EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE COLOR COVID-19 SELF-SWAB COLLECTION KIT DTC

For *In vitro* Diagnostic Use
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 14 Years of Age and Older when Self-collected Under Adult Supervision
For Use by Individuals 2 Years of Age and Older when Collected with Adult Assistance

Direct to consumer (DTC) collected anterior nasal swabs collected at home from individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) with the Color COVID-19 Self-Swab Collection Kit DTC will be sent to high complexity 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 to perform high complexity tests and that run the specimens collected from Color COVID-19 Self-Swab Collection Kit DTC on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit DTC.

INTENDED USE

The Color COVID-19 Self-Swab Collection Kit DTC is a direct to consumer (DTC) product for collecting an anterior nasal swab (nasal) specimen at home (which includes in a community-based setting) from individuals 18 years or older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), that is sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Color COVID-19 Self-Swab Collection Kit DTC, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

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.

All test results are delivered to the user via an online portal. Individuals with positive or inconclusive results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Color COVID-19 Self-Swab Collection Kit DTC is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

The Color COVID-19 Self-Swab Collection Kit DTC is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS FOR USE STATEMENTS
For Emergency Use Authorization (EUA) Only
For *In vitro* Diagnostic Use
For Use by Individuals 18 Years of Age and Older when Self-collected
For Use by Individuals 14 Years of Age and Older when Self-collected Under Adult Supervision
For Use by Individuals 2 Years of Age and Older when Collected with Adult Assistance

The Color COVID-19 Self-Swab Collection Kit DTC collection device is only authorized for use in conjunction with an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 indicated for use with this collection device for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Note that, throughout this document, the term "individual" includes the parent/guardian of a minor, as applicable.

The Color COVID-19 Self-Swab Collection Kit DTC is available direct to consumer (DTC) without a prescription for any individual 2 years and older. When requesting a kit at a designated collection site or when purchasing a kit from an authorized distributor, individuals must verify they are 18 years of age or older even if the collection kit will be used on a minor. Once the kit has been obtained, individuals must activate their kit online and complete a screening questionnaire as a means for data collection. Individuals are notified by email or text message which contains a link to Color's online HIPAA-compliant post-test portal to view their test results. Additionally, individuals with positive and inconclusive results are contacted by a healthcare provider (HCP) via phone. The HCP will be part of a contracted third-party company that has prescribing privileges in the state of residency of the tested individual. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists.

The Color COVID-19 Self-Swab Collection Kit DTC is composed of a sterile packaged spun polyester swab, collection tube, a rigid biohazard safety bag, barcode card, instructions for use, Fact Sheet for Individuals, and a shipping envelope with a prepaid return label. Instructions included in the kit guide users on how to appropriately collect the anterior nasal swab specimen. Following collection, the swab is inserted into a sterile dry tube without transport or preservative medium, and the cap is pushed on tightly to 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 safety bag is placed into the return shipping envelope for transport to Color or a designated testing laboratory. For those specimens collected at home, the completed Color COVID-19 Self-Swab

Collection Kit DTC must be deposited at a drop box location on the same day the specimen is collected to ensure timely receipt of an intact specimen. Each Color COVID-19 Self-Swab Collection Kit DTC is intended to be returned via 48-hour shipping (or same day shipping via a courier for those collections completed on-site) under ambient conditions.

Specimens received for testing at Color and designated high complexity certified laboratories (Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a) will undergo a thorough review and accessioning prior to acceptance for testing with an FDA authorized IVD molecular SARS-CoV-2 assay indicated to process dry anterior nasal swabs per the Instructions for Use.

REAGENTS AND MATERIALS

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

Component
Soft shipping envelope with prepaid return shipping label and UN 3373 Biological Substance Category B labeled*
Rigid biohazard safety bag for collected specimen
Sterile packaged spun polyester swab
Sterile collection tube
Barcode card
Instructions for self-collection
Fact sheet for individuals

*Not applicable to unsupervised on-site collection

INSPECTION OF ANTERIOR NASAL SWAB SPECIMENS

Applies to specimens received from individuals using the Color COVID-19 Self-Swab Collection Kit DTC

Specimens collected with the Color COVID-19 Self-Swab Collection Kit DTC 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 DTC" accessioning SOP:

- Sample collection tube must be intact and not visibly damaged.
- The tube barcode label must be present and readable by a barcode scanner.
- The tube cap must be properly secured onto the tube.
- The swab should be oriented correctly; bud at the bottom, shaft at the top.
- The expiration date on the kit is not exceeded.
- Accession date is within 56 hours of the collection date/time.
- Each laboratory's accessioning system must check that the collection kit has been activated via the online portal within the last 56 hours.

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

The following controls (at a minimum) must be included in the in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with dry anterior nasal swab specimens collected with the Color COVID-19 Self-Swab Collection Kit DTC:

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 medium 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 ≤ 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 targeting RNase P or another endogenous human gene is needed to verify that nucleic acid is present in every sample and is used for every sample that is processed with the assay. This also serves as a positive extraction control to ensure that samples resulting as negative contain 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 extraction.

INTERPRETATION OF RESULTS

All test controls must be examined prior to interpretation of individual 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.

- Individuals will receive a notification via email or text message containing a link to Color's online HIPAA-compliant post-test portal to access their test results.

- Individuals with positive and inconclusive results are contacted by a healthcare provider (HCP) via phone. The HCP will inform individuals of their results, provide education, and a recommended course of care or appropriate follow-up action.
- Results are reported by Color to public health agencies as required.

PERFORMANCE EVALUATION

The Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC is the same test as the FDA authorized prescription use only Color SARS-CoV-2 RT-LAMP Diagnostic Assay. The data described below are the same as those used to support authorization of the prescription use only Color COVID-19 Self-Swab Collection Kit. For consistency, the Color SARS-CoV-2 RT-LAMP Diagnostic Assay (Rx) and Color COVID-19 Self-Swab Collection Kit name are maintained.

1) **Color COVID-19 Self-Swab Collection Kit DTC Sample Stability Studies:**
Shipping stability of dry spun polyester swabs has been demonstrated by Quantigen Biosciences with support from The Gates Foundation and UnitedHealth Group. The Quantigen study demonstrated 56-hour stability for dry anterior nasal spun polyester swabs when subjected to both summer and winter thermal excursions. Quantigen Biosciences has granted a right of reference to the stability data to any sponsor, such as Color Health, Inc. pursing an EUA for which a claimed specimen type is dry spun polyester swabs. Therefore, the stability of anterior nasal samples collected using dry spun polyester swabs were not evaluated in the sample stability study.

2) **Dry Swab Resuspension Validation:**
To demonstrate that dry spun polyester swabs were acceptable specimen types for testing with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, performance of the assay was evaluated using dry swabs resuspended in 1.3 mL of lysis buffer included in the Chemagic Viral DNA/RNA Kit that is used to perform extraction on the automated Chemagic platform. Eluates underwent gentle shaking on an orbital shaker for 20 minutes at ambient conditions.

Contrived positive specimens at 2X and 5X LoD were prepared by spiking inactivated SARS-CoV-2 from ZeptoMetrix (isolate USAWA1/2020, Cat # 0810587CFHI) into DNA/RNA Shield (Zymo Research, Cat # R1100-250) containing negative clinical anterior nasal swab matrix followed by spiking the matrix directly onto the spun polyester swabs. Five technical replicates at both 2X and 5X LoD concentrations were tested in addition to 5 negatives (unspiked-negative clinical anterior nasal swab matrix resuspended in lysis buffer). Results are summarized in Table 1 for both viral targets (N and E-genes) and RNase P when tested simultaneously. There was 100% agreement with expected results for all positive contrived samples for both swab types. All negative samples were non-reactive for SARS-CoV-2 assay targets.

Table 1. Dry Swab Resuspension Study Results Stratified by Assay Target When the Color SARS-CoV-2 RT-LAMP Diagnostic Assay was Run with All 3 Assay Targets Simultaneously

Swab Type	Concentration	Samples (n)	Detection Rate		
			N-gene	E-gene	RNase P
Spun Polyester	2X LoD (1.5 copies/µL)	5	5/5	5/5	5/5
	5X LoD (3.75 copies/µL)	5	5/5	5/5	5/5
	Negative	5	0/5	0/5	5/5

3) Home Collection Kit Stability:

Swab (Reagent) Stability

The anterior nasal swabs used in the Color COVID-19 Self-Swab Collection Kit DTC are sourced from U.S. Cotton (product code KXG) and are registered and listed with FDA (Registration Number 3004118636; Owner Operator Number: 10071888)[1]. The swab expiration date is printed on the outer package and is one year from the date of manufacturing. Therefore, the kit's expiration date will be one year from the date of manufacture of the swab and is displayed on the swab sheath as well as the back of the soft-shell envelope. A specific accessioning criterion is to ensure that the kit's expiration date has not been exceeded.

4) Self-Collection Validation:

a. Usability Study Conducted on Individuals 18 Years of Age and Older

A usability study was conducted to assess user comprehension of the Color COVID-19 Self-Swab Collection Kit (Rx), including both collection and packaging the dry anterior nasal swab for shipment. The Color COVID-19 Self-Swab Collection Kit DTC uses the same instructions for collection and returning the sample as the Color COVID-19 Self-Swab Collection Kit (Rx). Therefore, an additional usability study was not required.

The study inclusion/exclusion criteria are detailed in Table 2. A demographic question was administered as part of the screening questionnaire to ensure recruitment of a user cohort reflective (or as closely as feasible) to that of the 2019 US population. Participants were also 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 3).

Table 2. Inclusion and Exclusion Criteria for Usability Study on Adults Only (18 Years +)

Inclusion Criteria	Exclusion Criteria
1. Participant has not received Covid-19 diagnostic testing. 2. Participants are 18 years old or older. 3. Participant resides in the United States.	1. Participant has no access to a computer or internet connection.

[1] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-gates-foundation-unitedhealth-group-quantigen-and-us-cotton

4. Participant speaks English. 5. Participant is able to attend study information session. 6. Participant has access to a working computer. 7. Participant has access to a stable internet connection. 8. Participant is willing to have the interview video recorded.	2. Participant does not speak English. 3. Participant has prior medical or laboratory training. 4. Participant has prior experience with self-collection.

Usability studies were conducted with two cohorts of individuals; 30 participants in cohort one and 15 participants in cohort two. The interviewer observed the participant using the collection kit through videoconferencing with the participant in their home environment. A total of 45 adults completed the study of which 37.8% were ≥51 years of age, 13.3% were between 41-50 years, and 22.2% were between 31-40 years old, 26.7% were between 18-30; 60.0% of participants were female and 40.0% were male. Additional characteristics/demographics of study participants is provided in Table 3.

Table 3. Usability Study Demographics for Adults Only (18 Years +)

Characteristics of Study Population		**N / N45 (%)**
Gender	Female	27 (60.0)
	Male	18 (40.0)
Age (Years)	18 - 30	12 (26.7)
	31 - 40	10 (22.2)
	41- 50	6 (13.3)
	≥ 51 years	17 (37.8)
Ethnicity	Hispanic or Latino/a	8 (17.8)
Race	Asian	7 (15.6)
	Black or African American	6 (13.3)
	White or Caucasian	26 (57.8)
	Other	6 (13.3)
Marital Status	Divorced	9 (20.0)
	Married	24 (53.3)
	Never married	12 (26.7)
Employment Status	A Homemaker	5 (11.1)
	A Student	1 (2.2)
	Employed for wages full time	25 (55.6)
	Employed for wages part-time	3 (6.7)
	Out of work for less than 1 year	3 (6.7)
	Retired	5 (11.1)

Characteristics of Study Population		N / N45 (%)
	Self-employed	2 (4.4)
	Unable to work	1 (2.2)
Educational Level	Grade 12 or GED (High School graduate)	4 (8.9)
	Some College, no degree	9 (20.0)
	Associate degree	6 (13.3)
	Bachelor's degree	20 (44.4)
	Graduate or professional degree	6 (13.3)
Geographic Location	Midwest	7(15.6)
	Northeast	11 (24.4)
	Southeast	11 (24.4)
	Southwest	5 (11.1)
	West	11 (24.4)

Of the 30 kits that were shipped to study participants for self-collection in cohort one, 29/30 (97%) of the sample kits were received in acceptable condition for processing according to the laboratory accessioning SOP. One specimen was damaged due to incomplete closure of the collection tube and was not processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay. Of those collection kits that were tested with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay, RNase P was detected in 28/29 (96.7%) samples, indicating successful collection of human biological material that was extracted and amplified. There was no known reason or explanation for the lack of RNase P detection for one of the 29 tested samples.

During the actual use testing, staff observed users following the instructions included with the collection kit; however, some participants had challenges with identifying the kit components. Participants used a prototype kit that differed slightly in the labeling from the final kit. A few participants had difficulty identifying or using the rigid biohazard safety bag, which appeared different in the prototype from the drawing provided on the instructions card (lack of a biohazard sticker). Due to these challenges, one participant did not use the rigid biohazard safety bag, and one did not properly seal the bag for transport. No other deviations from the Instructions for Use were noted by staff observing the sample collection. Despite this challenge, this task did not affect the ability to properly receive and process the samples with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay. As noted previously, one participant did not properly secure the collection tube lid prior to shipping and was damaged during transport to the laboratory, possibly indicating that the participant did not completely understand the tube closure step of the instructions. The two samples that either did not use the biohazard bag or used the biohazard bag incorrectly were still successfully processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Answers to the user 10-item questionnaire were also collected for the 30 sample kits that were received at Color for processing. 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.

For the usability study cohort one, the overall participant pass-rate was 97% for the 10-item survey. Pass-rate was 100% for all questions except for two which had pass rates of 80% and 90%. The failure rates for these specific questions were attributed to slight differences between the kit prototype and final product and unclear survey questions. Color staff observed some users' difficulty in identifying the biohazard bag, and the participants mentioned the difference in appearance of the bag used in the prototype versus the depiction in the collection instructions during the interview that was conducted following the actual use observation. The feedback obtained from participants in the first study cohort was used to refine the survey questions to make them more understandable. Note that no changes or modifications to the current instructions needed to be made based on discussions with the participants. However, the kits used in the second cohort did include a biosafety bag that matched the appearance of the bag in the collection instructions included with the Color COVID-19 Self-Swab Collection Kit.

Of the 15 kits that were shipped to study participants for self-collection in cohort two, 15/15 (100%) of the sample kits were received in acceptable condition for processing at the Color lab according to the accessioning SOP. All 15 processed samples were positive for human RNaseP (100%), indicating successful collection of human biological material that was extracted and amplified. 15/15 participants successfully answered all 10 questions of the post-study questionnaire 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 understandable, and the Color COVID-19 Self-Swab Collection Kit was easy to use.

The results from the usability study indicate users 18 years of age and older are able to collect a dry anterior nasal swab specimen safely and appropriately with sufficient human biological material for downstream SARS-CoV-2 testing.

b. Usability Study Conducted on Minors (2-13 and 14-17 Year-Olds)

An additional usability study was completed to validate collection of a dry anterior nasal swab from minors. The usability study was conducted in a simulated environment using two cohorts of parent/minor pairs. The first cohort included parents with minors aged 2-13, where the parent collected the anterior nasal swab sample from the minor, packaged the specimen for shipping, and answered the post-collection questions. The second cohort included parents with minors aged 14-17, where the minor collected the sample from themselves,

packaged the specimen for shipping, and answered the post-collection questions. Minors aged 14-17 could ask their parent for help with either the collection/shipping instructions or the post-collection survey questions if they desired.

A demographic questionnaire was administered to the parents as part of the screening questionnaire to ensure the usability study population included a diverse cross-section of the intended use population. The questionnaire included the parent's gender, ethnicity, race, marital status, employment status, education level, and household income bracket. A subset of these demographics was collected for minors (2-17 years old), including age and gender.

Color personnel observed the participants using the collection kit in-person in a simulated environment. In total, 35 parent/minor pairs completed usability testing which consisted of 19 pairs in the 2-13 age group and 16 pairs in the 14-17 age group. The demographics of the parent participants for the 2-13 age category and 14-17 age category are shown in Table 4. The self-reported information from minors aged 2-13 and 14-17 years old including gender and age is shown in Table 5.

Table 4. Participant Demographics for Parents Included in the 2-13 Age Group and 14-17 Age Group

Participants – Adults Paired with 2-13 Year-Olds		**N (%)**	**Participants – Adults Paired with 14-17 Year-Olds**		**N (%)**
Total		**N (N/19)**	**Total**		**N (N/16)**
Gender	Female	10 (52.6)	**Gender**	Female	10 (62.5)
	Male	9 (47.4)		Male	6 (37.5)
Ethnicity	Hispanic or Latino/a	2 (10.5)	**Ethnicity**	Hispanic or Latino/a	2 (12.5)
	Non-Hispanic or Latino/a	17 (89.5)		Non-Hispanic or Latino/a	14 (87.5)
Race	Asian	3 (15.8)	**Race**	American Indian or Alaska Native	1 (6.3)
	Black or African American	5 (26.3)		Asian	4 (25.0)
	Pacific Islander	1 (5.3)		Black or African American	1 (6.3)
	White or Caucasian	10 (52.6)		White or Caucasian	10 (62.5)
Marital Status	Married	17 (89.5)	**Marital Status**	Married	14 (87.5)
	Separated	1 (5.3)		Divorced	1 (6.3)
	Never married	1 (5.3)		Separated	1 (6.3)
Employment Status	Employed for wages full time	12 (63.2)	**Employment Status**	Employed for wages full time	11 (68.8)
	Employed for wages part-time	1 (5.3)		Homemaker	5 (31.3)
	Self-employed	1 (5.3)	**Educational Level**	Some College, no degree	2 (12.5)
	Homemaker	4 (21.1)		Associate degree	1 (6.3)
	Retired	1 (5.3)		Bachelor's degree	5 (31.3)
Educational Level	Never attended school or only attended kindergarten	1 (5.3)		Graduate or professional degree	8 (50.0)
	Some College, no degree	1 (5.3)	**Household Income Bracket**	75,000-99,999	4 (25.0)
	Associate degree	1 (5.3)		100,000-149,999	4 (25.0)
	Bachelor's degree	7 (36.8)		150,000-199,999	5 (31.3)

	Graduate or professional degree	9 (47.4)		200,000+	3 (18.8)
Household Income Bracket	25,000-49,999	1 (5.3)			
	75,000-99,999	4 (21.1)			
	100,000-149,999	6 (21.1)			
	150,000-199,999	4 (21.1)			
	200,000+	4 (21.1)			

Table 5. Minor Participant Demographics in the 2-13 and 14-17 Age Groups

Participants – Minors Aged 14-17 Years Olds		**N (%)**	**Participants – Minors Aged 2-13 Years Old**		**N (%)**
Total		**N (N/16)**	**Total**		**N (N/19)**
Gender	Female	10 (62.5)	**Gender**	Female	12 (63.2)
	Male	6 (37.5)		Male	7 (36.8)
Age (Years)	14	6 (37.5)	**Age (Years)**	2	1 (5.3)
	15	3 (18.75)		3	2 (10.5)
	16	3 (18.75)		5	3 (15.8)
	17	4 (25.0)		6	2 (10.5)
				7	2 (10.5)
				9	1 (5.3)
				10	1 (5.3)
				11	2 (10.5)
				12	3 (15.8)
				13	2 (10.5)

Of the 35 collected anterior nasal swab specimens from both study cohorts, all 35 (100%) samples were received in acceptable condition as defined by Color's accessioning standard operating procedure. Thirty-four of the 35 processed samples showed detection of human RNase P (97.1%) which indicated successful collection of human biological material. The sample that failed to amplify RNase P was likely due to specimen inadequacy, although the observer recorded no noticeable user errors associated with this specific sample.

During the usability study, staff observed participants (defined as "parents" in the 2-13 age group and "minors" in the 14-17 group) collecting an anterior nasal swab sample according to the collection kit instructions. Two of the children in the 2-13 age group touched the tip of the swab before their parents collected the sample, and four biohazard bags were improperly sealed (i.e., only partially sealed or not sealed at all) but found to be acceptable for processing. Touching the tip of the swab prior to swabbing each anterior naris invalidates the RNase P assay result. Therefore, Color incorporated an additional warning on the collection instructions emphasizing that the swab must only touch the inside of the nostrils and if compromised in any way, a new collection kit should be requested. No other deviations from the instructions were noted by research staff. None of the deviations noted above affected the accessioning and processing of the 35 samples with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay.

Following sample collection, participants completed an 8-item questionnaire. Results were analyzed qualitatively to determine if the design of the kit and/or instructions for use needed to be modified to reduce the use-related risks to acceptable levels. Cognitive

debriefing interviews were conducted following the usability testing to gather users' perspectives on each critical task.

In the 2-13 age group, where parents answered the post-collection questions, the rate of correct or positive responses was 98.7% (150/152). The rate was 100% for all eight questions except for one question to which the participant provided an unfavorable response and another question that a different participant answered incorrectly. The proportion of correct or positive responses for both these questions was 94.7% (18/19). Overall, the participants' responses to the post-collection questions and the cognitive debriefing interviews provided evidence that the instructions were understandable.

In the 14-17 age group, where the minors answered the post-collection questions, the rate of correct or positive responses was 98.4% (126/128). The rate was 100% for all eight questions except for two, for which there was one unfavorable and one incorrect response (15/16 [93.4%] positive or correct responses in each case). Overall, the participants' responses to the post-collection questions and the cognitive debriefing interviews provided evidence that the instructions were understandable, that parents were able to collect an adequate anterior nasal swab specimen from children as young as 2 years old and that minors aged 14-17 were able to self-collect an anterior nasal swab specimen successfully under adult supervision.

c. Additional Usability Study on 2-4 Year-Olds

Due to modifications made to the collection instructions pertaining to differences in the depth of insertion of the swab between a young child and an adult (See note under step 5 in the IFU), a supplemental usability study was completed using 18 parent/minor pairs where the minors were 2-4 years-old. Usability testing under observation by Color personnel was conducted in a simulated home environment in which the parent collected the anterior nasal swab sample from the minor child, packaged the specimen for shipping, and answered the post-collection questions.

A demographic questionnaire was administered to the parents as part of the screening questionnaire. The questionnaire included the parent's gender, ethnicity, race, marital status, employment status, education level, and household income bracket. A subset of these demographics was collected for the minors including age and gender. In total, 18 parent/minor pairs completed usability testing. The demographics of the parent and the paired minors are shown in Table 6 and Table 7, respectively.

Table 6. Participant Demographics for Parents Included in the 2-4 Age Group

Participants		**N (%)**
Total		**18 (100)**
Gender	Female	11 (61.1)
	Male	7 (38.9)
Ethnicity	Hispanic or Latino/a	0 (0.0)
	Non-Hispanic or Latino/a	18 (100.0)
Race	Asian	10 (55.6)
	White or Caucasian	5 (27.8)

	Other	3 (16.7)
Marital Status	Married	16 (88.9)
	Divorced	1 (5.6)
	Never married	1 (5.6)
Employment Status	Employed for wages full time	17 (94.4)
	Homemaker	1 (5.6)
Educational Level	Bachelor's degree	7 (38.9)
	Graduate or professional degree	11 (61.1)
Household Income Bracket	75,000-99,999	1 (5.6)
	100,000-149,999	1 (5.6)
	150,000-199,999	5 (27.8)
	200,000+	11 (61.1)

Table 7. Minor Participant Demographics in the 2-4 Age Group

Participants		**N (%)**
Total		**18 (100)**
Gender	Female	5 (27.8)
	Male	13 (72.2)
Age (Years)	2	4 (22.2)
	3	9 (50.0)
	4	5 (27.8)

Of the anterior nasal swab specimens collected, 18/18 (100%) were received in acceptable condition as defined by Color's accessioning standard operating procedure. Human RNase P nucleic acid was detected in all 18 samples (100%), which indicates successful collection of human biological material.

During the usability study, staff observed parent participants collecting an anterior nasal swab sample according to the updated collection kit instructions. No deviations from the instructions were noted by research staff and all 18 samples were processed with the Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC.

Following sample collection, parent participants completed a 9-item questionnaire. Results were analyzed qualitatively to determine if the design of the kit and/or instructions for use needed to be modified to reduce the use-related risks to acceptable levels. Cognitive debriefing interviews were conducted following the usability testing to gather users' perspectives on each critical task.

The overall rate of correct or positive responses provided by the parent participants was 98.1% (159/162). The rate was 100% for six of the nine questions. For three questions, the correct response rate was 94.4% (17/18) and in each case a different participant provided an incorrect response. Overall, the participants' responses to the post-collection questions and the cognitive debriefing interviews provided evidence that the modified instructions pertaining to differences in the depth of swab insertion between very young children and older individuals were understandable.

5) Additional Requirement:

Color and designated laboratories will submit a report to the FDA (within 30 days of this revised EUA Summary) summarizing any testing performed with the Color COVID-19 Self-Swab Collection Kit DTC including how many kits were activated via the online portal, purchased from an authorized distributor for home collection, or collected at a community-based site or distribution center. Designated laboratories will also document the number of kits that were processed, how many specimens were rejected during accessioning and the reasons for rejection, the ages of the patients, and the positivity rate.

WARNINGS:

- For *In vitro* Diagnostic Use
- For Use Under an Emergency Use Authorization (EUA) Only
- 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 home collection and maintenance of anterior nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.