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

The Quest 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 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 COVID-19 PCR DTC is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to four 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 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 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 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 COVID-19 PCR DTC test is a real-time reverse transcription polymerase chain reaction (RT-PCR) test available direct to consumer (DTC). The test is composed of two principal steps: (1) extraction of RNA from patient specimens, (2) one-step reverse transcription and PCR amplification with SARS-CoV-2 specific primers and real-time detection with 2019-nCoV specific probes. The assay targets regions of the virus nucleocapsid gene (N1 & N3) and is designed for the detection of SARS- CoV-2. Amplification and detection are accomplished using TaqMan chemistry on the ABI 7500.

The Quest 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 four 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.

INSTRUMENTS USED WITH THE TEST

Extraction of nucleic acids from anterior nasal swab specimens can be conducted on the Roche MagNA Pure 96 or the Hamilton MagEx STAR. RT-PCR is performed on the AB1 7500 Real Time PCR System.

REAGENTS AND MATERIALS

- MagnaPure or Omega Extraction
  MagnaPure
  - MagNa Pure 96 DNA and Viral NA – Small Volume Kit Roche Diagnostics #06 543 588 001 (3 x 192 isolations)

- MagNA Pure 96 External Lysis Buffer or other comparable lysis buffer that will be validated

Omega

- Mag-Bind Viral RNA Xpress Kit (Omega Bio-Tek, Cat. M6219-2304)

- 4X 1-Step RT-qPCR Master Mix, CG
- Exogenous NA Primer Pair
- Exogenous NA[1]
- TE Buffer pH 8.0
- Quest V-C-M transport medium, Quest PBS Specimen Transport Tubes or other comparable transport medium that will be validated
- Poly (A)
- DEPC-water
- PBS, 1X
- DTT
- **nCoV RT-PCR Mix Primers and Probes**
  - 2019-nCoV_N1 Forward Primer
  - 2019-nCoV_N1 Reverse Primer
  - 2019-nCoV_N1 Probe
  - 2019-nCoV_N3 Forward Primer
  - 2019-nCoV_N3 Reverse Primer
  - 2019-nCoV_N3 Probe

EQUIPMENT AND SUPPLIES

- Applied Biosystems 7500 Real Time PCR System (or ABI 7500 Fast System run as a standard ABI 7500)
- Roche MagNA Pure 96 System (Magna Pure Extraction)
- Hamilton MagEx Star (Omega Extraction)
- Bench-top centrifuge
- Serological Pipet (Pipette Aid)
- Sterile screw cap 15 mL conical tubes
- Sterile screw cap 50 mL conical tubes
- P10, P20, P200, P1000 pipettes
- P-10, P-10, P-200, P-100 ART Plugged Tips
- 1.5 mL or 2 mL microcentrifuge tubes
- Metal tubes
- Standard absorbent wipes
- Latex gloves and other protective equipment
- Biohazard absorbent wipes
- 96-well Optical Reaction Plate
- Optical adhesive cover
- Vortexer
- Microcentrifuge

[1]In the event that a RNA internal process control is temporarily unavailable, a DNA internal process control, exhibiting similar PCR performance, may be used temporarily.

HOME COLLECTION KIT

Quest COVID-19 PCR Test Home Collection Kit

CONTROLS TO BE USED WITH THE TEST

Controls used with the Quest COVID-19 PCR DTC test performed using the Quest Diagnostics SARS-CoV-2 rRT-PCR Assay include an internal control, positive control, and negative control, andare used in accordance with the package insert.

The Quest Diagnostics SARS-CoV-2 rRT-PCR Assay provides the positive and negative controls with the assay, 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.

INTERPRETATAION OF RESULTS AND REPORTING

Review patient results for unusual patterns, trends, or distributions, such as unusually high percentages of abnormal results, or unusually high percentage of non-reactive, indeterminate, or reactive results. Computer aided tools should be used when available. Refer to the Quality Control Program SOP, and the Real-Time Group Results Review and Release Process SOP.

Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

- When all controls exhibit the expected performance (Acceptance Criteria for Controls), a specimen is considered negative if all SARS-CoV-2 markers (N1, N3) cycle threshold amplification curves do not cross the threshold and the IPC amplification curve does cross the threshold line within the acceptance range.
- When all controls exhibit the expected performance, a specimen is considered Detected for SARS-CoV-2 if all makers (N1, N3) cycle threshold amplification curves cross the threshold line (>40.00 Ct). The IPC may or may not be positive as described above, but the SARS-CoV-2 result is still valid.
- When all controls exhibit the expected performance and the amplification curves for the SARS-CoV-2 markers (N1, N3) and the IPC amplification curve do not cross the threshold line within the acceptance range, possible PCR inhibition has occurred for the specimen. Specimen should be re-tested. If upon repeat testing the same situation occurs, the patient result is reported as “Indeterminate due to inhibition” (TNP1146).
- When all controls exhibit the expected performance and the cycle threshold amplification curve for any one of the two SARS-CoV-2 markers (N1, N3) but not both crosses the threshold line (<40.00 Ct), the result is inconclusive for SARS-CoV-2. The sample should be re-run. If upon repeat testing the same situation occurs, the patient result is reported as “Inconclusive.

Specimen Result Interpretation* (for specimens that are not pooled)				
nCoV-N1	**nCoV-N3**	**IPC**	**Interpretation**	**Actions**
ND	ND	Within +/- 3 Ct of Negative Control	**NOT DETECTED**	Report result to individual and public health authorities.
DET	DET	Not Applicable (+/-)	**DETECTED**	Report result to individual and public health authorities. Store samples at -70°C or colder to refer to the appropriate Public Health laboratory if requested.
Only one of two SARS-nCoV-2 targets are Detected		Not Applicable (+/-)	**INCONCLUSIVE**	Repeat extraction and RT-PCR. If the repeated result remains Inconclusive, store samples at -70°C or colder to refer to the appropriate Public Health laboratory if requested. Report result to individual and public health authorities.
ND	ND	Undetermined or IPC out of range (>3Ct)	**INVALID**	Repeat extraction and RT-PCR. If upon repeat testing the same situation occurs the patient result is reported as "Unable to report" due to inhibition (TNP1146). Report result to individual and public health authorities.

Specimen Result Interpretation for Pooled Specimens				
nCoV-N1	**nCoV-N3**	**IPC**	**Interpretation**	**Actions**
ND	ND	Within +/- 3 Ct of Negative Control	**NOT DETECTED**	Report result to individual and public health authorities.
DET	DET	Not Applicable (+/-)	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Only one of two SARS-nCoV-2 targets are Detected		Not Applicable (+/-)	**POOLED INCONCLUSIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
ND	ND	Undetermined or IPC out of range (>3Ct)	**INVALID**	Repeat each constituent specimen in the pool as a separate unpooled specimen.

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

PERFORMANCE EVALUATION

Quest COVID-19 PCR DTC Analytical and Clinical Performance Evaluation:

The Quest 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 Quest SARS-CoV-2 rRT-PCR test. The analytical and clinical performance of the Quest COVID-19 PCR DTC test are supported by the validation studies that were performed by Quest Diagnostics in the Emergency Use Authorization submissions authorized on March 17, 2020 (original) and March 26, 2020 (modified N targets) for the Quest SARS-CoV-2 rRT-PCR test (EUA200015). The EUA was re-authorized to allow testing of up to and including 4-sample pools on July 18, 2020. The details of the Quest SARS-CoV-2 rRT-PCR test can be found at Quest SARS-CoV-2 rRT-PCR - Instructions for Use (fda.gov).

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited numberof 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-2and 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.