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

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

**The Quest Diagnostics RC SARS-CoV-2 Assay 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 Diagnostics RC SARS-CoV-2 Assay is intended for the qualitative detection of nucleic acids from SARS-CoV-2 in healthcare provider-instructed self-collected anterior nasal (nasal) swab specimens (collected on site), and healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens collected from any individuals, including those suspected of COVID-19 by their healthcare provider, and those without symptoms or other reasons to suspect COVID-19.

The Quest Diagnostics RC SARS-CoV-2 Assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

The Quest Diagnostics RC SARS-CoV-2 Assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to and including six individual samples from healthcare provider-instructed self-collected nasal swab specimens (collected on site), or healthcare provider-collected nasal, nasopharyngeal, and oropharyngeal swab specimens, or anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

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 requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in respiratory 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 that are collected will not be tested with an internal control to confirm that the specimen was properly collected. Collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Negative results from pooled samples should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, pooled samples should be tested individually. Specimens included in pools with a positive or presumptive positive result must be tested individually prior to reporting a result. Specimens with low SARS-CoV-2 RNA concentrations may not be detected in sample pools due to the decreased sensitivity of pooled testing.

The Quest Diagnostics RC SARS-CoV-2 Assay 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 Diagnostics RC SARS-CoV-2 Assay 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
For Prescription Use only

This assay can be used with the Quest Diagnostics Collection Kit for COVID-19 and Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their respective authorizations.

## DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***Device Description:***

The Quest Diagnostics RC SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) 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 Diagnostics RC SARS-CoV-2 Assay is for use with certain upper respiratory swab specimens, including anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or Quest COVID-19 Nucleic Acid Test Collection Kit when used consistent with their authorizations.

This assay is also intended for the qualitative detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to six individual upper respiratory swab specimens, including anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Test Collection Kit when used consistent with their respective authorizations.

2) ***Test Principle:***

The Quest Diagnostics Collection Kit for COVID-19 is for use by 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.

The Quest COVID-19 Nucleic Acid Test Collection Kit, is for use by any individual, including individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider.

Specimens collected under observation of or by a healthcare provider, or anterior nasal swab specimens collected using either the Quest Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test Collection Kit are transported to a laboratory designated by Quest Diagnostics for SARS-CoV-2 testing using the Quest Diagnostics RC SARS-CoV-2 Assay. Specimens received at the laboratory will undergo review for integrity of packaging, liquid volume, verification of patient information, and acceptableinterval between specimen collection and receipt at the laboratory prior to acceptance for testing.

Testing with the Quest Diagnostics RC SARS-CoV-2 Assay is performed by laboratories designated by Quest Diagnostics and 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.

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

Medical oversight of the process is provided by the healthcare provider who is ordering the test.

4) ***Test Procedure***

Quest Diagnostics and laboratories designated by Quest Diagnostics will perform the procedure as described in the manufacturer's instructions for the cobas SARS-CoV-2 Assay (EUA200009; 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 200 µL) for a total pool sample volume of 0.8 mL 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 "Use of pooling based on prevalence" and "Monitoring plan for use of pooling" recommendations.
- In sample pooling, samples 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, presumptive positive, or invalid, then each of the constituent samples is re-tested as a separate individual sample. If the pool is negative, then each constituent sample is reported as negative.

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

Controls for the Quest Diagnostics RC SARS-CoV-2 Assay include an internal control, positive control, and negative control, that are used in accordance with the package insert for the cobas SARS-CoV-2 Assay.

**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 specimens 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 Diagnostics RC SARS-CoV-2 Assay will follow the result interpretation algorithm 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 specimen at concentrations near or below the limit of detection of the test, 2) a mutation inthe Target 2, target region, or 3) other factors. |
| 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 specimen 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 specimens witha 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 specimens with a Presumptive Positive Result, additionalconfirmatory 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 | Specimen should be retested. If the result is still invalid, anew specimen should be obtained. |
| Invalid | Negative | Invalid | Specimen should be retested. If the result is still invalid, anew specimen should be obtained. |
| Invalid | Invalid | Invalid | Specimen 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 Diagnostics Collection Kit for COVID-19 or the Quest COVID-19 Nucleic Acid Test 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 a refund of their purchase minus the ordering provider's fee.

**Specimen Result Interpretation for Pooled Samples**

| 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. 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 and if results are necessary for patient management, then the patient should be considered for individual testing. The use of sample pooling should be indicated in the test report for any samples with reported negative results. |
| 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 results are delivered electronically to the healthcare provider and the patient.

## PERFORMANCE EVALUATION

### ***Quest Diagnostics RC SARS-CoV-2 Assay Analytical and Clinical Performance Evaluation:***

The Quest Diagnostics RC SARS-CoV-2 Assay is performed by testing upper respiratory swab specimens, including anterior nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 or Quest COVID-19 Nucleic Acid Test Collection Kit, with the Roche cobas SARS-CoV-2 assay on the Roche cobas 6800/8800 Systems. The analytical and clinical performance of the Quest Diagnostics RC SARS-CoV-2 Assay are supported by the validation studies that were performed by Roche Molecular Systems in support of Emergency Use Authorization of the Roche cobas SARS-CoV-2 assay (EUA200009; originally authorized on March 12, 2020). The EUA for the Roche cobas SARS-CoV-2 assay was re-authorized to allow

testing of pools of up to 6 samples 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 April 12, 2021.

Roche Molecular Systems granted a Right of Reference to Quest Diagnostics for the data submitted in support of the Roche cobas SARS-CoV-2 Assay EUA. 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.
- Samples 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.