

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
COLOR COVID-19 SELF-SWAB COLLECTION KIT WITH SALINE**

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

Anterior nasal swabs self-collected at-home or self-collected unsupervised at a collection site using the Color COVID-19 Self-Swab Collection Kit with Saline will be sent to laboratories that have been designated by Color Health, Inc. 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 Color COVID-19 Self-Swab Collection Kit with Saline using an in vitro diagnostic (IVD) molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit with Saline.

INTENDED USE

The Color COVID-19 Self-Swab Collection Kit with Saline is intended for use by individuals 18 years or older, including individuals without symptoms or other reasons to suspect COVID-19 for unsupervised self-collection of anterior nasal swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider. Anterior nasal swab specimens collected using the Color COVID-19 Self-Swab Collection Kit with Saline are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the anterior nasal swab specimens is maintained in the specimen packaging and is suitable 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 Color COVID Self-Swab Collection Kit with Saline.

Testing is limited to laboratories designated by Color Health, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests. Testing is also limited to molecular diagnostic tests that are indicated for use with the Color COVID-19 Self-Swab Collection Kit with Saline.

The Color COVID-19 Self-Swab Collection Kit with Saline 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 or Older

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

The Color COVID-19 Self-Swab Collection Kit with Saline 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 Color COVID-19 Self-Swab Collection Kit with Saline.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Color Health, Inc. (Color) offers the Color COVID-19 Self-Swab Collection Kit with Saline as part of a community-based distribution framework that is physician ordered. Healthcare providers (HCP) at specific institutions, who are licensed and have prescriptive authority in their respective states, use a COVID-19 eligibility questionnaire that is based on current CDC testing guidelines to evaluate patient eligibility. Ordering physicians must be licensed in the state where the kits will be provided or shipped. At the physician's discretion, the patient accesses the Color website (color.com/covid/PARTNER/activate where "PARTNER" can be customized to the specific program) and answers questions related to patient identity, exposure to SARS-CoV-2, symptoms, as well as underlying health conditions and other risk factors. This task is to document the patient's responses and link the patient with a specific kit and barcode that will be used for accessioning at the testing laboratory.

The Color COVID-19 Self-Swab Collection Kit with Saline enables the self-collection of an anterior nasal swab sample that is transported in 0.9% saline to either; (1) Color for processing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay or (2) another laboratory designated by Color that has an authorized IVD molecular assay for detection of SARS-CoV-2 that is indicated for use with the Color COVID-19 Self-Swab Collection Kit with Saline. The Color Self-Swab Collection Kit with Saline can be provided at a designated on-site collection location that is part of a centrally coordinated program or can be ordered by a healthcare provider through Color's website and shipped to the patient's home via two-day shipping. Color does not accept requests for kits from patients directly. Results of the authorized IVD molecular assay for detection of SARS-CoV-2 are communicated to the ordering physician. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results. The authorizing physician and the sponsoring agency often give their patients the option to follow-up with a healthcare provider to discuss the test results.

The Color COVID-19 Self-Swab Collection Kit with Saline consists of consists of a sterile packaged spun polyester swab, collection tube filled with 1 mL of 0.9% saline, a rigid biohazard safety bag with leak proof adhesive closure and absorbent material, barcode card, instructions for use, cardboard return shipping box, and return shipping envelope with prepaid return label. Instructions included in the kit guide users on how to collect the anterior nasal swab specimen appropriately. Following collection, the swab is inserted into a sterile tube with saline, and the cap is screwed tightly onto the collection tube. The collected specimen is sealed in the biohazard bag and placed into a designated, secure collection bin or handed directly to on-site staff if collected at a designated location OR the specimen in the rigid biohazard bag is placed into the shipping box and

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

into the return shipping envelop for transport to a designated testing laboratory. For those specimens collected at home, the completed kit must be deposited at a drop box location on the same day the specimen is collected to ensure timely receipt at the testing laboratory. Each Color COVID-19 Test Self-Swab Collection Kit with Saline is intended to be returned via 48-hour shipping (or same day shipping via a courier for those collections completed on-site) at ambient conditions.

Specimens received for testing at Color and designated laboratories will undergo a thorough review and accessioning process prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated for use with the Color COVID-19 Test Self-Swab Collection Kit with Saline.

REAGENTS AND MATERIALS

The Color COVID-19 Self-Swab Collection Kit with Saline consists of the following components:

Component
Shipping Box – Polystyrene foam inside rigid cardboard box*
Mailer shipping envelope with UN3373 label and prepaid return label*
Specimen biohazard bag with absorbent pouch
Sterile packaged spun polyester swab
Plastic sterile collection tube filled with saline (95kPa rated)
Barcode card
Instructions for self-collection^

*Not applicable to unsupervised on-site collection

The shipping envelope provided with the kit will be specific to the testing program and additional information on the shipping vendor will be provided to the program managers.

^Self-collection instructions are specific to the on-site and at-home collection workflows. The nasal swab collection process is identical; however, the biohazard bags and preparation of the specimen for shipment differ. The rigid shipping component is part of the bulk packaging for the on-site collection, whereas the rigid component is part of the individual packaging of a biohazard bag for a sample collected at home.

MEDICAL OVERSIGHT AND PROCESS TO BE USED

Anterior nasal swabs can be collected in saline via two different workflows:

On-Site Unsupervised Collection Workflow

1. At the physician’s discretion, the patient completes the eligibility questionnaire via the Color website (color.com/covid/PARTNER/activate) which adheres to the CDC COVID-19 screening guidelines. A healthcare provider (HCP) at specific institutions authenticates the information and determines patient eligibility for the unsupervised nasal swab collection kit.
2. The patient collects their own anterior nasal swab specimen following the instructions provided with the kit and returns the completed kit to the on-site collection bin.

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

3. All samples collected on-site are delivered to Color's laboratory or Color designated laboratories within 48 hours for processing.
4. Test results are communicated back to the patient and the ordering physician. Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.
5. Results (both positive and negative SARS-CoV-2 results) are automatically shared with local Department of Public Health registries.

At-Home Unsupervised Collection Workflow

1. At the physician's discretion, the patient completes the eligibility questionnaire via the Color website (color.com/covid/PARTNER/activate) which adheres to the CDC COVID-19 screening guidelines. A healthcare provider (HCP) at specific institutions authenticates the information and determines patient eligibility for the unsupervised nasal swab collection kit.
2. Color will ship the self-collection nasal swab kit to the patient's home via 2-day shipping.
3. The patient collects their own anterior nasal swab specimen following the instructions provided with the kit and ships the completed kit to Color's laboratory or Color designated laboratories using a prepaid shipping pack.
4. Test results are communicated back to the patient and the ordering physician. Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.
5. Results (both positive and negative SARS-CoV-2 results) are automatically shared with local Department of Public Health registries.

PATIENT INCLUSION/EXCLUSION CRITERIA

Currently, Color offers the Color COVID-19 Self-Swab Collection Kit with Saline as part of centrally coordinated community programs that are under the direction of a supervising physician. Healthcare providers (HCPs) at specific institutions within the community-based framework use their medical expertise to determine patient eligibility. Ordering HCPs must be licensed in the state where the kits will be provided or shipped. Color will ship a kit to a patient's home when directed to do so as a part of an established program but does not accept requests for kits from patients directly. In practice, the inclusion and exclusion criteria are established by the program and authorizing physician.

INSPECTION OF ANTERIOR NASAL SWAB SPECIMENS IN SALINE RECEIVED AT A DESIGNATED LABORATORY FOR TESTING

Specimens collected with the Color COVID-19 Self-Swab Collection Kit with Saline must be checked for the following criteria upon receipt at designated testing laboratories prior to processing as outlined in the "Specimen Receipt and Handling for the Color COVID-19 Self-Swab Collection Kit" accessioning SOP:

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

- Sample collection tube must be intact and not visibly damaged.
- There are no signs of leakage in the biohazard bag.
- The tube barcode label must be present and readable by a barcode scanner.
- The tube cap must be properly secured onto the tube (i.e., screw cap closure).
- The medium must be in a liquid state and not congealed.
- The collection tube with saline contains exactly one swab.
- The swab is oriented correctly with the bud facing the bottom of the tube.
- The expiration date on the kit is not exceeded.
- Accession date/time is within 48 hours of the collection date/time.
- Each laboratory's accessioning system must check that the specimen is approved by a physician, a consent form is present, and that the collection kit has been activated via the on-line portal within the last 48 hours.

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

1) No Template Control (NTC)

A negative (no template) control must be used to monitor for sample contamination during nucleic acid extraction and RT-PCR assay set-up. Molecular grade, nuclease-free water or DNA/RNA Shield media can be processed as a clinical sample beginning with extraction (optional) or can exclude the extraction step and be added during RT-PCR set-up.

2) SARS-CoV-2 Positive Control

A positive SARS-CoV-2 control is needed to verify proper nucleic acid extraction, assay set-up, and SARS-CoV-2 reagent integrity. A positive control consisting of DNA/RNA Shield medium spiked with human total extracted nucleic acid and synthetic viral SARS-CoV-2 RNA (Twist Synthetic SARS-CoV-2 RNA Control 1; MT007544.1 or another applicable positive control at $\leq 5X$ LoD) can be used. The positive control must be used on every assay plate starting at master mix addition.

3) Endogenous Internal Control

An internal control such as RNase P or another endogenous human control gene is needed to verify that nucleic acid is present and is used for every sample that is processed with the assay. This also serves as a positive extraction control to ensure that samples with negative results contained nucleic acid for testing. Detection of the RNase P gene/other applicable endogenous human control in patient test samples verifies successful extraction of the sample, proper assay setup, sample integrity, and collection of human biological material.

4) A Negative Extraction Control (optional)

Typically, a negative extraction control is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that could occur during the nucleic acid extraction process, as well as an extraction control to validate extraction reagents and successful RNA recovery.

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.

SARS-CoV-2 test results are divided into SARS-CoV-2 positive/detected, SARS-CoV-2 negative/not detected, and inconclusive.

In the case of positive results:

- Test results are communicated back to the patient and ordering physician.
- Results are returned electronically or by fax to the ordering provider. If the ordering physician directs Color to do so, patients will also receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their results.
- The ordering physician and the sponsoring agency often give their patients the option to follow-up with a healthcare provider to discuss the test results.
- Results (both positive and negative SARS-CoV-2 results) are reported by Color and to public health agencies as required.

PERFORMANCE EVALUATION

1) Analytical Comparison/Equivalence Studies:

The LoD of the Color SARS-COV-2 RT-LAMP Diagnostic Assay (N-gene, E-gene and RNase P primers only) was established using whole heat-inactivated SARS-CoV-2 (ATCC VR-1986HK) spiked in negative anterior nasal swab clinical matrix in DNA/RNA Shield (Zymo Research, Cat # R1100-250). Please see EUA Summary for complete details (<https://www.fda.gov/media/138249/download>). The Color SARS-CoV-2 RT-LAMP Diagnostic Assay was shown to detect $\geq 95\%$ of replicates prepared in clinical matrix with 1X DNA/RNA Shield medium at 0.75 copies/ μ L.

For self-collected anterior nasal swab specimens that are collected with the Color COVID-19 Self-Swab Collection Kit with Saline, swabs are placed in 0.9% saline solution. Therefore, a study was performed to compare the performance of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay using samples in saline and 1X DNA/RNA Shield. The study was performed with contrived positive and negative samples that were prepared in parallel using pooled anterior nasal swab matrix in either DNA/RNA Shield or 0.9% saline. Negative anterior nasal swab matrices in DNA/RNA Shield and saline were spiked with inactivated whole SARS-CoV-2 from ATCC. Each spiked replicate was processed through the entire assay, beginning with RNA extraction using the Chemagic Viral DNA/RNA Kit on the Chemagic 360 instrument, followed by testing with the Color SARS-CoV-2 RT-LAMP Assay. Results from the study are shown in Table 1 below and demonstrate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with samples prepared in 1X DNA/RNA Shield and 0.9% saline.

Table 1. Comparative Study Results Between 1X DNA/RNA Shield Medium and 0.9% Sterile Saline

X LoD	Concentration (copies/ μ L)	DNA/RNA Shield	0.9% Saline
		# of Replicates Detected / Total Replicates Tested	# of Replicates Detected / Total Replicates Tested
2X LoD	1.50	5/5	5/5
3X LoD	2.25	5/5	5/5
5X LoD	3.75	5/5	5/5
Negative	N/A	0/5	0/5

N/A; Not applicable

Another study evaluated the performance of the Color SARS-CoV-2 RT-LAMP Diagnostic Assay with dry swabs resuspended in 1.3 mL of lysis buffer from the Chemagic Viral DNA/RNA Kit. Please see EUA Summary for complete details (<https://www.fda.gov/media/141797/download>). Testing was conducted using low and moderate positive samples (2X and 5X LoD, respectively, based on the LoD established with 1X DNA/RNA Shield). The results indicate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with dry anterior nasal swabs resuspended in lysis buffer and swabs in 1X DNA/RNA Shield.

In conclusion, the results of the above listed studies indicate that the Color SARS-CoV-2 RT-LAMP Diagnostic Assay generated similar results with anterior nasal swab samples in 1X DNA/RNA Shield, 0.9% saline and dry anterior nasal swabs resuspended in lysis buffer.

2) Color COVID-19 Self-Swab Collection Kit with Saline Sample Stability Studies:

Shipping stability of spun polyester swabs in saline has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and UnitedHealth Group. The Quantigen study demonstrated 48-hour stability for spun polyester nasal swabs transported in 0.9% saline under high ambient temperature conditions. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Color Health pursuing an EUA for which a claimed specimen type is spun polyester swabs transported in 0.9% saline. Therefore, the stability of anterior nasal swab samples collected using spun polyester swabs in saline was not evaluated in the sample stability study.

Color will conduct a post-authorization study to verify the stability of SARS-CoV-2 RNA in specimens collected using the Color COVID-19 Self-Swab Collection Kit with Saline that are transported under low ambient temperature conditions, including multiple freeze-thaw cycles.

3) Collection Device Reagent Stability (Shelf-Life):

The 0.9% sterile saline collection tube within the Color COVID-19 Self-Swab Collection Kit with Saline is manufactured by a third party. The manufacturer's claimed shelf-life/expiration date is 12 months when the product is stored at 2°C-25°C. All lots of sterile saline are tested by the manufacturer for microbial

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

contamination, and the ability to maintain viability of pathogens in specimens after 72 hours of storage in accordance with CLSI methods.^{1,2}

4) Self-Collection Validation:

A usability study was conducted to assess user comprehension of the instructions for use for the Color COVID-19 Self-Swab Collection Kit with Saline, including both specimen collection and packaging the anterior nasal swab for shipment. Participants were recruited to reflect a variety of ages and education levels, including participants with no high school diploma or equivalent, high school diploma or equivalent, and with higher education. Other demographics were also documented (See Table 2).

The usability study was conducted with 40 participants recruited from the San Francisco Bay area. The interviewer observed the participant using the collection kit through videoconferencing with the participant in a simulated-use environment (i.e., samples were collected at a research site using a collection bin that served as the drop box location for shipping). All participants prepared and packaged their specimens for shipment. At the conclusion of the usability study, the site bulk shipped the specimens to Color for processing. A total of 40 adults completed the study of which 35.0% were ≥51 years of age, 20.0% were between 41 - 50 years of age, 25.0% were between 31 - 40 years of age, and 20.0% were between 18 - 30 years of age; 60.0% of participants were female and 40.0% were male. Additional characteristics/demographics of study participants are provided in Table 2.

Table 2. Usability Study Demographics

Characteristics of Study Population		N / N40 (%)
Gender	Female	24 (60.0)
	Male	16 (40.0)
Age (Years)	18 - 30	8 (20.0)
	31 - 40	10 (25.0)
	41- 50	8 (20.0)
	≥ 51 years	14 (35.0)
Ethnicity	Hispanic or Latino/a	4 (10.0)
Race	American Indian or Alaska Native	1 (2.5)
	Asian	11 (27.5)
	Black or African American	6 (15.0)
	Pacific Islander	1 (2.5)
	White or Caucasian	15 (37.5)

¹ Clinical and Laboratory Standards Institute. 2014. Approved Standard-Second Edition M40-A2. Quality Control of Microbiological Transport Systems. CLSI, Wayne, PA.

² Clinical and Laboratory Standards Institute. 2004. Approved Standard - Third Edition M22-A3. Quality Control for Commercially Prepared Microbiological Culture Media. CLSI, Wayne, PA.

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

Characteristics of Study Population		N / N40 (%)
	Other	6 (15.0)
Marital Status	Divorced	4 (10.0)
	Married	17 (42.5)
	Never married	18 (45.0)
	Widowed	1 (2.5)
Employment Status	A Homemaker	1 (2.5)
	A Student	3 (7.5)
	Employed for wages full time	20 (50.0)
	Employed for wages part-time	3 (7.5)
	Out of work for 1 year or more	1 (2.5)
	Out of work for less than 1 year	4 (10.0)
	Retired	3 (7.5)
	Self-employed	4 (10.0)
	Unable to work	1 (2.5)
Educational Level	Grade 12 or GED (High school graduate)	4 (10.0)
	Some college, no degree	21 (52.5)
	Associate degree	1 (2.5)
	Bachelor's degree	13 (32.5)
	Graduate or professional degree	1 (2.5)

Of the 40 samples that were collected, 40/40 (100%) were received in acceptable condition for processing according to Color's laboratory accessioning SOP. Of those samples received at Color for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, RNase P was detected in 40/40 (100%) of samples, indicating successful collection of human biological material that was extracted and amplified.

During the actual use testing, staff observed users following the instructions included with the collection kit; however, some participants had difficulty sealing the biohazard bag due to not reading the instructions in their entirety. This resulted in 4 kits with improperly closed biohazard bags noted upon accessioning at Color. Color considers undamaged specimens (intact tube and no leaks) to be acceptable regardless of biohazard bag status. Despite this, no additional deviations from the Instructions for Use were noted by staff observing the sample collection and furthermore, this failure mode did not affect the ability to receive the samples and process them for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Answers to the post-collection usability 8-item questionnaire were also captured for the 40 sample kits that were received at Color for processing. The average proportion of correct results for the 8-item questionnaire was 99.6%. The pass-rate was 100% for all survey items except for the question pertaining to insertion of the swab tip into the

Color COVID-19 Self-Swab Collection Kit with Saline
EUA Summary April 14, 2021

nostril (97.5%). This failure rate was attributed to one participant's misunderstanding of the survey response options; all other study participants (39; 97.5%) correctly answered this question. Therefore, 39/40 participants successfully answered all questions and noted agree/strongly agree for understanding the instructions and finding them easy to follow and locate within the kit. Based on the usability study data and feedback, the collection instructions were determined to be understandable, and the kit was found to be easy to use.

Results of the usability testing were analyzed qualitatively to determine if the design of the kit and/or kit instructions needed to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the actual-use testing to gather users' perspectives on each critical task or use scenario. During the usability study Color staff observed some users experience difficulty with placing the collected specimen into the biohazard bag for shipping. These users discussed this scenario during the post-collection interview and indicated that they did not read the directions thoroughly. In response, step #9 pertaining to the biohazard bag on the current at-home instructions was bolded to emphasize the significance of this task.

The results from the usability study indicate users 18 years of age and older are able to collect an appropriate anterior nasal swab specimen, with sufficient human biological material, and to place it into saline for downstream SARS-CoV-2 testing.

5) Additional Requirement:

In addition to validation studies, Color and designated laboratories will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the Color COVID-19 Self-Swab Collection Kit with Saline including how many kits were requested, activated via the online portal, sent for home collection, or collected at a community-based site or distribution center. Designated laboratories will also document the number of kits that were shipped and returned to the laboratory according to the kit instructions, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first lot of the Color COVID-19 Self-Swab Collection Kit with Saline.

WARNINGS:

- This self-sample collection kit has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA;
- This self-sample collection kit has been authorized only for the self-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 self-sample collection kit in combination with an authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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.