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

The Quest RC 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 RC 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 RC COVID-19 PCR DTC is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to six 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 RC 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 RC 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 RC 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 RC COVID-19 PCR DTC is a real-time reverse transcription polymerase chain reaction (RT-PCR) test available direct to consumer (DTC) test that contains primers and probes designed for the detection of specific nucleic acid sequences within the SARS-CoV-2 ORF1 a/b and E genes.

The Quest RC COVID-19 PCR DTC is intended for use with anterior nasal swab specimens collected at home by any individual, including individuals without symptoms or other reasons to suspect COVID-19 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 six 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 (Roche Molecular Systems), except for sample pooling:

- **When preparing sample pools, combine and mix equal amounts of each specimen (e.g. for 4 specimens, combine 200µL) for a total pool sample volume of 0.8mL in the cobas omni secondary tube. Following the addition of the last specimen, mix by pipetting the pool up and down in the cobas omni secondary tube.**

- When performing pooling, laboratories will monitor sample pooling in accordance with Roche cobas SARS-CoV-2 assay Protocol for Monitoring of Sample Pooling Testing Strategies.
- In sample pooling, specimens are identified from populations based on positivity rate (for example, by county, zip code or by client). The positivity rate will be used to determine the pool size that provides the maximum testing efficiency. The assay is validated for up to six sample pooling, however, in practice, the pool size will not exceed four samples. If the pool is positive or invalid, then each of the constituent samples is re-tested as a separate individual specimen. If the pool is negative, then each constituent sample is reported as negative.

Testing with the Quest RC COVID-19 PCR DTC is performed 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.

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

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

The Roche assay requires a separate control kit that is not provided in the assay kit. The control kit includes the positive controls and negative controls, 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 RC COVID-19 PCR DTC will follow the result interpretation displayed in the tables below:

Specimen Result Interpretation for Unpooled Specimens

Target 1	Target 2	Result	Interpretation
Positive	Positive	Positive	Result for SARS-CoV-2 RNA is Detected
Positive	Negative	Positive	Result for SARS-CoV-2 RNA is Detected. A positive Target 1 result and a negative Target 2 result is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 2, target region, or 3) other factors.

Target 1	Target 2	Result	Interpretation
Negative	Positive	Presumptive Positive	Result for SARS-CoV-2 RNA is Presumptive Positive. A negative Target 1 result and a positive Target 2 result is suggestive of 1) a sample at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 1 target region in the oligo binding sites, or 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For samples with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Negative	Negative	Negative	Result for SARS-CoV-2 RNA is Not Detected
Positive	Invalid	Positive	Result for SARS-CoV-2 RNA is Detected
Invalid	Positive	Presumptive Positive	Result for SARS-CoV-2 is Presumptive Positive. For samples with a Presumptive Positive Result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Negative	Invalid	Invalid	Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	Negative	Invalid	Sample should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	Invalid	Invalid	Sample should be retested. If the result is still invalid, a new specimen should be obtained.

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

Target 1	Target 2	Result	Interpretation
Positive	Positive	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Positive	Negative	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Negative	Positive	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Negative	Negative	Negative	Result for SARS-CoV-2 RNA is Not Detected

Target 1	Target 2	Result	Interpretation
Positive	Invalid	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Invalid	Positive	**POOLED POSITIVE – DO NOT REPORT**	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Negative	Invalid	Invalid	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Invalid	Negative	Invalid	Repeat each constituent specimen in the pool as a separate unpooled specimen.
Invalid	Invalid	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 RC COVID-19 PCR DTC Analytical and Clinical PerformanceEvaluation:

The Quest RC 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 Roche cobas SARS-CoV-2 assay on the Roche cobas 6800/800 Systems. The analytical and clinical performance of the Quest RC COVID-19 PCR DTC test are supported by the validation studies that were performed by Roche Molecular Systems in the Emergency Use Authorization submission originally authorized on March 12, 2020 for the Roche cobas SARS-CoV-2 Assay (EUA200009). The EUA was re-authorized to allow testing of up to and including 6-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.

Roche Molecular Systems granted Right of Reference to Quest Diagnostics for Roche's authorized Roche cobas SARS-CoV-2 Assay. The details of the Roche cobas SARS-CoV-2 Assay can be found at https://www.fda.gov/media/136049/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.