# EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE QUEST DIAGNOSTICS COLLECTION KIT FOR COVID-19

For *In vitro* Diagnostic Use
Rx Only
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 or Older when Collected with Adult Assistance

**Anterior nasal swabs collected at-home (which includes in a community-based setting) using the Quest Diagnostics Collection Kit for COVID-19 will be sent to laboratories that have been designated by Quest Diagnostics, consistent with this EUA. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a and meet requirements to perform high complexity tests and test the specimens collected with the Quest Diagnostics Collection Kit for COVID-19 using an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest Diagnostics Collection Kit for COVID-19.**

## INTENDED USE

The Quest Diagnostics Collection Kit for COVID-19 is intended for use to collect anterior nares (nasal) swab specimens at-home (which includes in a community- based setting), from individuals age 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) when determined to be appropriate by a healthcare provider. The Quest Diagnostics Collection Kit for COVID-19 is intended to be delivered individually or as part of a testing program supported by an entity designated by Quest Diagnostics.

Nasal swab specimens collected using the Quest Diagnostics Collection Kit for COVID-19 are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swabs is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with the Quest Diagnostics Collection Kit for 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 that meet requirements to perform high complexity tests and that run the specimens collected from the Quest Diagnostics Collection Kit for COVID-19 on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest Diagnostics Collection Kit for COVID-19 when used consistent with its authorization. The Quest Diagnostics Collection Kit for COVID-19 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 Prescription Use Only
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 or Older when Collected with Adult Assistance

The Quest Diagnostics Collection Kit for COVID-19 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 anterior nasal swab specimens collected with the Quest Diagnostics Collection Kit for COVID-19.

**DEVICE DESCRIPTION AND TEST PRINCIPLE**

1) ***DEVICE DESCRIPTION:***

The Quest Diagnostics Collection Kit for COVID-19 device is available through individual or bulk workflows that both include either manual or on-line (i.e., Activate) processes for completing patient specific information, for a total of four kit options. The Quest Diagnostics Collection Kit for COVID-19 is intended for use to collect anterior nares (nasal) swab specimens at-home (which includes in a community- based setting), from individuals age 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) when determined to be appropriate by a healthcare provider. A basic overview of the bulk and individual workflows is summarized below:

**Quest Diagnostics Collection Kit for COVID-19 Options**

| Option Name | Basic Overview |
|---|---|
| Bulk<br>Bulk & Activate | The Entity, which can be for example a company, school or government agency, is designated by Quest Diagnostics and operates a testing program that includes collection kit supply pick-up locations and specimen drop-off locations overseen by a healthcare provider. Bulk collection kit supplies are sent to the designated entity where they are distributed to patients, when determined to be appropriate by a healthcare provider, at the pick-up location by trained front-line staff. Pa tients/adult caregivers then collect the specimen according to the provided authorized sample collection instructions and return the specimen to trained front-line staff at the drop-off location. Once the specimens are accepted by the drop-off location, arrangements are made to have them transferred to a laboratory designated by Quest Diagnostics for COVID-19 testing using a IVD molecular test that is indicated for use with the Quest Diagnostics Collection Kit for COVID-19. The specimens are accessioned by the laboratory using an authorized standard operating procedure (SOP) and tested before the results are electronically reported to the ordering healthcare provider and patient/adult caregiver. |
| Individual<br>Individual & Activate | A healthcare provider orders patient testing, then a pre-assembled Quest Diagnostics Collection Kit for COVID-19 is shipped to the patient. Patient/adult caregiver collects the specimen according to the provided |

| | |
|---|---|
| | authorized sample collection instructions and then returns it via shipping instructions back to a laboratory designated by Quest Diagnostics for COVID-19 testing using a IVD molecular test that is indica ted for use with the Quest Diagnostics Collection Kit for COVID-19. The specimens are accessioned by the laboratory using an authorized SOP and tested before the results are electronically reported to the ordering healthcare provider and patient/adult caregiver. |

The Quest Diagnostics COVID-19 Collection Kit (Bulk and Bulk & Activate) involves sending the following basic kit supplies to the designated Entity operating the testing program that includes collection kit supply pick-up locations and specimen drop-off locations overseen by a healthcare provider:

| |
|---|
| Swabs (nylon or polyester flocked or spun swabs)– individually wrapped |
| Specimen Transport Tubes – containing 2 or 3 mL of either PBS, normal saline or UTM |
| Zip-lock bag (biohazard symbol) and desiccant |

These materials are provided to the designated Entity as either bulk supplies (along with electronic versions of the authorized patient Sample Collection Instructions) or in convenience packs (containing 1 printed version of the authorized patient Sample Collection Instructions /pack). Using these supplies, the designated Entity's trained front-line staff then provides the patient/adult caregiver with the following materials at the supply pick-up location:

| |
|---|
| Sample Collection Instructions (printed by Entity and/or electronic) |
| Swab (nylon or polyester flocked or spun swabs) – individually wrapped |
| Specimen Transport Tube - containing 2 or 3 mL of either PBS, normal saline or UTM – tube either with unique barcode label (Bulk&Activate) or without (Bulk) |
| Zip-lock bag (biohazard symbol) and desiccant |
| Test Requisition (pre-printed) (Bulk) or Activation Card (Bulk&Activate) |
| Entity specific Specimen Return Instructions – at Drop-off Location |
| Pre-printed tube label (Bulk) |

The Quest Diagnostics COVID-19 Collection Kit (Individual and Individual & Activate) involves shipping the following pre-assembled kit supplies to the patient/adult caregiver that include the authorized patient Sample Collection Instructions:

| |
|---|
| Sample 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, normal saline or UTM – tube either with unique barcode label (Individual&Activate) or without (Individual) |
| Zip-lock bag (biohazard symbol) and desiccant |
| Test Requisition (pre-printed) (Individual) or Activation Card (Individual&Activate) |
| Shipping box and return bag with a UN3373 symbol with pre-paid return shipping label |

| Priority label (optional) |
| --- |
| Pre-printed tube label (Individual) |

***The Quest Diagnostics Collection kit for COVID-19 was reviewed for adherence tothe Department of Transportation's shipping requirements for hazardous materials.***
The kit was found to be acceptable and appropriate for shipping within the UnitedStates.

## 2) ***TEST PRINCIPLE:***

The Quest Diagnostics COVID-19 Collection Kit is only provided 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. Upon receipt of the Quest Diagnostics COVID-19 Collection Kit via any of the 4 options, the patient/adult caregiver will be directed to "Read all instructions before starting specimen collection". In the case of the Bulk & Activate and Individual & Activate kit options the patient/adult caregiver will be prompted to follow the instructions on the activation card to activate the kit materials online. Once the anterior nasal swab specimen is collected the patient/adult caregiver must return the specimen as indicated in the instructions included in both the patient collection instructions and, in the case of the Bulk and Bulk & Activate options, the Specimen Return Instructions provided by the Entity operating the testing program. Testing of the specimens is performed at laboratories designated by Quest Diagnostics 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.

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 Diagnostics Collection Kit for COVID-19. The test report will then be electronically delivered to both the ordering healthcare provider and the patient/adult caregiver.

## 3) ***MEDICAL OVERSIGHT AND PROCESS TO BEUSED:***

As described above medical oversight of the process is provided by the healthcare provider who is ordering the test. The Quest Diagnostics COVID-19 Collection Kit will only be distributed to patients who were previously qualified for SARS-CoV-2 testing by a healthcare provider based on symptoms, exposure, and/or risk factors.

In the case of the Bulk and Bulk&Activate workflows the designate Entity that operates a testing program that includes collection kit supply pick-up locations and specimen drop-off locations must ensure operations are overseen by a healthcare provider and all front-line staff are appropriate trained and supervised to perform their duties as outlined in their contractional agreement with Quest Diagnostics.

4) ***TEST RESULTS AND INTERPRETATION***

**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 Diagnostics Collection Kit for COVID-19. 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 ordering healthcare provider and the patient/adult caregiver. Patients/adult caregivers will have the opportunity to discuss the test results with a healthcare provider.

**PERFORMANCE EVALUATION**

***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 in 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:

**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 lowtemperatures 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. Allsamples 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.

***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 laboratoryfor 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 instructionsfor 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 NegativeRate inHealth Program Population (n = 37,084)***

Quest Diagnostics evaluated all nasal swab specimens (n = 37,084) that were collected using the Quest Diagnostics Collection Kit for COVID-19 without observation undera 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, almost100% (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.

**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 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.