EMERGENCY USE AUTHORIZATION (EUA)
SUMMARY
SelfCheck® COVID-19 TaqPath™ Multiplex PCR

The Cleveland Clinic Foundation

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

For Use by Individuals 18 Years of Age or Older

(The SelfCheck® COVID-19 TaqPath™ Multiplex PCR will be performed at the Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute located at 9500 Euclid Ave/LL2, Cleveland, OH 44195, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests. The Laboratory Standard Operating Procedures were reviewed by the FDA under this EUA.)

INTENDED USE

The SelfCheck® COVID-19 TaqPath™ Multiplex PCR is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in self-collected (unsupervised) anterior nasal swab specimens at home using the SelfCheck® COVID-19 Swabbing Kit, by individuals (18 years of age or older) suspected of COVID-19, when determined to be appropriate by a healthcare provider based on either a telemedicine visit or an in-person visit with a healthcare provider. Specimens collected using the SelfCheck® COVID-19 Swabbing Kit are transported at ambient temperature for testing at a laboratory.

Testing is limited to the Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute, located at 9500 Euclid Ave/LL2, Cleveland, OH 44195, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The 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.

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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The SelfCheck® COVID-19 TaqPath™ Multiplex PCR is intended for use by qualified laboratory personnel specifically instructed and trained in molecular testing and in vitro diagnostic procedures. The SelfCheck® COVID-19 TaqPath™ Multiplex PCR is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***SelfCheck® COVID-19 Swabbing Kit for Cleveland Clinic***

a) Product Overview/Test Principle:

The SelfCheck®COVID-19 Swabbing Kit provided to the patient consists of a nylon, flocked nasal swab, pre-labeled saline in a screw-capped collection tube, biohazard bag with absorbent sheet, padded envelope, test order requisition and SelfCheck instructions.

The molecular test to be used with the SelfCheck® COVID-19 Swabbing Kit is the TaqPath™ COVID-19 Combo Kit- which is a real-time reverse transcription polymerase chain reaction test for the detection of SARS-CoV-2 RNA, performed at the Robert J. Tomsich Pathology and Laboratory Medicine Institute at the Cleveland Clinic.

Components manufactured by Aero-Med 3006191977 and supplied with the SelfCheck® COVID-19 Swabbing Kit include:

Name	Description	Quantity	Material Supplier
Instructions	Instruction sheet, 8.5 x 11 in, full color, double-sided print, ¼ folded, customer art, text, logo	1	Various
Nasal Swab	Swab sampling, sterile, 152 mm length, nylon floss (flocked) tip; shaft: ABS (acrylonitrile butadiene styrene); item #8202-3	1	Jiangsu Hanheng Medical Technology (ASP)
Saline tube	0.85% sterile saline, 3 ml screw-capped tube; #4S0085; patient label is added at time of pickup	1	TEKNova
Absorbent sheet	Sheet desiccant 6 x 6 in	1	Consolidated packaging
Reclosable bag	Bag, reclosable, 2MIL 6 x 9 in MGRL2P0609	1	Minigrip
Biohazard bag	Specimen transport bag, 6 x 9 in; 2 MIL Clear	1	Cardinal Health

Name	Description	Quantity	Material Supplier
Padded envelope	Gold Self-seal padded mailer #0 - 6 x 10 in S-1412 with return label	1	Uline
Test Order Requisition	8 ½ x 11 in paper with orders printed from EPIC HIS	1	Cleveland Clinic providers

b) Description of Specimen Collection Steps:

Briefly, the patient should wash hands prior to opening the kit and removing the contents. The patient will verify name and date of birth on the pre-labeled tube. The cap is removed from the collection tube and set aside. The swab is removed from the wrapper. The tip of the swab is placed into the nares and the inside of one nostril is swabbed using a circular motion and light pressure. Specimen from the other nostril is similarly collected using the same swab.

After a nasal swab specimen(s) is collected, the swab is placed into the pre-labeled tube with 3 ml normal saline and the shaft is broken by bending at the breakpoint. The cap is screwed onto the tube tightly to prevent leakage. Upon contacting the saline, the virus/nucleic acids will be stabilized for up to 56 hours prior to testing.

For device return, the patient places the tube in a biohazard bag and puts the test order and biohazard bag into a return envelope. On the day of collection, the patient brings the sealed envelope to a Cleveland Clinic drop box located inside a designated Cleveland Clinic location, e.g., a Cleveland Clinic Pharmacy, Express Care or other designated facility. Drop-boxes are locked and specimens can only be accessed by Cleveland Clinic designated personnel. Specimens will be picked-up by Cleveland Clinic or contracted couriers on established routes and transported in cars at ambient temperature to the Robert J. Tomsich Pathology and Laboratory Medicine facility. Couriers use electronic scanning to track time of pickup and delivery. Specimens will not be received through the U.S. mail or by a shipping service.

An instructional video, answers to frequently asked questions and a list of Cleveland Clinic Pharmacy and Express Care Clinics, including hours of operation, is available at clevelandclinic.org/selfcheck. Help is available at 216.344.0300.

c) Medical Oversight and Process:

The SelfCheck® COVID-19 Swabbing kit will be distributed by Cardinal Health, Inc. A contract between Cardinal Health, Inc. and the Cleveland Clinic Foundation, ensures that the SelfCheck® COVID-19 Swabbing Kit product will only be distributed to the Cleveland Clinic Pharmacies, Express Cares, outpatient laboratory/phlebotomy stations and designated providers via the Cleveland Clinic electronic supply ordering system.

Outpatients will be evaluated for use of the SelfCheck® COVID-19 Swabbing kit by qualified providers either at an in-person or telemedicine visit. Licensed providers follow CDC guidelines for molecular testing. Consistent with CDC guidance, individuals might qualify for testing based on, inter alia, (i) signs and symptoms consistent with COVID-19; or (ii) recent known or suspected exposure to SARS-CoV-2. Only patients ≥18 years of age with an order for the test

either placed in the EPIC electronic hospital information system (HIS) or on a Cleveland Clinic requisition may receive the kit. Patients may pick-up the kit at a designated Cleveland Clinic location, e.g., a Cleveland Clinic pharmacy, Express Care, or from an authorized provider. Locations may be found at clevelandclinc.org/selfcheck or by calling 216-444-0300. A test order requisition and specimen label will be generated by the Cleveland Clinic location that gives the patient the kit. The specimen label will be placed on the tube. The test order requisition and labeled specimen tube will be placed inside the kit before the patient is given the kit.

d) Inspection of Nasal Swab Specimens at Cleveland Clinic:

Specimens collected with the SelfCheck® COVID-19 Swabbing kit for Cleveland Clinic must be checked for the following criteria upon receipt at Cleveland Clinic prior to processing as outlined in the SelfCheck® COVID-19 Swabbing kit for Cleveland Clinic accessioning standard operating procedure (SOP):

- Identifiers and Orders: The name and date of birth on the specimen label and paper requisition must match. The identifiers on the specimen and requisition are verified in comparison to orders.
- Specimen acceptability: The source, collection swab type and transport media are verified. (See rejection criteria below.)
- Transport time: The collection date and time on the specimen and received date and time are recorded electronically in the Laboratory information System. Specimens exceeding stability criteria are rejected.

Rejection criteria for the SelfCheck® COVID-19 Swabbing Kit:

- Patient <18 years old
- Patient order/specimen identification discrepancy
- Improper swab submitted (only the swab provided with the kit is accepted; wood, calcium alginate and gel swabs are rejected)
- Improper media used (only the saline provided in the kit is acceptable)
- Improper source (anything other than nasal)
- Broken or leaking specimen container
- Specimen outside of established stability (56 hours ambient)

Note: The specimen will not be rejected if collection date and time are missing on the requisition. The patient will be contacted to provide the information.
Note: If a test is rejected, the order will be cancelled, and the ordering provider will be contacted.

e) Partnering Laboratories:

Laboratory	**EUA Assay**	**Lab Testing Capacity (per day or week)**
Robert J. Tomsich Pathology and Laboratory Medicine Institute of the Cleveland Clinic 9500 Euclid Ave/LL2 Cleveland, OH 44195	EUA 200010 TaqPath™ COVID-19 Combo Kit-Multiplex PCR test for the detection of SARS-CoV-2 RNA	5,000/day

Phone: 216-444-5755 (Lab Client Services) CLIA #:36D0656094		

2) *TaqPath™ COVID-19 Combo Kit*

The TaqPath™ COVID-19 Combo Kit- is a real-time reverse transcription polymerase chain reaction test for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 primer and probe set is designed to detect RNA from the SARS-CoV-2 N, ORF1ab and S genes with one additional primer and probe set used to detect an MS2 internal control in anterior nasal specimens from suspected patients. The test consists of three processes in a single tube: 1) reverse transcription of target RNA to cDNA, 2) PCR amplification of target and internal control, and 3) simultaneous detection of all three target amplicons using different fluorescent dye labeled probes.

During the amplification process, each probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the bound probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. Fluorescence intensity is monitored at each PCR cycle by the Applied Biosystems™ (ABI) instruments. The data are analyzed, then interpreted by the ABI COVID-19 Interpretive Software.

INSTRUMENTS USED WITH TEST

TaqPath™ COVID-19 Combo Kit- multiplex real-time RT-PCR test is performed using the following real-time fluorescence PCR instruments and associated software:

- Applied Biosystems ABI 7500 Real-Time PCR System or Applied Biosystem 7500 Fast Dx Real-Time PCR System with 7500 software v2.3 or SDS software v1.4.

Automated RNA extraction is performed using the following:

- Applied Biosystems KingFisher™ Flex Magnetic Particle Processor with 96 Deep-Well Head.

EQUIPMENT, REAGENTS AND MATERIALS

The following equipment/reagents/materials are required to run the TaqPath™ COVID-19 Combo Kit- multiplex real-time RT-PCR test in addition to common laboratory reagents and the consumables for the extraction and PCR processes are summarized in the tables below:

1) RNA Extraction & RT-PCR Instrumentation

- Applied Biosystems King Fisher™ Flex
- Applied Biosystem 7500 Real-Time PCR System
- Applied Biosystem 7500 Fast Dx Real-Time PCR System

2) Equipment

1. Template Tamer

2. Biological Safety cabinet (BSC)
3. Pipettes (various volume and multichannel)
4. Bench-top micro-centrifuge
5. -70ºC and -20ºC Freezers
6. 4ºC Refrigerator
7. Vortex
8. Cold block (Cool safe)

3) Reagents

a. RNA Extraction kit: MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit (Cat# A42352, A48310) or MagMAX™ Viral/Pathogen II Nucleic Acid Isolation Kit (Cat# A48383) with a specimen input volume of 200 µL.

b. RT-PCR kit: TaqPath™ COVID-19 Combo Kit 1,000 reactions (Cat# A47814)

Component	Contents	Volume	Storage
TaqPath™ RT-PCR COVID-19 Kit, 1000 reactions	COVID-19 Real Time PCR Assay Multiplex (ORF1ab, N gene, S gene, MS2)	1,500 µl	-10 to -30˚C
	MS2 Page Control	10 x 1,000 µl	-10 to -30˚C
TaqPath™ COVID-19 Control Kit (1 x 10^4 copies/µl)		2 x 10 µl per kit; 5 kits included	≤-70˚C
Taqpath™ COVID-19 Control Dilution Buffer		2 x 250 µl per kit, 5 kits included	-10 to -30˚C

CONTROLS TO BE USED WITH THE SELFCHECK® COVID-19 TAQPATH™ MULTIPLEX PCR

The TaqPath™ COVID-19 Combo Kit includes the following controls:

1) Negative Control (NC): A negative (no template) control is needed to eliminate the possibility of specimen contamination on the assay run and is used on every assay plate. This control is molecular grade, nuclease-free water and is included with each extraction and with each RT-PCR run.

2) Positive RNA Control (PC): A positive template control is needed to verify that the assay run (ORF1ab, N gene, S gene of SARS-CoV-2) is performing as intended. TaqPath™ COVID-19 Control (1×10^4 copies/µL) diluted to a working stock of 25 copies/µL is used as the positive RNA control.

3) MS2 Phage Control is added in the assay as an internal process control (IC) for nucleic acid extraction.

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.

1) Interpretation of Controls and Clinical Specimens

a. All test controls should be examined prior to interpretation of patient results. The interpretation of results is performed by the COVID-19 Interpretive Software v1.5.

Table: Ct cutoff values used for assay targets

Specimen	**Target**	**Ct cutoff**
Positive Control	MS2	Valid Ct values are >37
	Viral targets	Valid Ct values are ≤37
Negative Control	MS2	Valid Ct values are ≤32
	Viral targets	Valid Ct values are >37
Clinical Specimens	MS2	Valid Ct values are ≤32
	Viral targets	Valid Ct values are ≤37

b. Quality Control and Result validity
The COVID19 Interpretative software requires one Negative Control (NC) and one Positive RNA Control (PC) to be present for each run.

Control Interpretation:

Negative Control (NC) Interpretive Table

Control	**COVID19 Interpretive Software Result**	**ORF1ab**	**N gene**	**S gene**	**MS2**	**Action**
NC	Valid	Negative	Negative	Negative	Positive	N/A
	Invalid (due to IC failure)	N/A	N/A	N/A	Negative	Repeat Run (extraction and PCR)
	Invalid (due to potential contamination)	Positive for one or more viral targets			Positive	Repeat Run (extraction and PCR)

Positive RNA Control (PC) Interpretive Table

Control	COVID19 Interpretive Software Result	ORF1ab	N gene	S gene	MS2	Action
PC	Valid	Positive	Positive	Positive	Negative	N/A

	Invalid	Negative	Negative	Negative	Negative	Repeat Run (PCR only, comment: PC improperly prepared)
	Invalid	Positive for only 1 or 2 of the viral targets.			Pos/Neg	Repeat Run (extraction and PCR)
	Invalid	Positive	Positive	Positive	Positive	Repeat Run (PCR only, comment: contamination of MS2 during PCR reaction plate set up)

c. **Clinical Specimens Interpretive Table**

The amplification curves on the AB7500 must be reviewed on ALL positive patients. If the amplification curve is valid, the patient result may be released. If the amplification curve is invalid, the patient result may not be released. The specimen must be repeated using TaqPath or another platform.

ORF1ab	**N gene**	**S gene**	**MS2**	**Status**	**Result**	**Action**
NEG	NEG	NEG	POS	VALID	SARS-CoV-2 Not detected	N/A
NEG	NEG	NEG	NEG	INVALID	N/A	REPEAT
NEG	NEG	POS	N/A	VALID	INCONCLUSIVE	REPEAT
NEG	POS	NEG	N/A	VALID	INCONCLUSIVE	REPEAT
POS	NEG	NEG	N/A	VALID	INCONCLUSIVE	REPEAT
POS	NEG	POS	N/A	VALID	INCONCLUSIVE	REPEAT
NEG	POS	POS	N/A	VALID	SARS-CoV-2 Detected	N/A
POS	POS	NEG	N/A	VALID	SARS-CoV-2 Detected	N/A
POS	POS	POS	N/A	VALID	SARS-CoV-2 Detected	N/A

Test results are communicated back to individuals that used the SelfCheck® COVID-19 Swabbing Kit via the following mechanisms: Patients are notified via MyChart (secure messaging within the HIS) when their results (positive, negative or invalid/indeterminate) are available. Patients who do not have the ability to use MyChart receive results from a healthcare provider. Positive or indeterminate/invalid results are communicated back to the patient by telephone from a provider. Cleveland Clinic patients are offered enrollment in the Cleveland Clinic Home Monitoring Program, which provides further daily guidance on how to manage symptoms and care. Care of patients with orders from Cleveland Clinic Reference Laboratory (CCL) providers will be managed by their ordering provider.

PERFORMANCE EVALUATION

1) TaqPath™ COVID-19 Combo Kit Analytical and Clinical Performance Evaluation:

The analytical and clinical performance of the TaqPath™ COVID-19 Combo Kit has been demonstrated by Thermo Fisher Scientific Inc. in the Emergency Use Authorization (EUA200010) submission authorized on 03/13/2020. The SelfCheck® COVID-19 TaqPath™ Multiplex PCR runs a specific workflow of the TaqPath™ COVID-19 Combo Kit per Thermo Fisher Instructions for Use (IFU) without modifications. Thermo Fisher has granted Cleveland Clinic right of reference to data in support of using the SelfCheck® COVID-19 Swabbing Kit with TaqPath™ COVID-19 Combo Kit. The details of the performance of the TaqPath™ COVID-19 Combo Kit can be found here: https://www.fda.gov/media/136112/download.

2) SelfCheck® COVID-19 Swabbing Kit Specimen Stability Studies:

Specimen Stability Studies of the SelfCheck® COVID-19 Swabbing kit were conducted with the previously authorized Cleveland Clinic SARS-CoV-2 Assay (https://www.fda.gov/media/140788/download) using identical kit components as described in this submission. The studies were designed to simulate specimen storage before transport and during transport at ambient temperature as well as the extreme temperature conditions that could be experienced during the summer and winter months. Summer and winter thermal profiles shown below were evaluated in the studies.

Summer temperature excursion:

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56

Winter temperature excursion:

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56

Briefly, simulated specimen stability and shipping studies were performed using a total of 40 specimens including 20 specimens at 2X LoD, 10 specimens at 5-10X LoD, and 10 negative specimens. The positive specimens were contrived by spiking negative nasal specimen matrix in saline with positive clinical specimens, the concentration of which were determined by comparing the Ct values of specimens and controls at known concentration tested by CDC EUA assay. Each

specimen contained the collection swab used in the kit. After the contrived positive and negative specimens underwent the thermal excursions, they were tested with the Cleveland Clinic SARS-CoV-2 Assay. The mean Ct values and percent agreements are presented in Table below. These data support the use of the SelfCheck® COVID-19 Swabbing kit for transport and storage of specimens following self-collection of nasal swabs in saline at room temperature for up to 56 hours from the time of collection.

Summary Results of SelfCheck® COVID-19 Swabbing Kit Stability Studies:

Specimen (N)	Gene	Baseline Ave Ct	Summer Ave ΔCt	Winter Ave ΔCt	Percent Agreement
Negative (10)	E	ND	ND	ND	100%
	RdRP	ND	ND	ND	100%
	RNase P	28.29	-1.00	0.14	100%
5x LoD (10)	E	27.30	-0.61	0.22	100%
	RdRP	33.23	-1.00	-0.03	100%
	RNase P	28.39	-0.84	0.12	100%
2x LoD (20)	E	28.88	-0.92	-0.09	100%
	RdRP	34.85	-1.09	0.09	100%

3) Human Usability study:

A Human Usability Study of the SelfCheck® COVID-19 Swabbing kit was previously conducted with the Cleveland Clinic SARS-CoV-2 Assay (https://www.fda.gov/media/140788/download) using identical kit components and SelfCheck instructions as described above. The study was conducted at a Cleveland Clinic Express Care site to simulate the at-home environment and the participants were observed directly by a health care worker during the specimen collection and packing process. The goal was to assess user comprehension of the SelfCheck® COVID-19 Swabbing Kit for both collection and packaging of the nasal specimens for transport.

Briefly, 38 participants ≥18 years of age with varied education levels who placed an order for COVID-19 molecular testing were recruited in the study. The study participants read the instructions in the SelfCheck® COVID-19 Swabbing Kit and used the instructions and materials to collect nasal specimens under observation of a health care worker who has been trained on use of the kit and has experience in collection of swabs for COVID-19 testing. The health care worker did not provide assistance or answer questions during the usability study. After collection, the patient placed the swab in a tube with 3 ml of normal saline and packaged the specimen for delivery to the lab as described in the kit instructions. A second specimen was collected by the health care worker using a

nasal swab and routine practices for COVID-19 testing. Upon the completion of the specimen collection, both patients and the health care worker who observed the patient using the SelfCheck® COVID-19 Swabbing Kit completed a questionnaire designed by the Cleveland Clinic to evaluate their experience and suggest enhancements. Based on answers from questionnaires, the Instructions for using the SelfCheck COVID-19 Swabbing Kit were modified slightly to provide clarification. Specimens collected by patients were tested with the Cleveland Clinic SARS-CoV-2 Assay and results were compared to nasal swabs collected by the health care worker.

Thirty-seven out of 38 participants were able to successfully collect the nasal swab. All 37 specimens were acceptable for SARS-CoV-2 molecular testing based on laboratory assessment. Adequate sampling was determined by the presence of RNase P in all 37 specimens and the amount of RNase P detected was similar to that detected with the health care worker -collected swab (average Δ Ct <0.2), indicating successful collection of human biological material that was extracted and amplified. All patients indicated that they would be comfortable using the SelfCheck® COVID-19 Swabbing Kit at home.

Based on the usability study data and feedback, the SelfCheck® COVID-19 Swabbing Kit instructions were understandable, the kit was easy to use, and specimens were successfully self-collected, which has demonstrated the usability that is acceptable to the FDA.

4) **Not including RNase P Control for Unobserved Self-Collection – RNase P Negative Rate in Consecutively collected specimens (n = 6,185)**

Cleveland Clinic tested anterior nasal swab specimens (*n = 6,185*) that were consecutively self-collected using the SelfCheck® COVID-19 Swabbing Kit without observation over a two-month period. All specimens were tested with the Cleveland Clinic SARS-CoV-2 Assay (EUA200313). Of the 6,185 specimens, almost 100% (6,180/6,185) had an acceptable Ct value (<40) for the RNase P marker and 0.08% (5/6,185) were undetected for the RNase P marker. These data demonstrate that nearly all patients were able to self-collect an adequate nasal swab specimen without observation using the SelfCheck® COVID-19 Swabbing Kit. Therefore, the requirement to run a separate RNase P assay to evaluate unobserved self-collection of adequate human specimen appears to be un-necessary.

Additional Requirement as a Post-Authorization Condition:
Cleveland Clinic will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the SelfCheck® COVID-19 TaqPath™ Multiplex PCR including how many SelfCheck® COVID-19 Swabbing Kits were requested and sent for home collection. Cleveland Clinic will also document the number of kits that were disseminated and returned to the laboratory according to the instructions, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first SelfCheck® COVID-19 Swabbing Kit lot using the TaqPath™ COVID-19 Combo Kit.

LMITATIONS:

• Nasal swabs are considered acceptable specimen types for use with SelfCheck COVID TaqPath Multiplex PCR, but performance has not been established. Testing of nasal swabs (self-collected, unsupervised) is limited to individuals suspected of COVID-19, when determined to be appropriate

be a healthcare provider based on either a telemedicine visit or an in-person visit with a healthcare provider.

• A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

• This test cannot rule out diseases caused by other bacterial or viral pathogens.

• Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.

• Results from the SelfCheck® COVID-19 TaqPath™ Multiplex PCR test should be used as an adjunct to clinical observations and other information available to the physician. The result is only for clinical reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.

• Although the detected target sequences of this kit are in conserved regions of the SARS-CoV-2 genome, rare mutations may lead to negative results.

• Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined.

• Specimens that are collected at home will not be tested with an internal control to confirm that the specimen was properly collected. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly

• The clinical performance has not been established in 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.

WARNINGS:

• This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory;

• This product has been authorized only for the 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 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.