EMERGENCY USE AUTHORIZATION (EUA)
SUMMARY
SelfCheck® cobas® SARS-CoV-2 Assay

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® cobas® SARS-CoV-2 Assay 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® cobas® SARS-CoV-2 Assay 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® cobas® SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in molecular testing and in vitro diagnostic procedures. The SelfCheck® cobas® SARS-CoV-2 Assay 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 cobas® SARS-CoV-2 qualitative assay for use on the cobas® 6800/8800 Systems, 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
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 Phone: 216-444-5755 (Lab Client Services) CLIA #: 36D0656094	EUA 200009 cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems (Roche Molecular Systems, Inc.)	5,000/day

2) ***cobas® SARS-CoV-2***

The molecular test to be used with the SelfCheck® cobas® SARS-CoV-2 Assay is an EUA test (EUA200009), cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems (Roche Molecular

Systems, Inc.), which 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 ORF1ab and E genes with one additional primer and probe set used to detect an MS2 internal control in anterior nasal specimens from suspected patients. cobas® SARS-CoV-2 is based on fully automated specimen preparation (nucleic acid extraction and purification) followed by PCR amplification and detection.

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 cobas® 6800/8800 Systems. The data are analyzed and interpreted using the cobas® 6800/8800 software and cobas® SARS-CoV-2 analysis package.

INSTRUMENTS USED WITH TEST

cobas® SARS-CoV-2 is run on the fully automated cobas® 6800/8800 Systems. The cobas® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module, and the analytic module.

Automated data management is performed by the cobas® 6800/8800 software, which assigns test results for all tests. The cobas® 6800/8800 software and cobas® SARS-CoV-2 analysis package must be installed on the cobas® 6800/8800 Systems. The Instrument Gateway (IG) server will be provided with the system.

Table: Instrumentation

Equipment	**P/N**
cobas® 6800 System (Option Moveable)	05524245001 and 06379672001
cobas® 6800 System (Fix)	05524245001 and 06379664001
cobas® 8800 System	05412722001
Sample Supply Module	06301037001
Instrument Gateway	06349595001

EQUIPMENT, REAGENTS AND MATERIALS

cobas® SARS-CoV-2 can be run with a minimum required specimen volume of 0.6 mL in the cobas omni secondary tube for anterior nasal swab specimens collected in physiological saline.

Reagents, materials and other consumables required for use on the cobas® 6800/8800 Systems are as follows:

Table: cobas® SARS-CoV-2 (192 test cassette P/N 09175431190)

Kit Components	**Reagent Ingredients**	**Quantity per kit 192 tests**	**Storage Temperature**

Proteinase Solution (PASE)	Tris buffer, < 0.05% EDTA, calcium chloride, calcium acetate, 8% proteinase, glycerol	22.3 mL	2–8°C
RNA Internal Control (RNA IC)	Tris buffer, <0.05% EDTA, <0.001% non-Sarbecovirus related armored RNA construct containing primer and probe specific primer sequence regions (non-infectious RNA in MS2 bacteriophage), <0.1% sodium azide	21.2 mL	2–8°C
Elution Buffer (EB)	Tris buffer, 0.2% methyl-4 hydroxybenzoate	21.2 mL	2–8°C
Master Mix Reagent 1 (MMX-R1)	Manganese acetate, potassium hydroxide, < 0.1% sodium azide	7.5 mL	2–8°C
SARS-CoV-2 Master Mix Reagent 2 (SARS-CoV-2 MMX-R2)	Tricine buffer, potassium acetate, < 18% dimethyl sulfoxide, glycerol, < 0.1% Tween 20, EDTA, < 0.12% dATP, dCTP, dGTP, dUTPs, < 0.01% upstream and downstream SARS-CoV-2 and Sarbecovirus primers, < 0.01% Internal Control forward and reverse primers, < 0.01% fluorescent-labeled oligonucleotide probes specific for SARS-CoV-2, Sarbecovirus, and the RNA Internal Control, < 0.01% oligonucleotide aptamer, < 0.1% Z05D DNA polymerase, < 0.10% AmpErase (uracil-N-glycosylase) enzyme (microbial), < 0.1% sodium azide	9.7 mL	2–8°C

Table: cobas® SARS-CoV-2 Control Kit (P/N 09175440190)

Kit Components	**Reagent Ingredients**	**Quantity per kit**	**Storage Temperature**
SARS-CoV-2 Positive Control (SARS-CoV-2 (+)C)	Tris buffer, < 0.05% Sodium azide, < 0.005% EDTA, < 0.003% Poly rA, < 0.01% Non-infectious plasmid DNA (microbial) containing SARS-CoV-2 sequence, < 0.01% Non-infectious plasmid DNA (microbial) containing pan-Sarbecovirus 1 sequence, < 0.01% Non-infectious plasmid DNA (microbial) containing pan-Sarbecovirus sequence	16 mL (16 x 1 mL)	2–8°C

Table: cobas® Buffer Negative Control Kit (P/N 07002238190)

Kit Components	**Reagent Ingredients**	**Quantity per kit**	**Storage Temperature**

cobas® Buffer Negative Control (BUF (-) C)	Tris buffer, < 0.1% sodium azide, EDTA, <0.002% Poly rA RNA (synthetic)	16 mL (16 x 1 mL)	2–8°C

Table: cobas omni reagents for sample preparation*

Reagents	**Reagent ingredients**	**Quantity per kit**	**Storage Temperature**
cobas omni MGP Reagent (MGP) (P/N 06997546190)	Magnetic glass particles, Tris buffer, 0.1% methyl-4 hydroxybenzoate, < 0.1% sodium azide	480 tests	2–8°C
cobas omni Specimen Diluent (SPEC DIL) (P/N 06997511190)	Tris buffer, 0.1% methyl-4 hydroxybenzoate, < 0.1% sodium azide	4 x 875 mL	2–8°C
cobas omni Lysis Reagent (LYS) (P/N 06997538190) 	43% (w/w) guanidine thiocyanate***, 5% (w/v) polydocanol***, 2% (w/v) dithiothreitol***, dihydro sodium citrate	4 x 875 mL	2–8°C
cobas omni Wash Reagent (WASH) (P/N 06997503190)	Sodium citrate dihydrate, 0.1% methyl-4 hydroxybenzoate	4.2 L	15–30°C

* These reagents are not included in the cobas® SARS-CoV-2 test kit.
** Product safety labeling primarily follows EU GHS guidance
***Hazardous substance

Table: Reagent storage (when reagent is not on the system)

Reagent	**Storage temperature**
cobas® SARS-CoV-2 -192T	2–8°C
cobas® SARS-CoV-2 -480T	2–8°C
cobas® SARS-CoV-2 Control Kit	2–8°C
cobas® Buffer Negative Control Kit	2–8°C
cobas omni Lysis Reagent	2–8°C
cobas omni MGP Reagent	2–8°C
cobas omni Specimen Diluent	2–8°C
cobas omni Wash Reagent	15–30°C

Table: Materials and consumables for use on cobas® 6800/8800 Systems

Material	**P/N**
cobas omni Processing Plate	05534917001
cobas omni Amplification Plate	05534941001
cobas omni Pipette Tips	05534925001
cobas omni Liquid Waste Container	07094388001
cobas omni Lysis Reagent	06997538190

cobas omni MGP Reagent	06997546190
cobas omni Specimen Diluent	06997511190
cobas omni Wash Reagent	06997503190
Solid Waste Bag and Solid Waste Container or Solid Waste Bag With Insert and Kit Drawer	07435967001 and 07094361001 or 08030073001 and 08387281001
cobas omni Secondary Tubes 13x75 (optional)	06438776001
cobas® PCR Media Tube Replacement Cap Kit	07958056190
cobas® PCR Media Disposable Tube Stand (Optional)	07958064190
MPA RACK 16 MM LIGHT GREEN 7001-7050	03143449001
RD5 RACK – RD Standard rack 0001-0050 LR	11902997001

CONTROLS TO BE USED WITH THE SELFCHECK® COBAS® SARS-COV-2 ASSAY

cobas® SARS-CoV-2 in the SelfCheck® cobas® SARS-CoV-2 Assay includes the following controls:

- Negative Control: The cobas® Buffer Negative Control (no template control) is included with each batch of specimens to monitor reagent and system contamination.

- Positive RNA Control: The SARS-CoV-2 Positive Control is non-infectious plasmid DNA containing SARS-CoV-2 sequence and pan-Sarbecovirus sequence that is included with each batch of specimens to monitor for failures of rRT-PCR reagents and reaction conditions.

- RNA Internal Control (RNA IC): Non-infectious RNA in MS2 bacteriophage is added to patient specimens to monitor the entire specimen preparation and PCR amplification process.

In addition to the above controls, AccuPlex™ SARS-CoV-2 Reference Material Kit (Cat# 0505-0126, SeraCare) is used as the external controls for quality control of each new lot or new shipment.

INTERPRETATION OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Results are reported as Positive, Presumptive Positive, Negative, or Invalid (Table).

Table: cobas® SARS-CoV-2 results interpretation

Target 1 (ORF 1a/b)	Target 2 (E-gene)	Interpretation
Positive	Positive	All Target Results were valid. Result for SARS-CoV-2 RNA is Detected.
Positive	Negative	All Target Results were valid. Result for SARS-CoV-2 RNA is Detected. A positive Target 1 result and a negative Target 2 result is suggestive of 1) a specimen at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 2, target region, or 3) other factors.
Negative	Positive	All Target Results were valid.

		Result for SARS-CoV-2 RNA is Presumptive Positive. A negative Target 1 result and a positive Target 2 result is suggestive of 1) a specimen at concentrations near or below the limit of detection of the test, 2) a mutation in the Target 1 target region in the oligo binding sites, or 3) infection with some other Sarbecovirus (e.g., SARS-CoV or some other Sarbecovirus previously unknown to infect humans), or 4) other factors. For specimens with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Negative	Negative	All Target Results were valid. Result for SARS-CoV-2 RNA is Not Detected.
Positive	Invalid	Not all Target Results were valid. Result for SARS-CoV-2 RNA is Detected.
Invalid	Positive	Not all Target Results were valid. Result for SARS-CoV-2 RNA is Presumptive Positive. For specimens with a Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
Negative	Invalid	Not all Target Results were valid. Specimen should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	Negative	Not all Target Results were valid. Specimen should be retested. If the result is still invalid, a new specimen should be obtained.
Invalid	Invalid	All Target Results were invalid. Specimen should be retested. If the result is still invalid, a new specimen should be obtained.

PERFORMANCE EVALUATION

1) cobas® SARS-CoV-2 Analytical and Clinical Performance Evaluation:

The analytical and clinical performance of the cobas® SARS-CoV-2 has been demonstrated by Roche Molecular Systems, Inc. in an Emergency Use Authorization (EUA200009). The SelfCheck® cobas® SARS-CoV-2 Assay runs the cobas® SARS-CoV-2 on the cobas® 6800/8800 Systems per Roche's Instructions for Use (IFU) without modifications. Roche has granted Cleveland Clinic right of reference to data in support of using cobas® SARS-CoV-2 in the SelfCheck® cobas® SARS-CoV-2 Assay. The details of the performance of the cobas® SARS-CoV-2 can be found here: https://www.fda.gov/media/136049/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 FDA-authorized Cleveland Clinic SARS-CoV-2 Assay (EUA200313/A001) 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 commencement of testing) summarizing any testing performed with the SelfCheck® cobas® SARS-CoV-2 Assay 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 cobas® SARS-CoV-2 assay.

LIMITATIONS:

• Nasal swabs are considered acceptable specimen types for use with SelfCheck® cobas® SARS-CoV-2 Assay. 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.

• Specimens 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® cobas® SARS-CoV-2 Assay 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.