EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE QUEST PF COVID-19 PCR DTC
For *In vitro* Diagnostic Use
For use under Emergency Use Authorization (EUA) only

The Quest PF COVID-19 PCR DTC test will be performed at laboratories designated by Quest Diagnostics that are certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests as described in the Laboratory Standard Operating Procedures that were reviewed by FDA under this EUA.

INTENDED USE

The Quest PF COVID-19 PCR DTC is a direct to consumer product intended for the qualitative detection of nucleic acids from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

The Quest PF COVID-19 PCR DTC is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

Testing is limited to laboratories designated by Quest Diagnostics, which are also 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 viral RNA. 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. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or if 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.

The Quest PF COVID-19 PCR DTC is not a substitute for visits to a healthcare provider. The information provided by this product should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The Quest PF COVID-19 PCR DTC is only intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR assays and in vitro diagnostic procedures. The Quest PF COVID-19 PCR DTC test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS OF USE STATEMENTS

For *in vitro* diagnostic use
For Emergency Use only

This assay can be used with the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***Device Description***

The Quest PF COVID-19 PCR DTC, is a real-time reverse transcription polymerase chain reaction (RT-PCR) test available direct to consumer (DTC) without a prescription that contains primers and probes designed for the detection of specific nucleic acid sequences within the SARS-CoV-2 ORF1 a/b gene.

The Quest PF COVID-19 PCR DTC is intended for use with anterior nasal swab specimens collected using the Quest COVID-19 PCR Test Home Collection kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

The test is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to five individual anterior nasal swab specimens that were collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization by any individual, including individuals without symptoms or other reasons to suspect COVID-19.

2) ***Test Procedure***

Quest Diagnostics and laboratories designated by Quest Diagnostics will perform the procedure as described in the manufacturer's instructions (Hologic Inc.) for the Hologic Panther Fusion SARS-CoV-2 Assay.

Testing with the Quest PF COVID-19 PCR DTC is performed by laboratories designated by Quest Diagnostics and 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.

CONTROLS TO BE USED WITH QUEST PF COVID-19 PCR DTC

Controls used with the Quest PF COVID-19 PCR DTC test performed using the Hologic Panther Fusion SARS-CoV-2 Assay include an internal control, positive control, and negative control, and are used in accordance with the package insert.

The Hologic Panther Fusion SARS-CoV-2 Assay provides the positive 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, Presumptive Positive, Negative, or Invalid.

The Quest PF COVID-19 PCR DTC will follow the result interpretation displayed in the tables below:

Specimen Result Interpretation for Unpooled Specimens

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 for a specimen collected using the Quest COVID-19 PCR Test Home Collection Kit when used consistent with its authorization 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 one or both of the following options: the opportunity to collect a second specimen at no additional cost and/or arefund of their purchase.

Specimen Result Interpretation for Pooled Specimens

Negative—Negative results from pooled sample testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result or if results are necessary for patient management, then the patient should be considered for individual testing. The utilization of sample pooling should be indicated for any specimens with reported negative results.

Positive—Specimens with a positive sample pool 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.

Invalid—Specimens with an invalid pool result must be tested individually prior to reporting a result. However, in instances of an invalid run, repeat testing of pooled specimens may be

appropriate depending on laboratory workflow and required result reporting time.

All test results are delivered to the end user via an online portal. Individuals with positive or invalid results will be contacted by a healthcare provider.

PERFORMANCE EVALUATION

Quest PF COVID-19 PCR DTC Analytical and Clinical PerformanceEvaluation:

The Quest PF COVID-19 PCR DTC is performed by testing anterior nasal swab specimens collected with the Quest COVID-19 PCR Test Home Collection Kit with the Hologic Panther Fusion SARS-CoV-2 Assay on the Panther Fusion System. The analytical and clinical performance of the Quest PF COVID-19 PCR DTC test are supported by the validation studies that were performed by Hologic Inc. in the Emergency Use Authorization submission originally authorized on March 16, 2020 for the Hologic Panther Fusion SARS-CoV-2 Assay (EUA200014). The EUA was re-authorized to allow testing of up to and including 5-sample pools on October 15, 2020, and to allow testing of any individuals, including individuals without signs and symptoms or other reasons to suspect COVID-19 on March 31, 2021.

Hologic Inc. granted Right of Reference to Quest Diagnostics for Hologic's authorized Hologic Panther Fusion SARS-CoV-2 Assay. The details of the Hologic Panther Fusion SARS-CoV-2 Assay can be found at https://www.fda.gov/media/136156/download

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.
- Samples should only be pooled when testing demand exceeds laboratory capacity and/or when testing reagents are in short supply.
- Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.
- 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.

WARNINGS

- For in vitro diagnostic use.
- For Emergency Use Authorization 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 Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.