

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY  
FOR THE QUEST COVID-19 PCR TEST HOME COLLECTION KIT**

For *In vitro* Diagnostic Use

For use under Emergency Use Authorization (EUA) only

For Use by Individuals 18 Years of Age and Older when Self-collected

For Use by Individuals 16 Years of Age and Older when Self-collected Under  
Adult Supervision

For Use by Individuals 2 Years of Age and Older when Collected with Adult  
Assistance

**Direct to consumer (DTC) collected anterior nasal swabs collected at-home from individuals age 18 years and older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Quest COVID-19 PCR Test Home Collection Kit will be sent to high complexity laboratories that have been designated by Quest Diagnostics. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet the requirements to perform high complexity tests and run the specimens collected from the Quest COVID-19 PCR Test Home Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 PCR Test Home Collection Kit.**

**INTENDED USE**

The Quest COVID-19 PCR Test Home Collection Kit is a direct to consumer (DTC) product for collecting an anterior nasal swab (nasal) specimen at home (which includes in a community-based setting), from individuals age 18 years and older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) that is sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 PCR Test Home Collection Kit, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

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.

All test results are delivered to the user via an online portal. Individuals with positive or inconclusive/invalid results will be contacted by a healthcare provider. The DTC home collection system is intended to enable users to access information about their COVID-19 status that could aid with determining if isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Quest COVID-19 PCR Test Home Collection Kit is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by a healthcare provider.

The Quest COVID-19 PCR Test Home Collection Kit 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 Authorization (EUA) Only

For Use by Individuals 18 Years of Age and Older when Self-collected

For Use by Individuals 16 Years of Age and Older when Self-collected Under Adult Supervision

For Use by Individuals 2 Years of Age and Older when Collected with Adult Assistance

The Quest COVID-19 PCR Test Home Collection Kit is only authorized for use in conjunction with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with this collection device for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

## **DEVICE DESCRIPTION AND TEST PRINCIPLE**

**Note that, throughout this document, the term "individual" includes the parent/guardian of a minor, as applicable.**

### ***1) Device Description:***

The Quest COVID-19 PCR Test Home Collection Kit is available direct to consumer (DTC) without a prescription for any individual 2 years and older. When requesting a kit at a designated collection site or when purchasing a kit from an authorized distributor, individuals must verify they are 18 years of age or older even if the collection kit will be used on a minor. Once the kit has been obtained, individuals must activate their kit online and complete a screening questionnaire as a means for data collection. Individuals are notified by email or text message which contains a link to Quest's online HIPAA-compliant patient portal to view their test results. Additionally, individuals with positive and inconclusive/invalid results are contacted by a healthcare provider (HCP) via phone and/or electronically. The HCP will be part of a contracted third-party company that has prescribing privileges in the state of residency of the tested individual. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

All Quest COVID-19 PCR Test Home Collection Kits include specimen collection instructions, a nylon or polyester flocked or spun swab, a uniquely barcoded specimen collection tube containing transport media, an Activation Card for on-line kit registration, a zip-log bag containing a desiccant, shipping instructions, a shipping box, and a UN3373 shipping bag with a pre-applied label necessary for returning collected specimens to a laboratory designated by Quest Diagnostics to perform COVID-19 testing. Kits are made available to customers via direct purchase from a traditional or online retailer, through QuestDirect, or may be picked up directly at a pick-up location designated by Quest diagnostics (e.g. employer, school, etc.).

## 2) **Test Principle**

Upon receipt of the Quest COVID-19 PCR Test Home Collection Kit, the patient/adult caregiver will be directed to read all instructions before starting specimen collection and watch a collection demonstration video on-line. The individual will be prompted to follow the instructions on the Activation Card to enter patient-specific information and to activate the kit materials online. Following collection of the specimen, the individual inserts the swab into a specimen transport tube containing transport media (PBS or normal saline) and the cap is attached tightly to the tube. The collected specimen is sealed in the biohazard bag, packaged in the return bag and shipping box, and mailed via the shipping instructions. Each specimen collected with the Quest COVID-19 PCR Test Home Collection Kit is intended to be returned on the same day the sample is collected under ambient conditions.

Specimens received for testing at laboratories designated by Quest Diagnostics that are certified under CLIA to perform high complexity tests will undergo a thorough review and accessioning prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 test indicated for use with the Quest COVID-19 PCR Test Home Collection Kit.

## **REAGENTS AND MATERIALS**

The Quest COVID-19 PCR Test Home Collection Kit is available for purchase through traditional or online retailers and includes the following components:

Specimen Collection Instructions that include Shipping Instructions
Swab (nylon or polyester flocked or spun swabs) – individually wrapped
Specimen Transport Tube - containing 2 or 3 mL of either PBS or normal saline – tube with unique barcode label
Zip-lock bag (biohazard symbol) and desiccant
Activation Card
Shipping box and return bag with a UN3373 symbol with pre-paid return shipping label

***The Quest COVID-19 PCR Test Home Collection 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.

## **INSPECTION OF SPECIMENS**

Upon arrival at a Quest Diagnostics designated laboratory, the specimens are accessioned according to the accessioning SOP submitted by Quest Diagnostics as part of its EUA submission package, where they 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. Accepted specimens are tested using an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with anterior nasal swab specimens collected with the Quest COVID-19 PCR Test Home Collection Kit.

## **ASSAY CONTROLS TO BE USED WITH THE AUTHORIZED SARS-COV-2 IVD MOLECULAR TEST**

Accepted specimens are tested using an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with anterior nasal swab specimens collected with the Quest COVID-19 PCR Test Home Collection Kit. The authorized IVD molecular test must be performed according to the authorized instructions for use and must incorporate at a minimum an internal control, positive control and negative control (no template), to monitor nucleic acid extraction, amplification, and detection, as well as operator and instrument error. All controls must generate expected results in order for a test to be considered valid, as outlined in its authorized labeling.

## **INTERPRETATION OF RESULTS**

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. COVID-19 test results must be interpreted according to the instructions for use for the authorized IVD. Typically, COVID-19 test results are divided into “positive” (reactive, detected), “negative” (non-reactive/not detected), and “invalid” (no result, indeterminate, inconclusive). The test report will then be electronically delivered to both the patient/adult caregiver. Patients/adult caregivers who receive a test result that is either positive or inconclusive/invalid will also be contacted by a healthcare provider (HCP) via phone and/or electronically. The HCP will be part of a contracted third-party company that has prescribing privileges in the state of residency of the tested individual.

## **PERFORMANCE EVALUATION**

**The performance data for the Quest COVID-19 PCR Test Home Collection Kit, described below, are the same data used to support the previous authorization of the Quest Diagnostics Collection Kit for COVID-19 (EUA210497) which represents the same collection kit used for a different indications for use. For consistency, the Quest Diagnostics Collection Kit for COVID-19 name is maintained.**

### ***1) Shipping Stability Study (Summer Excursion):***

A summer excursion study was performed using the Quest Diagnostics SARS-CoV-2 RT-PCR. 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 into 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:

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**Summer 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 SARS-CoV-2 assay. 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 demonstrated less than 1 Ct difference between time 0 and 56 hours, indicating acceptable specimen stability under simulated shipping conditions.

**2) Shipping Stability Study (Summer and Winter Excursion)**

A summer and winter excursion study was performed using the Quest Diagnostics RC COVID-19 +Flu RT-PCR.

A specimen stability study was conducted to confirm that signal degradation at high and low 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 negative patient samples at concentrations targeting 2X LoD and 10X LoD into two types of transport media: PBS and VCM. The SARS-CoV-2 remnant patient samples used for this study included upper respiratory swabs in sterile normal saline (0.9% NaCl). For each transport media, a total of 20 replicates at 2X LoD and 10 replicates at 10X LoD were tested for each analyte.

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

**Summer Excursion**

Storage Temperature	Time at Storage Temp (hours)	Total Time (hours)	Mean Ct Values			
			SCoV2		Pan SARS	
			2x	10x	2x	10x
N/A	0	0	34.11	32.59	33.47	32.12
40°C	8	8	34.06	33.02	33.47	32.34
22°C	4	12	34.20	32.71	33.47	32.19
40°C	2	14	34.04	32.66	33.48	31.99
30°C	36	50	34.03	32.77	33.37	32.03
40°C	6	56	34.08	32.73	33.36	32.02

**Winter Excursion**

Storage Temperature	Time at Storage Temp (hours)	Total Time (hours)	Mean Ct Values			
			SCoV2		Pan SARS	
			2x	10x	2x	10x
N/A	0	0	34.26	32.88	33.67	32.23
40°C	8	8	34.52	32.92	33.91	32.29
22°C	4	12	34.30	32.85	33.70	32.23
40°C	2	14	34.41	32.97	33.90	32.26
30°C	36	50	34.49	32.92	33.54	32.08
40°C	6	56	34.43	33.23	33.67	32.50

Samples were tested at each timepoint with the Quest Diagnostics RC COVID-19 +Flu RT-PCR assay. The Ct values at each timepoint were compared to the Ct values at time zero. All samples remained positive at 56 hours after cycling in and out of high and low temperatures. Additionally, Ct values remained within 3.0 Ct between time 0 and 56 hours, indicating acceptable specimen stability under simulated shipping conditions.

An additional specimen stability study was conducted to confirm that RNA degradation would not occur during shipping (summer and winter excursion) and subsequent storage of specimens for up to 14 days in two types of transport medium: PBS and normal saline (0.9% NaCl). This study was performed using the Quest Diagnostics SARS-CoV-2 RT-PCR assay. The limit of detection (LoD) of the Quest Diagnostics SARS-CoV-2 RT-PCR assay was reevaluated using dilutions of a known SARS-CoV-2 positive patient sample and determined to be 245 copies/mL for anterior nasal swab specimens collected in PBS and 320 copies/mL for specimens collected in normal saline. The contrived samples for specimen stability study were then prepared by spiking a quantified upper respiratory sample from a SARS-CoV-2 positive patient into pooled remnant SARS-CoV-2 negative anterior nasal swab matrix collected in normal saline or PBS at either 2X LoD or 5-10X LoD. The contrived samples were first subjected to a shipping temperature excursion (either a summer excursion or winter excursion as shown above) followed by storage at refrigerated (2-8°C), frozen (-10 to -30°C) or room temperature (15-30°C) and testing at five time points: 0, 2-, 5-, 10- and 14-days post excursion. At each time point, a total of 20 replicates at 2X LoD and 10 replicates at 5-10X LoD were tested.

Two samples at 2X LoD (1 in PBS at Day 5 and 1 in saline at Day 14) produced invalid results on both initial and repeat testing. All other samples for both transport media at both target levels produced the expected positive results at each time point. In addition, the mean Ct values at each timepoint remained within  $\pm 3$  of those at time 0. The results of the study demonstrated acceptable specimen stability under simulated shipping conditions (winter and summer excursion time of 56 hours) followed by storage at refrigerated (2-8°C), frozen (-10 to -30°C) or room temperature (15-30°C) for up to 14 days.

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

A usability study was conducted to confirm that patients could follow the instructions included in the Quest Diagnostics Collection Kit for COVID-19 to appropriately collect, package, and ship a 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 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 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 returned specimens (40/40) yielded strong RNase P signals, indicating successful sampling of human biological material.

**4) Data to Support Collection of Anterior Nasal Swab Specimens in Individuals <18 years of age Using the Quest Diagnostics Collection Kit for COVID-19:**

The above human usability study included a total of 10 individuals <18 years of age including 2 from 2-4 years old patients, 0 from 5-10 years old patients, 7 from 11-15 years old patients and 1 from 16-17 years old patients.

In addition, Quest Diagnostics evaluated sequentially submitted specimens from all persons under 18 that had requested an at-home collected specimen for molecular testing through the QuestDirect consumer-initiated testing platform using the Quest Diagnostics Collection Kit for COVID-19. Of the 84 specimens evaluated, 4 were from 2-4 years old patients, 32 were from 5-10 years old patients, 34 were from 11-15 years old patients and 14 were from 16-17 years old patients. Within 8 days of the SARS-CoV-2 NAAT testing, the specimens were further tested using an in-house RNase P PCR to evaluate specimen adequacy. Of the collected pediatric anterior nasal swab specimens, 100% (84/84, 95%CI 95.7-100%) were RNase P positive indicating successful sampling of human biological material.

**5) Not including RNase P Control for Unobserved Collection – RNase P Negative Rate in Health Program Population (n = 37,084)**

Quest Diagnostics evaluated all nasal swab specimens (n = 37,084) that were collected

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using the Quest Diagnostics Collection Kit for COVID-19 without observation under a health program sponsored by an employer or school of higher education. All specimens were tested with the Quest SARS-CoV-2 rRT-PCR and RNase P RT-PCR. Of the 37,084 specimens, 12,303 were from females and 24,781 were males. Of the 12,303 females, almost 100% (12,302/12,303 95% CI 99.95-100%) had an acceptable Ct value for the RNase P marker, and 0.008% (1/12,303) had an unacceptable Ct value (>35) for the RNase P marker. Of the 24,781 males, almost 100% (24,776/24,781, 95% CI 99.95-100%) had an acceptable Ct value for the RNase P marker and 0.020% (5/24,781) had an unacceptable Ct value (>35) for the RNase P marker. These data demonstrate that nearly all participants were able to collect an adequate nasal swab specimen without observation for SARS-CoV-2 testing. Therefore, the requirement to observe patients using the Quest Diagnostics Collection Kit for COVID-19 to collect nasal specimens appears to be un-necessary. Furthermore, the data support that samples collected without observation do not require testing with the RNase P control.

**Warnings:**

- This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA;
- This product has been authorized only for the home collection and maintenance of anterior nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- 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 medical devices 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.