



CONTRACT NO. MA-042-22011297

FOR

**DIAGNOSTIC TESTING AND WHOLE
GENOME SEQUENCING SERVICES**

BETWEEN

**COUNTY OF ORANGE
(HEALTH CARE AGENCY)**

AND

FULGENT THERAPEUTICS LLC

Contract No. MA-042-22011297
FOR
Diagnostic Testing and Whole Genome Sequencing Services
WITH
Fulgent Therapeutics LLC

This Contract Number MA-042-22011297 (“Contract”) is made and entered into this 23rd day of March, 2022 (“Effective Date”) between Fulgent Therapeutics LLC (“Contractor”), with a place of business at 4978 Anita Ave., Temple City, CA 91780, and County of Orange, a political subdivision of the State of California (“County”), through its Health Care Agency with a place of business at 405 W. 5th St., Ste. 600, Santa Ana, CA 92701. Contractor and County may sometimes be referred to hereinafter individually as “Party” or collectively as “Parties”.

ATTACHMENTS

This Contract is comprised of this document and the following Attachments, which are incorporated by reference into this Contract and constitute a part of this Contract:

Attachment A – Scope of Work/Pricing
Attachment B – Compensation and Invoicing
Attachment C – Business Associate Contract
Attachment D – Personal Information Privacy and Security Contract

RECITALS

WHEREAS, Contractor and County are entering into this Contract for Diagnostic Testing and Whole Genome Sequencing Services under a firm fixed fee Contract; and

WHEREAS, Contractor agrees to provide Diagnostic Testing and Whole Genome Sequencing Services to County as further set forth in the Scope of Work/Pricing, attached hereto as Attachment A; and

WHEREAS, County agrees to pay Contractor based on the schedule of fees set forth in Compensation and Invoicing, attached hereto as Attachment B; and

NOW, THEREFORE, the Parties mutually agree as follows:

DEFINITIONS

DPA means the Deputy Purchasing Agent assigned to this Contract.

ARTICLES

General Terms and Conditions:

- A. **Governing Law and Venue:** This Contract has been negotiated and executed in the state of California and shall be governed by and construed under the laws of the state of California. In the event of any legal action to enforce or interpret this Contract, the sole and exclusive venue shall be a court of competent jurisdiction located in Orange County, California, and the parties hereto agree to and do hereby submit to the jurisdiction of such court, notwithstanding Code of Civil Procedure Section 394. Furthermore, the parties specifically agree to waive any and all rights to request that an action be transferred for adjudication to another county.
- B. **Entire Contract:** This Contract contains the entire contract between the parties with respect to the matters herein, and there are no restrictions, promises, warranties or undertakings other than those set forth herein or referred to herein. Electronic acceptance of any additional terms, conditions or supplemental contracts by any County employee or agent, including but not limited to installers of software, shall not be valid or binding on County unless accepted in writing by County.
- C. **Amendments:** No alteration or variation of the terms of this Contract shall be valid unless made in writing and signed by the parties; no oral understanding or agreement not incorporated herein shall be binding on either of the parties; and no exceptions, alternatives, substitutes or revisions are valid or binding on County unless authorized by County in writing.
- D. **Taxes:** Unless otherwise provided herein or by law, the price stated in Attachment B does not include California state sales or use tax. Out-of-state Contractors must indicate California Board of Equalization permit number and sales permit number on invoices, if California sales tax is added and collectable. If no permit numbers are shown, sales tax will be deducted from payment. The Auditor-Controller will then pay use tax directly to the State of California in lieu of payment of sales tax to Contractor.
- E. **Delivery:** Time of delivery of goods or services is of the essence in this Contract. County reserves the right to refuse any goods or services and to cancel all or any part of the goods not conforming to applicable specifications, drawings, samples or descriptions or services that do not conform to the prescribed scope of work. Acceptance of any part of the order for goods shall not bind County to accept future shipments nor deprive it of the right to return goods already accepted at Contractor's expense. Over shipments and under shipments of goods shall be only as agreed to in writing by County. Delivery shall not be deemed to be complete until all goods or services have actually been received and accepted in writing by County.
- F. **Acceptance Payment:** Unless otherwise agreed to in writing by County, 1) acceptance shall not be deemed complete unless in writing and until all the goods/services have actually been received, inspected, and tested to the satisfaction of County, and 2) payment shall be made in arrears after satisfactory acceptance in accordance with Attachment B.
- G. **Warranty:** Contractor expressly warrants that the goods covered by this Contract are 1) free of liens or encumbrances, 2) merchantable and good for the ordinary purposes for

which they are used, and 3) fit for the particular purpose for which they are intended. Contractor agrees to indemnify, defend and hold County and County Indemnitees, as more fully described in Paragraph Z, harmless from liability, loss, damage and expense, including reasonable counsel fees, incurred or sustained by County by reason of the failure of the goods/services to conform to such warranties, faulty work performance, negligent or unlawful acts, and non-compliance with any applicable state or federal codes, ordinances, orders, or statutes, including the Occupational Safety and Health Act (OSHA) and the California Industrial Safety Act. Such remedies are in addition to any other remedies provided by law.

- H. **Patent/Copyright Materials/Proprietary Infringement:** Unless otherwise expressly provided in this Contract, Contractor is solely responsible for clearing the right to use any patented or copyrighted materials in the performance of this Contract. Contractor warrants that any software as modified through services provided hereunder will not infringe upon or violate any patent, proprietary right, or trade secret right of any third party. Contractor agrees that, in accordance with the more specific requirement contained in Paragraph Z, it shall indemnify, defend and hold County and County Indemnitees harmless from any and all such claims and be responsible for payment of all costs, damages, penalties and expenses related to or arising from such claim(s), including, costs and expenses and attorney's fees.
- I. **Assignment:** The terms, covenants, and conditions contained herein shall apply to and bind the heirs, successors, executors, administrators and assigns of the parties. Furthermore, neither the performance of this Contract nor any portion thereof may be assigned by Contractor without the express prior written consent of County. Contractor must provide County no less than sixty (60) calendar days written notification of its intent to assign, sell, delegate or otherwise dispose of the rights and obligations of this Contract. Any attempt by Contractor to assign the performance or any portion thereof of this Contract without the express prior written consent of County shall be invalid and shall constitute a material breach of this Contract.
- J. **Non-Discrimination:** In the performance of this Contract, Contractor agrees that it will comply with the requirements of Section 1735 of the California Labor Code and not engage nor permit any subcontractors to engage in discrimination in employment of persons because of the race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, marital status, or sex of such persons. Contractor acknowledges that a violation of this provision shall subject Contractor to penalties pursuant to Section 1741 of the California Labor Code.
- K. **Termination:** In addition to any other remedies or rights it may have by law, County has the right to immediately terminate this Contract without penalty for cause or after thirty (30) calendar days' written notice without cause, unless otherwise specified. Cause is defined as including, but not limited to, any material breach of contract and any misrepresentation or fraud on the part of Contractor. County's exercise of its right to terminate the Contract shall relieve County of all further obligations.
- L. **Consent to Breach Not Waiver:** No term or provision of this Contract shall be deemed waived and no breach excused, unless such waiver or consent is in writing and signed by the party claimed to have waived or consented. Any consent by any party to, or waiver

of, a breach by the other, whether express or implied, shall not constitute consent to, waiver of, or excuse for any other different or subsequent breach.

- M. **Independent Contractor:** Contractor shall be considered an independent contractor and neither Contractor, its employees, nor anyone working under Contractor shall be considered an agent or an employee of County. Neither Contractor, its employees nor anyone working under Contractor shall qualify for workers' compensation or other fringe benefits of any kind through County.
- N. **Performance Warranty:** Contractor shall warrant all work under this Contract, taking necessary steps and precautions to perform the work to County's satisfaction. Contractor is responsible for the professional quality, technical assurance, timely completion and coordination of all documentation and other goods/services furnished by Contractor under this Contract. Contractor must perform all work diligently, carefully, and in a good and workmanlike manner; must furnish all necessary labor, supervision, machinery, equipment, materials, and supplies, shall at its sole expense obtain and maintain all permits and licenses required by public authorities, including those of County required in its governmental capacity, in connection with performance of the work. If permitted to subcontract, Contractor shall be fully responsible for all work performed by subcontractors.
- O. **Insurance Requirements:** Contractor must comply with the following insurance requirements if making the deliveries to the County of Orange. No insurance is required if a common carrier makes deliveries to the County of Orange.

Prior to the provision of services under this Contract, Contractor must purchase all required insurance at Contractor's expense, including all endorsements required herein, necessary to satisfy County that the insurance provisions of this Contract have been complied with. Contractor agrees to keep such insurance coverage, Certificates of Insurance, and endorsements on deposit with County during the entire term of this Contract. In addition, all subcontractors performing work on behalf of Contractor pursuant to this Contract must obtain insurance subject to the same terms and conditions as set forth herein for Contractor.

Contractor must ensure that all subcontractors performing work on behalf of Contractor pursuant to this Contract are covered under Contractor's insurance as an Additional Insured or maintain insurance subject to the same terms and conditions as set forth herein for Contractor. Contractor must not allow subcontractors to work if subcontractors have less than the level of coverage required by County from Contractor under this Contract. It is Contractor's obligation to provide notice of the insurance requirements to every subcontractor and to receive proof of insurance prior to allowing any subcontractor to begin work. Such proof of insurance must be maintained by Contractor through the entirety of this Contract for inspection by County representative(s) at any reasonable time.

All self-insured retentions (SIRs) shall be clearly stated on the Certificate of Insurance. Any SIR in an amount in excess of Fifty Thousand Dollars (\$50,000) must be specifically approved by County's Risk Manager, or designee, upon review of Contractor's current audited financial report. If Contractor's SIR is approved, Contractor, in addition to, and without limitation of, any other indemnity provision(s) in this Contract, agrees to all of the following:

1. In addition to the duty to indemnify and hold County harmless against any and all liability, claim, demand or suit resulting from Contractor's, its agents, employee's or subcontractor's performance of this Contract, Contractor shall defend County at its sole cost and expense with counsel approved by Board of Supervisors against same; and
2. Contractor's duty to defend, as stated above, shall be absolute and irrespective of any duty to indemnify or hold harmless; and
3. The provisions of California Civil Code Section 2860 shall apply to any and all actions to which the duty to defend stated above applies, and Contractor's SIR provision shall be interpreted as though Contractor was an insurer and County was the insured.

If Contractor fails to maintain insurance acceptable to County for the full term of this Contract, County may immediately terminate this Contract for cause pursuant to Paragraph K, Termination.

Qualified Insurer

The policy or policies of insurance must be issued by an insurer with a minimum rating of A- (Secure A.M. Best's Rating) and VIII (Financial Size Category as determined by the most current edition of the **Best's Key Rating Guide/Property-Casualty/United States or ambest.com**). It is preferred, but not mandatory, that the insurer be licensed to do business in the state of California (California Admitted Carrier).

If the insurance carrier does not have an A.M. Best Rating of A-/VIII, the CEO/Office of Risk Management retains the right to approve or reject a carrier after a review of the company's performance and financial ratings.

The policy or policies of insurance maintained by Contractor shall provide the minimum limits and coverage as set forth below:

<u>Coverage</u>	<u>Minimum Limits</u>
Commercial General Liability	\$1,000,000 per occurrence \$2,000,000 aggregate
Automobile Liability including coverage for owned, non-owned and hired vehicles	\$1,000,000 per occurrence
Workers Compensation	Statutory
Employers Liability Insurance	\$1,000,000 per occurrence
Professional Liability*	\$1,000,000 per claims-made \$1,000,000 aggregate

Required Coverage Forms

The Commercial General Liability coverage shall be written on Insurance Services Office (ISO) form CG 00 01, or a substitute form providing liability coverage at least as broad.

The Business Auto Liability coverage shall be written on ISO form CA 00 01, CA 00 05, CA 00 12, CA 00 20, or a substitute form providing coverage at least as broad.

Required Endorsements

The Commercial General Liability policy shall contain the following endorsements, which shall accompany the Certificate of Insurance:

1. An Additional Insured endorsement using ISO form CG 20 26 04 13 or a form at least as broad naming the **County of Orange, its elected and appointed officials, officers, agents and employees** as Additional Insureds, or provide blanket coverage, which will state **AS REQUIRED BY WRITTEN CONTRACT**.
2. A primary non-contributing endorsement using ISO form CG 20 01 04 13, or a form at least as broad evidencing that Contractor's insurance is primary and any insurance or self-insurance maintained by the County of Orange shall be excess and non-contributing.

The Workers' Compensation policy shall contain a waiver of subrogation endorsement waiving all rights of subrogation against the **County of Orange, its elected and appointed officials, officers, agents and employees** or provide blanket coverage, which will state **AS REQUIRED BY WRITTEN CONTRACT**.

All insurance policies required by this Contract shall waive all rights of subrogation against the County of Orange, its elected and appointed officials, officers, agents and employees when acting within the scope of their appointment or employment.

Contractor shall notify County in writing within thirty (30) calendar days of any policy cancellation and ten (10) calendar days for non-payment of premium and provide a copy of the cancellation notice to County. Failure to provide written notice of cancellation may constitute a material breach of the Contract, upon which County may suspend or terminate this Contract for cause pursuant to Paragraph K, Termination.

If Contractor's Professional Liability is "Claims-Made" policy, Contractor must maintain coverage for two (2) years following the completion of the Contract.

The Commercial General Liability policy shall contain a severability of interests clause also known as a "separation of insureds" clause (standard in the ISO CG 00 01 policy).

Insurance certificates should be forwarded to the department address listed in Paragraph 16, Notices.

If Contractor fails to provide the insurance certificates and endorsements within seven (7) calendar days of notification by CEO/Purchasing or the department purchasing division, this Contract may be terminated immediately for cause pursuant to Paragraph K, Termination.

County expressly retains the right to require Contractor to increase or decrease insurance of any of the above insurance types throughout the term of this Contract. Any increase or decrease in insurance will be as deemed by County of Orange Risk Manager as appropriate to adequately protect County.

County will notify Contractor in writing of changes in the insurance requirements. If Contractor does not deposit copies of acceptable Certificates of Insurance and endorsements with County incorporating such changes within thirty (30) calendar days of receipt of such notice, this Contract may be in breach without further notice to Contractor, and County shall be entitled to all legal remedies.

The procuring of such required policy or policies of insurance shall not be construed to limit Contractor's liability hereunder nor to fulfill the indemnification provisions and requirements of this Contract, nor act in any way to reduce the policy coverage and limits available from the insurer.

P. **Changes:** Contractor shall make no changes in the work or perform any additional work without County's express prior written consent.

Q. **Change of Ownership/Name, Litigation Status, Conflicts with County Interests:** Contractor agrees that if there is a change or transfer in ownership of Contractor's business prior to completion of this Contract, and County agrees to an assignment of the Contract, the new owners shall be required under the terms of sale or other instruments of transfer to assume Contractor's duties and obligations contained in this Contract, and complete them to the satisfaction of County.

County reserves the right to immediately terminate the Contract in the event County determines that the assignee is not qualified or is otherwise unacceptable to County for the provision of services under the Contract.

In addition, Contractor has the duty to notify County in writing of any change in Contractor's status with respect to name changes that do not require an assignment of the Contract. Contractor is also obligated to notify County in writing if Contractor becomes a party to any litigation against the County, or a party to litigation that may reasonably affect Contractor's performance under the Contract, as well as any potential conflicts of interest between Contractor and County that may arise prior to or during the period of Contract performance. While Contractor must provide this information without prompting from County any time there is a change in Contractor's name, conflict of interest or litigation status, Contractor must also provide an update to County of its status in these areas whenever requested by County.

Contractor shall exercise reasonable care and diligence to prevent any actions or conditions that could result in a conflict with County interests. In addition to Contractor, this obligation applies to Contractor's employees, agents, and subcontractors associated with the provision of goods and services provided under this Contract. Contractor's efforts shall include, but not be limited to, establishing rules and procedures preventing its employees, agents, and subcontractors from providing or offering gifts, entertainment, payments, loans or other considerations which could be deemed to influence or appear to influence County staff or elected officers in the performance of their duties.

- R. **Force Majeure:** Contractor shall not be assessed with liquidated damages or unsatisfactory performance penalties during any delay beyond the time named for the performance of this Contract to the extent such delay is caused by any act of God, war, civil disorder, employment strike or other cause beyond Contractor's reasonable control, provided Contractor gives written notice of the cause of the delay to County within thirty-six (36) hours of the start of the delay and Contractor avails itself of any available remedies to end the delay and minimize the effects of such delay. County may terminate this Contract by written notice to Contractor if the delay continues substantially uninterrupted for a period of five (5) business days or more.
- S. **Confidentiality:** Contractor must maintain the confidentiality of all County and County-related records and information pursuant to all statutory laws relating to privacy and confidentiality that currently exist or exist at any time during the term of this Contract. All such records and information shall be considered confidential and kept confidential by Contractor and Contractor's staff, agents and employees.
- T. **Compliance with Laws:** Contractor represents and warrants that services to be provided under this Contract shall fully comply, at Contractor's expense, with all standards, laws, statutes, restrictions, ordinances, requirements, and regulations (collectively "laws"), including, but not limited to those issued by County in its governmental capacity and all other laws applicable to the services at the time services are provided to and accepted by County. Contractor acknowledges that County is relying on Contractor to ensure such compliance, and pursuant to the requirements of Paragraph Z, Contractor agrees that it shall defend, indemnify and hold County and County Indemnitees harmless from all liability, damages, costs and expenses arising from or related to a violation of such laws.
- U. **Freight:** Prior to County's express acceptance of delivery of products, Contractor assumes full responsibility for all transportation, transportation scheduling, packing, handling, insurance, and other services associated with delivery of all products deemed necessary under this Contract.
- V. **Severability:** If any term, covenant, condition or provision of this Contract is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remainder of the provisions hereof shall remain in full force and effect and shall in no way be affected, impaired or invalidated thereby.
- W. **Attorney Fees:** In any action or proceeding to enforce or interpret any provision of this Contract, each party shall bear its own attorney's fees, costs and expenses.
- X. **Interpretation:** This Contract has been negotiated at arm's length and between persons sophisticated and knowledgeable in the matters dealt with in this Contract. In addition,

each party has been represented by experienced and knowledgeable independent legal counsel of its own choosing or has knowingly declined to seek such counsel despite being encouraged and given the opportunity to do so. Each party further acknowledges that it has not been influenced to any extent whatsoever in executing this Contract by any other party hereto or by any person representing them, or both. Accordingly, any rule or law (including California Civil Code Section 1654) or legal decision that would require interpretation of any ambiguities in this Contract against the party that has drafted it is not applicable and is waived. The provisions of this Contract shall be interpreted in a reasonable manner to effect the purpose of the parties and this Contract.

- Y. **Employee Eligibility Verification:** Contractor warrants that it is and will remain in full compliance with all Federal and State statutes and regulations regarding the employment of aliens and others and that all its employees performing work under this Contract meet the citizenship or alien status requirement set forth in Federal statutes and regulations. Contractor must obtain, from all employees performing work hereunder, all verification and other documentation of employment eligibility status required by Federal or State statutes and regulations including, but not limited to, the Immigration Reform and Control Act of 1986, 8 U.S.C. §1324 et seq., as they currently exist and as they may be hereafter amended. Contractor must retain all such documentation for all covered employees for the period prescribed by the law. Contractor must indemnify, defend with counsel approved in writing by County, and hold harmless, County, its agents, officers, and employees from employer sanctions and any other liability which may be assessed against Contractor or County or both in connection with any alleged violation of any Federal or State statutes or regulations pertaining to the eligibility for employment of any persons performing work under this Contract.
- Z. **Indemnification:** Contractor agrees to indemnify, defend with counsel approved in writing by County, and hold County, its elected and appointed officials, officers, employees, agents and those special districts and agencies which County's Board of Supervisors acts as the governing Board ("County Indemnitees") harmless from any claims, demands or liability of any kind or nature, including but not limited to personal injury or property damage, arising from or related to the services, products or other performance provided by Contractor pursuant to this Contract. If judgment is entered against Contractor and County by a court of competent jurisdiction because of the concurrent active negligence of County or County Indemnitees, Contractor and County agree that liability will be apportioned as determined by the court. Neither party shall request a jury apportionment.
- AA. **Audits/Inspections:** Contractor must permit the County's Auditor-Controller or the Auditor-Controller's authorized representative (including auditors from a private auditing firm hired by County) access during normal working hours to all books, accounts, records, reports, files, financial records, supporting documentation, including payroll and accounts payable/receivable records, and other papers or property of Contractor for the purpose of auditing or inspecting any aspect of performance under this Contract. The inspection and/or audit will be confined to those matters connected with the performance of the Contract including, but not limited to, the costs of administering the Contract. County will provide reasonable notice of such an audit or inspection.

County reserves the right to audit and verify Contractor's records before final payment is made.

Contractor must 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 under this Contract or by law. Contractor agrees to allow interviews of any employees or others who might reasonably have information related to such records. Further, Contractor must include in each subcontract a similar right for County to audit records and interview staff of any subcontractor related to performance of this Contract.

Should Contractor cease to exist as a legal entity, Contractor's records pertaining to this Contract must be forwarded to County's Project Manager.

- BB. **Contingency of Funds:** Contractor acknowledges that funding or portions of funding for this Contract may be contingent upon state budget approval; receipt of funds from, and/or obligation of funds by, the state of California to County; and inclusion of sufficient funding for the services hereunder in the budget approved by County's Board of Supervisors for each fiscal year covered by this Contract. If such approval, funding or appropriations are not forthcoming, or are otherwise limited, County may immediately terminate or modify this Contract without penalty.
- CC. **Expenditure Limit:** Contractor shall notify the DPA in writing when the expenditures against the Contract reach seventy-five percent (75%) of the dollar limit on the Contract. County is not responsible for any expenditure overruns and will not pay for work exceeding the dollar limit on the Contract unless a change order to cover those costs has been issued.

Additional Terms and Conditions:

1. **Scope of Contract:** This Contract specifies the contractual terms and conditions by which Contractor must provide Diagnostic Testing and Whole Genome Sequencing Services to County, as further detailed in the Scope of Work, identified and incorporated herein by this reference as "Attachment A".
2. **Term of Contract:** This Contract shall commence on March 23, 2022 through and including June 30, 2025. County does not have to give reason if it decides not to renew. Contract shall be in effect for the time periods specified, unless this Contract is earlier terminated by the Parties. This Contract may be renewed for two (2) additional years upon agreement of both Parties. County does not have to give a reason if it elects not to renew. Renewal periods may be subject to approval by the County of Orange Board of Supervisors.
3. **Breach of Contract:** The failure of Contractor to comply with any of the provisions, covenants or conditions of this Contract shall be a material breach of this Contract. In such event, County may, and in addition to any other remedies available at law, in equity, or otherwise specified in this Contract, do any of the following:
 - a. Terminate the Contract immediately for cause pursuant to Paragraph K, Termination;
 - b. Afford Contractor written notice of the breach and ten (10) calendar days or such shorter time that may be specified in this Contract within which to cure the breach, if the breach is curable;

- c. Discontinue payment to Contactor for and during the period in which Contractor is in breach; and
 - d. Offset against any monies billed by Contractor but yet unpaid by County those monies disallowed pursuant to the above.
4. **Civil Rights:** Contractor attests that services provided shall be in accordance with the provisions of Title VI and Title VII of the Civil Rights Act of 1964, as amended; Section 504 of the Rehabilitation Act of 1973, as amended; the Age Discrimination Act of 1975, as amended; Title II of the Americans with Disabilities Act of 1990; and other applicable State and federal laws and regulations prohibiting discrimination on the basis of race, color, national origin, ethnic group identification, age, religion, marital status, sex or disability.
 5. **Conflict of Interest – County Personnel:** The County of Orange Board of Supervisors policy prohibits its employees from engaging in activities involving a conflict of interest. Contractor must not, during the period of this Contract, employ any County employee for any purpose.
 6. **Contractor’s Project Manager:** Contractor must appoint a Project Manager to direct Contractor’s efforts in fulfilling Contractor’s obligations under this Contract. This Project Manager is subject to approval by County and must not be changed without the written consent of County’s Project Manager, which consent must not be unreasonably withheld.

Contractor’s Project Manager must be assigned to this Contract for the duration of the Contract and must diligently pursue all work and services to meet the project time lines. County’s Project Manager has the right to require the removal and replacement of Contractor’s Project Manager from providing services to County under this Contract. County’s Project Manager will notify Contractor in writing of such action. Contractor must accomplish the removal within five (5) business days after written notice by County’s Project Manager. County’s Project Manager must review and approve the appointment of the replacement for Contractor’s Project Manager. County is not required to provide any information, reason or rationale in the event it requires the removal of Contractor’s Project Manager from providing further services under the Contract.

7. **Contractor’s Records:** Contractor must keep true and accurate accounts, records, books and data which must correctly reflect the business transacted by Contractor in accordance with generally accepted accounting principles. These records must be stored in Orange County for a period of three (3) years after final payment is received from County. Storage of records in another county will require written approval from the DPA.
8. **Conditions Affecting Work:** Contractor is responsible for taking all steps reasonably necessary to ascertain the nature and location of the work to be performed under this Contract and to know the general conditions which can affect the work or the cost thereof. Any failure by Contractor to do so will not relieve Contractor from responsibility for successfully performing the work without additional cost to County. County assumes no responsibility for any understanding or representations concerning the nature, location(s) or general conditions made by any of its officers or agents during the Contract or prior to the execution of this Contract, unless such understanding or representations by County

are expressly stated in the Contract and the Contract expressly provides that County assumes the responsibility.

9. **Data – Title To:** All materials, documents, data or information obtained from County data files or any County medium furnished to Contractor in the performance of this Contract will at all times remain the property of County. Such data or information may not be used or copied for direct or indirect use by Contractor after completion or termination of this Contract without the express written consent of County. All materials, documents, data or information, including copies, must be returned to County at the end of this Contract.
10. **Disputes – Contract:**
- a. The Parties must deal in good faith and attempt to resolve potential disputes informally. If the dispute concerning a question of fact arising under the terms of this Contract is not disposed of in a reasonable period of time by Contractor's Project Manager and County's Project Manager, such matter must be brought to the attention of the County Deputy Purchasing Agent by way of the following process:
- 1) Contractor must submit to the DPA a written demand for a final decision regarding the disposition of any dispute between the Parties arising under, related to, or involving this Contract, unless County, on its own initiative, has already rendered such a final decision.
 - 2) Contractor's written demand must be fully supported by factual information, and, if such demand involves a cost adjustment to the Contract, Contractor must include with the demand a written statement signed by a senior official indicating that the demand is made in good faith, that the supporting data are accurate and complete, and that the amount requested accurately reflects the Contract adjustment for which Contractor believes County is liable.
- b. Pending the final resolution of any dispute arising under, related to, or involving this Contract, Contractor must diligently proceed with the performance of this Contract, including the delivery of goods and/or provision of services. Contractor's failure to diligently proceed shall be considered a material breach of this Contract.

Any final decision of County shall be expressly identified as such, shall be in writing, and shall be signed by the County Deputy Purchasing Agent or his designee. If County does not render a decision within ninety (90) calendar days after receipt of Contractor's demand, it shall be deemed a final decision adverse to Contractor's contentions. Nothing in this paragraph shall be construed as affecting County's right to terminate the Contract for cause or for convenience as provided in Paragraph K, Termination.

11. **Drug-Free Workplace:** Contractor hereby certifies compliance with Government Code Section 8355 in matters relating to providing a drug-free workplace. Contractor will:
- a. Publish a statement notifying employees that unlawful manufacture, distribution, dispensation, possession, or use of a controlled substance is prohibited and specifying actions to be taken against employees for violations, as required by Government Code Section 8355(a)(1).

- b. Establish a drug-free awareness program as required by Government Code Section 8355(a)(2) to inform employees about all of the following:
 - 1) The dangers of drug abuse in the workplace;
 - 2) The organization's policy of maintaining a drug-free workplace;
 - 3) Any available counseling, rehabilitation and employee assistance programs; and
 - 4) Penalties that may be imposed upon employees for drug abuse violations.
- c. Provide as required by Government Code Section 8355(a)(3) that every employee who works under this Contract:
 - 1) Will receive a copy of the company's drug-free policy statement; and
 - 2) Will agree to abide by the terms of the company's statement as a condition of employment under this Contract.

Failure to comply with these requirements may result in suspension of payments under the Contract or termination of the Contract or both, and Contractor may be ineligible for award of any future County contracts if County determines that any of the following has occurred:

- a. Contractor has made false certification, or
 - b. Contractor violates the certification by failing to carry out the requirements as noted above.
12. **Emergency/Declared Disaster Requirements:** In the event of an emergency or if Orange County is declared a disaster area by County, state or federal government, this Contract may be subjected to unusual usage. Contractor must service County during such an emergency or declared disaster under the same terms and conditions that apply during non-emergency/disaster conditions. The pricing in Attachment B must apply to serving County's needs regardless of the circumstances. If Contractor is unable to supply the goods/services under the terms of the Contract, then Contractor must provide proof of such disruption and a copy of the invoice for the goods/services from Contractor's supplier(s). Additional profit margin as a result of supplying goods/services during an emergency or a declared disaster is not permitted. In the event of an emergency or declared disaster, emergency purchase order numbers will be assigned. All applicable invoices from Contractor must show both the emergency purchase order number and the Contract number.
13. **Errors and Omissions:** All reports, files and other documents prepared and submitted by Contractor must be complete and must be carefully checked by the professional(s) identified by Contractor as project manager, prior to submission to County. Contractor agrees that County review is discretionary and Contractor must not assume that County will discover errors and/or omissions. If County discovers any errors or omissions prior to approving Contractor's reports, files and other written documents, the reports, files or

documents will be returned to Contractor for correction. Should County or others discover errors or omissions in the reports, files or other written documents submitted by Contractor after County approval thereof, County approval of Contractor's reports, files or documents must not be used as a defense by Contractor in any action between County and Contractor, and the reports, files or documents will be returned to Contractor for correction.

14. **Equal Employment Opportunity:** Contractor must comply with U.S. Executive Order 11246 entitled, "Equal Employment Opportunity" as amended by Executive Order 11375 and as supplemented in Department of Labor regulations (41 CFR, Part 60) and applicable State of California regulations as may now exist or be amended in the future. Contractor must not discriminate against any employee or applicant for employment on the basis of race, color, national origin, ancestry, religion, sex, marital status, political affiliation or physical or mental condition.

Regarding handicapped persons, Contractor will not discriminate against any employee or applicant for employment because of physical or mental handicap in regard to any position for which the employee or applicant for employment is qualified. Contractor agrees to provide equal opportunity to handicapped persons in employment or in advancement in employment or otherwise treat qualified handicapped individuals without discrimination based upon their physical or mental handicaps in all employment practices such as the following: employment, upgrading, promotions, transfers, recruitments, advertising, layoffs, terminations, rate of pay or other forms of compensation, and selection for training, including apprenticeship. Contractor agrees to comply with the provisions of Sections 503 and 504 of the Rehabilitation Act of 1973, as amended, pertaining to prohibition of discrimination against qualified handicapped persons in all programs and/or activities as detailed in regulations signed by the Secretary of the Department of Health and Human Services effective June 3, 1977, and found in the Federal Register, Volume 42, No. 68 dated May 4, 1977, as may now exist or be amended in the future.

Regarding Americans with disabilities, Contractor agrees to comply with applicable provisions of Title 1 of the Americans with Disabilities Act enacted in 1990 as may now exist or be amended in the future.

15. **News/Information Release:** Contractor must not issue any news releases in connection with either the award of this Contract or any subsequent amendment of or effort under this Contract without first obtaining review and written approval of said news releases from County through County's Project Manager.
16. **Notices:** Any and all notices, requests, demands and other communications contemplated, called for, permitted, or required to be given hereunder shall be in writing with a copy provided to the DPA, except through the course of the parties' project managers' routine exchange of information and cooperation during the terms of the work and services. Any written communications shall be deemed to have been duly given upon actual in-person delivery, if delivery is by direct hand, or upon delivery on the actual day of receipt or no greater than four (4) calendar days after being mailed by US certified or registered mail, return receipt requested, postage prepaid, whichever occurs first. The date of mailing shall count as the first day. All communications shall be addressed to the appropriate Party at the address stated herein or such other address as the parties hereto may designate by written notice from time to time in the manner aforesaid.

For Contractor: Name: Fulgent Therapeutics LLC
 Attention: Rachel Blake
 Address: 4978 Anita Ave.
 Temple City, CA 92701
 Telephone: 626-350-0537
 E-mail: BD@fulgentgenetics.com

For County: Name: County of Orange HCA/Procurement and Contract
 Services
 Attention: Brittany Davis
 Address: 405 W. 5th St. Ste. 600
 Santa Ana, CA 92701
 Telephone: (714) 834-5326
 E-mail: bdavis@ochca.com

CC: Name: County of Orange HCA
 Attention: Anza Vang
 E-mail: avang@ochca.com

17. **Precedence:** The Contract documents consist of this Contract and its Attachments. In the event of a conflict between or among the Contract documents, the order of precedence shall be the provisions of the main body of this Contract, i.e., those provisions set forth in the recitals and articles of this Contract, and then the Attachments.
18. **Promotional/Advertisement:** County owns all rights to the name, trademarks, logos and symbols of County. The use and/or reproduction of County's name, trademark, logo and/or symbol for any purpose, including commercial advertisement, promotional purposes, announcements, displays or press releases, without County's express prior written consent is expressly prohibited. No use or reproduction may state or imply that County endorses Contractor's products or services.
19. **Publication:** No copies of sketches, schedules, written documents, computer-based data, photographs, maps or graphs, including graphic artwork, resulting from performance or prepared in connection with this Contract, are to be released by Contractor and/or anyone acting under the supervision of Contractor to any person, partnership, company, corporation, or agency, without County's express prior written consent, except as necessary for the performance of the services of this Contract. All press contacts, including graphic display information to be published in newspapers, magazines, etc., are to be administered by County or only after County approval.
20. **Subcontracting:** No performance of this Contract or any portion thereof may be subcontracted by Contractor without the express written consent of County. Any attempt by Contractor to subcontract any performance of this Contract without the express written consent of County shall be invalid and shall constitute a breach of this Contract.

In the event that Contractor is authorized by County to subcontract, this Contract shall take precedence over the terms of the Contract between Contractor and subcontractor

and shall incorporate by reference the terms of this Contract. County shall look to Contractor for performance and indemnification and not deal directly with any subcontractor. All work performed by a subcontractor must meet the approval of the County of Orange.

21. **Termination – Orderly:** After receipt of a termination notice from the County of Orange, Contractor may submit to County a termination claim, if applicable. Such claim must be submitted promptly, but in no event later than sixty (60) calendar days from the effective date of the termination, unless one or more extensions in writing are granted by County upon written request of Contractor. Upon termination and submission of a termination claim, County agrees to pay Contractor for all services performed prior to termination which meet the requirements of the Contract, provided, however, that such compensation combined with previously paid compensation must not exceed the total compensation set forth in the Contract. Upon termination or other expiration of this Contract, each party must promptly return to the other party all papers, materials, and other properties of the other held by each for purposes of performance of the Contract.
22. **Usage:** No guarantee is given by County to Contractor regarding usage of this Contract. Usage figures, if provided, are approximations. Contractor agrees to supply services and/or commodities requested, as needed by the County of Orange, at rates/prices listed in the Contract, regardless of quantity requested.
23. **Usage Reports:** Contractor must submit usage reports on an annual basis to the DPA. The usage report must be in a format specified by the user department and must be submitted ninety (90) calendar days prior to the expiration date of the contract term, or any subsequent renewal term, if applicable.
24. **Contractor Screening:** Throughout the term of this Contract, Contractor must not be listed on any state or federal exclusionary rosters, listed below. County may screen Contractor on a monthly basis to ensure Contractor is not listed on the exclusionary rosters, listed below. If Contractor or its employee(s) are found to be included on any of the rosters indicated below, Contractor shall be deemed in default of its obligation under this Paragraph and shall constitute a cause for County to exercise its right to terminate this Contract immediately. County, in its sole discretion, may afford Contractor an opportunity to cure said default within a reasonable time.
 - a. United States Department of Health and Human Services, Office of Inspector General (OIG) List of Excluded Individuals & Entities (LEIE) (<http://exclusions.oig.hhs.gov>).
 - b. General Services Administration (GSA) System for Award Management (SAM) Excluded Parties List (<http://sam.gov>).
 - c. State of California Department of Health Care Services Medi-Cal Suspended and Ineligible Provider List (County Health Care Agency Internal Database).
25. **Debarment:** Contractor certifies that neither Contractor nor its employee(s) are presently debarred, proposed for debarment, declared ineligible or voluntarily excluded from participation in a contractual transaction by any state or federal department or agency. County has the right to immediately terminate this Contract if Contractor is the subject of any debarment, pending debarment, declared ineligibility or voluntary exclusion from participation by any state or federal department or agency.

26. **Lobbying:** On the best information and belief, Contractor certifies no federal appropriated funds have been paid or will be paid by, or on behalf of, Contractor to any person influencing or attempting to influence an officer or employee of Congress; or an employee of a member of Congress in connection with the awarding of any federal contract, continuation, renewal, amendment, or modification of any federal contract, grant, loan, or cooperative contract.
27. **California Public Records Act:** Contractor and County agree and acknowledge that all information and documents related to the award and performance of this Contract are subject to disclosure pursuant to the California Public Records Act, California Government Code Section 6250 et seq.
28. **Gratuities:** Contractor warrants that no gratuities, in the form of entertainment, gifts or otherwise, were offered or given by Contractor or any agent or representative of Contractor to any officer or employee of County with a view toward securing the Contract or securing favorable treatment with respect to any determinations concerning the performance of the Contract. For breach or violation of this warranty, County has the right to terminate the Contract, either in whole or in part, and any loss or damage sustained by County in procuring on the open market any goods or services which Contractor agreed to supply must be borne and paid for by Contractor. The rights and remedies of County provided in this paragraph are not exclusive and are in addition to any other rights and remedies provided by law or under the Contract.
29. **Parking for Delivery Services:** County shall not provide free parking for delivery services.

(SIGNATURE PAGE FOLLOWS)

CONTRACT SIGNATURE PAGE

IN WITNESS WHEREOF, the Parties hereto have executed this Contract No. MA-042-22011297 the date set forth opposite their signatures. If Contractor is a corporation, Contractor shall provide two signatures as follows: 1) the first signature must be either the Chairman of the Board, the President, or any Vice President; 2) the second signature must be either the Secretary, an Assistant Secretary, the Chief Financial Officer, or any Assistant Treasurer. In the alternative, a single corporate signature is acceptable when accompanied by a corporate resolution or by-laws demonstrating the legal authority of the signature to bind the company.

Contractor: Fulgent Therapeutics LLC

Jakub Sram _____ VP Business Development
Print Name _____ Title

DocuSigned by:
Jakub Sram _____ 4/19/2022
9A3FA282D2A64E0...
Signature _____ Date

Paul Kim _____ CFO
Print Name _____ Title

DocuSigned by:
Paul Kim _____ 4/20/2022
9AB1366B7C70450...
Signature _____ Date

County of Orange, a political subdivision of the State of California

Purchasing Agent/Designee Authorized Signature:

_____ Deputy Purchasing Agent
Print Name _____ Title

_____ Date
Signature _____

APPROVED AS TO FORM
Office of the County Counsel
Orange County, California

Brittany McLean _____ Deputy County Counsel
Print Name _____ Title

DocuSigned by:
Brittany McLean _____ 4/20/2022
9713A4061D4343D...
Signature _____ Date

ATTACHMENT A

SCOPE OF WORK/PRICING

1. **BACKGROUND:** County requires COVID-19 testing using several mechanisms:
 - a. COVID-19 RT-PCR Diagnostic Testing
 - b. At-home testing collection available for residents
 - c. Mobile testing services to be mobilized in the event of a surge
 - d. Whole genome sequencing for COVID-19 variant surveillance
2. **SUMMARY OF SERVICES:** Contractor shall provide COVID-19 laboratory testing services on specimens provided by County, as described below, and report results or outcomes of testing as described herein.
3. **LICENSE AND CERTIFICATION:**
 - a. Contractor shall be licensed in the State of California as a medical provider pursuant to Title 17, California Code of Regulations, and shall be eligible to participate as a provider in (and bill services to) Medi-Cal, Medicare, CalOptima Health Networks (including pre-authorizations), most commercial insurers, and the US Health Resource and Services Administration (HRSA).
 - b. Any subcontractors proposed by Contractor shall be licensed in the State of California for appropriate clinical ancillary services or as a clinical laboratory, and shall be eligible to participate as a provider in (and bill services to) Medi-Cal, Medicare, CalOptima Health Networks (including pre-authorizations), most commercial insurers, and the HRSA.
 - c. Clinical laboratory personnel providing services under this Contract requiring professional licensure or certification pursuant to Title 17, California Code of Regulations, Section 1029, et, seq., must hold current valid licensure or certification from the State of California Department of Public Health and meet all applicable standards for all work performed.
 - d. Contractor is required to have and maintain during the period of the Contract all valid laboratory licenses required by the State of California and the Federal Government to operate as a licensed clinical laboratory.
 - e. Contractor shall maintain compliance with all HIPAA requirements for all work performed under this Contract.
 - f. Contractor shall maintain necessary safeguards, records, and controls relative to the handling and processing of submitted specimens, and waste disposal.
4. **COVID-19 DIAGNOSTIC TESTING:** Contractor shall offer only Food and Drug Administration (FDA) authorized (including Emergency Use Authorized) testing and shall conduct all testing according to that authorization. Contractor must keep County informed of what test Contractor is utilizing and must immediately notify County of any changes.
 - A. **FULGENT ONSITE COVID-19 TESTS.** The Fulgent Coronavirus Disease (COVID-19) RT-PCR test (the "COVID-19 Test") is a reverse transcription polymerase chain reaction test to detect SARS-CoV-2, the virus that causes COVID-19. The SARS-CoV-2 primer

and probe sets are designed to detect RNA from 2019-nCoV in specimens from patients who meet CDC 2019-nCoV clinical criteria. Primer and probe set sequences are based on CDC recommended guidelines that identify two known distinct regions within the SARS-CoV-2 genome. Amplification of both targets will signify a positive result; amplification of one of two targets will signify an indeterminate result; and no amplification of either target, but amplification of internal control, will signify a negative result. Contractor recommends a new specimen be collected if the first COVID-19 Test generates indeterminate results.

- 1) Institutional cost of testing.
 - a) Fulgent COVID-19 RT-PCR test: \$55 USD per test.
 - b) Fulgent COVID-19 plus test: \$55 USD per test. Influenza a and b tests may be provided at no additional charge. However, influenza testing must be opted-in at institutional level for all individuals.
- 2) Insurance billing. Contractor will make reasonable commercial efforts to bill insurance for all tests rendered. Contractor's ability to bill insurance is dependent on testing individuals providing accurate and complete insurance information. County agrees to work with contractor in good faith to ensure that all testing individuals provide accurate insurance information for insurance billing. Contractor will credit County up to \$55 per test for all insurance claims that are fully reimbursed. For any insurance claims that are not fully reimbursed within 90 days of sample collection, County will pay the amount specified in this contract. ***To ensure efficient and accurate claims processing, healthcare providers who are contracted to perform the specific task of either collection and handling of the patient specimen for COVID-19 diagnostic testing, clinical diagnostic laboratory COVID-19 testing processes, or coronavirus vaccine administration should bill using the allowable CPT or HCPCS codes corresponding to the service(s) performed in accordance with centers for disease control & prevention (CDC) and the centers for medicare & medicaid services (CMS). Contractor shall ensure appropriateness of claims and adequate documentation of clinical services provided to maximize proper reimbursement and to avoid denials.***
- 3) Test Requisition Form Requirements.
 - a) County must provide Contractor with all information required for such state reporting, including, a test requisition which includes the name, gender, pregnancy status, address and date-of-birth of the person from whom the specimen was obtained, in the required format via Fulgent portal.
- 4) Specimen Requirement.
 - a) Acceptable specimen types include nasopharyngeal, mid-turbinate and anterior nasal swab collection with specimen collection kit validated by the LAB.
 - b) Specimens must be labeled with a minimum of two unique identifiers, such as name, DOB.
 - c) Specimens must be returned to Contractor as soon as reasonably practicable upon collection, and may be shipped at room temperature.

- d) There may be delays if specimens are improperly labeled, if the specimen is of insufficient quality or quantity, or if the test requisition forms are not completed in the form and manner required.
 - e) If discrepancies in the information provided cannot be resolved within 48 hours of receipt of specimen, the specimens will be discarded, and a replacement specimen will be required.
- 5) Reporting. Contractor shall deliver results for COVID-19 tests to County via Fulgent portal and result notification system. Contractor will comply with state-by-state reporting requirements for all COVID-19 results performed at the Temple City, CA or Houston, TX location.
- 6) Physician authorization.
- a) All Fulgent COVID-19 tests must be authorized by a properly qualified physician, who holds a current NPI, provided by County.
 - b) County must provide contractor with the name, address, NPI and telephone number of licensed and authorized physician or health care provider.
- B. AT-HOME TEST KIT SERVICES:** Contractor shall provide RT-PCR at-home test kits with the specification outlined below and provide contractor testing services and provide medical oversight of tests.
- 1) Shipping: Contractor shall ship order requests at least up to the daily minimum as agreed upon within 48 hours.
 - 2) Contractor must provide a written projection of kit availability and a contractor capacity schedule by contract execution.
 - 3) Kit contents must include:
 - a) Registration instructions
 - b) Biohazard bag
 - c) FDA EUA collection device + transport media
 - d) Pre-paid Fedex overnight express label
 - 4) Additional services that are included in the cost of purchasing kits and laboratory services:
 - a) Project management
 - b) Marketing and communications support
 - c) Compliance with reporting requirements
 - d) Instructions and software interface in Five O.C. Threshold languages shall be developed on an agreed-upon schedule
 - e) Maintenance of website portal through picture genetics for residents to order test kits for at-home collection
 - f) Creation and maintenance of county human resources portal for county use.
 - 5) Pricing
 - a) Billing
 - i. Test Kits and Logistics Fees. County will pay Contractor \$42.50 per kit regardless of insurance reimbursement for every Test Kit dispatched by Contractor. Test Kits and Logistics Fees will be billed monthly in arrears for test kits shipped in the prior month.

- ii. COVID-19 RT-PCR Testing with Picture Genetics At-home collection kit and telehealth authorization: \$40 per test if not fully reimbursed by insurance. This includes clinical support for patients with positive results and shipping.
 - iii. Insurance billing. Contractor will bill County for all tests rendered. County agrees to work with Contractor in good faith to ensure accurate insurance information is provided for insurance billing. Contractor will credit County up to \$40 per test for all insurance claims that are fully reimbursed. For any insurance claims that are not fully reimbursed within 90 days, County will pay the amount specified in this Contract.
 - b) County's payment of uncompensated COVID-19 testing services is limited to the following:
 - i. Testing requested by County without third-party information and/or authorized to be billed to "County."
 - ii. Claims legally denied by insurers or HRSA for testing ordered by County.
 - iii. Claims legally denied by insurers or HRSA for testing ordered by providers partnering with County at designated test sites. This only applies to testing provided at test sites and dates specifically authorized by County in writing.
 - c) Contractor agrees to bill all available insurance plans, including the U.S. Health Services Resources Administration (HRSA), and any other third-party responsible for payment including, but not limited to, employers, for payment for the COVID-19 testing services requested herein, to the greatest extent possible. Contractor agrees that payments received from third-parties shall be considered payment in full for testing services requested herein, and will not charge any copayment to County clients, and absolves County of any and all financial responsibility except as detailed below.
 - d) Contractor shall provide a report of claim data to County on a monthly basis. County agrees to work with Contractor in good faith, and to assist Contractor in addressing and resolving any claim related issues with payers, including but not limited to commercial payers, government payers, and Independent Practice Association payers.
 - e) County agrees to pay Contractor for all tests rendered upon completion of testing. Contractor shall bill third-party payers for insurance, and for any claims accepted and paid by the insurance, Contractor will issue a refund to County of the amount previously charged to County. Such refunds will be made at the end of each month. A summary report entailing total claims submitted in the relevant month and total claims paid in the relevant month will be provided on a monthly basis. Any remaining credit balance at the termination of the Contract shall be remitted back to County. County and Contractor agree to reconcile any discrepancies at the end of each month. A final reconciliation must be submitted to County by Contractor within 45 days of contract term expiration unless extended with written approval from County.
 - f) County reserves the right to terminate the Contract if performance is not met. Contractor is obligated to fulfill any request already in process and complete services for any test shipped out at the time of termination.

C. COVID-19 MOBILE VAN TEST KIT DISTRIBUTION SERVICES: Contractor shall provide the following services:

- 1) Eligible for Picture At-Home Kit distribution only.
- 2) Contractor shall coordinate distribution of test kits in priority areas identified in Orange County by zip code
- 3) County must request van service a minimum of two (2) weeks in advance of desired event day
- 4) Van service is limited to locations within a 50 mile radius of Fulgent Headquarters (4978 Santa Anita Ave. Temple City, Ca 91780)
- 5) Contractor’s Mobile Van shall include either 2 staff and 1 supervisor or 3 staff and 1 supervisor; Interpreter(s) who speak Vietnamese and Spanish; and, Security Guard. Availability of bilingual interpreters is not guaranteed. Contractor shall provide their staff with all necessary PPE and equipment for distribution of Picture Test Kits
- 6) Contractor’s staff shall set up in the parking lot and instruct onsite the following:
 - a) How to register online by using the Fulgent provided laptop if the consumer does not have his/her own smartphone or laptop. Nitrile gloves will be provided for each consumer who uses the Fulgent laptop to register for the testing; the gloves will then be disposed after registering - HOW to perform the self-swab testing. Interpreter will assist as needed, where possible.
- 7) Billing
 - a) Mobile Van Services must be billed to County institutionally, and cannot be billed to Insurance.
 - b) Mobile Van Services will be billed at the following rates:

Mobile Test Kit Distribution Event (8 hours)	
Mobile Testing Van with (2) non-clinical staff	\$150/hour
Travel Fee from 4978 Santa Anita Ave. Temple City, CA 91780	\$.58/mile
Additional non-clinical staff	\$65/hour

D. FULGENT SARS-CoV-2 GENOMIC SEQUENCING SERVICES:

- 1) Specimen requirements (For samples not processed via RT-PCR at Fulgent)
 - a) Extracted RNA: Must be shipped overnight on dry ice.
 - b) Nasal/Nasopharyngeal/Oropharyngeal swabs
- 2) County agrees to provide the following information for each sample:
 - a) Collection Date
 - b) Location (Continent / Country / State)
 - c) Gender (optional)
 - d) Patient Age (optional)
 - e) Patient Status (optional)

- i. Samples meet minimum QC requirements
 - ii. Shipping to be arranged by County
- 3) Deliverables
- a) Fulgent will ensure sequencing data meets the following QC criteria:
 - i. <10% indeterminate N's
 - ii. 95% coverage
 - iii. ~20x (some areas of the genome have much higher coverage)
 - iv. Contractor must provide FASTA, VCF, and comprehensive report in .json format. FASTA files will be made available upon request of OCPHL.
 - v. Contractor must deliver these via FTP or Amazon S3.
 - vi. Contractor must routinely update the Pangolin software version to reflect the most current version.
 - vii. Contractor must report to CalREDIE and submit SARS-CoV-2 Sequence Data in accordance with Title 17 of the California Code of Regulations.
- 4) The comprehensive report will include the following so long as these fields are provided to LAB:
- i. Reported on
 - ii. Sample Accession ID
 - iii. Last Name
 - iv. First Name
 - v. Date of Birth
 - vi. MRN
 - vii. Date of collection
 - viii. External Accession
 - ix. Patient Address
 - x. Patient Phone
 - xi. Gender
 - xii. Postal County
 - xiii. GISAID ID
 - xiv. Mean Coverage Depth
 - xv. Consensus Indeterminate
 - xvi. PANGO Lineage
 - xvii. PANGO probability
 - xviii. Approximate TAT for deliverables is 7-10 business days.
 - xix. Contractor will upload sequences to GISAID and provide the GISAID ID # in the comprehensive report.
- 5) Pricing for Fulgent SARS-CoV-2 Genomic Sequencing:
- i. Standard pricing from: \$150/sample
 - ii. RNA extraction: \$18/sample

E. Test Results:

- 1) Contractor will perform testing as samples are received. Contractor shall use commercially reasonable efforts to perform and complete the testing within 24-48 hours of receipt of valid specimens.

- 2) Contractor shall ensure results are reported electronically to the State of California using CalREDIE, and to Public Health in accordance with Title 17, California Code of Regulations (CCR) 2500 and 2500 reporting requirements. <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Reportable-Disease-and-Conditions.aspx>

F. Reports:

- 1) Notwithstanding reporting requirements for communicable diseases, Contractor shall provide access to information on the number of tests conducted and the number of positive tests in a format approved and or provided by and on a schedule approved and or provided by County.
- 2) Contractor shall provide a monthly report itemizing the quantity of tests billed to County and the total dollar amount billed to County. In addition, all charges for actual tests shall include a unique identifier (without protected information) for audit purposes. Contractor is required to maintain records of all services provided – regardless of third party billing – and make those available upon request to County.

G. Changes To Scope Of Work And Pricing:

- 1) Upon mutual agreement of both parties via an amendment, changes may be made to the services, testing types, and pricing described herein. Additional provisions regarding pricing are in Attachment B.

No material adjustments made to the Scope of Work are authorized without County's prior written approval. Non-material adjustments may be made with the DPA's prior written approval.

ATTACHMENT B

COMPENSATION AND INVOICING

1. **Compensation:** This is a fixed price Contract not to exceed the amount of \$6,000,000 for the Term of Contract. Contract is renewable for two additional years.

Contractor agrees to accept the specified compensation as set forth in this Contract as full payment for performing all services and furnishing all staffing and materials required, for any reasonably unforeseen difficulties which may arise or be encountered in the execution of the services until acceptance, for risks connected with the services, and for performance by the Contractor of all its duties and obligations hereunder. The Contractor shall only be compensated as set forth herein for work performed in accordance with the Scope of Work.

2. **Fees and Charges:** County will pay the following fees in accordance with the provisions of this Contract.

See Attachment A

3. **Price Increase/Decreases:** No price increases are permitted during the term of the Contract. County requires documented proof of cost increases on contracts prior to any price adjustment. A minimum of thirty (30) calendar days advance notice in writing is required to secure such adjustment. No retroactive price adjustments will be considered. All price decreases shall automatically be extended to County. County may enforce, negotiate, or cancel escalating price contracts or take any other action it deems appropriate, as it sees fit. The net dollar amount of profit must remain firm during the period of the Contract. Adjustments increasing Contractor's profit are not allowed.
4. **Firm Discount and Pricing Structure:** Contractor guarantees that prices in this Attachment B are equal to or less than prices quoted to any other local, State or Federal government entity for services of equal or lesser scope. Contractor agrees that no price increases shall be passed along to County during the term of this Contract not otherwise specified and provided for within this Contract.
5. **Contractor's Expense:** Contractor is responsible for all costs related to photo copying, telephone communications and fax communications while on County sites during the performance of work and services under this Contract.
6. **Payment Terms:** Payment will be net thirty (30) calendar days after receipt of an invoice in a format acceptable to County and verified and approved by the department and subject to routine processing requirements.

Billing shall cover services and/or goods not previously invoiced. Contractor shall reimburse County for any monies paid to Contractor for services and/or goods not provided or when services and/or goods do not meet the Contract requirements.

Payments made by County shall not preclude the right of County from thereafter disputing any items or services involved or billed under this Contract and shall not be construed as acceptance of any part of the services or goods.

7. **Taxpayer ID Number:** Contractor shall include its taxpayer ID number on all invoices submitted to County for payment to ensure compliance with IRS requirements and to expedite payment processing.
8. **Payment – Invoicing Instructions:** Contractor must provide an invoice on Contractor's letterhead for goods delivered and/or services rendered. In the case of goods, Contractor must leave an invoice with each delivery. Each invoice must have a unique number and must include the following information:
 - a. Contractor's name and address
 - b. Contractor's remittance address
 - c. Contractor's Taxpayer ID Number
 - d. Name of County Department
 - e. Delivery/service address
 - f. Master Agreement (MA) MA-042-22011297
 - g. Department's Account Number, if applicable
 - h. Date of invoice
 - i. Product/service description, quantity, and prices
 - j. Sales tax, if applicable
 - k. Freight/delivery charges, if applicable
 - l. Total

The responsibility for providing acceptable invoices to County for payment rests with Contractor. Incomplete or incorrect invoices are not acceptable and shall be returned to Contractor.

Invoice and support documentation must be forwarded to the department at the following address, unless otherwise directed in this Contract:

Orange County Health Care Agency
Accounts Payable
PO Box 689
Santa Ana, CA 92702

9. **Payment (Electronic Funds Transfer)**
County offers Contractor the option of receiving payment directly to its bank account via an Electronic Fund Transfer (EFT) process in lieu of a check payment. Payment made via EFT shall also receive an Electronic Remittance Advice with the payment details via e-mail. An e-mail address must be provided to County via an EFT Authorization Form. Contractor may request a form from the department representative listed in the Contract.

ATTACHMENT C**BUSINESS ASSOCIATE CONTRACT****A. GENERAL PROVISIONS AND RECITALS**

1. The parties agree that the terms used, but not otherwise defined below in Paragraph B, shall have the same meaning given to such terms 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"), and their implementing regulations at 45 CFR Parts 160 and 164 ("the HIPAA regulations") as they may exist now or be hereafter amended.

2. The parties agree that a business associate relationship under HIPAA, the HITECH Act, and the HIPAA regulations between the CONTRACTOR and COUNTY arises to the extent that CONTRACTOR performs, or delegates to subcontractors to perform, functions or activities on behalf of COUNTY pursuant to, and as set forth in, the Agreement that are described in the definition of "Business Associate" in 45 CFR § 160.103.

3. The COUNTY wishes to disclose to CONTRACTOR certain information pursuant to the terms of the Agreement, some of which may constitute Protected Health Information ("PHI"), as defined below in Subparagraph B.10, to be used or disclosed in the course of providing services and activities pursuant to, and as set forth, in the Agreement.

4. The parties intend to protect the privacy and provide for the security of PHI that may be created, received, maintained, transmitted, used, or disclosed pursuant to the Agreement in compliance with the applicable standards, implementation specifications, and requirements of HIPAA, the HITECH Act, and the HIPAA regulations as they may exist now or be hereafter amended.

5. The parties understand and acknowledge that HIPAA, the HITECH Act, and the HIPAA regulations do not pre-empt any state statutes, rules, or regulations that are not otherwise pre-empted by other Federal law(s) and impose more stringent requirements with respect to privacy of PHI.

6. The parties understand that the HIPAA Privacy and Security rules, as defined below in Subparagraphs B.9 and B.14, apply to the CONTRACTOR in the same manner as they apply to a covered entity (COUNTY). CONTRACTOR agrees therefore to be in compliance at all times with the terms of this Business Associate Contract and the applicable standards, implementation specifications, and requirements of the Privacy and the Security rules, as they may exist now or be hereafter amended, with respect to PHI and electronic PHI created, received, maintained, transmitted, used, or disclosed pursuant to the Agreement.

B. DEFINITIONS

1. "Administrative Safeguards" are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic PHI and to manage the conduct of CONTRACTOR's workforce in relation to the protection of that information.

2. "Breach" means the acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule which compromises the security or privacy of the PHI.

a. Breach excludes:

i. Any unintentional acquisition, access, or use of PHI by a workforce member or person acting under the authority of CONTRACTOR or COUNTY, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under the Privacy Rule.

ii. Any inadvertent disclosure by a person who is authorized to access PHI at CONTRACTOR to another person authorized to access PHI at the CONTRACTOR, or organized health care arrangement in which COUNTY participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under the HIPAA Privacy Rule.

iii. A disclosure of PHI where CONTRACTOR or COUNTY has a good faith belief that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such information.

b. Except as provided in paragraph (a) of this definition, an acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule is presumed to be a breach unless CONTRACTOR demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment of at least the following factors:

i. The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;

ii. The unauthorized person who used the PHI or to whom the disclosure was made;

iii. Whether the PHI was actually acquired or viewed; and

iv. The extent to which the risk to the PHI has been mitigated.

3. "Data Aggregation" shall have the meaning given to such term under the HIPAA Privacy Rule in 45 CFR § 164.501.

4. "Designated Record Set" shall have the meaning given to such term under the HIPAA Privacy Rule in 45 CFR § 164.501.

5. "Disclosure" shall have the meaning given to such term under the HIPAA regulations in 45 CFR § 160.103.

6. "Health Care Operations" shall have the meaning given to such term under the HIPAA Privacy Rule in 45 CFR § 164.501.

7. "Individual" shall have the meaning given to such term under the HIPAA Privacy Rule in 45 CFR § 160.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR § 164.502(g).

8. "Physical Safeguards" are physical measures, policies, and procedures to protect CONTRACTOR's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

9. "The HIPAA Privacy Rule" shall mean the Standards for Privacy of Individually Identifiable Health Information at 45 CFR Part 160 and Part 164, Subparts A and E.

10. "Protected Health Information" or "PHI" shall have the meaning given to such term under the HIPAA regulations in 45 CFR § 160.103.

11. "Required by Law" shall have the meaning given to such term under the HIPAA Privacy Rule in 45 CFR § 164.103.

12. "Secretary" shall mean the Secretary of the Department of Health and Human Services or his or her designee.

13. "Security Incident" means attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with system operations in

an information system. "Security incident" does not include trivial incidents that occur on a daily basis, such as scans, "pings", or unsuccessful attempts to penetrate computer networks or servers maintained by CONTRACTOR.

14. "The HIPAA Security Rule" shall mean the Security Standards for the Protection of electronic PHI at 45 CFR Part 160, Part 162, and Part 164, Subparts A and C.

15. "Subcontractor" shall have the meaning given to such term under the HIPAA regulations in 45 CFR § 160.103.

16. "Technical safeguards" means the technology and the policy and procedures for its use that protect electronic PHI and control access to it.

17. "Unsecured PHI" or "PHI that is unsecured" means PHI that is not rendered unusable, unreadable, or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary of Health and Human Services in the guidance issued on the HHS Web site.

18. "Use" shall have the meaning given to such term under the HIPAA regulations in 45 CFR § 160.103.

C. OBLIGATIONS AND ACTIVITIES OF CONTRACTOR AS BUSINESS ASSOCIATE:

1. CONTRACTOR agrees not to use or further disclose PHI COUNTY discloses to CONTRACTOR other than as permitted or required by this Business Associate Contract or as required by law.

2. CONTRACTOR agrees to use appropriate safeguards, as provided for in this Business Associate Contract and the Agreement, to prevent use or disclosure of PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY other than as provided for by this Business Associate Contract.

3. CONTRACTOR agrees to comply with the HIPAA Security Rule at Subpart C of 45 CFR Part 164 with respect to electronic PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY.

4. CONTRACTOR agrees to mitigate, to the extent practicable, any harmful effect that is known to CONTRACTOR of a Use or Disclosure of PHI by CONTRACTOR in violation of the requirements of this Business Associate Contract.

5. CONTRACTOR agrees to report to COUNTY immediately any Use or Disclosure of PHI not provided for by this Business Associate Contract of which CONTRACTOR becomes aware. CONTRACTOR must report Breaches of Unsecured PHI in accordance with Paragraph E below and as required by 45 CFR § 164.410.

6. CONTRACTOR agrees to ensure that any Subcontractors that create, receive, maintain, or transmit PHI on behalf of CONTRACTOR agree to the same restrictions and conditions that apply through this Business Associate Contract to CONTRACTOR with respect to such information.

7. CONTRACTOR agrees to provide access, within fifteen (15) calendar days of receipt of a written request by COUNTY, to PHI in a Designated Record Set, to COUNTY or, as directed by COUNTY, to an Individual in order to meet the requirements under 45 CFR § 164.524. If CONTRACTOR maintains an Electronic Health Record with PHI, and an individual requests a copy of such information in an electronic format, CONTRACTOR shall provide such information in an electronic format.

8. CONTRACTOR agrees to make any amendment(s) to PHI in a Designated Record Set that COUNTY directs or agrees to pursuant to 45 CFR § 164.526 at the request of COUNTY or an Individual, within thirty (30) calendar days of receipt of said request by COUNTY.

CONTRACTOR agrees to notify COUNTY in writing no later than ten (10) calendar days after said amendment is completed.

9. CONTRACTOR agrees to make internal practices, books, and records, including policies and procedures, relating to the use and disclosure of PHI received from, or created or received by CONTRACTOR on behalf of, COUNTY available to COUNTY and the Secretary in a time and manner as determined by COUNTY or as designated by the Secretary for purposes of the Secretary determining COUNTY'S compliance with the HIPAA Privacy Rule.

10. CONTRACTOR agrees to document any Disclosures of PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY, and to make information related to such Disclosures available as would be required for COUNTY to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR § 164.528.

11. CONTRACTOR agrees to provide COUNTY or an Individual, as directed by COUNTY, in a time and manner to be determined by COUNTY, that information collected in accordance with the Agreement, in order to permit COUNTY to respond to a request by an Individual for an accounting of Disclosures of PHI in accordance with 45 CFR § 164.528.

12. CONTRACTOR agrees that to the extent CONTRACTOR carries out COUNTY'S obligation under the HIPAA Privacy and/or Security rules CONTRACTOR will comply with the requirements of 45 CFR Part 164 that apply to COUNTY in the performance of such obligation.

13. If CONTRACTOR receives Social Security data from COUNTY provided to COUNTY by a state agency, upon request by COUNTY, CONTRACTOR shall provide COUNTY with a list of all employees, subcontractors and agents who have access to the Social Security data, including employees, agents, subcontractors and agents of its subcontractors.

14. CONTRACTOR will notify COUNTY if CONTRACTOR is named as a defendant in a criminal proceeding for a violation of HIPAA. COUNTY may terminate the Agreement, if CONTRACTOR is found guilty of a criminal violation in connection with HIPAA. COUNTY may terminate the Agreement, if a finding or stipulation that CONTRACTOR has violated any standard or requirement of the privacy or security provisions of HIPAA, or other security or privacy laws are made in any administrative or civil proceeding in which CONTRACTOR is a party or has been joined. COUNTY will consider the nature and seriousness of the violation in deciding whether or not to terminate the Agreement.

15. CONTRACTOR shall make itself and any subcontractors, employees or agents assisting CONTRACTOR in the performance of its obligations under the Agreement, available to COUNTY at no cost to COUNTY to testify as witnesses, or otherwise, in the event of litigation or administrative proceedings being commenced against COUNTY, 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 CONTRACTOR, except where CONTRACTOR or its subcontractor, employee or agent is a named adverse party.

16. The Parties acknowledge that federal and state laws relating to electronic data security and privacy are rapidly evolving and that amendment of this Business Associate Contract 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 COUNTY'S request, CONTRACTOR agrees to promptly enter into negotiations with COUNTY concerning an amendment to this Business Associate Contract embodying written assurances consistent with

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

- a. CONTRACTOR does not promptly enter into negotiations to amend this Business Associate Contract when requested by COUNTY pursuant to this Paragraph C; or
- b. CONTRACTOR does not enter into an amendment providing assurances regarding the safeguarding of PHI that COUNTY deems are necessary to satisfy the standards and requirements of HIPAA, the HITECH Act, and the HIPAA regulations.

17. CONTRACTOR shall work with COUNTY upon notification by CONTRACTOR to COUNTY of a Breach to properly determine if any Breach exclusions exist as defined in Subparagraph B.2.a above.

D. SECURITY RULE

1. CONTRACTOR shall comply with the requirements of 45 CFR § 164.306 and establish and maintain appropriate Administrative, Physical and Technical Safeguards in accordance with 45 CFR § 164.308, § 164.310, and § 164.312, with respect to electronic PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY. CONTRACTOR shall develop and maintain a written information privacy and security program that includes Administrative, Physical, and Technical Safeguards appropriate to the size and complexity of CONTRACTOR's operations and the nature and scope of its activities.

2. CONTRACTOR 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 § 164.316. CONTRACTOR will provide COUNTY with its current and updated policies upon request.

3. CONTRACTOR shall ensure the continuous security of all computerized data systems containing electronic PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY. CONTRACTOR shall protect paper documents containing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY. These steps shall include, at a minimum:

- a. Complying with all of the data system security precautions listed under Paragraphs E, below;
- b. Achieving and maintaining compliance with the HIPAA Security Rule, as necessary in conducting operations on behalf of COUNTY;
- c. Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies;

4. CONTRACTOR shall ensure that any subcontractors that create, receive, maintain, or transmit electronic PHI on behalf of CONTRACTOR agree through a contract with CONTRACTOR to the same restrictions and requirements contained in this Paragraph D of this Business Associate Contract.

5. CONTRACTOR shall report to COUNTY immediately any Security Incident of which it becomes aware. CONTRACTOR shall report Breaches of Unsecured PHI in accordance with Paragraph E below and as required by 45 CFR § 164.410.

6. CONTRACTOR shall designate a Security Officer to oversee its data security

program who shall be responsible for carrying out the requirements of this paragraph and for communicating on security matters with COUNTY.

E. DATA SECURITY REQUIREMENTS

1. Personal Controls

a. Employee Training. All workforce members who assist in the performance of functions or activities on behalf of COUNTY in connection with Agreement, or access or disclose PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY, must complete information privacy and security training, at least annually, at CONTRACTOR's expense. Each workforce member who receives information privacy and security training must sign a certification, indicating the 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 the termination of Agreement.

b. Employee Discipline. Appropriate sanctions must be applied against workforce members who fail to comply with any provisions of CONTRACTOR's privacy policies and procedures, including termination of employment where appropriate.

c. Confidentiality Statement. All persons that will be working with PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 such PHI. The statement must be renewed annually. The CONTRACTOR shall retain each person's written confidentiality statement for COUNTY inspection for a period of six (6) years following the termination of the Agreement.

d. Background Check. Before a member of the workforce may access PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY, a background screening of that worker must be conducted. The screening should be commensurate with the risk and magnitude of harm the employee could cause, with more thorough screening being done for those employees who are authorized to bypass significant technical and operational security controls. The CONTRACTOR shall retain each workforce member's background check documentation for a period of three (3) years.

2. Technical Security Controls

a. Workstation/Laptop encryption. All workstations and laptops that store PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY either directly or temporarily 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 COUNTY.

b. Server Security. Servers containing unencrypted PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY required to perform necessary business functions may be copied, downloaded, or exported.

d. Removable media devices. All electronic files that contain PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on

behalf of COUNTY 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. Such PHI shall not be considered "removed from the premises" if it is only being transported from one of CONTRACTOR's locations to another of CONTRACTOR's locations.

e. Antivirus software. All workstations, laptops and other systems that process and/or store PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must have installed 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 30 days of vendor release. Applications and systems that cannot be patched due to operational reasons must have compensatory controls implemented to minimize risk, where possible.

g. User IDs and Password Controls. All users must be issued a unique user name for accessing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY. 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 90 days, preferably every 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 by COUNTY.

i. System Timeout. The system providing access to PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY, or which alters such PHI. 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 such PHI is stored in a database, database logging functionality must be enabled. Audit trail data must be archived for at least 3 years after occurrence.

l. Access Controls. The system providing access to PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must use role based access controls for all user authentications, enforcing the principle of least privilege.

m. Transmission encryption. All data transmissions of PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 in motion such as website access, file transfer, and E-Mail.

n. Intrusion Detection. All systems involved in accessing, holding, transporting, and protecting PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY that are accessible via the Internet must be protected by a comprehensive intrusion detection and prevention solution.

3. Audit Controls

a. System Security Review. CONTRACTOR must ensure audit control mechanisms that record and examine system activity are in place. All systems processing and/or storing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must have a routine procedure in place to review system logs for unauthorized access.

c. Change Control. All systems processing and/or storing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must have a documented change control procedure that ensures separation of duties and protects the confidentiality, integrity and availability of data.

4. Business Continuity/Disaster Recovery Control

a. Emergency Mode Operation Plan. CONTRACTOR must establish a documented plan to enable continuation of critical business processes and protection of the security of PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY kept in an electronic format 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 this Agreement for more than 24 hours.

b. Data Backup Plan. CONTRACTOR must have established documented procedures to backup such PHI to maintain retrievable exact copies of the PHI. The plan must

include a regular schedule for making backups, storing backup offsite, an inventory of backup media, and an estimate of the amount of time needed to restore DHCS PHI or PI should it be lost. At a minimum, the schedule must be a weekly full backup and monthly offsite storage of DHCS data. Business Continuity Plan (BCP) for contractor and COUNTY (e.g. the application owner) must merge with the DRP.

5. Paper Document Controls

a. Supervision of Data. PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 an employee authorized to access the information. Such PHI 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 PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY is contained shall be escorted and such PHI shall be kept out of sight while visitors are in the area.

c. Confidential Destruction. PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must be disposed of through confidential means, such as cross cut shredding and pulverizing.

d. Removal of Data. PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY must not be removed from the premises of the CONTRACTOR except with express written permission of COUNTY.

e. Faxing. Faxes containing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 containing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY shall be sealed and secured from damage or inappropriate viewing of PHI to the extent possible. Mailings which include 500 or more individually identifiable records containing PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 COUNTY to use another method is obtained.

F. BREACH DISCOVERY AND NOTIFICATION

1. Following the discovery of a Breach of Unsecured PHI , CONTRACTOR shall notify COUNTY of such Breach, however both parties agree to a delay in the notification if so advised by a law enforcement official pursuant to 45 CFR § 164.412.

a. A Breach shall be treated as discovered by CONTRACTOR as of the first day on which such Breach is known to CONTRACTOR or, by exercising reasonable diligence, would have been known to CONTRACTOR.

b. CONTRACTOR shall be deemed to have knowledge of a Breach, if the Breach is known, or by exercising reasonable diligence would have known, to any person who is an

employee, officer, or other agent of CONTRACTOR, as determined by federal common law of agency.

2. CONTRACTOR shall provide the notification of the Breach immediately to the COUNTY Privacy Officer.

a. CONTRACTOR'S notification may be oral, but shall be followed by written notification within 24 hours of the oral notification.

3. CONTRACTOR'S notification shall include, to the extent possible:

a. The identification of each Individual whose Unsecured PHI has been, or is reasonably believed by CONTRACTOR to have been, accessed, acquired, used, or disclosed during the Breach;

b. Any other information that COUNTY is required to include in the notification to Individual under 45 CFR §164.404 (c) at the time CONTRACTOR is required to notify COUNTY or promptly thereafter as this information becomes available, even after the regulatory sixty (60) day period set forth in 45 CFR § 164.410 (b) has elapsed, including:

(1) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;

(2) A description of the types of Unsecured PHI that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);

(3) Any steps Individuals should take to protect themselves from potential harm resulting from the Breach;

(4) A brief description of what CONTRACTOR is doing to investigate the Breach, to mitigate harm to Individuals, and to protect against any future Breaches; and

(5) Contact procedures for Individuals to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.

4. COUNTY may require CONTRACTOR to provide notice to the Individual as required in 45 CFR § 164.404, if it is reasonable to do so under the circumstances, at the sole discretion of the COUNTY.

5. In the event that CONTRACTOR is responsible for a Breach of Unsecured PHI in violation of the HIPAA Privacy Rule, CONTRACTOR shall have the burden of demonstrating that CONTRACTOR made all notifications to COUNTY consistent with this Paragraph F and as required by the Breach notification regulations, or, in the alternative, that the acquisition, access, use, or disclosure of PHI did not constitute a Breach.

6. CONTRACTOR shall maintain documentation of all required notifications of a Breach or its risk assessment under 45 CFR § 164.402 to demonstrate that a Breach did not occur.

7. CONTRACTOR shall provide to COUNTY all specific and pertinent information about the Breach, including the information listed in Section E.3.b.(1)-(5) above, if not yet provided, to permit COUNTY to meet its notification obligations under Subpart D of 45 CFR Part 164 as soon as practicable, but in no event later than fifteen (15) calendar days after CONTRACTOR's initial report of the Breach to COUNTY pursuant to Subparagraph F.2 above.

8. CONTRACTOR shall continue to provide all additional pertinent information about the Breach to COUNTY as it may become available, in reporting increments of five (5) business days after the last report to COUNTY. CONTRACTOR shall also respond in good faith to any

reasonable requests for further information, or follow-up information after report to COUNTY, when such request is made by COUNTY.

9. If the Breach is the fault of CONTRACTOR, CONTRACTOR shall bear all expense or other costs associated with the Breach and shall reimburse COUNTY for all expenses COUNTY incurs in addressing the Breach and consequences thereof, including costs of investigation, notification, remediation, documentation or other costs associated with addressing the Breach.

G. PERMITTED USES AND DISCLOSURES BY CONTRACTOR

1. CONTRACTOR may use or further disclose PHI COUNTY discloses to CONTRACTOR as necessary to perform functions, activities, or services for, or on behalf of, COUNTY as specified in the Agreement, provided that such use or Disclosure would not violate the HIPAA Privacy Rule if done by COUNTY except for the specific Uses and Disclosures set forth below.

a. CONTRACTOR may use PHI COUNTY discloses to CONTRACTOR, if necessary, for the proper management and administration of CONTRACTOR.

b. CONTRACTOR may disclose PHI COUNTY discloses to CONTRACTOR for the proper management and administration of CONTRACTOR or to carry out the legal responsibilities of CONTRACTOR, if:

i. The Disclosure is required by law; or

ii. CONTRACTOR obtains reasonable assurances from the person to whom the PHI is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person and the person immediately notifies CONTRACTOR of any instance of which it is aware in which the confidentiality of the information has been breached.

c. CONTRACTOR may use or further disclose PHI COUNTY discloses to CONTRACTOR to provide Data Aggregation services relating to the Health Care Operations of CONTRACTOR.

2. CONTRACTOR may use PHI COUNTY discloses to CONTRACTOR, if necessary, to carry out legal responsibilities of CONTRACTOR.

3. CONTRACTOR may use and disclose PHI COUNTY discloses to CONTRACTOR consistent with the minimum necessary policies and procedures of COUNTY.

4. CONTRACTOR may use or disclose PHI COUNTY discloses to CONTRACTOR as required by law.

H. PROHIBITED USES AND DISCLOSURES

1. CONTRACTOR shall not disclose PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY 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 USC § 17935(a) and 45 CFR § 164.522(a).

2. CONTRACTOR shall not directly or indirectly receive remuneration in exchange for PHI COUNTY discloses to CONTRACTOR or CONTRACTOR creates, receives, maintains, or transmits on behalf of COUNTY, except with the prior written consent of COUNTY and as permitted by 42 USC § 17935(d)(2).

I. OBLIGATIONS OF COUNTY

1. COUNTY shall notify CONTRACTOR of any limitation(s) in COUNTY'S notice of privacy practices in accordance with 45 CFR § 164.520, to the extent that such limitation may affect CONTRACTOR'S Use or Disclosure of PHI.

2. COUNTY shall notify CONTRACTOR of any changes in, or revocation of, the permission by an Individual to use or disclose his or her PHI, to the extent that such changes may affect CONTRACTOR'S Use or Disclosure of PHI.

3. COUNTY shall notify CONTRACTOR of any restriction to the Use or Disclosure of PHI that COUNTY has agreed to in accordance with 45 CFR § 164.522, to the extent that such restriction may affect CONTRACTOR'S Use or Disclosure of PHI.

4. COUNTY shall not request CONTRACTOR to use or disclose PHI in any manner that would not be permissible under the HIPAA Privacy Rule if done by COUNTY.

J. BUSINESS ASSOCIATE TERMINATION

1. Upon COUNTY'S knowledge of a material breach or violation by CONTRACTOR of the requirements of this Business Associate Contract, COUNTY shall:

a. Provide an opportunity for CONTRACTOR to cure the material breach or end the violation within thirty (30) business days; or

b. Immediately terminate the Agreement, if CONTRACTOR is unwilling or unable to cure the material breach or end the violation within (30) days, provided termination of the Agreement is feasible.

2. Upon termination of the Agreement, CONTRACTOR shall either destroy or return to COUNTY all PHI CONTRACTOR received from COUNTY or CONTRACTOR created, maintained, or received on behalf of COUNTY in conformity with the HIPAA Privacy Rule.

a. This provision shall apply to all PHI that is in the possession of Subcontractors or agents of CONTRACTOR.

b. CONTRACTOR shall retain no copies of the PHI.

c. In the event that CONTRACTOR determines that returning or destroying the PHI is not feasible, CONTRACTOR shall provide to COUNTY notification of the conditions that make return or destruction infeasible. Upon determination by COUNTY that return or destruction of PHI is infeasible, CONTRACTOR shall extend the protections of this Business Associate Contract to such PHI and limit further Uses and Disclosures of such PHI to those purposes that make the return or destruction infeasible, for as long as CONTRACTOR maintains such PHI.

3. The obligations of this Business Associate Contract shall survive the termination of the Agreement.

Attachment D

Personal Information Privacy and Security Contract

ATTACHMENT D**PERSONAL INFORMATION PRIVACY AND SECURITY CONTRACT**

Any reference to statutory, regulatory, or contractual language herein shall be to such language as in effect or as amended.

A. DEFINITIONS

1. "Breach" shall have the meaning given to such term under the IEA and CMPPA. It shall include a "PII loss" as that term is defined in the CMPPA.

2. "Breach of the security of the system" shall have the meaning given to such term under the California Information Practices Act, Civil Code § 1798.29(d).

3. "CMPPA Agreement" means the Computer Matching and Privacy Protection Act Agreement between the Social Security Administration and the California Health and Human Services Agency (CHHS).

4. "DHCS PI" shall mean Personal Information, as defined below, accessed in a database maintained by the COUNTY or California Department of Health Care Services (DHCS), received by CONTRACTOR from the COUNTY or DHCS or acquired or created by CONTRACTOR in connection with performing the functions, activities and services specified in the Agreement on behalf of the COUNTY.

5. "IEA" shall mean the Information Exchange Agreement currently in effect between the Social Security Administration (SSA) and DHCS.

6. "Notice-triggering Personal Information" shall mean the personal information identified in Civil Code section 1798.29(e) whose unauthorized access may trigger notification requirements under Civil Code § 1709.29. 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 a finger or voice print, a photograph or a biometric identifier. Notice-triggering Personal Information includes PI in electronic, paper or any other medium.

7. "Personally Identifiable Information" (PII) shall have the meaning given to such term in the IEA and CMPPA.

8. "Personal Information" (PI) shall have the meaning given to such term in California Civil Code § 1798.3(a).

9. "Required by law" means a mandate contained in law that compels an entity to make a use or disclosure of PI or PII 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.

10. "Security Incident" means the attempted or successful unauthorized access, use, disclosure, modification, or destruction of PI, or confidential data utilized in complying with this Agreement; or interference with system operations in an information system that processes, maintains or stores PI.

B. TERMS OF AGREEMENT

1. Permitted Uses and Disclosures of DHCS PI and PII by CONTRACTOR. Except as otherwise indicated in this Exhibit, CONTRACTOR may use or disclose DHCS PI only to perform functions, activities, or services for or on behalf of the COUNTY pursuant to the terms of the Agreement provided that such use or disclosure would not violate the California Information Practices Act (CIPA) if done by the COUNTY.

2. Responsibilities of CONTRACTOR

CONTRACTOR agrees:

a) Nondisclosure. Not to use or disclose DHCS PI or PII other than as permitted or required by this Personal Information Privacy and Security Contract or as required by applicable state and federal law.

b) Safeguards. To implement appropriate and reasonable administrative, technical, and physical safeguards to protect the security, confidentiality and integrity of DHCS PI and PII, to protect against anticipated threats or hazards to the security or integrity of DHCS PI and PII, and to prevent use or disclosure of DHCS PI or PII other than as provided for by this Personal Information Privacy and Security Contract. CONTRACTOR shall develop and maintain a written information privacy and security program that include administrative, technical and physical safeguards appropriate to the size and complexity of CONTRACTOR's operations and the nature and scope of its activities, which incorporate the requirements of Paragraph (c), below. CONTRACTOR will provide COUNTY with its current policies upon request.

c) Security. CONTRACTOR shall ensure the continuous security of all computerized data systems containing DHCS PI and PII. CONTRACTOR shall protect paper documents containing DHCS PI and PII. These steps shall include, at a minimum:

i. Complying with all of the data system security precautions listed in Paragraph E of the Business Associate Contract, Attachment C to the Agreement; and

ii. Providing a level and scope of security that is at least comparable to the level and scope of security established by the Office of Management and Budget in OMB Circular No. A-130, Appendix III-Security of Federal Automated Information Systems, which sets forth guidelines for automated information systems in Federal agencies.

iii. If the data obtained by CONTRACTOR from COUNTY includes PII, CONTRACTOR shall also comply with the substantive privacy and security requirements in the Computer Matching and Privacy Protection Act Agreement between the SSA and the California Health and Human Services Agency (CHHS) and in the Agreement between the SSA and DHCS, known as the Information Exchange Agreement (IEA). The specific sections of the IEA with substantive privacy and security requirements to be complied with are sections E, F, and G, and in Attachment 4 to the IEA, Electronic Information Exchange Security Requirements, Guidelines and Procedures for Federal, State and Local Agencies Exchanging Electronic Information with the SSA. CONTRACTOR also agrees to ensure that any of CONTRACTOR's agents or subcontractors, to whom CONTRACTOR provides DHCS PII agree to the same requirements for privacy and security safeguards for confidential data that apply to CONTRACTOR with respect to such information.

d) Mitigation of Harmful Effects. To mitigate, to the extent practicable, any harmful

effect that is known to CONTRACTOR of a use or disclosure of DHCS PI or PII by CONTRACTOR or its subcontractors in violation of this Personal Information Privacy and Security Contract.

e) CONTRACTOR's Agents and Subcontractors. To impose the same restrictions and conditions set forth in this Personal Information and Security Contract on any subcontractors or other agents with whom CONTRACTOR subcontracts any activities under the Agreement that involve the disclosure of DHCS PI or PII to such subcontractors or other agents.

f) Availability of Information. To make DHCS PI and PII available to the DHCS and/or COUNTY for purposes of oversight, inspection, amendment, and response to requests for records, injunctions, judgments, and orders for production of DHCS PI and PII. If CONTRACTOR receives DHCS PII, upon request by COUNTY and/or DHCS, CONTRACTOR shall provide COUNTY and/or DHCS with a list of all employees, contractors and agents who have access to DHCS PII, including employees, contractors and agents of its subcontractors and agents.

g) Cooperation with COUNTY. With respect to DHCS PI, to cooperate with and assist the COUNTY to the extent necessary to ensure the DHCS's compliance with the applicable terms of the CIPA including, but not limited to, accounting of disclosures of DHCS PI, correction of errors in DHCS PI, production of DHCS PI, disclosure of a security breach involving DHCS PI and notice of such breach to the affected individual(s).

h) Breaches and Security Incidents. During the term of the Agreement, CONTRACTOR agrees to implement reasonable systems for the discovery of any breach of unsecured DHCS PI and PII or security incident. CONTRACTOR agrees to give notification of any breach of unsecured DHCS PI and PII or security incident in accordance with Paragraph F, of the Business Associate Contract, Attachment c to the Agreement.

i) Designation of Individual Responsible for Security. CONTRACTOR shall designate an individual, (e.g., Security Officer), to oversee its data security program who shall be responsible for carrying out the requirements of this Personal Information Privacy and Security Contract and for communicating on security matters with the COUNTY.