EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
DIVERSIFIED MEDICAL HEALTHCARE SARS-CoV-2 ASSAY

For *in vitro* Diagnostic Use
Rx Only
For Use Under Emergency Use Authorization (EUA) Only

The Diversified Medical Healthcare SARS-CoV-2 Assay will be performed at laboratories designated by Premier Medical Laboratory Services, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity Tests, as described in the Laboratory Standard Operating Procedures that were reviewed by the FDA under this EUA.

INTENDED USE

1) *Intended Use*

The Diversified Medical Healthcare SARS-CoV-2 Assay is an *in vitro* diagnostic real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens that are collected at home using the DoINeedaCOVID19Test.com Self-Collection Kit by any individual, 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider.

This test is also for use with anterior nasal swab specimens that are collected using the RapidRona Self-Collection Kit when used consistent with its authorization.

Testing is limited to laboratories designated by Premier Medical Laboratory Services, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263, and meet requirements to perform high-complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The Diversified Medical Healthcare SARS-CoV-2 Assay is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Diversified Medical Healthcare SARS-CoV-2 Assay and DoINeedaCOVID19Test.com Self-Collection Kit are only for use under the Food and Drug Administration's Emergency Use Authorization.

2) *Special Conditions of Use Statements*
For prescription use only
For in vitro diagnostic use
For use under Emergency Use Authorization (EUA) only

This assay can be used with the RapidRona Self-Collection Kit. RapidRona, Inc. is owned by Diversified Medical Healthcare, which is the parent company of Premier Medical Laboratory Services, Inc. and therefore has right of reference to the data supporting use of this collection kit.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Device Description
The Diversified Medical Healthcare SARS-CoV-2 Assay is performed using the reagents and procedures for the FDA-authorized Thermo Fisher TaqPath COVID-19 RNase P Combo Kit 2.0 (EUA210403). Life Technologies (a part of Thermo Fisher Scientific, Inc.) has granted a Right of Reference to Premier Medical Laboratory Services to information submitted under EUA210403 and subsequent authorized Supplements S001 through S004 to support an EUA request for the Diversified Medical Healthcare SARS-CoV-2 Assay.

The DoINeedaCOVID19Test.com Self-Collection Kit is provided in one of two configurations depending on the method of return shipment of the specimen to the testing laboratory. Both configurations include a packaged sterile swab, sterile collection tube containing transport medium (saline), shipping materials, barcode labels for specimen identification, and printed Instructions For Use (IFU) that indicate how to register, collect and return the sample to the testing laboratory. Depending on the kit configuration and associated Instructions For Use, collected specimens are either returned by bulk shipment after being deposited at a participating drop-off location or by mail using the U.S. Postal Service. Each DoINeedaCOVID19Test.com Self-Collection Kit is intended to be shipped to the designated testing laboratory on the day of specimen collection at ambient temperature for next day delivery.

The components of the DoINeedaCOVID19Test.com Self-Collection Kit and associated instructions for specimen collection are based on those for the previously authorized RapidRona Self-Collection Kit (EUA202347). RapidRona, Inc. has granted a Right of Reference to Premier Medical Laboratory Services to data contained in EUA202347 for the RapidRona Self-Collection Kit, including information regarding sample stability and usability.

DoINeedaCOVID19Test.com Self-Collection Kit Ordering and Processing
The DoINeedaCOVID19Test.com Self-Collection Kit will be available by prescription to individuals who request Testing for SARS-CoV-2 though eTrueNorth's on-line platform (ineedacovidTest.com). Individuals seeking a test must first register with eTrueNorth, complete an assessment questionnaire and then chose a location at which to pick up their collection kit. This process triggers a physician order for the test. To obtain their collection kit, the individual presents a copy of the test order at their designated participating pharmacy or elects for the kit to be shipped directly to their home. They then follow the Instructions For Use for kit registration, specimen collection, packaging and same day return of the kit either to the drop-off location (in person or to a drop-box located in the participating pharmacy) or via the U.S. Postal Service.

Test results are reported directly to the ordering physician, consumer, and relevant public health authorities in accordance with local, state and federal requirements using appropriate LOINC and SNOMED codes.

Specimen Transport and Storage
Anterior nasal swabs collected in Phosphate Buffered Saline (PBS) using the DoINeedaCOVID19Test.com Self-Collection Kit may be transported and stored at ambient temperature for up to 48 hours prior to testing.

Specimen Accessioning
Specimens received in the laboratory undergo accessioning prior to acceptance for testing. A summary of the criteria used for specimen accessioning is provided in **Table 1**. All acceptable specimens are processed by the laboratory. The Accessioning Supervisor is notified of any specimens that do not meet the accessioning acceptance criteria and procedures are implemented to gather missing information, as appropriate. If the measures to remediate specimen rejection cannot be rectified, the status is logged as "Test Not Performed" and the individual is notified that the specimen has been rejected with the option to re-collect a specimen.

Table 1. Accessioning criteria applied to specimens collected with the DoINeedaCOVID19Test.com Self-Collection Kit or RapidRona Self-Collection Kit and received for analysis with the Diversified Medical Healthcare SARS-CoV-2 Assay

Rejection Reason	Description
Missing requisition	Kits that are received but for which there is no Test requisition
Improper packaging/physical damage	Samples not received in a biohazard bag containing one vial with transport medium and one swab
Expired shipping time	Kits received ≥ 48 hours after specimen collection
Expired collection kit	Kits that have exceeded their assigned expiration date
Collection kit other than DoINeedaCOVID19Test.com Self-Collection Kit or RapidRona Self-Collection Kit	Use of sample collection and transport devices other than those authorized
Damaged, leaking or empty tubes	--
Tubes with missing or damaged identifiers	--

1) *Specimen Testing*
   The Diversified Medical Healthcare SARS-CoV-2 Assay is performed using the reagents and procedures for the FDA-authorized TaqPath COVID-19 RNase P Combo Kit 2.0 (EUA210403) and includes primers and probes for the detection of the SARS-CoV-2 ORF1a, ORF1b and N genes, as well as human RNase P nucleic acid as an endogenous control for specimen adequacy and process integrity. Amplified products are detected in the same reaction using TaqMan probes that are labeled with different combinations of fluorophores and quencher molecules. The 5' exonuclease activity of the Taq polymerase hydrolyses the probes during the annealing/extension phase of PCR amplification, leading to generation of target-specific fluorescent signal.

   Automated nucleic acid extraction is performed using the KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head, KingFisher Flex 96 Deep-Well Heating Block, and the

MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit with a sample input volume of 200 µL. RT-PCR amplification is performed in 384-well format using an Applied Biosystems (QuantStudio 7 Flex Real-Time PCR Instrument (software V1.7.2).

2) *Result Reporting for specimens collected with the DoINeedaCOVID19Test.com Self-Collection Kit*
Individuals will be notified by email that their results are available on the eTrueNorth platform and must log-in to their account to retrieve their results and obtain guidance for appropriate next steps, including access to the Patient Fact Sheet. All test results are reported to the requesting healthcare provider and public health authorities in accordance with local, state, and federal requirements.

INSTRUMENTS USED WITH THE TEST

Table 2. Instruments and software for use with the Diversified Medical Healthcare SARS-CoV-2 Assay

Instrument	Manufacturer
KingFisher Flex Magnetic Particle Processor with 96 Deep-Well	Applied Biosystems (Thermo Fisher)
QuantStudio 7 Flex Real-Time PCR Instrument with instrument firmware v1.0.4	Applied Biosystems (Thermo Fisher)

Table 3. Software required for use of the Diversified Medical Healthcare SARS-CoV-2 Assay

Item	Description
Pathogen Interpretive Software v1.1	Data analysis and results interpretation
Pathogen Interpretive Software 1.0.0 DAT (SAE Profle)	Provides settings to connect the SAE Administrator Console Dx with the Pathogen Interpretive Software
SAE Administrator Console Dx v1.0	Security and audit tool
QuantStudio Real-Time PCR Software v1.3	Data collection
QuantStudio 7 Flex Real-Time PCR System C19-RNaseP-EUA_QS7-384_1.0.0	Assay panel for QuantStudio 7 Flex Real-Time PCR Instrument (384 well block)

REAGENTS AND MATERIALS

Table 4. Components of the TaqPath COVID-19 RNase P Combo Kit 2.0 (Cat. No. A51333)

Component	Quantity	Storage Temperature
TaqPath COVID-19 RNase P Kit 2.0 (assay mix tube)	1 x 1500 µL	-30 to -10 °C
TaqPath COVID-19 Plus Control (1 x 10^4 copies/µL)	10 x 10 µL	≤ -20 °C
TaqPath COVID-19 Control Dilution Buffer	10 x 250 µL	-30 to -10 °C

Table 5. Additional kits and reagents required but not provided

Component		Catalogue Number	Storage Temperature
MagMAX Viral/Pathogen II Nucleic Acid Isolation Kit	Binding Solution	A48383	15 to 25 °C
	Wash Solution		
	MVP II Binding Beads		
	Proteinase K		
	Elution Buffer		
TaqPath 1-Step Multiplex Master Mix (No ROX)		A28522 A28523	-30 to -5 °C

Table 6. Additional materials and equipment required but not provided with the TaqPath COVID-19 RNase P Combo Kit 2.0

Material/Equipment	Catalog Number	Model Number	Manufacturer
Applied Biosystems QuantStudio 7 Flex	4485701	N/A	Thermo Fisher
Applied Biosystems 384-well block	N/A	4453553	Thermo Fisher
Multidrop Combi	836-81695	5840300	Thermo Fisher
Sorvall ST 16 centrifuge	42385424	N/A	Thermo Fisher
Vortex 120V	300240334	1321	Thermo Fisher
Micropipettes (P10, P100, P1000)	N/A	N/A	Thermo Fisher
E1-ClipTip Bluetooth Electronic Multichannel Pipettes	4671090BT	N/A	Thermo Fisher
Multi-channel pipettors	PH71356, PH69975	4672070BT, 4671100BT	Thermo Fisher
KingFisher Deepwell 96 Plate	N/A	95040450	Thermo Fisher
KingFisher 96 KF microplate	N/A	97002540	Thermo Fisher
KingFisher 96 tip comb for DW magnets	N/A	97002534	Thermo Fisher
KingFisher Flex Magnetic Particle Processor with 96 Deep-Well Head	N/A	5400630	Thermo Fisher
KingFisher Flex 96 Deep-Well Heating Block	N/A	24075430	Thermo Fisher
RNase-Free Microcentrifuge Tubes	108-01633	10-180	Thermo Fisher
Reagent Reservoir	42385424	N/A	Thermo Fisher
DNase/RNase-free sterile tips	300240334	1321	Thermo Fisher
100% ethanol, ACS reagent grade or equivalent	N/A	N/A	Fisher Scientific
Nuclease-free Water (not DEPC - Treated)	N/A	N/A	Fisher Scientific
MicroAmp Optical Adhesive Film	N/A	4311971 4360954	Thermo Fisher
MicroAmp Adhesive Film Applicator	N/A	4333183	Thermo Fisher
Conical Tubes (50 mL)	N/A	AM12501	Thermo Fisher
MicroAmp Fast Optical 384-Well Reaction Plate with Barcode	N/A	4309849	Thermo Fisher
384-Well Calibration Plate W/ JUN	N/A	A24735	Thermo Fisher
384-Well Calibration Plate W/ ABY	N/A	A24734	Thermo Fisher

Table 7. DoINeedaCOVID19Test.com Self Collection Kit

Component [1]	Description	Supplier	Part Number
Swab	Sterile polyester-tipped swab with polypropylene shaft	Steripak	60564
Saline-filled Transport Tube	Sterile polypropylene tube containing 3 mL 0.9 % saline	Global Scientific	6101G
Sample Bag	Biohazard bag with absorbent pad	Elkay	10790-168
Instructions	Printed pamphlet	Printplace.com	Not Applicable

[1] 1 of each component per kit

CONTROLS

Table 8. Assay controls used with the Diversified Medical Healthcare SARS-CoV-2 Assay

Control	Description	Purpose	Frequency
Positive Control	TaqPath COVID-19 Plus Control	Monitors RT-PCR set-up and reagent integrity	1 per 384-well RT-PCR plate
Negative Control	Nuclease-free water (not DEPC-treated)	Monitors for cross-contamination during RNA extraction and RT-PCR set-up	1 per extraction plate of up to 96 samples and controls (up to 4 per RT-PCR plate)
RNase P Internal Control	Endogenous human RNase P nucleic acid	Monitors for specimen adequacy and process integrity	Every patient sample and Positive Control

INTERPRETATION OF RESULTS

Assay Controls

The criteria for interpretation of the results obtained with the assay controls are shown in **Table 9**. All controls must produce the expected results to enable interpretation of the results from testing of patient samples.

Table 9. Interpretation of results for assay controls

Assay Control	Expected Result			
	ORF1a	N Gene	ORF1b	RNase P
Positive Control	Positive Ct ≤ 37	Positive Ct ≤ 37	Positive Ct ≤ 37	Positive Ct ≤ 35
Negative Control	Negative Ct > 37	Negative Ct > 37	Negative Ct > 37	Negative Ct > 35

Clinical Specimens

Table 9. Interpretation of results from clinical specimens

Result [1, 2, 3]				Interpretation	Action
ORF1a	**N Gene**	**ORF1b**	**RNase P**		
Positive	Positive	Positive	Positive or Negative	Presence	Report SARS-CoV-2 Detected
Positive	Positive	Negative	Positive or Negative	Presence	Report SARS-CoV-2 Detected
Positive	Negative	Positive	Positive or Negative	Presence	Report SARS-CoV-2 Detected
Negative	Positive	Positive	Positive or Negative	Presence	Report SARS-CoV-2 Detected
Negative	Negative	Negative	Positive	Absence	Report SARS-CoV-2 Not Detected
Negative	Negative	Negative	Negative	Invalid	Retest
Negative	Negative	Positive	Positive or Negative	Inconclusive	Retest or Report SARS-CoV-2 Inconclusive
Negative	Positive	Negative	Positive or Negative	Inconclusive	Retest or Report SARS-CoV-2 Inconclusive
Positive	Negative	Negative	Positive or Negative	Inconclusive	Retest or Report SARS-CoV-2 Inconclusive

[1] Viral analytes: Positive: Ct ≤ 37; Negative: Ct > 37 or no value
[2] RNase P: Positive: Ct ≤ 32; Negative: Ct > 32 or no value
[3] If any of the viral targets is positive, the Ct for RNase P can be > 32
[4] Retesting must be performed by re-extracting the original sample and repeating the RT-PCR. If the repeat result is remains invalid, consider collecting a new specimen. If the repeat result remains inconclusive, the healthcare provider should conduct confirmation testing with a new specimen, if clinically indicated.

PERFORMANCE EVALUATION

The Diversified Medical Healthcare SARS-CoV-2 Assay is performed using reagents and procedures that were previously authorized for use under EUA210403 for the TaqPath COVID-19 RNase P Combo Kit 2.0. Thermo Fisher, Inc. has granted a Right of Reference to Premier Medical Laboratory Services to information, including analytical and clinical validation data, submitted under EUA210403. For detailed information regarding the analytical Limit of Detection, Inclusivity, Specificity (Cross-reactivity), Interference Testing and Clinical Performance of the Diversified Medical Healthcare SARS-CoV-2 Assay, please refer to the authorized Instructions for Use for the TaqPath COVID-19 RNase P Combo Kit 2.0.

1) Specimen Shipping Stability:

The stability of anterior nasal swab specimens in 0.9% saline was evaluated under EUA210247 for the PMLS SARS-CoV-2 Assay and the data are incorporated herein by reference. The simulated shipping conditions included exposer to temperature extremes that may reasonably be anticipated during specimen transport. The results of the study support the

stability of anterior nasal swab specimens collected with the DoINeedaCOVID19Test.com Self-Collection Kit for up to 48 hours at ambient temperature.

2) Usability:

A Usability Study was performed to evaluate the ease-of-use of the DoINeedaCOVID19Test.com Self-Collection Kit for collection of specimens from individuals aged 2 to 18 years under EUA210247 for the PMLS SARS-CoV-2 Assay and the data are incorporated herein by reference. The study included 38 participants who either self-collected an anterior nasal swab specimen according to the Instructions For Use (ages 14 to 18, n = 14) or who had a sample collected by their parent or guardian (ages 2-13, n = 24). Sample collection was performed in a simulated home environment and the collected samples were shipped to the laboratory for testing for the presence of human RNase P nucleic acid. All 38 samples received in the laboratory were accepted for testing and all 38 produced a positive result for the RNase P target, indicating collection of an acceptable sample. Fourteen of the participants (or their parents or guardians) completed a usability survey. None of the respondents indicated difficulty in understanding the instructions or using the collection kit.

The ease of use of the RapidRona Self Collection Kit was evaluated independently under EUA202347. An additional Usability Study conducted in support of the current submission confirmed the ability of intended users of the RapidRona Self-Collection Kit to collect acceptable anterior nasal swab specimens for use with the Diversified Medical Healthcare SARS-CoV-2 Assay.

WARNINGS

- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For *in vitro* diagnostic use.
- For prescription use only.
- For use under Emergency Use Authorization (EUA) only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product 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 Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary

depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

- Asymptomatic individuals infected with COVID-19 may not shed enough virus to reach the limit of detection of the Test, giving a false negative result.
- Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.