EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE QUEST DIAGNOSTICS PF SARS-COV-2 ASSAY

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

INTENDED USE

The Quest Diagnostics PF SARS-CoV-2 Assay is intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected at home observed under healthcare provider (HCP) supervision via telemedicine, using the Quest Diagnostics Self-Collection Kit for COVID-19, or other authorized home-collection kit, by individuals suspected of COVID-19 when home collection is determined to be appropriate by a healthcare provider. Specimens collected using the Quest Diagnostics Self-Collection Kit for COVID-19 can be transported at ambient temperature for testing.

Testing is limited to laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the 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 nasal swabs 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 positive 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.

Testing with the Quest Diagnostics PF SARS-CoV-2 Assay is intended for use by qualified and trained laboratory personnel specifically instructed and trained in the molecular testing and in vitro diagnostic procedures. The Quest Diagnostics PF SARS-CoV-2 Assay and the Quest Diagnostics Self-Collection Kit for COVID-19 are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***Device Description:***

The Quest Diagnostics PF SARS-CoV-2 Assay for use with the Quest Diagnostics Self-Collection kit for COVID-19 enables the self-collection of a nasal swab specimen by an individual qualified by their healthcare provider as needing SARS-CoV-2 testing. This

specimen is then transported to a laboratory designated by Quest Diagnostics for SARS-CoV-2 testing using the Quest Diagnostics PF SARS-CoV-2 Assay. The Quest Diagnostics COVID-19 Self-Collection Kit includes the following materials:

Sample Collection and Shipping Instructions
Swab (foam or a wrapped polyester)
Specimen Transport Tube
Zip-lock bag (biohazard symbol) and desiccant
Test Requisition (pre-printed)
Shipping box
FedEx Bag with FedEx Label (pre-printed)
Priority label (optional)
Pre-printed tube label

The Quest Diagnostics Self-Collection kit for COVID-19 was reviewed for adherence to the Department of Transportation's shipping requirements for hazardous materials. The kit was found to be acceptable and appropriate for shipping within the United States.

2) ***Test Principle:***

The Quest Diagnostics PF SARS-CoV-2 Assay is only used for patients who have been previously qualified by their healthcare provider as needing SARS-CoV-2 testing based on the provider's medical judgement regarding symptoms, exposure, and risk factors. After a healthcare provider qualifies a patient for testing using the self-collection kit, the healthcare provider will submit the order to Quest Diagnostics. The order will indicate that the self-collection will be observed. Quest Diagnostics will then ship the self-collection kit to the patient. The patient will make a virtual appointment for a healthcare provider to observe their sample collection (i.e., via telemedicine) to ensure proper self-collection of the nasal swab.

Upon receipt of the kit, the patient will be directed to review the Instructions' READ FIRST FOR YOUR SAFETY section, which includes direction to watch a self-collection demo video available online. The participant will then log on to their scheduled video connection with a healthcare professional to collect their specimen while under observation. Once the observer sees that the specimen was collected properly, the observer will tell the patient to record a code on the test requisition form that will serve as verification to the laboratory that the specimen collection was observed and done properly. The patient then ships the specimens to Quest Diagnostics via FedEx overnight shipping as per the self-collection instructions for use.

Self-collected nasal swab specimens will be tested using the Quest Diagnostics PF SARS-CoV-2 Assay which is performed using the FDA EUA-authorized Hologic Panther Fusion SARS-CoV-2 molecular test, which is an automated RT-PCR based platform. The test report will then be electronically delivered to both the ordering healthcare provider and the participant.

The Quest Diagnostics Self-Collection Kit for COVID-19 will include instructions, a pre-printed test requisition form, nasal swab, transport tube containing appropriate fluid (i.e., 1 to 3 mL of VCM, 0.9% saline, or PBS), pre-printed tube label, zip-lock bag (with biohazard symbol) containing a desiccant, shipping box, and FedEx UN3373 shipping bag with pre-printed FedEx Shipping Label attached. Instructions are included in the kit to direct the home users how to appropriately collect the nasal swab specimen, place the specimen into the transport tube, properly package the specimen, and mail the specimen back to the laboratory using the pre-labeled FedEx return bag. Each Quest Diagnostics COVID-19 Self-Collection Kit is intended to be returned via FedEx service at ambient conditions on the same day of collection.

Specimens received at the laboratory designated by Quest Diagnostics will undergo review for integrity of packaging, adequacy of sample, verification of patient information, and acceptable time window between specimen collection and receipt at the laboratory prior to acceptance for testing. Additionally, Quest Diagnostics will determine if the test requisition form returned with the kit contains the code that confirms observation of the collection. If the code is present, the specimen will be routed to be tested with the Quest Diagnostics PF SARS-CoV-2 Assay. If the code is not present, then the specimen will be routed to be tested with a SARS-CoV-2 assay that has been EUA-authorized for use with unobserved collection of specimens using the Quest Diagnostics Self-Collection Kit for COVID-19. This is to ensure specimen adequacy in the absence of observation.

Laboratories designated by Quest Diagnostics are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests using an FDA authorized NAAT test per the Instructions for Use.

3) ***Medical Oversight and Process to be Used:***

Medical oversight of the process is provided by the healthcare provider who is ordering the test. Quest Diagnostics will only distribute self-collection kits to patients who were previously qualified for SARS-CoV-2 testing by a healthcare provider based on symptoms, exposure, and risk factors.

The scheduling of the telemedicine appointment for observation of collection will be overseen by Quest Diagnostics or the entity responsible for prescribing the test to the patient. During the telemedicine encounter, a physician or a trained healthcare provider will guide and observe the patient through the nasal swab collection process. The observer will then tell the patient to record a code on the test requisition after the observer sees that the specimen was collected properly. When the self-collected specimen arrives at the laboratory, Quest Diagnostics will verify if the test was collected under observation by checking the code on the requisition form. If the correct code is present, the specimen will be tested with the Quest Diagnostics PF SARS-CoV-2 Assay. This verification is necessary to ensure optimal collection of the sample, since the RNaseP internal control is not present in the Quest Diagnostics PF SARS-CoV-2 Assay preformed using the

Hologic assay at the Quest Diagnostics Laboratory or other laboratories designated by Quest Diagnostics.

PATIENT INCLUSION/EXCLUSION CRITERIA

Only patients who are suspected of COVID-19 by a healthcare provider are eligible to receive the Quest Diagnostics COVID-19 self-collection kit.

INSPECTION OF SPECIMENS AND VERIFICATION OF OBSERVED SELF-COLLECTION

Quest Diagnostics has submitted an SOP for Receipt and accessioning of COVID-19 self-collection kits at Quest Diagnostics Laboratory. This protocol is summarized below.

Applies to specimens received from patients using the home collection kit: Specimens received through the self-collection kit will be checked for the following criteria before entering the workflow:

- **Proper return of sample packaging:** confirm that sample is present, test requisition is present, the sample tube is not broken, sample is not leaking,
- **Verification of Patient Information:** ensure the patient information on the sample container matches the information on test requisition
- **Verification of observation:** if the test was ordered for observed collection, determine if observation code on test requisition matches the expected observation code
- **Sample Acceptability:** ensure sufficient sample volume, acceptable sample temperature, sample was received within 2 days from patient shipping date, and sample was received within acceptable stability window after collection

4) ***Test results and interpretation***

CONTROLS TO BE USED WITH QUEST DIAGNOSTICS PF SARS-COV-2 ASSAY

Quest Diagnostics will use the observation code verifying that the collection was observed. Additionally, the controls used with the Quest Diagnostics PF SARS-CoV-2 Assay preformed using the Hologic Panther Fusion SARS-CoV-2 Assay, which include an internal control, positive control and negative control, will be used in accordance with the package insert.

The Hologic Panther Fusion SARS-CoV-2 Assay provides the positive controls and negative controls with the kit, and the controls are ready-to-use. The instrument assesses the validity of the run and will not run patient samples until valid results are achieved.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Results are reported as Positive, Negative, or Invalid.

The Quest Diagnostics PF SARS-CoV-2 Assay will use the result interpretation displayed in the table below:

SARS-CoV-2 Result	IC Result	Interpretation
Neg	Valid	SARS-CoV-2 not detected.
POS	Valid	SARS-CoV-2 detected.
Invalid	Invalid	Invalid. There was an error in the generation of the result; retest sample.

If a result is invalid, then the assay will be repeated if adequate specimen is available. If on repeat the specimen is still invalid, then Quest Diagnostics will offer the patient the opportunity to collect a second specimen at no additional cost and/or a refund of their purchase minus the ordering provider's fee.

All results are delivered electronically to the healthcare provider and the participant.

Collection Device Stability:

Quest Diagnostics will evaluate stability of specimen collection media and container/closure systems in real time (25%, 50%, 75%, 100% and 125% of shelf life) and may use accelerated stability analysis to supplement the real time studies. Stability inspection of transport media would include: pH, bioburden, precipitation, leakage, and integrity of the container/closure system.

PERFORMANCE EVALUATION

1) Quest Diagnostics Self-Collection Kit for COVID-19 Sample Stability Studies:

A specimen stability study was conducted to confirm that signal degradation at high temperatures would not occur during shipping. Contrived samples for this study were prepared by spiking a SARS-CoV-2 remnant positive patient sample into pooled remnant SARS-CoV-2 negative patient samples at concentrations targeting 2X LoD and 5-10X LoD. The remnant patient samples used for this study included upper respiratory swabs in two different transport media: VCM and sterile saline (0.9% NaCl). For each transport media, a total of 20 replicates at 2X LoD and 10 replicates at 5-10X LoD were tested.

This study simulated shipping conditions by cycling the samples through the following temperature excursion:

Storage Temperature	Time at Storage Temp (hours)	Total Time (hours)
40°C	8	8
22°C	4	12
40°C	2	14
30°C	36	50
40°C	6	56

Samples were tested at each timepoint with the Quest Diagnostics EUA assay, Quest SARS-CoV-2 rRT-PCR. The Ct values at each timepoint were compared to the Ct values at time zero. All samples for both transport media remained positive at 56 hours after cycling in and out of high temperatures. Additionally, Ct values remained less than 1 Ct between time 0 and 56 hours, indicating acceptable specimen stability under simulated shipping conditions.

2) ***Human Usability Studies for the Quest Diagnostics Self-Collection Kit for COVID-19:***

A usability study was conducted to confirm that patients could follow the instructions included in the Quest Diagnostics Self-Collection Kit for COVID-19 to appropriately collect, package, and ship a self-collected nasal specimen to a Quest Diagnostics laboratory for testing. The study was completed in an actual home-use environment.

After providing informed consent, participants were mailed a Quest Diagnostics Self-Collection Kit for COVID-19, which included the instructions for use, test requisition form, foam nasal swab, specimen transport tube containing transport media, biohazard bag containing desiccant, transport box, pre-printed FedEx label and shipping bag. The participants proceeded to collect a nasal specimen unobserved in their home environment and then shipped the specimens back to a laboratory designated by Quest Diagnostics via FedEx following the instructions on the kit. Participants were also asked to fill out a questionnaire that assessed their ability to understand the different steps in the instructions for use.

A total of 47 individuals were consented to participate in the study. These participants included individuals representing varying education levels and age ranges. Of the 47 individuals, 42 returned the kit and questionnaire within the study window. Of these 42, 95.2% (40/42) returned a specimen that was acceptable for testing according to pre-determined acceptance criteria. The returned specimens were also tested with a PCR assay detecting the internal house-keeping gene RNase P. All specimens yielded strong RNase P signals, indicating successful sampling of human biological material.

3) ***Quest Diagnostics PF SARS-CoV-2 Assay Analytical and Clinical Performance Evaluation:***

The Quest Diagnostics PF SARS-CoV-2 Assay is performed on the Hologic Panther Fusion SARS-CoV-2 Assay using nasal swabs collected with the Quest Diagnostics Self-Collection Kit for COVID-19. The analytical and clinical performance of the Hologic Panther Fusion SARS-CoV-2 Assay has been demonstrated by Hologic in the Emergency Use Authorization submission authorized on 03/16/2020. The details of the performance of the authorized Hologic Panther Fusion SARS-CoV-2 test can be found here: https://www.fda.gov/media/136156/download. Hologic granted Right of Reference to Quest Diagnostics for Hologic's authorized Hologic Panther Fusion SARS-CoV-2 test.

Warnings:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic 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 authorization is terminated or revoked sooner.