

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

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

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 by individuals using the Quest COVID-19 Nucleic Acid Test Collection Kit will be sent to laboratories that have been designated by Quest Diagnostics. All designated 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 using the Quest COVID-19 Nucleic Acid Test Collection Kit on an in vitro diagnostic (IVD) molecular test for SARS-CoV-2 that is indicated for use with the Quest COVID-19 Nucleic Acid Test Collection Kit.

INTENDED USE

The Quest COVID-19 Nucleic Acid Test Collection Kit is intended for the collection of anterior nasal swab specimens by any individual 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), including individuals without symptoms or other reasons to suspect COVID-19 when determined to be appropriate by a healthcare provider. The Quest COVID-19 Nucleic Acid Test Collection Kit is intended to be delivered as part of a testing program supported by an entity designated by Quest Diagnostics.

Anterior nasal swab specimens collected using the Quest COVID-19 Nucleic Acid Test Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the anterior 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 COVID-19 Nucleic Acid Test Collection Kit.

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 test the specimens collected using the Quest COVID-19 Nucleic Acid Test Collection Kit with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Quest COVID-19 Nucleic Acid Test Collection Kit. The Quest COVID-19 Nucleic Acid Test 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 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 COVID-19 Nucleic Acid Test 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

1) Collection Kit Description

The Quest COVID-19 Nucleic Acid Test Collection Kit consists of a sterile nylon flocked anterior nasal swab, a specimen transport tube pre-labeled with patient specific information containing 3 mL normal saline, printed specimen collection and drop-off instructions, and a zip-lock bag with biohazard symbol.

Table 1: Quest COVID-19 Nucleic Acid Test Collection Kit Components

Swab (nylon flocked swab)– individually wrapped
Specimen Transport Tube – containing 3 mL of normal saline with unique barcode label
Specimen Collection and Drop-off Instructions
Zip-lock bag with biohazard symbol

2) Collection Kit Ordering and Processing

The Quest COVID-19 Nucleic Acid Test Collection Kit is available by prescription to individuals from participating entities via locker units or collection sites managed by trained front-line staff as part of the Increasing Community Access to Testing (ICATT) program.

Quest COVID-19 Nucleic Acid Test Collection Kit Locker System Ordering and Processing

The Quest COVID-19 Nucleic Acid Test Collection Kit will be provided in locker units at participating authorized entities. To obtain a collection kit from a locker unit, an individual must first register for the kit through the entities online registration platform during which a test order is generated by a licensed health-care provider (HCP). The registration platform requires the individual to complete an assessment questionnaire and provides information to the individual about the specimen collection kit pick-up process, such as where to pick-up collection materials, a secure access code for retrieving the collection kit from the locker unit, and a scheduled time to arrive at the specified location. A unique barcode is placed on the specimen

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

transport tube during loading of the locker unit by trained front-line staff that links to the patient's personal information and test order. When the patient arrives during their scheduled appointment time, the individual enters their access code into the locker system, verifies their personal information displayed on the locker screen, and obtains the collection kit materials from the locker unit. The date of pick-up is recorded as the date of specimen collection. If the patient information on the locker screen is not verified by the individual, the locker unit will not open.

Once the kit is retrieved from the locker unit, the individual is given the option of collecting the specimen on-site or in their chosen location and is instructed to return the specimen to the drop-box located next to the locker unit on the same day it is collected. A specimen collection video, sanitizer station, and shelf for laying out the collection kit materials is available at each locker unit location for individuals who choose to collect the specimen on-site.

Quest COVID-19 Nucleic Acid Test Collection Kit Concierge Site Ordering and Processing

The Quest COVID-19 Nucleic Acid Test Collection Kit will also be available at participating authorized entities that employ trained front-line staff ("Concierge") who prepare and distribute collection kits in-person to registered individuals on-site. Individuals may register for pick-up of Quest COVID-19 Nucleic Acid Test Collection Kits from front-line staff through the entities online registration platform during which a test order is generated by a licensed health-care provider (HCP). The registration platform requires the individual to complete an assessment questionnaire and provides information to the individual about the specimen collection kit pick-up process, such as where to pick-up collection materials, a reference number for retrieving the collection kit from the pick-up site, and a scheduled time to arrive at the specified location. A unique barcode is placed on the specimen transport tube prior to pick-up that links to the patient's personal information and test order. When the patient arrives at the pick-up site, front-line staff will verify the patient's identity and provide the individual with the test order and Quest COVID-19 Nucleic Acid Test Collection Kit containing printed specimen collection and return instructions. The date of pick-up is recorded as the date of specimen collection.

Once the kit is retrieved from a front-line staff member, the individual collects the specimen in their chosen location and is instructed to return the specimen to a drop-box location that may be the same as or different from the pick-up location on the same day the specimen is collected.

3) *Collection Kit Stability*

The specimen transport tube and anterior nasal swab within the Quest COVID-19 Nucleic Acid Test Collection Kit are manufactured by third parties. The assigned shelf-life of the Quest COVID-19 Nucleic Acid Test Collection Kit is up to 18 months from the date of manufacture of the specimen transport tube and the swab when stored at the recommended temperature. The lockers and specimen drop-boxes shall be located indoors in the entity's retail space or other temperature-controlled location (20°C to 25°C or 68°F to 77°F).

4) *Specimen Stability, Transport and Storage*

Drop-boxes containing specimens collected using the Quest COVID-19 Nucleic Acid Test Collection Kit are emptied by trained staff at least once every 8 hours. After removal from the

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

drop-box, specimens are held at refrigerated temperatures (2-8°C) or picked up directly and transferred daily to Quest Diagnostics at ambient temperature by a Quest Diagnostics courier. Appropriate standard operating procedures (SOPs) are implemented to account for leaky specimen transport tubes to prevent cross-contamination among collected specimens.

5) Inspection of Specimens

Upon arrival at a Quest Diagnostics designated laboratory, the specimens are accessioned, during which they will undergo review for integrity of packaging, liquid volume, verification of patient information, and acceptable interval 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 Nucleic Acid Test Collection Kit. The test report will then be electronically delivered to both the ordering healthcare provider and the patient/adult caregiver.

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 Nucleic Acid Test 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 for a test to be considered valid, as outlined in the test's 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

The performance data for the Quest COVID-19 Nucleic Acid Test 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 different indications for use. For consistency, the Quest Diagnostics Collection Kit for COVID-19 name is maintained.

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

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 specimens for this study were prepared by spiking a SARS-CoV-2 remnant positive patient specimen into pooled remnant SARS-CoV-2 negative patient specimens at concentrations targeting 2X LoD and 5-10X LoD. The remnant patient specimens 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 specimens 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

Specimens 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 specimens 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 specimens for this study were prepared by spiking a SARS-CoV-2 remnant positive patient specimen into pooled remnant negative patient specimens at concentrations targeting 2X LoD and 10X LoD into two types of transport media: PBS and VCM. The SARS-CoV-2 remnant patient specimens 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 specimens through the following temperature excursion:

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
 March 10, 2023

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

Specimens 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 specimens 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 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 medium, 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

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

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 collection kit 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 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, it is not necessary to observe patients using the Quest Diagnostics Collection Kit for COVID-19 to collect nasal specimens to ensure specimen adequacy. Furthermore, the data support that specimens 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 collection and maintenance of

EUA Summary: Quest COVID-19 Nucleic Acid Test Collection Kit
March 10, 2023

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.