STATE OF CALIFORNIA - DEPARTMENT OF GENERAL SERVICES

STANDARD AGREEMENT - AMENDMENT

SCO ID: 4265 2010648A01

STD 213A (Rev. 10/2019)

☐ CHECK HERE IF ADDITIONAL PAGES ARE ATTACHED PAGES

AGREEMENT NUMBER	AMENDMENT NUMBER	Purchasing Authority Number
20-10648	A01	

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

STATE AGENCY NAME
California Department of Public Health

CONTRACTOR NAME
PerkinElmer Health Sciences, Inc.

2. The term of this Agreement is:

START DATE
8/26/2020

THROUGH END DATE
10/31/2021

3. The maximum amount of this Agreement after this Amendment is:
$1,700,000,000.00
One Billion Seven Hundred Million Dollars and Zero Cents

4. The parties mutually agree to this amendment as follows. All actions noted below are by this reference made a part of the Agreement and incorporated herein:

I. This amendment:
   a. Adds Attachment A-3 to Exhibit A - (20 Pages)
   b. Replaces Exhibit B-1 with Attachment B-1a - (1 Page)

Where applicable the above supersedes the original agreement.

All other terms and conditions shall remain the same.

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

CONTRACTOR

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

CONTRACTOR BUSINESS ADDRESS	CITY	STATE	ZIP
940 Winter Street	Waltham	MA	02451

PRINTED NAME OF PERSON SIGNING	TITLE
LeeAnn L. Dennewitz	VP/GM Global Commercial Excellence

CONTRACTOR AUTHORIZED SIGNATURE

DATE SIGNED
3/4/2021

STATE OF CALIFORNIA

CONTRACTING AGENCY NAME
California Department of Public Health

CONTRACTING AGENCY ADDRESS	CITY	STATE	ZIP
1615 Capitol Ave	Sacramento	CA	95835

PRINTED NAME OF PERSON SIGNING	TITLE
Tim Bow	Procurement Officer

CONTRACTING AGENCY AUTHORIZED SIGNATURE
Timothy Bow
Digitally signed by Timothy Bow
Date: 2021.03.04 14:55:22 -08'00'

DATE SIGNED

CALIFORNIA DEPARTMENT OF GENERAL SERVICES APPROVAL

EXEMPTION (If Applicable)
PCC 1102
Executive Order N-25-20-COVID19

CDPH CONTRACT 20-10648
AMENDMENT 01
EXHIBIT A (ATTACHMENT A-3)

THIS AMENDMENT ONE TO STANDARD AGREEMENT (this "Amendment One"), effective as indicated on the STD213 is entered into by and between the California Department of Public Health ("CDPH") and PerkinElmer Health Sciences, Inc. ("Contractor"). The above-identified parties are at times referred to herein each as a "Party" and collectively as the "Parties."

RECITALS:

WHEREAS, the CDPH and PerkinElmer entered into an agreement for PerkinElmer to provide certain laboratory testing and reporting services in response to the SARS-CoV-2 pandemic effective August 26, 2020 (the "Agreement"); and

WHEREAS, the Parties are desirous of modifying the Agreement for PerkinElmer to provide additional or modified services going forward from the Amendment One Effective Date;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties amend the Agreement and otherwise agree as follows:

1. Except as otherwise expressly modified by this Amendment One, the Agreement shall remain in full force and effect in accordance with its terms. All terms capitalized herein but not defined shall have the meanings ascribed to them in the Agreement.

2. Exhibit A, Section 3(A) of the Agreement is deleted and replaced with the following:

A. Contractor Responsibilities

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

1. Developing and implementing a plan for a) pooling samples provided by CDPH in pools of up to five samples ("Pool Samples"), and b) conducting testing of routine diagnostic testing of samples other than Pool Samples.

2. Delivery and installation of equipment necessary for SARS CoV-2 diagnostic testing described in Section 3(A)(1) of this Exhibit A, as itemized in Attachment 1 (the "Equipment").

3. Supply of all consumables, reagents and Personal Protective Equipment ("PPE") necessary for performing the Services.

4. Supply furniture and all equipment necessary for performance of the Services at the Facilities.

5. Supply of all personnel, duly licensed as required by, and in compliance with, applicable federal and state law and regulations to operate at the Facilities (the "Personnel"), including, as needed:

    - Logistics and Supply Chain Management
    - Quality Assurance/ Quality Control
    - Lab Testing Personnel
    - Laboratory Supervisors
    - Information Technology Professionals
    - Specimen Processors
    - Service Engineers
    - Human Resources
    - Laboratory Management (including CA State accredited Medical and Laboratory Directors)
    - A designated project manager to collaborate with CDPH with respect to Facility maintenance.

6. Performance of all necessary service for proper installation and maintenance of the Equipment (the "Maintenance Services").

7. Supply and installation of PerkinElmer Genomics' proprietary laboratory information management system (the "LIMS") at the Facilities. Contractor shall implement an interface to the LIMS enabling collecting healthcare providers to enter required demographic information and sample identification, and CDPH shall require collection sites to enter all such information through the interface, unless otherwise agreed for specific, remote collection sites as may be agreed by the Parties from time to time. All reports from the testing Services will be generated through the LIMS and the laboratory director will be able to sign out reports through the LIMS. Notwithstanding anything else in the foregoing, Contractor shall have no liability for errors or delays resulting from any sample collection site's failure to submit timely and accurate information.

8. Reporting of the results of the Services in a mutually agreed upon format and medium. Reporting of quality metrics for the Services to be agreed by the Parties, which shall include, at a minimum, total samples tested, Pool Samples tested, average turnaround time, summary of corrected / amended reports, overview of corrective actions and process improvements ("Quality Metrics"). In addition to these reports, Contractor shall provide CDPH laboratory oversight personnel direct access to all necessary data/reporting systems.

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9. Upon CDPH request, Contractor and CDPH will jointly review and evaluate current Quality Metrics. If CDPH or Contractor determines that improvement in the Quality Metrics is necessary, such Party shall provide the other with a detailed list of requested changes to Quality Metrics. The Contractor shall provide either an implementation plan or written explanation of why the requested changes are impracticable or unnecessary within five (5) business days, unless additional time is granted by CDPH. The Contractor shall execute any implementation plan upon written confirmation from CDPH.

10. Operation of Facilities in compliance with all state and federal regulations and requirements, and the Facility's accreditation under LFS and CAP (CLIA).

11. Performance of all necessary service for proper response to communications from CDPH and third parties in a mutually agreed upon format, medium and timeliness (the "Customer Services"). This shall be documented in a Customer Service Business Plan to ensure consistency in responding to client questions that arise.

12. Facilities operations management, including cleaning, and biohazard disposal at the Facilities.

13. Reporting of the testing results within the Contractor's then-current daily testing capacity within twenty-four (24) to forty-eight (48) hours after the receipt of the sample in the Facility.

14. All services under this Section 3(A) and Backup Services (as defined below) will be performed in compliance with the requirements of the FDA Emergency Use Authorization (the "EUA") described in Attachment 2 or a laboratory developed test (LDT) as may be agreed by the Parties.

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

    The parties understand and agree that for all purposes under this agreement, daily testing capacity is a measure of tests capable of being performed pursuant to this Section 3(A) and not samples

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tested. Unless otherwise instructed by CDPH, Contractor will 1) routine diagnostic samples, and then 2) Pooled Samples. The volume of results reported will vary depending on the mix of routine diagnostic samples and Pooled Samples.

3. Attachment 2 to Exhibit A of the Agreement is deleted and replaced with the Attachment 2 attached as Annex 1 hereto.

4. The following is added as Exhibit A, Section 3(A1) of the Agreement:

A1. Sequencing Services

Contractor will be responsible for developing and implementing a plan for sequencing services ("Sequencing Services") related to samples testing positive for SARS CoV-2 through the Services or otherwise forward to a CDPH approved Facility. Sequencing Services will be performed at the Facilities under the guidance of and in collaboration with the California Novel Coronavirus Testing Task Force. The Sequencing Services shall consist of:

1. Delivery and installation of equipment necessary for performing whole genome sequencing of the SARS-CoV-2 virus, as itemized in Attachment 1A (the "Sequencing Equipment").

2. Supply of all consumables and reagents necessary for performing the Sequencing Services.

3. Performance of all necessary service for proper installation and maintenance of the Sequencing Equipment. The Parties agree that PerkinElmer may subcontract installation and maintenance of the Sequencing Agreement to a third party.

4. Sequencing the SARS CoV-2 virus from up to 5,000 positive samples from the Services per week, delivering ~1 million reads per sample using PerkinElmer COVID sequencing assay and automation.

5. Reporting of the results of the Sequencing Services in either FASTA format or FASTQ raw data to CDPH by a medium to be agreed by the Parties. Reporting of the results of Sequencing Services will be within seven (7) days of reporting the positive PCR result for the applicable sample.

6. Performance of Sequencing Services on an expedited basis when notified by CDPH or its designee by phone or email, of the need for STAT treatment ("STAT Sequencing Services"), such notice to include the barcode for the sample to be sequenced. Contractor will provide appropriate phone number and email address for CDPH to provide notice of the need for STAT Sequencing Services. Contractor shall provide STAT Sequencing Services on up to twenty-four (24) samples

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per day. Reporting of the results of STAT Sequencing Services will be within twenty-four (24) to forty-eight (48) hours of receipt of notice from CDPH of the need for such services.

7. No later than March 8, 2021, Contractor shall provide an implementation plan, including a timeline, for launch of the Sequencing Services.

8. Until implementation of Sequencing Services at the Facility, Contractor shall conduct Sequencing Services on all SARS-CoV-2 positive samples from the date of the Sequencing Services implementation plan with Ct values less than 30 for both viral gene targets (i.e., ORF1ab and N targets) at the PerkinElmer Genetics, Inc. laboratory lts Pittsburgh, PA, and provide FASTA format or FASTQ raw data to CDPH by a medium to be agreed by the Parties.

9. Commencing March 1, 2021, Contractor will send 300 to 500 positive SARS-CoV-2 samples in 96-well deep well storage plates to CDPH Richmond on a weekly basis.

5. In Exhibit A, Section 3(B) of the Agreement, each instance of the phrase "the Services" is deleted and replaced with "the Services and Sequencing Services."

6. In Exhibit A, Section 3(B) of the agreement, Section 3(B)(10) is deleted and replaced with the following:

> Monitoring Quality Metrics and advising Contractor on CDPH concerns and priorities. CDPH may provide Contractor with requested improvements to the Quality Metrics on an as-needed basis. CDPH and Contractor will communicate regularly about the Quality Metrics and Facility Operations.

7. The following is added as Exhibit A, Section 3(C)(6) of the Agreement:

> 6) All Sequencing Equipment is provided by Contractor on a no-cost loan basis. CDPH, in the capacity of bailee, will take possession of any Sequencing Equipment provided by Contractor only as provided in this Agreement. The continued bailment of the Sequencing Equipment to CDPH is contingent upon CDPH purchasing the Sequencing Services as provided in this Agreement.

8. In Exhibit A, Section 3(C) of the Agreement, i) each instance of the phrase "the Services" is deleted and replaced with "the Services or Sequencing Services," and ii) each instance of the word "Equipment" is deleted and replaced with "Equipment or Sequencing Equipment."

9. In Exhibit A, Section 6(3) of the Agreement, the word "Services" is deleted and replaced with "Services or Sequencing Services."

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10. The Sequencing Equipment list attached hereto as Annex 2 is added as Exhibit A, Attachment 1A of the Agreement.

11. In Exhibit B of the Agreement, Section 1(E)(3) is deleted and replaced with the following:

> 3) CDPH shall pay Contractor a monthly fee for testing (the "Monthly Fee"), which shall be the lesser of: (a) a fee comprised of a fixed fee for maintenance of Contractor's testing carrying capacity (the "Monthly Fixed Fee") based on Contractor's declared average testing capacity for the following month, plus the price per test performed in the prior month for each of the Pool Samples and routine diagnostic samples as provided below (the "Variable Fee"), or (b) Contractor's Best Price. "Best Price" means the lowest price, on a per test basis, accepted by Contractor from any purchaser for SARS CoV-2 diagnostic testing under substantially similar commercial terms and circumstances, including, but not limited to, labor, utilities, taxes, insurance and other third-party costs, testing volume, technology used, personnel requirements, and facilities as under this Agreement. For the purpose of determining Best Price, Contractor shall divide the Monthly Fee by the total number of tests performed in the applicable month, excluding any credits or penalties other than as provided in Section 1(E)(4). Upon ten (10) days written notice, CDPH may audit Contractor's books and records as reasonably applicable to services rendered that meet the prerequisites for a Best Price in the foregoing sentence. A detailed cost breakdown for the Services is attached to this Exhibit as Attachment 1.

Contractor's Daily Testing Capacity	Monthly Fixed Fee	Average Daily Aggregate Tests performed	Variable Fee Per Routine Diagnostic Sample	Variable Fee Per Pool Tested
40,000	$24,000,000	40,000=<X<50,000	$19.95	$24.95
50,000	$30,000,000	50,000=<X<60,000	$20.63	$25.63
60,000	$36,000,000	60,000=<X<70,000	$19.59	$24.59
70,000	$42,000,000	70,000=<X<80,000	$19.91	$24.91
80,000	$48,000,000	80,000=<X<90,000	$18.66	$23.66
90,000	$54,000,000	90,000=<X<100,000	$18.85	$23.85
100,000	$60,000,000	100,000=<X<110,000	$18.00	$23.00
110,000	$65,000,000	110,000=<X<120,000	$17.12	$22.12
120,000	$70,000,000	120,000=<X<130,000	$16.24	$21.24
130,000	$75,000,000	130,000=<X<140,000	$15.33	$20.33
140,000	$80,000,000	140,000=<X<150,000	$14.40	$19.40
150,000	$85,000,000	X>=150,000	$13.47	$18.47

> By way of example, if for a given month contractor's declared average testing capacity is 110,000, and contractor performs an average of 42,000 pools and 37,000 routine diagnostic tests per month, the Monthly Fee for

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that month will be $65,000,000 + ($19.91 * routine diagnostic samples tested) + ($24.91 * actual pools tested).

Each pool tested shall be considered a single test against the contactor's declared daily testing capacity.

12. In Exhibit B of the Agreement, Section 1(E)(4) is deleted and replaced with the following:

4) Each Monthly Fee shall be credited as follows:

a. Startup Payments: $5.51 per test charged up to 120,000 tests per day each day of the applicable month, until the aggregate of all such credits equals the sum of the first two Startup Payments; and b) if CDPH has made the 3rd payment, $5.04 per test charged in excess of 120,000 tests each day of the applicable month (subject to reduction to maintain overall per-test cost pursuant to Section 1(E)(2), until the aggregate of all such credits equals the amount of the 3rd Startup Payment.

b. Balancing Credits: For purposes of this Section "Contract Month" means each successive thirty (30) day period following the effective date of this Agreement.

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

Beginning the Contract Month for which Contractor invoices CDPH an average of 130,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that

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point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 120,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $15.33.

Beginning the Contract Month for which Contractor invoices CDPH an average of 140,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 130,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $14.40.

Beginning the Contract Month for which Contractor invoices CDPH an average of 150,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 140,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $13.47.

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

Total amount of Variable Fees paid or payable by CDPH =
(47,000*30*20.95) + (73,000*30*$19.91) +
(122,000*30*$16.24) =
$131,170,800

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

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

Total Balancing Credit Value =
$131,170,800 - ($13.47 * 7,260,000) =
$33,378,600

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Number of tests credited =
(150,000 * 3 * 30) - 7,260,000 =
6,240,000

Credit per test =
$33,378,600 / 6,240,000 =
$5.349

13. The following is added to Exhibit B, Section 1(E) of the Agreement:

8) CDPH shall pay Contractor a fixed fee of $20 per reported result of Sequencing Services, including STAT Sequencing Services.

9) CDPH shall reimburse Contractor the costs of delivery, installation and maintenance of Sequencing Equipment as those costs come due, with prior notification to CDPH of proposed costs.

14. In Exhibit B of the Agreement, Section 1(E)(6) is deleted and replaced with the following:

6) On a monthly basis, CDPH shall reimburse Contractor for Facility management and maintenance, including, but not limited to, personnel costs, actual third-party service provider expenses including cleaning and biohazard disposal, and associated overhead.

15. Exhibit B, Attachment 1 of the Agreement is deleted and replaced with the Attachment 1 in Annex 3 hereto.

16. Save and except as amended and extended herein, the Agreement shall remain in full force and effect binding upon the Parties.

IN WITNESS WHEREOF, the Parties have caused this Amendment One to be executed by their duly authorized representatives as of the Amendment One Effective Date.

CDPH

By: _____

Name: _____

Title: _____

Date: _____

PerkinElmer Health Sciences, Inc.

By: [signature]

Name: LeeAnn L. Dennewitz

Title: VP GM, Global Commercial Excellence

Date: 3/4/2021

U.S. FOOD & DRUG ADMINISTRATION

February 5, 2021

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

Device:	PerkinElmer New Coronavirus Nucleic Acid Detection Kit
EUA Number:	EUA200055
Company:	PerkinElmer, Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare provider (HCP) and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Mr. Ciccariello:

On March 24, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to laboratories certified under

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

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CLIA, 42 U.S.C. §263a, to perform high complexity tests. Based on your request, FDA also granted updates to the authorized labeling on April 1, 2020,[2] July 30, 2020,[3] and September 25, 2020.[4] On October 28, 2020, based on your request, FDA reissued the March 24, 2020, letter in its entirety with revisions incorporated.[5] On January 12, 2021, based on your request, FDA reissued the October 28, 2020, letter in its entirety with revisions incorporated.[6]

On December 4, 2020, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the January 12, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the January 12, 2021, letter in its entirety with the revisions incorporated.[7] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[8] is now authorized for use consistent with the indication described above.

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

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[2] On April 1, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add an additional nucleic acid extraction method which utilizes the chemagic Viral DNA/RNA 300 Kit H96 on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor related changes and edits to the IFU.

[3] On July 30, 2020, your request was granted via email to update the intended use of your product to add anterior nasal swab specimens and the IFU, Fact Sheet Healthcare Providers and Fact Sheet for Patients were also updated accordingly.

[4] On September 25, 2020, your request was granted via email to update the IFU of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing.

[5] On October 28, 2020, the revisions to the March 24, 2020, letter and authorized labeling included: (1) revisions to the authorized labeling to add 4 additional PCR instruments for use with your product, (2) revisions to the intended use and authorized labeling documents to include testing of pooled samples containing up to five individual upper respiratory swab specimens (oropharyngeal, nasopharyngeal, or anterior nasal swabs), where each specimen is collected under observation or by a healthcare provider using individual vials containing transport media, (3) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations, and (4) revisions to the Conditions of Authorization as a result of the new intended use and for consistency with recent authorizations.

[6] On January 12, 2021, the revisions to the October 28, 2020, letter and authorized labeling included: (1) revisions to the intended use to include testing of oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP, and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection, (2) update the inclusivity study data to include information about the emergence of mutations in one of the SARS-CoV-2 target (N) forward primer sequences, and (3) revisions to the Conditions of Authorization for consistency with recent authorizations.

[7] The revisions to the January 12, 2021, letter include: (1) addition of condition of authorization Q in section IV below to address electromagnetic compatibility (EMC) testing, (2) removal of condition of authorization Q in the letter issued on January 12, 2021, requiring the submission of additional pooling information and *in silico* analysis across multiple geographical locations, that is fulfilled.. There are no revisions to the authorized labeling.

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

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vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[9]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (IFU - identified below).

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

I. Criteria for Issuance of Authorization

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

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.[10]

II. Scope of Authorization

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

The Authorized Product

Your product is a test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab

[9] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* 85 FR 7316 (February 7, 2020).

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

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specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If patient's clinical signs and symptoms are inconsistent with a negative result and results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

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

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. below), that are to be run as outlined in the IFU. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the IFU:

- nCoV Internal Control - bacteriophage MS2 added clinical samples and controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.

- nCoV Negative Control - buffer used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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

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The labeling entitled "Instructions for PerkinElmer New Coronavirus Nucleic Acid Detection Kit" IFU (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) and the following fact sheets pertaining to the emergency use, which is required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referenced as "authorized labeling":

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

The above described product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

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

III. Waiver of Certain Requirements

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

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I

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(Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

PerkinElmer, Inc. (You) and Authorized Distributor(s)[11]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the authorized Instructions for Use with each shipped product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

PerkinElmer, Inc. (You)

[11] "Authorized Distributor(s)" are identified by you, PerkinElmer, Inc., in your EUA submission as an entity allowed to distribute your product.

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I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT 7) - Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

L. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your products for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You must evaluate the analytical limit of detection and assess traceability[12] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the date by FDA you must update your labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must further evaluate the clinical performance of your product, with specimens collected from asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and FDA's review of and concurrence with the data, you must update the authorized labeling to reflect the additional testing. Such labeling updates must be made in

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

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consultation with, and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH.

Q. You will further perform electromagnetic compatibility (EMC) testing to International Electrotechnical Commission (IEC) 60601-1-2 Edition 4.0:2014 standards within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional analysis. Such labeling updates will be made in consultation with, and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH.

R. You must develop a laboratory procedure whereby authorized laboratories can verify that the RUO instrument(s) authorized with your product is capable of performing the PerkinElmer New Coronavirus Nucleic Acid Detection Kit test with sufficient accuracy, as stated in the authorized labeling. You must submit the procedure to FDA within 21 calendar days of authorization. After DMD/OHT7-OIR/OPEQ/CDRH's review and concurrence, you must update the authorized labeling to reflect the laboratory procedure within 45 calendar days of authorization.

S. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA in accordance with 21 CFR Part 803.

Authorized Laboratories

T. Authorized laboratories using your product must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

U. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

W. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

X. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that *"Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."*

Y. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Specimen Pooling Implementation and Monitoring Guidelines" provided in

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the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

Z. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring Guidelines. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

AA. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and You (via email: COVID-19.TechnicalSupport@PerkinElmer.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

BB. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

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

CC. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

DD. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

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

FF. All descriptive printed matter, advertising, and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;

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- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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

V. Duration of Authorization

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

Sincerely,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure

Annex 2
Sequencing Equipment

Item #	Description
1	Illumina NovaSeq6000
2	Sciclone G3 NGSx
3	Sciclone G3 NGSx IQ
4	FlexDrop IQ Workstation
5	Zephyr G3 Workstation
6	Cellink IDOT
7	Thermal Cycler and associated parts and accessories
8	JANUS G3 Expanded 8-Tip MDT
9	Victor Nivo

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CDPH Contract 20-10648
AMENDMENT 01 Attachment B-1a

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

Pooling Test Methodology												
Fixed Monthly Fee		Variable Fee					Total Cost					
Contractor's Daily Pooling Capacity	Monthly Fixed Fee	Average Pools Per Month	Average Pools Per Year	Variable Fee/Pool Performed (Variable fee increased by $5 to account for extra accessioning personnel (5X sample amount per run), consumables and reagents per run.)	Pool Cost (Including Credit)	Monthly Cost	Monthly	Yearly	Cost Per Pool (Excluding Startup)	Total Cost (Including Startup)	Total Cost Per Pool (Including Startup)	Total Cost Per Test @ 5 Sample Pool (Including Startup)
-	$6,000,000						$6,000,000	$72,000,000		$272,447,200		
10,000	$9,000,000	303,333	3,640,000	$35.67	$30.16	$9,149,507	$18,149,507	$217,794,080	$59.83	$418,241,280	$ 114.90	$ 22.98
20,000	$12,000,000	606,667	7,280,000	$27.52	$22.01	$13,354,680	$25,354,680	$304,256,160	$41.79	$504,703,360	$ 69.33	$ 13.87
30,000	$18,000,000	910,000	10,920,000	$29.80	$24.29	$22,106,820	$40,106,820	$481,281,840	$44.07	$681,729,040	$ 62.43	$ 12.49
40,000	$24,000,000	1,213,333	14,560,000	$24.95	$19.44	$23,591,093	$47,591,093	$571,093,120	$39.22	$771,540,320	$ 52.99	$ 10.60
50,000	$30,000,000	1,516,667	18,200,000	$25.63	$20.12	$30,520,200	$60,520,200	$726,242,400	$39.90	$926,689,600	$ 50.92	$ 10.18
60,000	$36,000,000	1,820,000	21,840,000	$24.59	$19.08	$34,731,440	$70,731,440	$848,777,280	$38.86	$1,049,224,480	$ 48.04	$ 9.61
70,000	$42,000,000	2,123,333	25,480,000	$24.91	$19.40	$41,199,480	$83,199,480	$998,393,760	$39.18	$1,198,840,960	$ 47.05	$ 9.41
80,000	$48,000,000	2,426,667	29,120,000	$23.66	$18.15	$44,051,787	$92,051,787	$1,104,621,440	$37.93	$1,305,068,640	$ 44.82	$ 8.96
90,000	$54,000,000	2,730,000	32,760,000	$23.85	$18.34	$50,076,960	$104,076,960	$1,248,923,520	$38.12	$1,449,370,720	$ 44.24	$ 8.85
100,000	$60,000,000	3,033,333	36,400,000	$23.00	$17.49	$53,062,733	$113,062,733	$1,356,752,800	$37.27	$1,557,200,000	$ 42.78	$ 8.56
110,000	$65,000,000	3,336,667	40,040,000	$22.12	$16.61	$55,432,740	$120,432,740	$1,445,192,880	$36.09	$1,645,640,080	$ 41.10	$ 8.22
120,000	$70,000,000	3,640,000	43,680,000	$21.24	$16.20	$58,962,800	$128,962,800	$1,547,553,600	$35.43	$1,748,000,800	$ 40.02	$ 8.00
130,000	$75,000,000	3,943,333	47,320,000	$20.33	$15.29	$60,287,933	$135,287,933	$1,623,455,200	$34.31	$1,823,902,400	$ 38.54	$ 7.71
140,000	$80,000,000	4,246,667	50,960,000	$19.40	$14.36	$60,976,067	$140,976,067	$1,691,712,800	$33.20	$1,892,160,000	$ 37.13	$ 7.43
150,000	$85,000,000	4,550,000	54,600,000	$18.47	$13.43	$61,100,000	$146,100,000	$1,753,200,000	$32.11	$1,953,647,200	$ 35.78	$ 7.16

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CDPH CONTRACT 20-10648
AMENDMENT 01
EXHIBIT A (ATTACHMENT A-3)

THIS AMENDMENT ONE TO STANDARD AGREEMENT (this "Amendment One"), effective as indicated on the STD213 is entered into by and between the California Department of Public Health ("CDPH") and PerkinElmer Health Sciences, Inc. ("Contractor"). The above-identified parties are at times referred to herein each as a "Party" and collectively as the "Parties."

RECITALS:

WHEREAS, the CDPH and PerkinElmer entered into an agreement for PerkinElmer to provide certain laboratory testing and reporting services in response to the SARS-CoV-2 pandemic effective August 26, 2020 (the "Agreement"); and

WHEREAS, the Parties are desirous of modifying the Agreement for PerkinElmer to provide additional or modified services going forward from the Amendment One Effective Date;

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants set forth below, the Parties amend the Agreement and otherwise agree as follows:

1. Except as otherwise expressly modified by this Amendment One, the Agreement shall remain in full force and effect in accordance with its terms. All terms capitalized herein but not defined shall have the meanings ascribed to them in the Agreement.

2. Exhibit A, Section 3(A) of the Agreement is deleted and replaced with the following:

A. Contractor Responsibilities

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

1. Developing and implementing a plan for a) pooling samples provided by CDPH in pools of up to five samples ("Pool Samples"), and b) conducting testing of routine diagnostic testing of samples other than Pool Samples.

2. Delivery and installation of equipment necessary for SARS CoV-2 diagnostic testing described in Section 3(A)(1) of this Exhibit A, as itemized in Attachment 1 (the "Equipment").

3. Supply of all consumables, reagents and Personal Protective Equipment ("PPE") necessary for performing the Services.

4. Supply furniture and all equipment necessary for performance of the Services at the Facilities.

5. Supply of all personnel, duly licensed as required by, and in compliance with, applicable federal and state law and regulations to operate at the Facilities (the "Personnel"), including, as needed:

    - Logistics and Supply Chain Management
    - Quality Assurance/ Quality Control
    - Lab Testing Personnel
    - Laboratory Supervisors
    - Information Technology Professionals
    - Specimen Processors
    - Service Engineers
    - Human Resources
    - Laboratory Management (including CA State accredited Medical and Laboratory Directors)
    - A designated project manager to collaborate with CDPH with respect to Facility maintenance.

6. Performance of all necessary service for proper installation and maintenance of the Equipment (the "Maintenance Services").

7. Supply and installation of PerkinElmer Genomics' proprietary laboratory information management system (the "LIMS") at the Facilities. Contractor shall implement an interface to the LIMS enabling collecting healthcare providers to enter required demographic information and sample identification, and CDPH shall require collection sites to enter all such information through the interface, unless otherwise agreed for specific, remote collection sites as may be agreed by the Parties from time to time. All reports from the testing Services will be generated through the LIMS and the laboratory director will be able to sign out reports through the LIMS. Notwithstanding anything else in the foregoing, Contractor shall have no liability for errors or delays resulting from any sample collection site's failure to submit timely and accurate information.

8. Reporting of the results of the Services in a mutually agreed upon format and medium. Reporting of quality metrics for the Services to be agreed by the Parties, which shall include, at a minimum, total samples tested, Pool Samples tested, average turnaround time, summary of corrected / amended reports, overview of corrective actions and process improvements ("Quality Metrics"). In addition to these reports, Contractor shall provide CDPH laboratory oversight personnel direct access to all necessary data/reporting systems.

9. Upon CDPH request, Contractor and CDPH will jointly review and evaluate current Quality Metrics. If CDPH or Contractor determines that improvement in the Quality Metrics is necessary, such Party shall provide the other with a detailed list of requested changes to Quality Metrics. The Contractor shall provide either an implementation plan or written explanation of why the requested changes are impracticable or unnecessary within five (5) business days, unless additional time is granted by CDPH. The Contractor shall execute any implementation plan upon written confirmation from CDPH.

10. Operation of Facilities in compliance with all state and federal regulations and requirements, and the Facility's accreditation under LFS and CAP (CLIA).

11. Performance of all necessary service for proper response to communications from CDPH and third parties in a mutually agreed upon format, medium and timeliness (the "Customer Services"). This shall be documented in a Customer Service Business Plan to ensure consistency in responding to client questions that arise.

12. Facilities operations management, including cleaning, and biohazard disposal at the Facilities.

13. Reporting of the testing results within the Contractor's then-current daily testing capacity within twenty-four (24) to forty-eight (48) hours after the receipt of the sample in the Facility.

14. All services under this Section 3(A) and Backup Services (as defined below) will be performed in compliance with the requirements of the FDA Emergency Use Authorization (the "EUA") described in Attachment 2 or a laboratory developed test (LDT) as may be agreed by the Parties.

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

    The parties understand and agree that for all purposes under this agreement, daily testing capacity is a measure of tests capable of being performed pursuant to this Section 3(A) and not samples

tested. Unless otherwise instructed by CDPH, Contractor will 1) routine diagnostic samples, and then 2) Pooled Samples. The volume of results reported will vary depending on the mix of routine diagnostic samples and Pooled Samples.

3. Attachment 2 to Exhibit A of the Agreement is deleted and replaced with the Attachment 2 attached as Annex 1 hereto.

4. The following is added as Exhibit A, Section 3(A1) of the Agreement:

A1. Sequencing Services

Contractor will be responsible for developing and implementing a plan for sequencing services ("Sequencing Services") related to samples testing positive for SARS CoV-2 through the Services or otherwise forward to a CDPH approved Facility. Sequencing Services will be performed at the Facilities under the guidance of and in collaboration with the California Novel Coronavirus Testing Task Force. The Sequencing Services shall consist of:

1. Delivery and installation of equipment necessary for performing whole genome sequencing of the SARS-CoV-2 virus, as itemized in Attachment 1A (the "Sequencing Equipment").

2. Supply of all consumables and reagents necessary for performing the Sequencing Services.

3. Performance of all necessary service for proper installation and maintenance of the Sequencing Equipment. The Parties agree that PerkinElmer may subcontract installation and maintenance of the Sequencing Agreement to a third party.

4. Sequencing the SARS CoV-2 virus from up to 5,000 positive samples from the Services per week, delivering ~1 million reads per sample using PerkinElmer COVID sequencing assay and automation.

5. Reporting of the results of the Sequencing Services in either FASTA format or FASTQ raw data to CDPH by a medium to be agreed by the Parties. Reporting of the results of Sequencing Services will be within seven (7) days of reporting the positive PCR result for the applicable sample.

6. Performance of Sequencing Services on an expedited basis when notified by CDPH or its designee by phone or email, of the need for STAT treatment ("STAT Sequencing Services"), such notice to include the barcode for the sample to be sequenced. Contractor will provide appropriate phone number and email address for CDPH to provide notice of the need for STAT Sequencing Services. Contractor shall provide STAT Sequencing Services on up to twenty-four (24) samples

per day. Reporting of the results of STAT Sequencing Services will be within twenty-four (24) to forty-eight (48) hours of receipt of notice from CDPH of the need for such services.

7. No later than March 8, 2021, Contractor shall provide an implementation plan, including a timeline, for launch of the Sequencing Services.

8. Until implementation of Sequencing Services at the Facility, Contractor shall conduct Sequencing Services on all SARS-CoV-2 positive samples from the date of the Sequencing Services implementation plan with Ct values less than 30 for both viral gene targets (i.e., ORF1ab and N targets) at the PerkinElmer Genetics, Inc. laboratory its Pittsburgh, PA, and provide FASTA format or FASTQ raw data to CDPH by a medium to be agreed by the Parties.

9. Commencing March 1, 2021, Contractor will send 300 to 500 positive SARS-CoV-2 samples in 96-well deep well storage plates to CDPH Richmond on a weekly basis.

5. In Exhibit A, Section 3(B) of the Agreement, each instance of the phrase "the Services" is deleted and replaced with "the Services and Sequencing Services."

6. In Exhibit A, Section 3(B) of the agreement, Section 3(B)(10) is deleted and replaced with the following:

> Monitoring Quality Metrics and advising Contractor on CDPH concerns and priorities. CDPH may provide Contractor with requested improvements to the Quality Metrics on an as-needed basis. CDPH and Contractor will communicate regularly about the Quality Metrics and Facility Operations.

7. The following is added as Exhibit A, Section 3(C)(6) of the Agreement:

> 6) All Sequencing Equipment is provided by Contractor on a no-cost loan basis. CDPH, in the capacity of bailee, will take possession of any Sequencing Equipment provided by Contractor only as provided in this Agreement. The continued bailment of the Sequencing Equipment to CDPH is contingent upon CDPH purchasing the Sequencing Services as provided in this Agreement.

8. In Exhibit A, Section 3(C) of the Agreement, i) each instance of the phrase "the Services" is deleted and replaced with "the Services or Sequencing Services," and ii) each instance of the word "Equipment" is deleted and replaced with "Equipment or Sequencing Equipment."

9. In Exhibit A, Section 6(3) of the Agreement, the word "Services" is deleted and replaced with "Services or Sequencing Services."

10. The Sequencing Equipment list attached hereto as Annex 2 is added as Exhibit A, Attachment 1A of the Agreement.

11. In Exhibit B of the Agreement, Section 1(E)(3) is deleted and replaced with the following:

> 3) CDPH shall pay Contractor a monthly fee for testing (the "Monthly Fee"), which shall be the lesser of: (a) a fee comprised of a fixed fee for maintenance of Contractor's testing carrying capacity (the "Monthly Fixed Fee") based on Contractor's declared average testing capacity for the following month, plus the price per test performed in the prior month for each of the Pool Samples and routine diagnostic samples as provided below (the "Variable Fee"), or (b) Contractor's Best Price. "Best Price" means the lowest price, on a per test basis, accepted by Contractor from any purchaser for SARS CoV-2 diagnostic testing under substantially similar commercial terms and circumstances, including, but not limited to, labor, utilities, taxes, insurance and other third-party costs, testing volume, technology used, personnel requirements, and facilities as under this Agreement. For the purpose of determining Best Price, Contractor shall divide the Monthly Fee by the total number of tests performed in the applicable month, excluding any credits or penalties other than as provided in Section 1(E)(4). Upon ten (10) days written notice, CDPH may audit Contractor's books and records as reasonably applicable to services rendered that meet the prerequisites for a Best Price in the foregoing sentence. A detailed cost breakdown for the Services is attached to this Exhibit as Attachment 1.

Contractor's Daily Testing Capacity	Monthly Fixed Fee	Average Daily Aggregate Tests performed	Variable Fee Per Routine Diagnostic Sample	Variable Fee Per Pool Tested
40,000	$24,000,000	40,000=<X<50,000	$19.95	$24.95
50,000	$30,000,000	50,000=<X<60,000	$20.63	$25.63
60,000	$36,000,000	60,000=<X<70,000	$19.59	$24.59
70,000	$42,000,000	70,000=<X<80,000	$19.91	$24.91
80,000	$48,000,000	80,000=<X<90,000	$18.66	$23.66
90,000	$54,000,000	90,000=<X<100,000	$18.85	$23.85
100,000	$60,000,000	100,000=<X<110,000	$18.00	$23.00
110,000	$65,000,000	110,000=<X<120,000	$17.12	$22.12
120,000	$70,000,000	120,000=<X<130,000	$16.24	$21.24
130,000	$75,000,000	130,000=<X<140,000	$15.33	$20.33
140,000	$80,000,000	140,000=<X<150,000	$14.40	$19.40
150,000	$85,000,000	X>=150,000	$13.47	$18.47

> By way of example, if for a given month contractor's declared average testing capacity is 110,000, and contractor performs an average of 42,000 pools and 37,000 routine diagnostic tests per month, the Monthly Fee for

that month will be $65,000,000 + ($19.91 * routine diagnostic samples tested) + ($24.91 * actual pools tested).

Each pool tested shall be considered a single test against the contactor's declared daily testing capacity.

12. In Exhibit B of the Agreement, Section 1(E)(4) is deleted and replaced with the following:

4) Each Monthly Fee shall be credited as follows:

a. Startup Payments: $5.51 per test charged up to 120,000 tests per day each day of the applicable month, until the aggregate of all such credits equals the sum of the first two Startup Payments; and b) if CDPH has made the 3rd payment, $5.04 per test charged in excess of 120,000 tests each day of the applicable month (subject to reduction to maintain overall per-test cost pursuant to Section 1(E)(2), until the aggregate of all such credits equals the amount of the 3rd Startup Payment.

b. Balancing Credits: For purposes of this Section "Contract Month" means each successive thirty (30) day period following the effective date of this Agreement.

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

Beginning the Contract Month for which Contractor invoices CDPH an average of 130,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that

point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 120,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $15.33.

Beginning the Contract Month for which Contractor invoices CDPH an average of 140,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 130,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $14.40.

Beginning the Contract Month for which Contractor invoices CDPH an average of 150,000 tests per day for testing under this Agreement, the Balancing Credit will be recalculated with such Contract Month being the new Full Run Rate Month. From that point forward, for each Contract Month that Contractor invoices CDPH for an average of greater than 140,000 tests per day, Contractor shall provide a Balancing Credit until the average of all Variable Fees paid on all tests invoiced by Contractor for testing under this Agreement reaches $13.47.

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

Total amount of Variable Fees paid or payable by CDPH =
(47,000*30*20.95) + (73,000*30*$19.91) +
(122,000*30*$16.24) =
$131,170,800

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

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

Total Balancing Credit Value =
$131,170,800 - ($13.47 * 7,260,000) =
$33,378,600

Number of tests credited =
(150,000 * 3 * 30) - 7,260,000 =
6,240,000

Credit per test =
$33,378,600 / 6,240,000 =
$5.349

13. The following is added to Exhibit B, Section 1(E) of the Agreement:

8) CDPH shall pay Contractor a fixed fee of $20 per reported result of Sequencing Services, including STAT Sequencing Services.

9) CDPH shall reimburse Contractor the costs of delivery, installation and maintenance of Sequencing Equipment as those costs come due, with prior notification to CDPH of proposed costs.

14. In Exhibit B of the Agreement, Section 1(E)(6) is deleted and replaced with the following:

6) On a monthly basis, CDPH shall reimburse Contractor for Facility management and maintenance, including, but not limited to, personnel costs, actual third-party service provider expenses including cleaning and biohazard disposal, and associated overhead.

15. Exhibit B, Attachment 1 of the Agreement is deleted and replaced with the Attachment 1 in Annex 3 hereto.

16. Save and except as amended and extended herein, the Agreement shall remain in full force and effect binding upon the Parties.

IN WITNESS WHEREOF, the Parties have caused this Amendment One to be executed by their duly authorized representatives as of the Amendment One Effective Date.

CDPH	**PerkinElmer Health Sciences, Inc.**
By: _____	By: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

U.S. FOOD & DRUG ADMINISTRATION

February 5, 2021

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

Device:	PerkinElmer New Coronavirus Nucleic Acid Detection Kit
EUA Number:	EUA200055
Company:	PerkinElmer, Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare provider (HCP) and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection. Qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Dear Mr. Ciccariello:

On March 24, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal swab and nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Testing was limited to laboratories certified under

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

CLIA, 42 U.S.C. §263a, to perform high complexity tests. Based on your request, FDA also granted updates to the authorized labeling on April 1, 2020,[2] July 30, 2020,[3] and September 25, 2020.[4] On October 28, 2020, based on your request, FDA reissued the March 24, 2020, letter in its entirety with revisions incorporated.[5] On January 12, 2021, based on your request, FDA reissued the October 28, 2020, letter in its entirety with revisions incorporated.[6]

On December 4, 2020, you requested to further revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the January 12, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the January 12, 2021, letter in its entirety with the revisions incorporated.[7] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[8] is now authorized for use consistent with the indication described above.

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

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[2] On April 1, 2020, your request was granted to update the Instructions for Use (IFU) of your product to: (1) add an additional nucleic acid extraction method which utilizes the chemagic Viral DNA/RNA 300 Kit H96 on a new extraction platform, the chemagic 360 equipped with the chemagic Rod Head Set 96; and (2) make other minor related changes and edits to the IFU.

[3] On July 30, 2020, your request was granted via email to update the intended use of your product to add anterior nasal swab specimens and the IFU, Fact Sheet Healthcare Providers and Fact Sheet for Patients were also updated accordingly.

[4] On September 25, 2020, your request was granted via email to update the IFU of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing.

[5] On October 28, 2020, the revisions to the March 24, 2020, letter and authorized labeling included: (1) revisions to the authorized labeling to add 4 additional PCR instruments for use with your product, (2) revisions to the intended use and authorized labeling documents to include testing of pooled samples containing up to five individual upper respiratory swab specimens (oropharyngeal, nasopharyngeal, or anterior nasal swabs), where each specimen is collected under observation or by a healthcare provider using individual vials containing transport media, (3) revisions to the Healthcare Provider and Patient Fact Sheets to reflect the intended use updates and language more consistent with recent authorizations, and (4) revisions to the Conditions of Authorization as a result of the new intended use and for consistency with recent authorizations.

[6] On January 12, 2021, the revisions to the October 28, 2020, letter and authorized labeling included: (1) revisions to the intended use to include testing of oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP, and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection, (2) update the inclusivity study data to include information about the emergence of mutations in one of the SARS-CoV-2 target (N) forward primer sequences, and (3) revisions to the Conditions of Authorization for consistency with recent authorizations.

[7] The revisions to the January 12, 2021, letter include: (1) addition of condition of authorization Q in section IV below to address electromagnetic compatibility (EMC) testing, (2) removal of condition of authorization Q in the letter issued on January 12, 2021, requiring the submission of additional pooling information and *in silico* analysis across multiple geographical locations, that is fulfilled.. There are no revisions to the authorized labeling.

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

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[9]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (IFU - identified below).

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

I. Criteria for Issuance of Authorization

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

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product for diagnosing COVID-19.[10]

II. Scope of Authorization

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

The Authorized Product

Your product is a test for the qualitative detection of nucleic acid from SARS-CoV-2 in human oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19 infection.

Your product is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 individual upper respiratory swab specimens (i.e., oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab

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[9] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3.* 85 FR 7316 (February 7, 2020).

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

specimens collected by an HCP or self-collected under the supervision of an HCP) using individual vials containing transport media. Negative results from pooled testing should not be treated as definitive. If patient's clinical signs and symptoms are inconsistent with a negative result and results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

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

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition K. below), that are to be run as outlined in the IFU. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the IFU:

- nCoV Internal Control - bacteriophage MS2 added clinical samples and controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

- nCoV Positive Control - SARS-CoV-2 RNA fragments capsulated in bacteriophage. The positive control is used to monitor for failures of rRT-PCR reagents and reaction conditions.

- nCoV Negative Control - buffer used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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

The labeling entitled "Instructions for PerkinElmer New Coronavirus Nucleic Acid Detection Kit" IFU (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) and the following fact sheets pertaining to the emergency use, which is required to be made available as set forth in the Conditions of Authorization (Section IV), are collectively referenced as "authorized labeling":

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

The above described product, with the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

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

III. Waiver of Certain Requirements

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

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I

(Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

PerkinElmer, Inc. (You) and Authorized Distributor(s)[11]

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

D. You and authorized distributor(s) will include a physical copy of the authorized Instructions for Use with each shipped product to authorized laboratories.

E. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and/or authorized labeling.

F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number they distribute.

G. You and authorized distributor(s) must collect information on the performance of your product. You must report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

PerkinElmer, Inc. (You)

[11] "Authorized Distributor(s)" are identified by you, PerkinElmer, Inc., in your EUA submission as an entity allowed to distribute your product.

I. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

J. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

K. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT 7) - Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

L. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your products for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

O. You must evaluate the analytical limit of detection and assess traceability[12] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the date by FDA you must update your labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

P. You must further evaluate the clinical performance of your product, with specimens collected from asymptomatic individuals in an FDA agreed upon post authorization clinical evaluation study within 30 calendar days of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to FDA and FDA's review of and concurrence with the data, you must update the authorized labeling to reflect the additional testing. Such labeling updates must be made in

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

consultation with, and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH.

Q. You will further perform electromagnetic compatibility (EMC) testing to International Electrotechnical Commission (IEC) 60601-1-2 Edition 4.0:2014 standards within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional analysis. Such labeling updates will be made in consultation with, and require concurrence of DMD/OHT7-OIR/OPEQ/CDRH.

R. You must develop a laboratory procedure whereby authorized laboratories can verify that the RUO instrument(s) authorized with your product is capable of performing the PerkinElmer New Coronavirus Nucleic Acid Detection Kit test with sufficient accuracy, as stated in the authorized labeling. You must submit the procedure to FDA within 21 calendar days of authorization. After DMD/OHT7-OIR/OPEQ/CDRH's review and concurrence, you must update the authorized labeling to reflect the laboratory procedure within 45 calendar days of authorization.

S. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA in accordance with 21 CFR Part 803.

Authorized Laboratories

T. Authorized laboratories using your product must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

U. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

V. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

W. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

X. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that *"Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."*

Y. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Specimen Pooling Implementation and Monitoring Guidelines" provided in

the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

Z. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Specimen Pooling Implementation and Monitoring Guidelines. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

AA. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and You (via email: COVID-19.TechnicalSupport@PerkinElmer.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

BB. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

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

CC. You, authorized distributor(s), and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records must be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

DD. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

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

FF. All descriptive printed matter, advertising, and promotional materials, relating to the use of your product shall clearly and conspicuously state that:

- This test has not been FDA cleared or approved, but has been authorized by FDA under an EUA for use by authorized laboratories;

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

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

V. Duration of Authorization

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

Sincerely,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure

Annex 2
Sequencing Equipment

Item #	Description
1	Illumina NovaSeq6000
2	Sciclone G3 NGSx
3	Sciclone G3 NGSx IQ
4	FlexDrop IQ Workstation
5	Zephyr G3 Workstation
6	Cellink IDOT
7	Thermal Cycler and associated parts and accessories
8	JANUS G3 Expanded 8-Tip MDT
9	Victor Nivo

CDPH Contract 20-10648
AMENDMENT 01 Attachment B-1a

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

Pooling Test Methodology												
Fixed Monthly Fee		Variable Fee					Total Cost					
Contractor's Daily Pooling Capacity	Monthly Fixed Fee	Average Pools Per Month	Average Pools Per Year	Variable Fee/Pool Performed (Variable fee increased by $5 to account for extra accessioning personnel (5X sample amount per run), consumables and reagents per run.)	Pool Cost (Including Credit)	Monthly Cost	Monthly	Yearly	Cost Per Pool (Excluding Startup)	Total Cost (Including Startup)	Total Cost Per Pool (Including Startup)	Total Cost Per Test @ 5 Sample Pool (Including Startup)
-	$6,000,000						$6,000,000	$72,000,000		$272,447,200		
10,000	$9,000,000	303,333	3,640,000	$35.67	$30.16	$9,149,507	$18,149,507	$217,794,080	$59.83	$418,241,280	$ 114.90	$ 22.98
20,000	$12,000,000	606,667	7,280,000	$27.52	$22.01	$13,354,680	$25,354,680	$304,256,160	$41.79	$504,703,360	$ 69.33	$ 13.87
30,000	$18,000,000	910,000	10,920,000	$29.80	$24.29	$22,106,820	$40,106,820	$481,281,840	$44.07	$681,729,040	$ 62.43	$ 12.49
40,000	$24,000,000	1,213,333	14,560,000	$24.95	$19.44	$23,591,093	$47,591,093	$571,093,120	$39.22	$771,540,320	$ 52.99	$ 10.60
50,000	$30,000,000	1,516,667	18,200,000	$25.63	$20.12	$30,520,200	$60,520,200	$726,242,400	$39.90	$926,689,600	$ 50.92	$ 10.18
60,000	$36,000,000	1,820,000	21,840,000	$24.59	$19.08	$34,731,440	$70,731,440	$848,777,280	$38.86	$1,049,224,480	$ 48.04	$ 9.61
70,000	$42,000,000	2,123,333	25,480,000	$24.91	$19.40	$41,199,480	$83,199,480	$998,393,760	$39.18	$1,198,840,960	$ 47.05	$ 9.41
80,000	$48,000,000	2,426,667	29,120,000	$23.66	$18.15	$44,051,787	$92,051,787	$1,104,621,440	$37.93	$1,305,068,640	$ 44.82	$ 8.96
90,000	$54,000,000	2,730,000	32,760,000	$23.85	$18.34	$50,076,960	$104,076,960	$1,248,923,520	$38.12	$1,449,370,720	$ 44.24	$ 8.85
100,000	$60,000,000	3,033,333	36,400,000	$23.00	$17.49	$53,062,733	$113,062,733	$1,356,752,800	$37.27	$1,557,200,000	$ 42.78	$ 8.56
110,000	$65,000,000	3,336,667	40,040,000	$22.12	$16.61	$55,432,740	$120,432,740	$1,445,192,880	$36.09	$1,645,640,080	$ 41.10	$ 8.22
120,000	$70,000,000	3,640,000	43,680,000	$21.24	$16.20	$58,962,800	$128,962,800	$1,547,553,600	$35.43	$1,748,000,800	$ 40.02	$ 8.00
130,000	$75,000,000	3,943,333	47,320,000	$20.33	$15.29	$60,287,933	$135,287,933	$1,623,455,200	$34.31	$1,823,902,400	$ 38.54	$ 7.71
140,000	$80,000,000	4,246,667	50,960,000	$19.40	$14.36	$60,976,067	$140,976,067	$1,691,712,800	$33.20	$1,892,160,000	$ 37.13	$ 7.43
150,000	$85,000,000	4,550,000	54,600,000	$18.47	$13.43	$61,100,000	$146,100,000	$1,753,200,000	$32.11	$1,953,647,200	$ 35.78	$ 7.16