licensees and assignees, and its officers, directors, employees, agents, representatives, successors, and users of its products, ("Indemnitees") from and against all claims, actions, damages, losses, liabilities (or actions or proceedings with respect to any thereof), whether or not rightful, arising from any and all actions or claims by any third party or expenses related thereto (including, but not limited to, all legal expenses, court costs, and attorney's fees incurred in investigating, preparing, serving as a witness in, or defending against, any such claim, action, or proceeding, commenced or threatened) to which any of the Indemnitees may be subject, whether or not Contractor is a party to any pending or threatened litigation, which arise out of or are related to (i) the incorrectness or breach of any of the representations, warranties, covenants or agreements of Contractor pertaining to Intellectual Property; or (ii) any Intellectual Property infringement, or any other type of actual or alleged infringement claim, arising out of CDPH's use, reproduction, manufacture, sale, offer to sell, distribution, import, export, modification, public and private performance/display, license, and disposition of the Intellectual Property made, conceived, derived from, or reduced to practice by Contractor or CDPH and which result directly or indirectly

from this Agreement. This indemnity obligation shall apply irrespective of whether the infringement claim is based on a patent, trademark or copyright registration that issued after the effective date of this Agreement. CDPH reserves the right to participate in and/or control, at Contractor's expense, any such infringement action brought against CDPH.

- 2) Should any Intellectual Property licensed by the Contractor to CDPH under this Agreement become the subject of an Intellectual Property infringement claim, Contractor will exercise its authority reasonably and in good faith to preserve CDPH's right to use the licensed Intellectual Property in accordance with this Agreement at no expense to CDPH. CDPH shall have the right to monitor and appear through its own counsel (at Contractor's expense) in any such claim or action. In the defense or settlement of the claim, Contractor may obtain the right for CDPH to continue using the licensed Intellectual Property; or, replace or modify the licensed Intellectual Property so that the replaced or modified Intellectual Property becomes non-infringing provided that such replacement or modification is functionally equivalent to the original licensed Intellectual Property. If such remedies are not reasonably available, CDPH shall be entitled to a refund of all monies paid under this Agreement, without restriction or limitation of any other rights and remedies available at law or in equity.
- 3) Contractor agrees that damages alone may be inadequate to compensate CDPH for breach of any term of this Intellectual Property Exhibit by Contractor. Contractor acknowledges CDPH could suffer irreparable harm in the event of such breach and agrees CDPH shall be entitled to seek equitable relief, including without limitation an injunction, from a court of competent jurisdiction, without restriction or limitation of any other rights and remedies available at law or in equity.

D. Federal Funding

In any agreement funded in whole or in part by the federal government, CDPH may acquire and maintain the Intellectual Property rights, title, and ownership, which results directly or indirectly from the Agreement; except as provided in 37 Code of Federal Regulations part 401.14; however, the federal government shall have a non-exclusive, nontransferable, irrevocable, paid-up license throughout the world to use, duplicate, or dispose of such Intellectual Property throughout the world in any manner for governmental purposes and to have and permit others to do so.

E. Survival

The provisions set forth herein shall survive any termination or expiration of this Agreement or any project schedule.

4. Confidentiality of Information

- A. The Contractor and its employees, agents, or subcontractors shall protect from unauthorized disclosure names and other identifying information concerning persons either receiving services pursuant to this Agreement or persons whose names or identifying information become available or are disclosed to the Contractor, its employees, agents, or subcontractors as a result of services performed under this Agreement, except for statistical information not identifying any such person.

- B. The Contractor and its employees, agents, or subcontractors shall not use such identifying information for any purpose other than carrying out the Contractor's obligations under this Agreement.
- C. The Contractor and its employees, agents, or subcontractors shall promptly transmit to the CDPH Program Contract Manager all requests for disclosure of such identifying information not emanating from the client or person.
- D. The Contractor shall not disclose, except as otherwise specifically permitted by this Agreement or authorized by the client, any such identifying information to anyone other than CDPH without prior written authorization from the CDPH Program Contract Manager, except if disclosure is required by State or Federal law.
- E. For purposes of this provision, identity shall include, but not be limited to name, identifying number, symbol, or other identifying particular assigned to the individual, such as finger or voice print or a photograph.
- F. As deemed applicable by CDPH, this provision may be supplemented by additional terms and conditions covering personal health information (PHI) or personal, sensitive, and/or confidential information (PSCI). Said terms and conditions will be outlined in one or more exhibits that will either be attached to this Agreement or incorporated into this Agreement by reference.

5. Dispute Resolution Process

A Contractor grievance exists whenever there is a dispute arising from CDPH's action in the administration of an agreement. If there is a dispute or grievance between the Contractor and CDPH, the Contractor must seek resolution using the procedure outlined below.

- A. The Contractor should first informally discuss the problem with the CDPH Program Contract Manager. If the problem cannot be resolved informally, the Contractor shall direct its grievance together with any evidence, in writing, to the program Branch Chief. The grievance shall state the issues in dispute, the legal authority or other basis for the Contractor's position and the remedy sought. The Branch Chief shall render a decision within ten (10) working days after receipt of the written grievance from the Contractor. The Branch Chief shall respond in writing to the Contractor indicating the decision and reasons therefore. If the Contractor disagrees with the Branch Chief's decision, the Contractor may appeal to the second level.
- B. When appealing to the second level the Contractor must prepare an appeal indicating the reasons for disagreement with the Branch Chief's decision. The Contractor shall include with the appeal a copy of the Contractor's original statement of dispute along with any supporting evidence and a copy of the Branch Chief's decision. The appeal shall be addressed to the Deputy Director of the division in which the branch is organized within ten (10) working days from receipt of the Branch Chief's decision. The Deputy Director of the division in which the branch is organized or his/her designee shall meet with the Contractor to review the issues raised. A written decision signed by the Deputy Director of the division in which the branch is organized or his/her designee shall be directed to the Contractor within twenty (20) working days of receipt of the Contractor's second level appeal. The decision rendered by the Deputy Director or his/her designee shall be the final administrative determination of the Department.

- C. Unless otherwise stipulated in writing by CDPH, all dispute, grievance and/or appeal correspondence shall be directed to the CDPH Program Contract Manager.
- D. There are organizational differences within CDPH's funding programs and the management levels identified in this dispute resolution provision may not apply in every contractual situation. When a grievance is received and organizational differences exist, the Contractor shall be notified in writing by the CDPH Program Contract Manager of the level, name, and/or title of the appropriate management official that is responsible for issuing a decision at a given level.

6. Excise Tax

The State of California is exempt from federal excise taxes, and no payment will be made for any taxes levied on employees' wages.

Exhibit E**HIPAA Business Associate Addendum****I. Recitals**

- A.** The underlying contract (Agreement), to which this HIPAA Business Associate Addendum is attached to and made a part of, has been determined to potentially constitute a business associate relationship under the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("the HITECH Act"), 42 U.S.C. section 17921 et seq., and their implementing privacy and security regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations").
- B.** The Department of Public Health ("CDPH") may disclose to Business Associate certain information pursuant to the terms of the Agreement, some of which may constitute Protected Health Information ("PHI"), including protected health information in electronic media ("ePHI"), under federal law, and personal information ("PI") under state law.
- C.** As set forth in the Agreement, Contractor, here and after, is the Business Associate of CDPH acting on CDPH's behalf and provides services, arranges, performs or assists in the performance of functions or activities on behalf of CDPH and creates, receives, maintains, transmits, uses or discloses PHI and PI. CDPH and Business Associate are each a party to the Agreement and are collectively referred to as the "parties."
- D.** The purpose of this Addendum is to protect the privacy and security of the PHI and PI that may be created, received, maintained, transmitted, used or disclosed pursuant to the Agreement, and to comply with certain standards and requirements of HIPAA, the HITECH Act and the HIPAA regulations, including, but not limited to, the requirement that CDPH must enter into a contract containing specific requirements with Contractor prior to the disclosure of PHI to Contractor, as set forth in 45 CFR Parts 160 and 164 and the HITECH Act.
- E.** The terms used in this Addendum, but not otherwise defined, shall have the same meanings as those terms have in the HIPAA regulations. Any reference to statutory or regulatory language shall be to such language as in effect or as amended.

II. Definitions

- A.** Breach shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- B.** Business Associate shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- C.** Covered Entity shall have the meaning given to such term under HIPAA, the HITECH Act, and the HIPAA regulations.
- D.** Electronic Health Record shall have the meaning given to such term in the HITECH Act, including, but not limited to, 42 U.S.C section 17921 and implementing regulations.
- E.** Electronic Protected Health Information (ePHI) means individually identifiable health information transmitted by electronic media or maintained in electronic media, including but not limited to electronic media as set forth under 45 CFR part 160.103.
- F.** Individually Identifiable Health Information means health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer

Exhibit E**HIPAA Business Associate Addendum**

or health care clearinghouse, and relates to the past, present or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, that identifies the individual or where there is a reasonable basis to believe the information can be used to identify the individual, as set forth under 45 CFR section 160.103.

- G.** Privacy Rule shall mean the HIPAA Regulation that is found at 45 CFR Parts 160 and 164.
- H.** Personal Information shall have the meaning given to such term in California Civil Code sections 1798.3 and 1798.29.
- I.** Protected Health Information means individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or is transmitted or maintained in any other form or medium, as set forth under 45 CFR section 160.103.
- J.** Required by law, as set forth under 45 CFR part 164.103, means a mandate contained in law that compels an entity to make a use or disclosure of PHI that is enforceable in a court of law. This includes, but is not limited to, court orders and court-ordered warrants, subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information, and a civil or an authorized investigative demand. It also includes Medicare conditions of participation with respect to health care providers participating in the program, and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.
- K.** Secretary means the Secretary of the U.S. Department of Health and Human Services ("HHS") or the Secretary's designee.
- L.** Security Incident means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PHI or PI, or confidential data that is essential to the ongoing operation of Business Associate's organization and intended for internal use; or interference with system operations in an information system.
- M.** Security Rule shall mean the HIPAA regulation that is found at 45 CFR Parts 160 and 164.
- N.** Unsecured PHI shall have the meaning given to such term under the HITECH Act, 42 U.S.C. section 17932(h), any guidance issued pursuant to such Act and the HIPAA regulations.

III. Terms of Agreement**A. Permitted Uses and Disclosures of PHI by Business Associate**

Permitted Uses and Disclosures. Except as otherwise indicated in this Addendum, Business Associate may use or disclose PHI only to perform functions, activities or services specified in the Agreement, for, or on behalf of CDPH, provided that such use or disclosure would not violate the HIPAA regulations, if done by CDPH. Any such use or disclosure must, to the extent practicable, be limited to the limited data set, as defined in 45 CFR section 164.514(e)(2), or, if needed, to the minimum necessary to accomplish the intended purpose of such use or disclosure, in compliance with the HITECH Act and any guidance issued pursuant to such Act, and the HIPAA regulations.

- 1. *Specific Use and Disclosure Provisions.*** Except as otherwise indicated in this Addendum, Business Associate may:

Exhibit E**HIPAA Business Associate Addendum**

- a. ***Use and disclose for management and administration.*** Use and disclose PHI for the proper management and administration of Business Associate provided that such disclosures are required by law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and will be used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies Business Associate of any instances of which it is aware that the confidentiality of the information has been breached.
- b. ***Provision of Data Aggregation Services.*** Use PHI to provide data aggregation services to CDPH. Data aggregation means the combining of PHI created or received by Business Associate on behalf of CDPH with PHI received by Business Associate in its capacity as Business Associate of another covered entity, to permit data analyses that relate to the health care operations of CDPH.

B. Prohibited Uses and Disclosures

1. Business Associate shall not disclose PHI about an individual to a health plan for payment or health care operations purposes if the PHI pertains solely to a health care item or service for which the health care provider involved has been paid out of pocket in full and the individual requests such restriction, in accordance with 42 U.S.C. section 17935(a) and 45 CFR section 164.522(a).
2. Business Associate shall not directly or indirectly receive remuneration in exchange for PHI, except with the prior written consent of CDPH and as permitted by 42 U.S.C. section 17935(d)(2).

C. Responsibilities of Business Associate

Business Associate agrees:

1. ***Nondisclosure.*** Not to use or disclose PHI other than as permitted or required by the Agreement or as required by law.
2. ***Safeguards.*** To implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the PHI, including electronic PHI, that it creates, receives, maintains, uses or transmits on behalf of CDPH, in compliance with 45 CFR parts 164.308, 164.310 and 164.312, and to prevent use or disclosure of PHI other than as provided for by the Agreement. Business Associate shall implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications and other requirements of 45 CFR part 164, subpart C, in compliance with 45 CFR part 164.316. Business Associate shall develop and maintain a written information privacy and security program that includes administrative, technical and physical safeguards appropriate to the size and complexity of Business Associate's operations and the nature and scope of its activities, and which incorporates the requirements of section 3, Security, below. Business Associate will provide CDPH with its current and updated policies.
3. ***Security.*** To take any and all steps necessary to ensure the continuous security of all computerized data systems containing PHI and/or PI, and to protect paper documents containing PHI and/or PI. These steps shall include, at a minimum:
 - a. Complying with all of the data system security precautions listed in Attachment A, Business Associate Data Security Requirements;

Exhibit E**HIPAA Business Associate Addendum**

- b. Achieving and maintaining compliance with the HIPAA Security Rule (45 CFR Parts 160 and 164), as necessary in conducting operations on behalf of CDPH under the Agreement;
- c. In case of a conflict between any of the security standards contained in any of these enumerated sources of security standards, the most stringent shall apply. The most stringent means that safeguard which provides the highest level of protection to PHI from unauthorized disclosure. Further, Business Associate must comply with changes to these standards that occur after the effective date of the Agreement; and
- d. Business Associate shall designate a Security Officer to oversee its data security program who shall be responsible for carrying out the requirements of this section and for communicating on security matters with CDPH.

D. *Mitigation of Harmful Effects.* To mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate or its subcontractors in violation of the requirements of this Addendum.

E. *Business Associate's Agents and Subcontractors.*

- 1. To enter into written agreements with any agents, including subcontractors and vendors, to whom Business Associate provides PHI or PI received from or created or received by Business Associate on behalf of CDPH, that impose the same restrictions and conditions on such agents, subcontractors and vendors that apply to Business Associate with respect to such PHI and PI under this Addendum, and that comply with all applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations.
- 2. In accordance with 45 CFR section 164.504(e)(1)(ii), upon Business Associate's knowledge of a material breach or violation by its subcontractor of the agreement between Business Associate and the subcontractor, Business Associate shall:
 - a. Provide an opportunity for the subcontractor to cure the breach or end the violation and terminate the agreement if the subcontractor does not cure the breach or end the violation within the time specified by CDPH; or
 - b. Immediately terminate the agreement if the subcontractor has breached a material term of the agreement and cure is not possible.

F. *Availability of Information to CDPH and Individuals.* To provide access and information:

- 1. To provide access as CDPH may require, and in the time and manner designated by CDPH (upon reasonable notice and during Business Associate's normal business hours) to PHI in a Designated Record Set, to CDPH (or, as directed by CDPH), to an Individual, in accordance with 45 CFR section 164.524. Designated Record Set means the group of records maintained for CDPH that includes medical, dental and billing records about individuals; enrollment, payment, claims adjudication, and case or medical management systems maintained for CDPH health plans; or those records used to make decisions about individuals on behalf of CDPH. Business Associate shall use the forms and processes developed by CDPH for this purpose and shall respond to requests for access to records transmitted by CDPH within fifteen (15) calendar days of receipt of the request by producing the records or verifying that there are none.

Exhibit E**HIPAA Business Associate Addendum**

2. If Business Associate maintains an Electronic Health Record with PHI, and an individual requests a copy of such information in an electronic format, Business Associate shall provide such information in an electronic format to enable CDPH to fulfill its obligations under the HITECH Act, including but not limited to, 42 U.S.C. section 17935(e).
3. If Business Associate receives data from CDPH that was provided to CDPH by the Social Security Administration, upon request by CDPH, Business Associate shall provide CDPH with a list of all employees, contractors and agents who have access to the Social Security data, including employees, contractors and agents of its subcontractors and agents.

G. Amendment of PHI. To make any amendment(s) to PHI that CDPH directs or agrees to pursuant to 45 CFR section 164.526, in the time and manner designated by CDPH.

H. Internal Practices. To make Business Associate's internal practices, books and records relating to the use and disclosure of PHI received from CDPH, or created or received by Business Associate on behalf of CDPH, available to CDPH or to the Secretary in a time and manner designated by CDPH or by the Secretary, for purposes of determining CDPH's compliance with the HIPAA regulations. If any information needed for this purpose is in the exclusive possession of any other entity or person and the other entity or person fails or refuses to furnish the information to Business Associate, Business Associate shall so certify to CDPH and shall set forth the efforts it made to obtain the information.

I. Documentation of Disclosures. To document and make available to CDPH or (at the direction of CDPH) to an Individual such disclosures of PHI, and information related to such disclosures, necessary to respond to a proper request by the subject Individual for an accounting of disclosures of PHI, in accordance with the HITECH Act and its implementing regulations, including but not limited to 45 CFR part 164.528 and 42 U.S.C. section 17935(c). If Business Associate maintains electronic health records for CDPH as of January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after January 1, 2014. If Business Associate acquires electronic health records for CDPH after January 1, 2009, Business Associate must provide an accounting of disclosures, including those disclosures for treatment, payment or health care operations, effective with disclosures on or after the date the electronic health record is acquired, or on or after January 1, 2011, whichever date is later. The electronic accounting of disclosures shall be for disclosures during the three years prior to the request for an accounting.

J. Breaches and Security Incidents. During the term of the Agreement, Business Associate agrees to implement reasonable systems for the discovery and prompt reporting of any breach or security incident, and to take the following steps:

1. **Notice to CDPH.** (1) To notify CDPH **immediately by telephone call plus email or fax** upon the discovery of a breach of unsecured PHI or PI in electronic media or in any other media if the PHI or PI was, or is reasonably believed to have been, accessed or acquired by an unauthorized person, or upon the discovery of a suspected security incident that involves data provided to CDPH by the Social Security Administration. (2) To notify CDPH **within 24 hours by email or fax** of the discovery of any suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI in violation of the Agreement and this Addendum, or potential loss of confidential data affecting the Agreement. A breach shall be treated as discovered by Business Associate as of the first day on which the breach is known, or by exercising reasonable diligence would have been known, to any person (other than the person committing the breach) who is an employee, officer or other agent of Business Associate.

Exhibit E**HIPAA Business Associate Addendum**

Notice shall be provided to the CDPH Program Contract Manager, the CDPH Privacy Officer and the CDPH Information Security Officer. If the incident occurs after business hours or on a weekend or holiday and involves electronic PHI, notice shall be provided by calling the CDPH ITSD Service Desk. Notice shall be made using the "CDPH Privacy Incident Report" form, including all information known at the time. Business Associate shall use the most current version of this form, which is posted on the CDPH Privacy Office website (www.CDPH.ca.gov).

Upon discovery of a breach or suspected security incident, intrusion or unauthorized access, use or disclosure of PHI or PI, Business Associate shall take:

- a. Prompt corrective action to mitigate any risks or damages involved with the breach and to protect the operating environment; and
 - b. Any action pertaining to such unauthorized disclosure required by applicable Federal and State laws and regulations.
2. **Investigation and Investigation Report.** To immediately investigate such security incident, breach, or unauthorized access, use or disclosure of PHI or PI. Business Associate shall cooperate in good faith with CDPH in the investigation of any Breach or Security Incident. CDPH preserves the right to participate in the investigation of a security incident involving its data or conduct its own independent investigation, and Business Associate shall cooperate fully in such investigations. Within 72 hours of the discovery, Business Associate shall submit an updated "CDPH Privacy Incident Report" containing the information marked with an asterisk and all other applicable information listed on the form, to the extent known at that time, to the CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer.
3. **Complete Report.** To provide a complete report of the investigation to the CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer within ten (10) working days of the discovery of the breach or unauthorized use or disclosure. The report shall be submitted on the "CDPH Privacy Incident Report" form and shall include an assessment of all known factors relevant to a determination of whether a breach occurred under applicable provisions of HIPAA, the HITECH Act, the HIPAA regulations and/or state law. The report shall also include a full, detailed corrective action plan, including information on measures that were taken to halt and/or contain the improper use or disclosure. If CDPH requests information in addition to that listed on the "CDPH Privacy Incident Report" form, Business Associate shall make reasonable efforts to provide CDPH with such information. If necessary, a Supplemental Report may be used to submit revised or additional information after the completed report is submitted, by submitting the revised or additional information on an updated "CDPH Privacy Incident Report" form. CDPH will review and approve the determination of whether a breach occurred and individual notifications are required, and the corrective action plan.
4. **Notification of Individuals.** If the cause of a breach of PHI or PI is attributable to Business Associate or its subcontractors, agents or vendors, Business Associate shall notify individuals of the breach or unauthorized use or disclosure when notification is required under state or federal law and shall pay any costs of such notifications, as well as any costs associated with the breach. The notifications shall comply with the requirements set forth in California Civil Code section 1798.29 and 42 U.S.C. section 17932 and its implementing regulations, including, but not limited to, the requirement that the notifications be made without unreasonable delay and in no event later than 60 calendar days. The CDPH Program Contract Manager, the CDPH Privacy Officer, and the CDPH Information Security Officer shall approve the time, manner and content of any such notifications and their review and approval must be obtained before the notifications are made.

Exhibit E**HIPAA Business Associate Addendum**

5. **Responsibility for Reporting of Breaches.** If the cause of a breach of PHI or PI is attributable to Business Associate or its agents, subcontractors or vendors, Business Associate is responsible for all required reporting of the breach as specified in 42 U.S.C. section 17932 and its implementing regulations, including notification to media outlets and to the Secretary. If a breach of unsecured PHI involves more than 500 residents of the State of California or its jurisdiction, Business Associate shall notify the Secretary of the breach immediately upon discovery of the breach. If Business Associate has reason to believe that duplicate reporting of the same breach or incident may occur because its subcontractors, agents or vendors may report the breach or incident to CDPH in addition to Business Associate, Business Associate shall notify CDPH, and CDPH and Business Associate may take appropriate action to prevent duplicate reporting. The breach reporting requirements of this paragraph are in addition to the reporting requirements set forth in subsection 1, above.
6. **CDPH Contact Information.** To direct communications to the above referenced CDPH staff, the Business Associate shall initiate contact as indicated herein. CDPH reserves the right to make changes to the contact information below by giving written notice to the Business Associate. Said changes shall not require an amendment to this Addendum or the Agreement to which it is incorporated.

CDPH Program Contract Manager	CDPH Privacy Officer	CDPH Information Security Officer
See the Scope of Work exhibit for Program Contract Manager information	Privacy Officer Privacy Office, c/o Office of Legal Services California Department of Public Health 1415 L Street, 5 th Floor Sacramento, CA 95814 Email: privacy@cdph.ca.gov Telephone: (877) 421-9634	Chief Information Security Officer Information Security Office California Department of Public Health P.O. Box 997413, MS 6302 Sacramento, CA 95899-7413 Email: cdphiso@cdph.ca.gov Telephone: IT Service Desk (916) 440-7000 or (800) 579-0874

- K. **Due Diligence.** Business Associate shall exercise due diligence and shall take reasonable steps to ensure that it remains in compliance with this Addendum and is in compliance with applicable provisions of HIPAA, the HITECH Act and the HIPAA regulations, and that its agents, subcontractors and vendors are in compliance with their obligations as required by this Addendum.
- L. **Sanctions and/or Penalties.** Business Associate understands that a failure to comply with the provisions of HIPAA, the HITECH Act and the HIPAA regulations that are applicable to Business Associate may result in the imposition of sanctions and/or penalties on Business Associate under HIPAA, the HITECH Act and the HIPAA regulations.

IV. Obligations of CDPH

CDPH agrees to:

- A. **Notice of Privacy Practices.** Provide Business Associate with the Notice of Privacy Practices that CDPH produces in accordance with 45 CFR section 164.520, as well as any changes to such notice.

Exhibit E**HIPAA Business Associate Addendum**

- B. *Permission by Individuals for Use and Disclosure of PHI.*** Provide Business Associate with any changes in, or revocation of, permission by an Individual to use or disclose PHI, if such changes affect Business Associate's permitted or required uses and disclosures.
- C. *Notification of Restrictions.*** Notify Business Associate of any restriction to the use or disclosure of PHI that CDPH has agreed to in accordance with 45 CFR section 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.
- D. *Requests Conflicting with HIPAA Rules.*** Not request Business Associate use or disclose PHI in any manner that would not be permissible under the HIPAA regulations if done by CDPH.

V. Audits, Inspection and Enforcement

- A.** From time to time, CDPH may inspect the facilities, systems, books and records of Business Associate to monitor compliance with the Agreement and this Addendum. Business Associate shall promptly remedy any violation of any provision of this Addendum and shall certify the same to the CDPH Privacy Officer in writing. The fact that CDPH inspects, or fails to inspect, or has the right to inspect, Business Associate's facilities, systems and procedures does not relieve Business Associate of its responsibility to comply with this Addendum, nor does CDPH's:
1. Failure to detect; or
 2. Detection, but failure to notify Business Associate or require Business Associate's remediation of any unsatisfactory practices constitute acceptance of such practice or a waiver of CDPH's enforcement rights under the Agreement and this Addendum.
- B.** If Business Associate is the subject of an audit, compliance review, or complaint investigation by the Secretary or the Office of Civil Rights, U.S. Department of Health and Human Services, that is related to the performance of its obligations pursuant to this HIPAA Business Associate Addendum, Business Associate shall notify CDPH and provide CDPH with a copy of any PHI or PI that Business Associate provides to the Secretary or the Office of Civil Rights concurrently with providing such PHI or PI to the Secretary. Business Associate is responsible for any civil penalties assessed due to an audit or investigation of Business Associate, in accordance with 42 U.S.C. section 17934(c).

VI. *Requests for CDPH PHI or PI by Third Parties.* Business Associate and its employees, agents, or subcontractors shall promptly transmit to the CDPH Program Contract Manager all requests for disclosure of any CDPH PHI or PI requested by third parties to the agreement between Business Associate and CDPH (except from an Individual for an accounting of disclosures of the individual's personal information pursuant to applicable state or federal law), including but not limited to, requests under the California Public Records Act, subpoenas, or court orders, unless prohibited from doing so by applicable state or federal law.

VII. Termination

- A. *Term.*** The Term of this Addendum shall commence as of the effective date of this Addendum and shall extend beyond the termination of the Agreement and shall terminate when all the PHI provided by CDPH to Business Associate, or created or received by Business Associate on behalf of CDPH, is destroyed or returned to CDPH, in accordance with 45 CFR part 164.504(e)(2)(ii)(J).
- B. *Termination for Cause by CDPH.*** In accordance with 45 CFR part 164.504(e)(1)(ii), upon CDPH's knowledge of a material breach or violation of this Addendum by Business Associate, CDPH shall:

Exhibit E**HIPAA Business Associate Addendum**

1. Provide an opportunity for Business Associate to cure the breach or end the violation and terminate the Agreement if Business Associate does not cure the breach or end the violation within the time specified by CDPH; or
2. Immediately terminate the Agreement if Business Associate has breached a material term of this Addendum and cure is not possible.

C. *Termination for Cause by Business Associate.* In accordance with 42 U.S.C. section 17934(b) of the HITECH Act and to the extent required by the HIPAA regulations, if Business Associate knows of a material breach or violation by CDPH of this Addendum, it shall take the following steps:

1. Provide an opportunity for CDPH to cure the breach or end the violation and terminate the Agreement if CDPH does not cure the breach or end the violation within the time specified by Business Associate; or
2. Immediately terminate the Agreement if CDPH has breached a material term of the Addendum and cure is not possible.

D. *Judicial or Administrative Proceedings.* Business Associate will notify CDPH if it is named as a defendant in a criminal proceeding for a violation of HIPAA. CDPH may terminate the Agreement if Business Associate is found guilty of a criminal violation of HIPAA. CDPH may terminate the Agreement if a finding or stipulation that Business Associate has violated any standard or requirement of HIPAA, or other security or privacy laws is made in any administrative or civil proceeding in which Business Associate is a party or has been joined.

E. *Effect of Termination.* Upon termination or expiration of the Agreement for any reason, Business Associate shall return or destroy all PHI received from CDPH (or created or received by Business Associate on behalf of CDPH) that Business Associate still maintains in any form, and shall retain no copies of such PHI, unless otherwise required by applicable law or regulation. If return or destruction is not feasible or prohibited by applicable law or regulation, Business Associate shall notify CDPH of the conditions that make the return or destruction infeasible or contrary to applicable law or regulation, and CDPH and Business Associate shall determine the terms and conditions under which Business Associate may retain the PHI. Business Associate shall continue to extend the protections of this Addendum to such PHI, and shall limit further use of such PHI to those purposes that make the return or destruction of such PHI infeasible. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate.

VIII. Miscellaneous Provisions

A. *Disclaimer.* CDPH makes no warranty or representation that compliance by Business Associate with this Addendum, HIPAA or the HIPAA regulations will be adequate or satisfactory for Business Associate's own purposes or that any information in Business Associate's possession or control, or transmitted or received by Business Associate, is or will be secure from unauthorized use or disclosure. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

B. *Amendment.* The parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Addendum may be required to provide for procedures to ensure compliance with such developments. The parties specifically agree to take such action as is necessary to implement the standards and requirements of HIPAA, the HITECH Act, the HIPAA regulations and other applicable laws relating to the security or privacy of PHI. Upon CDPH's request, Business Associate agrees to promptly enter into negotiations with CDPH concerning an amendment to this Addendum embodying written assurances consistent with the standards and

Exhibit E**HIPAA Business Associate Addendum**

requirements of HIPAA, the HITECH Act, the HIPAA regulations or other applicable laws. CDPH may terminate the Agreement upon thirty (30) days written notice in the event:

1. Business Associate does not promptly enter into negotiations to amend this Addendum when requested by CDPH pursuant to this Section; or
2. Business Associate does not enter into an amendment providing assurances regarding the safeguarding of PHI that CDPH in its sole discretion, deems sufficient to satisfy the standards and requirements of HIPAA and the HIPAA regulations.

- C. *Assistance in Litigation or Administrative Proceedings.*** Business Associate shall make itself and any subcontractors, employees or agents assisting Business Associate in the performance of its obligations under the Agreement, available to CDPH at no cost to CDPH to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against CDPH, its directors, officers or employees based upon claimed violation of HIPAA, the HIPAA regulations or other laws relating to security and privacy, which involves inactions or actions by Business Associate, except where Business Associate or its subcontractor, employee or agent is a named adverse party.
- D. *No Third-Party Beneficiaries.*** Nothing express or implied in the terms and conditions of this Addendum is intended to confer, nor shall anything herein confer, upon any person other than CDPH or Business Associate and their respective successors or assignees, any rights, remedies, obligations or liabilities whatsoever.
- E. *Interpretation.*** The terms and conditions in this Addendum shall be interpreted as broadly as necessary to implement and comply with HIPAA, the HITECH Act, the HIPAA regulations and applicable state laws. The parties agree that any ambiguity in the terms and conditions of this Addendum shall be resolved in favor of a meaning that complies and is consistent with HIPAA, the HITECH Act and the HIPAA regulations.
- F. *Regulatory References.*** A reference in the terms and conditions of this Addendum to a section in the HIPAA regulations means the section as in effect or as amended.
- G. *Survival.*** The respective rights and obligations of Business Associate under Section VII.E of this Addendum shall survive the termination or expiration of the Agreement.
- H. *No Waiver of Obligations.*** No change, waiver or discharge of any liability or obligation hereunder on any one or more occasions shall be deemed a waiver of performance of any continuing or other obligation, or shall prohibit enforcement of any obligation, on any other occasion.

Exhibit E**HIPAA Business Associate Addendum****Attachment A****Business Associate Data Security Requirements****I. Personnel Controls**

- A. *Employee Training.*** All of the Business Associate's workforce members (workforce member) who assist in the performance of functions or activities on behalf of CDPH, or access or disclose CDPH PHI or PI must complete information privacy and security training, at least annually, at Business Associate's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the workforce member's name and the date on which the training was completed. These certifications must be retained for a period of six (6) years following contract termination. Business Associate shall provide CDPH with its employee's certifications within five (5) business days of a request by CDPH for the employee's certifications.
- B. *Employee Discipline.*** Appropriate sanctions must be applied against workforce members who fail to comply with privacy policies and procedures or any provisions of these requirements, including termination of employment where appropriate.
- C. *Confidentiality Statement.*** All persons that will be working with CDPH PHI or PI must sign a confidentiality statement that includes, at a minimum, General Use, Security and Privacy Safeguards, Unacceptable Use, and Enforcement Policies. The statement must be signed by the workforce member prior to access to CDPH PHI or PI. The statement must be renewed annually. Business Associate shall retain each workforce member's written confidentiality statement for CDPH inspection for a period of six (6) years following contract termination.
- D. *Workforce Member Assessment.*** Before a member of the Contractor's workforce may access CDPH PHI or PI, Contractor must ensure that all workforce members that will have access to CDPH PCI have been assessed to assure that there is no indication that the workforce member may present a risk to the security or integrity of CDPH PHI or PI. Contractor shall retain each workforce member's assessment documentation, whether in physical or electronic format, for a period of three (3) years following contract termination.

II. Technical Security Controls

- A. *Workstation/Laptop encryption.*** All workstations and laptops that process and/or store CDPH PHI or PI must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as Advanced Encryption Standard (AES). The encryption solution must be full disk unless approved by the CDPH Information Security Office.
- B. *Server Security.*** Servers containing unencrypted CDPH PHI or PI must have sufficient administrative, physical, and technical controls in place to protect that data, based upon a risk assessment/system security review.
- C. *Minimum Necessary.*** Only the minimum necessary amount of CDPH PHI or PI required to perform necessary business functions may be copied, downloaded, or exported.
- D. *Removable media devices.*** All electronic files that contain CDPH PHI or PI data must be encrypted when stored on any removable media or portable device (i.e. USB thumb drives, floppies, CD/DVD, Blackberry, backup tapes etc.). Encryption must be a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES.

Exhibit E**HIPAA Business Associate Addendum**

- E. *Antivirus software.*** All workstations, laptops and other systems that process and/or store CDPH PHI or PI must install and actively use comprehensive anti-virus software solution with automatic updates scheduled at least daily.
- F. *Patch Management.*** All workstations, laptops and other systems that process and/or store CDPH PHI or PI must have critical security patches applied, with system reboot if necessary. There must be a documented patch management process which determines installation timeframe based on risk assessment and vendor recommendations. At a maximum, all applicable patches must be installed within thirty (30) days of vendor release.
- G. *User IDs and Password Controls.*** All users must be issued a unique user name for accessing CDPH PHI or PI. Username must be promptly disabled, deleted, or the password changed upon the transfer or termination of an employee with knowledge of the password, at maximum within 24 hours. Passwords are not to be shared. Passwords must be at least eight characters and must be a non-dictionary word. Passwords must not be stored in readable format on the computer. Passwords must be changed every ninety (90) days, preferably every sixty (60) days. Passwords must be changed if revealed or compromised. Passwords must be composed of characters from at least three of the following four groups from the standard keyboard:
- Upper case letters (A-Z)
 - Lower case letters (a-z)
 - Arabic numerals (0-9)
 - Non-alphanumeric characters (punctuation symbols)
- H. *Data Destruction.*** When no longer needed, all CDPH PHI or PI must be wiped using the Gutmann or US Department of Defense (DoD) 5220.22-M (7 Pass) standard, or by degaussing. Media may also be physically destroyed in accordance with NIST Special Publication 800-88. Other methods require prior written permission of the CDPH Information Security Office.
- I. *System Timeout.*** The system providing access to CDPH PHI or PI must provide an automatic timeout, requiring re-authentication of the user session after no more than 20 minutes of inactivity.
- J. *Warning Banners.*** All systems providing access to CDPH PHI or PI must display a warning banner stating that data is confidential, systems are logged, and system use is for business purposes only by authorized users. User must be directed to log off the system if they do not agree with these requirements.
- K. *System Logging.*** The system must maintain an automated audit trail which can identify the user or system process which initiates a request for CDPH PHI or PI, or which alters CDPH PHI or PI. The audit trail must be date and time stamped, must log both successful and failed accesses, must be read only, and must be restricted to authorized users. If CDPH PHI or PI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least three (3) years after occurrence.
- L. *Access Controls.*** The system providing access to CDPH PHI or PI must use role based access controls for all user authentications, enforcing the principle of least privilege.

Exhibit E**HIPAA Business Associate Addendum**

- M. *Transmission encryption.*** All data transmissions of CDPH PHI or PI outside the secure internal network must be encrypted using a FIPS 140-2 certified algorithm which is 128bit or higher, such as AES. Encryption can be end to end at the network level, or the data files containing PHI can be encrypted. This requirement pertains to any type of PHI or PI in motion such as website access, file transfer, and E-Mail.
- N. *Intrusion Detection.*** All systems involved in accessing, holding, transporting, and protecting CDPH PHI or PI that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

III. Audit Controls

- A. *System Security Review.*** All systems processing and/or storing CDPH PHI or PI must have at least an annual system risk assessment/security review which provides assurance that administrative, physical, and technical controls are functioning effectively and providing adequate levels of protection. Reviews should include vulnerability scanning tools.
- B. *Log Reviews.*** All systems processing and/or storing CDPH PHI or PI must have a routine procedure in place to review system logs for unauthorized access.
- C. *Change Control.*** All systems processing and/or storing CDPH PHI or PI must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

IV. Business Continuity / Disaster Recovery Controls

- A. *Emergency Mode Operation Plan.*** Business Associate must establish a documented plan to enable continuation of critical business processes and protection of the security of electronic CDPH PHI or PI in the event of an emergency. Emergency means any circumstance or situation that causes normal computer operations to become unavailable for use in performing the work required under the Agreement for more than 24 hours.
- B. *Data Backup Plan.*** Business Associate must have established documented procedures to backup CDPH PHI to maintain retrievable exact copies of CDPH PHI or PI. The plan must include a regular schedule for making backups, storing backups offsite, an inventory of backup media, and an estimate of the amount of time needed to restore CDPH PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of CDPH data.

V. Paper Document Controls

- A. *Supervision of Data.*** CDPH PHI or PI in paper form shall not be left unattended at any time, unless it is locked in a file cabinet, file room, desk or office. Unattended means that information is not being observed by a workforce member authorized to access the information. CDPH PHI or PI in paper form shall not be left unattended at any time in vehicles or planes and shall not be checked in baggage on commercial airplanes.
- B. *Escorting Visitors.*** Visitors to areas where CDPH PHI or PI is contained shall be escorted and CDPH PHI or PI shall be kept out of sight while visitors are in the area.
- C. *Confidential Destruction.*** CDPH PHI or PI must be disposed of through confidential means, such as cross cut shredding and pulverizing.

Exhibit E

HIPAA Business Associate Addendum

- D. *Removal of Data.*** CDPH PHI or PI must not be removed from the premises of the Business Associate except with express written permission of CDPH.
- E. *Faxing.*** Faxes containing CDPH PHI or PI shall not be left unattended and fax machines shall be in secure areas. Faxes shall contain a confidentiality statement notifying persons receiving faxes in error to destroy them. Fax numbers shall be verified with the intended recipient before sending the fax.
- F. *Mailing.*** Mailings of CDPH PHI or PI shall be sealed and secured from damage or inappropriate viewing of PHI or PI to the extent possible. Mailings which include 500 or more individually identifiable records of CDPH PHI or PI in a single package shall be sent using a tracked mailing method which includes verification of delivery and receipt, unless the prior written permission of CDPH to use another method is obtained.

Exhibit F

Additional Legal Terms Required for FEMA Reimbursement

A. Early Termination

Termination for convenience and for cause language is already incorporated in Exhibit A, Section 8.

B. Remedies

In the event of a breach by the Contractor of any term or provision of this Agreement, CDPH shall have the right to pursue all available remedies at law or equity, including recovery of damages and specific performance of this Agreement. The parties hereto agree that monetary damages would not provide adequate compensation for any losses incurred by reason of a breach by it of any of the provisions of this Agreement and hereby further agrees that, in the event of any action for specific performance in respect of such breach, it shall waive the defense that a remedy at law would be adequate. Except as expressly provided elsewhere in this Agreement, each party's rights and remedies under this Agreement are cumulative and in addition to, not exclusive of or in substitution for, any rights or remedies otherwise available to that party.

C. Compliance with the Contract Work Hours and Safety Standards Act (where applicable)

1. Overtime requirements. No contractor or subcontractor contracting for any part of the contract work which may require or involve the employment of laborers or mechanics shall require or permit any such laborer or mechanic in any workweek in which he or she is employed on such work to work in excess of forty hours in such workweek unless such laborer or mechanic receives compensation at a rate not less than one and one-half times the basic rate of pay for all hours worked in excess of forty hours in such workweek.

2. Violation; liability for unpaid wages; liquidated damages. In the event of any violation of the clause set forth in paragraph C.1 of this section the contractor and any subcontractor responsible therefor shall be liable for the unpaid wages. In addition, such contractor and subcontractor shall be liable to the United States (in the case of work done under contract for the District of Columbia or a territory, to such District or to such territory), for liquidated damages. Such liquidated damages shall be computed with respect to each individual laborer or mechanic, including watchmen and guards, employed in violation of the clause set forth in paragraph C.1 of this section, in the sum of \$27 for each calendar day on which such individual was required or permitted to work in excess of the standard workweek of forty hours without payment of the overtime wages required by the clause set forth in paragraph C.1 of this section.

3. Withholding for unpaid wages and liquidated damages. The Governor's Office of Emergency Services shall upon its own action or upon written request of an authorized representative of the Department of Labor withhold or cause to be withheld, from any moneys payable on account of work performed by the contractor or subcontractor under any such contract or any other Federal contract with the same prime contractor, or any other federally-assisted contract subject to the Contract Work Hours and Safety Standards Act, which is held by the same prime contractor, such sums as may be determined to be necessary to satisfy any liabilities of such contractor or subcontractor for unpaid wages and liquidated damages as provided in the clause set forth in paragraph C.2 of this section.

4. Subcontracts. The Contractor or subcontractor shall insert in any subcontracts the clauses set forth in paragraph C.1 through C.4 of this section and also a clause requiring the subcontractors to include these clauses in any lower tier subcontracts. The prime contractor shall be responsible for compliance by any subcontractor or lower tier subcontractor with the clauses set forth in paragraphs C.1 through C.4 of this section.

D. Clean Air Act

1. The Contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Clean Air Act, as amended, 42 U.S.C. Section 7401 et seq.

2. The Contractor agrees to report each violation to CDPH and understands and agrees that CDPH will, in turn, report each violation as required to assure notification to the California Air Resources Board, Federal Emergency Management Agency (FEMA), and the appropriate Environmental Protection Agency Regional Office.

3. The Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

E. Federal Water Pollution Control Act

1. The Contractor agrees to comply with all applicable standards, orders, or regulations issued pursuant to the Federal Water Pollution Control Act, as amended, 33 U.S.C. Sections 1251 et seq.

2. The Contractor agrees to report each violation to the State Water Resources Control Board and understands and agrees that the State Water Resources Control Board will, in turn, report each violation as required to assure notification to the Federal Emergency Management Agency (FEMA), and the appropriate Environmental Protection Agency Regional Office.

3. The Contractor agrees to include these requirements in each subcontract exceeding \$150,000 financed in whole or in part with Federal assistance provided by FEMA.

F. Debarment and Suspension Clause

1. This Agreement is a covered transaction for purposes of 2 C.F.R. pt. 180 and 2 C.F.R. pt. 3000. As such the Contractor is required to verify that none of the Contractor, its principals (defined at 2 C.F.R. § 180.995), or its affiliates (defined at 2 C.F.R. § 180.905) are excluded (defined at 2 C.F.R. § 180.940) or disqualified (defined at 2 C.F.R. § 180.935).

2. The Contractor must comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C and must include a requirement to comply with these regulations in any lower tier covered transaction it enters into.

3. This certification is a material representation of fact relied upon by the State. If it is later determined that the Contractor did not comply with 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C, in addition to remedies available to the State, the Federal Government may pursue available remedies, including but not limited to suspension and/or debarment.

4. The bidder or proposer agrees to comply with the requirements of 2 C.F.R. pt. 180, subpart C and 2 C.F.R. pt. 3000, subpart C while this offer is valid and throughout the period of any contract that may arise from this offer. The bidder or proposer further agrees to include a provision requiring such compliance in its lower tier covered transactions.

G. Byrd Anti- Lobbying Amendment, 31 U.S.C. § 1352 (as amended)

Contractors who apply or bid for an award of \$100,000 or more shall file the required certification. Each tier certifies to the tier above that it will not and has not used Federal appropriated funds to pay any person or organization for influencing or attempting to influence an officer or employee of any agency, a member of Congress, officer or employee of Congress, or an employee of a member of Congress in connection with obtaining any Federal contract, grant, or any other award covered by 31 U.S.C. § 1352. Each tier shall also disclose any lobbying with non-Federal funds that takes place in connection with obtaining any Federal award. Such disclosures are forwarded from tier to tier up to the recipient who in turn will forward the certification(s) to the state.

APPENDIX A, 44 C.F.R. PART 18- CERTIFICATION REGARDING LOBBYING

The undersigned [Contractor] certifies, to the best of his or her knowledge, that:

A. No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, 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.

B. 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 this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

C. The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31, U.S.C. § 1352 (as amended by the Lobbying Disclosure Act of 1995). Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

The Contractor certifies or affirms the truthfulness and accuracy of each statement of its certification and disclosure, if any. In addition, the Contractor understands and agrees that the provisions of 31 U.S.C. § 3801 et seq., apply to this certification and disclosure, if any.

CONTRACTOR

By _____
Date _____

H. Procurement of Recovered Materials

1. In the performance of this Agreement, the Contractor shall make maximum use of products containing recovered materials that are EPA-designated items unless the product cannot be acquired:

- i. Competitively within a timeframe providing for compliance with the contract performance schedule;
- ii. Meeting contract performance requirements; or
- iii. At a reasonable price.

2. Information about this requirement, along with the list of EPA-designated items, is available at EPA's Comprehensive Procurement Guidelines web site, <https://www.epa.gov/smm/comprehensive-procurement-guideline-cpg-program>

3. The Contractor also agrees to comply with all other applicable requirements of Section 6002 of the Solid Waste Disposal Act.

I. Access to Records

The following access to records requirements apply to this Agreement:

i. The Contractor agrees to provide the state, the FEMA Administrator, the Comptroller General of the United States, or any of their authorized representatives access to any books, documents, papers, and records of the Contractor which are directly pertinent to this Agreement for the purposes of making audits, examinations, excerpts, and transcriptions.

ii. The Contractor agrees to permit any of the foregoing parties to reproduce by any means whatsoever or to copy excerpts and transcriptions as reasonably needed.

iii. The Contractor agrees to provide the FEMA Administrator or his or her authorized representatives access to construction or other work sites pertaining to the work being completed under the contract.

iv. In compliance with the Disaster Recovery Act of 2018, the State and the Contractor acknowledge and agree that no language in this Agreement is intended to prohibit audits or internal reviews by the FEMA Administrator or the Comptroller General of the United States.

J. Changes and Modifications

Any cost of a change, modification, change order, or constructive change to the Agreement must be allowable and allocable within the scope of this Agreement, and reasonable for the completion of project scope. Changes can be made by either party to alter the method, price, or schedule of the work without breaching the Agreement if both parties approve in writing.

K. Department of Homeland Security Seal, Logo, Flags

The Contractor shall not use the DHS seal(s), logos, crests, or reproductions of flags or likenesses of DHS agency officials without specific FEMA pre-approval.

L. Compliance with Federal Law, Regulations, and Executive Orders

This is an acknowledgement that FEMA financial assistance will be used to fund all or a portion of the contract. The Contractor will comply with all applicable Federal law, regulations, executive orders, FEMA policies, procedures, and directives.

M. No Obligation by Federal Government

The Federal Government is not a party to this Agreement and is not subject to any obligations or liabilities to the non-Federal entity, contractor, or any other party pertaining to any matter resulting from the Agreement.

N. Program Fraud and False or Fraudulent Statements or Related Acts

The Contractor acknowledges that 31 U.S.C. Chapter 38 (Administrative Remedies for False Claims and Statements) applies to the Contractor's actions pertaining to this Agreement.