[redacted]

Study Number:	2020-06
Exact Sciences Statistician:	[redacted]
Exact Sciences Medical Monitor:	[redacted]
Exact Sciences Scientist:	[redacted]

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1. OBJECTIVES

1.1 Primary Objective

1.1.1 The primary objective is to determine the usability of the SARS-CoV-2 Specimen Collection Materials for at-home collection and mailing of sample to the testing laboratory.

1.2 Secondary Objectives

1.2.1 Evaluate perceived usability of the Instructions for Use (IFU).

1.2.2 Evaluate comprehension of IFU by the subject.

1.2.3 Identify problems that occur while following the IFU.

1.2.4 Evaluate root causes of problems that occur while following the IFU.

1.2.5 Develop strategies to mitigate problems occurring while following the IFU.

1.3 Exploratory Analyses

[redacted]

2. SCOPE

This Statistical Analysis Plan (SAP) pre-specifies the methodology for analyzing the primary, secondary, and exploratory objectives of the Usability Study of Home Collection and Mailing with SARS-CoV-2 Test Specimen Collection Materials, study Protocol 2020-06. This study is a prospective observational human factors usability study of approximately 30 subjects. The study design, methods and results will be described in a Clinical Study Report (CSR). The CSR will be attached to a regulatory filing with the United States Food and Drug Administration (FDA). The filing will support the Accelerated Emergency Use Authorization (EUA) (EUA 200367) for the at home self-collection of a nasal specimen and return to the testing laboratory for the Exact Sciences Laboratories (ESL) SARS-CoV-2 (N gene detection) Test [redacted]

3. BACKGROUND

The Centers for Disease Control and Prevention (CDC) in the United States suggests laboratory testing to identify the SARS-CoV-2 virus that causes COVID-19. The FDA has given EUA for select Real-Time reverse transcription polymerase chain reaction (RT-PCR) Diagnostic Panels that detect ribonucleic acid (RNA) specific to SARS-CoV-2. This study will use the ESL SARS-CoV-2 (N gene detection) Test.

The ESL SARS-CoV-2 (N gene detection) Test provides a qualitative result based on detection of RNA. The test measures the presence of two regions of the RNA related to the SARS-CoV-2 nucleocapsid protein N gene (N1 and N2), which are specific for this virus. Both N1 and N2 RNA must be detected for a positive result and are indicative of active infection by the virus. A positive result does not rule out other infections. Detection of only one of the two viral RNAs results in an Inconclusive test. Negative results (Not detected) do not rule out infection and should be used in combination with clinical and epidemiological information for patient management decisions. The ESL SARS-CoV-2 (N gene detection) Test also measures RNA related to ribonuclease (RNase) P, which is a human protein and acts as an internal reference. The absence of the viral and human RNA would lead to an invalid test result.

SARS-CoV-2 N1	SARS-CoV-2 N2	Human RNase P	Report Result	Next Step
+	+	+/-	Positive	N/A
one +, one -		+/-	Inconclusive	Sample sent for alternative testing
-	-	+	Not Detected	N/A
-	-	-	Invalid	Specimen inadequate. Recollect if clinically indicated.

Table 1: Possible ESL SARS-CoV-2 (N gene detection) Test results based on RNA detected.

While the CDC provides guidelines for the collection of a wide range of upper and lower respiratory samples, the ESL SARS-CoV-2 (N gene detection) Test is for use with upper respiratory (nasal swab) samples from subjects receiving a clinically indicated COVID-19 Test.[1]

Emphasis has been placed on increasing overall testing availability, and the access to at home SARS-CoV-2 specimen collection (without healthcare worker supervision) is believed to improve the effectiveness of public health tools in preventing spread of the disease during this pandemic in the United States.

This study is a prospective observational human factors usability study. It will be complete when approximately 30 self-collected nasal swab samples have corresponding SARS-CoV-2 test results (positive, negative, inconclusive, or invalid). Subject participation is up to one day from enrollment to completion.

4. REFERENCES AND ATTACHMENTS

[redacted]

1. Centers for Disease Control and Prevention (US). *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19)*. 2020 [cited 2020 April 8]; Available from: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.
2. Lewis, J.R., *IBM Computer Usability Satisfaction Questionnaires: Psychometric Evaluation and Instructions for Use.* International Journal of Human-Computer Interaction, 1995. 7: p. 57-78.

3. Lewis, J.R., *Psychometric evaluation of an after-scenario questionnaire for computer usability studies: The ASQ.* ACM SIGCHI Bulletin, 1991. **23**: p. 78-81.

Study Protocol: [redacted]

Study Case Report Forms:

Observer Form: [redacted]

Subject Survey: [redacted]

Data Streams [redacted]

5. ACRONYMS, TERMS AND DEFINITIONS

Term (Acronym)	Definition
2019-nCoV	2019 Novel Coronavirus (see also SARS-CoV-2)
AE	Adverse Event
ASQ	After-Scenario Questionnaire
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CLIA	Clinical Laboratory Improvement Amendments
COVID-19	Coronavirus disease 2019
CRF	Case Report Form
CSR	Clinical Study Report
[redacted]	[redacted]
Epic	Epic Health Research Network
ESL	Exact Sciences Laboratories
EUA	Emergency Use Authorization
FDA	Food and Drug Administration
GCP	Good Clinical Practice
IFU	Instructions for Use
IRB	Institutional Review Board
LIS	Laboratory Information System
RNA	Ribonucleic acid

RNase	Ribonuclease
RT-PCR	Reverse transcription polymerase chain reaction
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2 (see also 2019-nCoV)
SARS-CoV-2 (N gene detection) Test	ESL SARS-CoV-2 (N ne det c ion) st[redacted]
SDV	Source Data Verification

6. STUDY DESIGN

This study is a prospective observational human factors usability study designed to evaluate the IFU in the SARS-CoV-2 Specimen Collection Materials based on the successful completion of self-collection of a nasal swab sample, which includes a valid SARS-CoV-2 test result.

At the request of the FDA, subjects with a range of education levels and ages but without medical, laboratory, or COVID-19 specimen self-collection experience are being recruited. Study volunteers are pre-screened for highest education level attained and age group. The options for highest education level attained are: no high school; some high school; high school degree only; college degree; and advanced degree. Pre-screen age groupings are <18, 18-30 (early career), 31-45 (mid-career), 46-65 (later career), >65 (nearing retirement). Pre-screening for medical and laboratory experience is focused on identifying volunteers who have experience: collecting laboratory specimens in a medical setting; preparing specimens in a medical or laboratory setting; following a protocol in a medical or laboratory setting, e.g., for laboratory testing, R&D, and quality; or, who have been trained on any process or instrumentation in a medical or laboratory setting. Subject participation is up to one day from enrollment to completion.

Subjects are considered enrolled when they provide written informed consent. Subjects who provide informed consent are observed while following the IFU for the SARS-CoV-2 Specimen Collection Materials in a setting that simulates a home environment.

After following the IFU, subjects do the following: provide feedback on the usability of the IFU by completing a survey; answer comprehension questions; provide written feedback on the experience; and, address questions from the observer about problems during use. The observer is an employee of Exact Sciences.

The specimens collected by the subjects are tested in the laboratory for SARS-CoV-2. Subjects remain blinded to the test results.

Subjects' participation is considered completed following completion of the self-survey, forms, and potential interview with the observer or at the point of early termination. The study is considered complete when approximately 30 self-collected nasal swab samples have corresponding SARS-CoV-2 test results (positive, negative, inconclusive, or invalid).

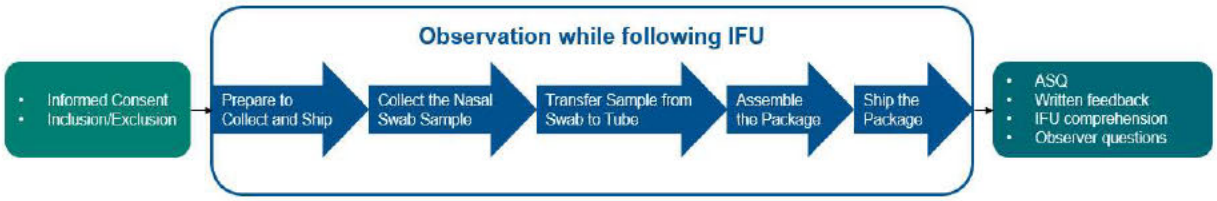

Figure 1: Overview of study procedures.

7. ANALYSIS DATA

7.1 There are four data streams for this study: Electronic Data Capture (EDC), Epic Health Research Network (Epic), Laboratory Information System (LIS), and Laboratory Workbook. A hyperlink to the data dictionary for each data stream is available in Section 4.

7.1.1 Subject and observer reported surveys are collected on paper Case Report Forms (CRFs). Data are entered into an EDC system, after which they undergo source data verification (SDV). Data entry and SDV are completed by Exact Sciences. Hyperlinks to final CRFs are available in Section 4.

7.1.2 Laboratory results are reported via three data streams: Epic, LIS, and Lab Workbook.

7.1.2.1 The Epic data stream will provide the final SARS-CoV-2 laboratory test result.

7.1.2.2 The LIS data stream [redacted]

7.1.2.3 The Lab Workbook data stream [redacted]

7.1.2.4 Only data corresponding to the final reported result will be contained within the laboratory file transfers.

7.2 Observer Collected Variables

7.2.1 After the observer provides the SARS-CoV-2 Specimen Collection Materials, which includes the IFU, to the subject, the observer records the following information by IFU task (check one): *subject completed step with no issues; subject completed step with issues or unexpected effort; subject did not complete step or required assistance; or, not applicable*, e.g., if the subject discontinued their participation. There are three sections to the IFU that contain a total of 26 steps for specimen collection and packaging. The three sections are summarized below, and the observer records a response for each task.

7.2.1.1 *Before you collect*, which includes reading the instructions (one step) and preparing for collection (two steps).

7.2.1.2 *Collect your nasal swab sample*, which includes twenty steps in total:

7.2.1.2.1 preparing the tube label (two steps);

7.2.1.2.2 opening nasal swab (two steps);

7.2.1.2.3 removing the tube cap (four steps);

7.2.1.2.4 swabbing nose (two steps);

7.2.1.2.5 add swap to tube (two steps);

7.2.1.2.6 removing swab from tube (two steps);

7.2.1.2.7 replacing the tube cap (two steps);

7.2.1.2.8 placing label on tube (one step); and,

7.2.1.2.9 washing hands and adding [redacted] to bag (three steps).

7.2.1.3 *Ship your kit back to the lab*, which includes placing bag in bubble wrap (one step) and placing bubble wrapped bag in box (two steps).

7.2.2 The observer records *free form notes* during their observation of the subject while the subject is completing the IFU.

7.2.3 Upon the subject's completion of both the IFU and the patient self-administered After-Scenario Questionnaire (ASQ), the observer records responses to three questions that they ask the subject about the subject's comprehension of the IFU. The observer records the subject's responses as '*correct*' or '*incorrect*' and may also record *free form text* observer comments for each of the three questions:

7.2.3.1 After collection a nasal swab sample, when should a person ship it to the lab?

7.2.3.2 How should a person store the package with the nasal swab sample inside before shipping it back to the lab?

7.2.3.3 What could happen to your nasal swab sample if you do not follow the steps in the IFU?

7.2.4 The observer asks the subject two general questions after assessing IFU comprehension and responses are *free form text*:

7.2.4.1 What information in the IFU is confusing?

7.2.4.2 Is there anything we could do to make it easier to collect a nasal swab sample using these materials?

7.2.5 The observer may ask the subject follow-up questions to clarify areas of misunderstanding about the IFU and to identify the root causes of tasks that the observer recorded as completed with issues or unexpected effort or not completed (did not complete or required assistance). This will be recorded as *free form text* in the comments section available for each task.

7.2.6 At study completion, the observer responds '*yes*' or '*no*' to the following three questions:

7.2.6.1 Did the subject experience/report Adverse Events?

7.2.6.2 Were any protocol deviations noted?

7.2.6.3 Did the subject complete the study?

7.3 Subject Reported Data

7.3.1 Demographic and background information: date of birth, gender, race (mark one or more options: *American Indian or Alaska Native; Asian; Black or Afrian-American; Native Hawaiian or other Pacific Islander; White; Unknown*), ethnicity (mark one option: *Hispanic or Latino, Not Hispanic or Latino, Unknown*), and highest level of education attained (mark one option: *No high school; Some high school; High school degree only; College degree; Advanced degree*).

7.3.2 Prior experience with laboratory training (*yes/no*), COVID-19 specimen self-collection (*yes/no*), and COVID-19 testing (*yes/no*).

7.3.3 Subjects complete the psychometrically-validated three-item After-Scenario Questionnaire (ASQ) to measure their satisfaction with using the IFU to complete the sample collection [2,3].

	After-scenario Questionnaire (ASQ)	Strongly Agree	1	2	3	4	5	6	7	Strongly Disagree	NA
1	Overall, I am satisfied with the ease of completing the tasks in this scenario.										
2	Overall, I am satisfied with the amount of time it took to complete the tasks in this scenario.										
3	Overall, I am satisfied with the support information (online help, messages, documentation) when completing the tasks.										

7.3.4 Subjects will have the opportunity to provide written feedback on their experience by responding in *free form text* (*or checking a box if none*) to two questions:

7.3.4.1 What, if any, steps did you have trouble completing?

7.3.4.2 Do you have suggestions for improving the collection instructions?

7.3.5 Subjects will respond to IFU comprehension questions that are posed by the observer and will respond to questions about tasks completed with issues or unexpected effort, or tasks not completed. The responses to these questions will be documented by the observer in the form of *free text* (see Section 7.2).

7.4 Laboratory Data Variables

7.4.1 The specimens collected by the subject will be tested in the laboratory for SARS-CoV-2 RNA. The qualitative result for the SARS-CoV-2 test will be returned by the Epic data stream as: *positive, negative, inconclusive,* or *invalid*.

[redacted]

[redacted]

7.5 Description of Study Endpoints

7.5.1 The primary endpoint is the percentage of samples from the fully enrolled cohort to return a valid SARS-CoV-2 test result (positive, negative, or inconclusive). The target is 80% as an acceptable rate of success given the first-time task completion for minimally trained users.

7.5.2 The secondary endpoints are:

7.5.2.1 *Perceived usability of IFU:* The subject's self-reported satisfaction and ease of using the IFU, assessed using the ASQ. The ASQ is a valid and reliable 3-item survey on user satisfaction associated with completing a task. Item response options are on a 7-point Likert scale where 1 = strongly agree and 7 = strongly disagree. An overall satisfaction score is calculated as the average of the non-missing responses to the items (theoretical range 1-7 with a lower score indicating higher satisfaction). Endpoints from the ASQ include:

7.5.2.1.1 Overall score (*continuous*), where an average of 3.5 or lower on the overall ASQ score will be considered acceptable self-reported user satisfaction.

7.5.2.1.2 Categorization of overall ASQ score as 1 to 3 (indicating that the subject agrees to strongly agrees that they are satisfied) vs. 4 to 7 (indicating that the subject is neutral or strongly disagrees that they are satisfied).

7.5.2.2 *General comprehension of IFU:*

7.5.2.2.1 Total out of three questions accurately answered by subject when the observer evaluates the subject's comprehension of the IFU. The questions are summarized in Sections 7.2.3.1 – 7.2.3.3.

7.5.2.2.2 Responses to individual questions.

7.5.2.3 *Problems associated with following the IFU:*

7.5.2.3.1 The total number of tasks that the subject does not complete (as opposed to completes without issues or completes with issues or unexpected effort). The 26 tasks are summarized in Section 7.2.1.

7.5.2.3.2 The total number of critical tasks that the subject does not complete (as opposed to completes with no issues or completes with issues or unexpected effort).

7.5.2.3.3 Critical tasks are outlined in Table 2 of the Study Protocol and are summarized in the table below. A hyperlink to the Study Protocol is available in Section 4. Fifteen of the 26 tasks in the IFU have been pre-specified as critical. An additional three critical tasks are assessed through the IFU comprehension questions, i.e., data collected as per Section 7.2.3.

Specimen Collection Tasks from Protocol	Equivalent in CRF (Question or task numbers match those on Observer Form)	Test Method
Read these 2 pages instructions completely	1.1 Read these 2 pages of instructions completely.	Simulated use
Plan your collection	Q#1 after collecting a nasal swab sample, when should a person ship it to the lab?	IFU comprehension questions
Prepare the tube label	2.1 Using blue or black ink, write your name, date of birth, and date and time of collection on the Collection Tube Label. 2.2 Set label aside.	Simulated use
Remove tube cap	2.5 While holding the swab, remove cap from tube.	Simulated use
Swab nose	2.9 Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle inside the nose 4 times. 2.10 Repeat in other nostril.	Simulated use
Add swab to tube. Remove swab from tube	2.11 Remove swab from nostril and place in collection tube liquid. 2.12 Swirl in tube for 10 seconds. 2.13 Press the tip of the swab against the side of the tube to squeeze liquid from the swab.	Simulated use
Replace tube cap	2.15 Put the cap back on the tube. 2.16 Securely tighten so liquid does not leak.	Simulated use
Place label on tube	2.17 Using the completed label from Step 1, place middle of label on tube, wrap label ends around tube, stick label ends together.	Simulated use

Place bubble wrapped bag in box	2.19 Put your tube in the bag with the absorbent pad. 3.2 Place bubble wrapped biohazard bag into Shipping box. 3.3 Remove paper backing from tape, fold box flaps closed, press to seal box closed.	Simulated use
Store sample in sealed box away from direct heat and sunlight until shipment.	Q#2 how should a person store the package with the nasal swab sample inside before shipping it back to the lab?	IFU comprehension questions
Ship package by UPS	Q#1 after collecting a nasal swab sample, when should a person ship it to the lab?	IFU comprehension questions

7.5.2.3.4 Responses to individual task completion.

7.5.2.4 *Root causes of problems that occur while following the IFU*: an evaluation of the root causes of problems associated with user tasks, including but not limited to critical tasks, will be done through qualitative review of listings of *free form text* summarized in Sections 7.2.2 to 7.2.5 and 7.3.4.

7.5.2.5 The final secondary objective is to develop strategies to mitigate problems occurring while following the IFU. This does not have an associated statistical endpoint.

7.5.3 The exploratory endpoints are:

[redacted]

7.6 Analysis Dataset

7.6.1 There are three analytic datasets for this study:

7.6.1.1 Subject analysis file: CRF data

7.6.1.2 Laboratory test analysis file: including Epic, LIS and Laboratory Workbook data

7.6.1.3 Final Analysis file: Combining CRF and lab test data with variables required for analysis retained.

7.6.2 All subjects enrolled will be included in the analytic cohort.

8. STATISTICAL METHODS

8.1 Primary Analysis

The primary endpoint will be summarized descriptively using frequency and percentage. These measurements will be calculated for the overall analytic cohort. The frequency and percentage (out of valid test results) of each valid lab result (positive, negative, inconclusive) will also be provided.

8.2 Secondary Analyses

8.2.1 *Perceived usability of IFU*: A descriptive characterization of subjects' self-reported ease of use of the Specimen Collection Materials, as assessed by the ASQ, will be provided. This will be presented overall and by valid vs. invalid test result.

8.2.1.1 The mean, standard deviation, median, and interquartile range of the overall ASQ score will be calculated.

8.2.1.2 The frequency and percentage of subjects with an overall score of 1 to 3 (indicating that the subject agrees to strongly agrees that they are satisfied) vs. 4 to 7 (indicating that the subject is neutral or strongly disagrees that they are satisfied) will be presented.

8.2.1.3 The frequency and percentage of each response to all three items will be presented. The denominator for the percentage across the mutually exclusive categories (responses 1 through 7, not applicable, and missing) will be the total number of enrolled patients.

8.2.2 *General comprehension of IFU*: A descriptive characterization of acceptable answers on general comprehension of the IFU will be provided. This will presented overall and by valid vs. invalid test result.

8.2.2.1 The mean, standard deviation, median, and interquartile range of the total number of questions accurately answered will be calculated.

8.2.2.2 The frequency and percentage of total correct vs. incorrect responses will be presented.

8.2.2.3 The frequency and percentage of each response to all three questions will be presented.

8.2.3 *Problems associated with following the IFU:* A descriptive characterization of observer-reported problems associated with following the IFU will be provided overall and by valid vs. invalid test result.

8.2.3.1 The n, mean, standard deviation, median, and interquartile range of total number of tasks that the subject does not complete (as opposed to completes without issues or completes with issues or unexpected effort) will be calculated, overall and for the subset of fifteen critical tasks from the IFU. The frequency and percent of total problems in categories of 5-unit increments will also be reported. This will be presented for the subset of patients for whom the observer was able to observe the subject attempt all tasks. Subjects where the observer responded "not applicable" to one or more tasks will not contribute to this analysis.

8.2.3.2 The frequency and percentage of each observer-response to all 26 tasks will be presented.

8.2.3.3 Critical tasks will be explicitly labeled for easy identification.

8.2.4 *Root causes of problems that occur while following the IFU:* A qualitative evaluation of listings from the user reported data, external observer feedback on user interactions, and laboratory testing will be conducted by Clinical and Regulatory Affairs to assess the root cause of problems and evaluate mitigating solutions, e.g., whether specific parts of the IFU should be modified. The listings will be provided by Clinical Biostatistics to Clinical and Regulatory Affairs, presented by question within data stream. Critical tasks will be explicitly labeled for easy identification. Post-hoc analyses may be performed at the request of Clinical and Regulatory Affairs to help summarize their assessment of root cause issues.

8.2.5 The final secondary objective is to develop strategies to mitigate problems occurring while following the IFU. This does not have an associated statistical endpoint or quantitative analyses.

8.3 Exploratory Analyses

[redacted]

8.4 Demographic Analyses

Demographic and subject disposition characteristics will be described using frequency and percentage for categorical measures (age group, gender, race, ethnicity, highest level of education attained, and experience with laboratory and COVID-19 testing, completion of IFU [vs. discontinuation]) and mean, standard deviation, median, and interquartile range for continuous measures (age).

8.5 Handling of Missing Data

Missing data will not be imputed. All percentages will be out of the number of non-missing responses, unless otherwise specified. Per the published scoring guidelines for the ASQ, the overall score is calculated by taking the average of the non-missing items.

8.6 Testing Analysis Assumptions

All analyses will be descriptive in nature.

8.7 Sample Size and Power

Based on feedback from the US FDA on the Exact Sciences submission Pre-EUA PEUA200414 as well as the recent Laboratory Corporation of America (LabCorp) accelerated EUA for Test Number 139900, which included a self-collection validation, 30 patients will be targeted for enrollment in this study. Per FDA recommendation, an attempt is being made to enroll subjects of varying age and educational status.

9. RECORDS

Records generated by this process are maintained, archived and dispositioned in accordance with GHI's process for controlling quality records (see QS-0004, *Control of Records*).

10. APPENDICES

Appendix I, *Table, Listing, and Figure Table of Contents*

Appendix II, *Table Shells*

Appendix III, *Figure Descriptions*

Appendix IV, *Listing Descriptions*

The following reviewers have approved this document.
See DCO for signatures and approval dates.

Name and Department	Signature	Date Signed
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[redacted]	[redacted]	22-May-2020
[redacted]	[redacted]	22-May-2020
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]

APPENDIX I
Table of Contents for Tables and Listings

Name and Number	Analysis	Cohort	Description
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Table 2	Secondary	Enrolled	Perceived usability of subjects' self-reported ease of use of the specimen collection materials as assessed by the After-Scenario Questionnaire (ASQ) Scale, Overall and by SARS-CoV-2 Test Outcome
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Table 10	Secondary	Enrolled	Observed Problems Using SARS-CoV-2 Test Specimen Collection Materials, by User Task
Table 11	Exploratory	Enrolled	[redacted]
Table 12	Exploratory	Enrolled	[redacted]
Table 13	Exploratory	Enrolled	[redacted]

Table 14	Exploratory	Enrolled	Demographic and Subject Characteristics, Overall and by SARS-CoV-2 Test Outcome
Listing 1	Secondary	Enrolled	Observation for Problems, Task 1.1 Read these 2 pages of instructions completely.
Listing 2	Secondary	Enrolled	Observation for Problems, Task 1.2 Wash your hands with soap and water. Dry your hands with a clean towel.
Listing 3	Secondary	Enrolled	Observation for Problems, Task 1.3 Put all collection materials on a clean dry surface. Refer to page 2 for kit contents.
Listing 4	Secondary	Enrolled	Observation for Problems, Task 2.1 Using blue or black ink, write your name, date of birth, and date and time of collection on the Collection Tube Label.
Listing 5	Secondary	Enrolled	Observation for Problems, Task 2.2 Set label aside.
Listing 6	Secondary	Enrolled	Observation for Problems, Task 2.3 Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart.
Listing 7	Secondary	Enrolled	Observation for Problems, Task 2.4 Be careful to only touch the swab handle, not the swab tip.
Listing 8	Secondary	Enrolled	Observation for Problems, Task 2.5 While holding the swab, remove cap from tube.
Listing 9	Secondary	Enrolled	Observation for Problems, Task 2.6 Be careful to not spill liquid.
Listing 10	Secondary	Enrolled	Observation for Problems, Task 2.7 Do not drink liquid.
Listing 11	Secondary	Enrolled	Observation for Problems, Task 2.8 Set cap aside.
Listing 12	Secondary	Enrolled	Observation for Problems, Task 2.9 Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle inside the nose 4 times.
Listing 13	Secondary	Enrolled	Observation for Problems, Task 2.10 Repeat in other nostril.
Listing 14	Secondary	Enrolled	Observation for Problems, Task 2.11 Remove swab from nostril and place in collection tube liquid.
Listing 15	Secondary	Enrolled	Observation for Problems, Task 2.12 Swirl in tube for 10 seconds.
Listing 16	Secondary	Enrolled	Observation for Problems, Task 2.13 Press the tip of the swab against the side of the tube to squeeze liquid from swab.
Listing 17	Secondary	Enrolled	Observation for Problems, Task 2.14 Discard swab into your waste.
Listing 18	Secondary	Enrolled	Observation for Problems, Task 2.15 Put the cap back on the tube.

Listing 19	Secondary	Enrolled	Observation for Problems, Task 2.16 Securely tighten so liquid does not leak.
Listing 20	Secondary	Enrolled	Observation for Problems, Task 2.17 Using the completed label from Step 1, place middle of label on tube, wrap label ends around tube, stick label ends together.
Listing 21	Secondary	Enrolled	Observation for Problems, Task 2.18 Wash and dry your hands again.
Listing 22	Secondary	Enrolled	Observation for Problems, Task 2.19 Put your tube in the bag with the absorbent pad.
Listing 23	Secondary	Enrolled	Observation for Problems, Task 2.20 Seal the bag.
Listing 24	Secondary	Enrolled	Observation for Problems, Task 3.1 Fold the bubble wrap around sealed biohazard bag.
Listing 25	Secondary	Enrolled	Observation for Problems, Task 3.2 Place bubble wrapped biohazard bag into shipping box.
Listing 26	Secondary	Enrolled	Observation for Problems, Task 3.3 Remove paper backing from tape, fold box flaps closed, press to seal box closed.
Listing 27	Secondary	Enrolled	Instructions for Use (IFU) Comprehension, Q1. After collecting a nasal swab, when should a person ship it to the lab?
Listing 28	Secondary	Enrolled	Instructions for Use (IFU) Comprehension, Q2. After collecting a nasal swab, when should a person ship it to the lab?
Listing 29	Secondary	Enrolled	Instructions for Use (IFU) Comprehension, Q3. What could happen to your nasal swab sample if you do not follow the steps in the IFU?
Listing 30	Secondary	Enrolled	General Questions to Subject by Observer, Q1. What information in the instruction for use is confusing?
Listing 31	Secondary	Enrolled	General Questions to Subject by Observer, Q2. Is there anything we could do to make it easier to collect a nasal swab sample using these materials?
Listing 32	Secondary	Enrolled	Subject Written Feedback, Q1. What, if any, steps did you have trouble completing?
Listing 33	Secondary	Enrolled	Subject Written Feedback, Q2. Do you have suggestions for improving the collection instructions?
Listing 34		Enrolled	Listing of Adverse Events, Serious Adverse Events, and Deviations (if any are reported)

APPENDIX II
Table Shells

Table 1: SARS-CoV-2 Laboratory Test Outcome

Laboratory result	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
Valid SARS-CoV-2 test result, n (%)		(100%)	(0%)
Positive			
Negative			
Inconclusive			
Invalid SARS-CoV-2 test result		(0%)	(100%)

Table 2. Perceived usability of subjects' self-reported ease of use of the specimen collection materials as assessed by the After-Scenario Questionnaire (ASQ) Scale, Overall and by SARS-CoV-2 Test Outcome

ASQ available item average	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
N			
Mean			
Standard Deviation			
Median			
Inter quartile range			

Table 3. Satisfaction ategories of the After-Scenario Questionnaire (ASQ) Scale, Overall and by SARS-CoV-2 Test Outcome

ASQ satisfaction categories	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
ASQ average score of 1 to 3 (indicating satisfaction to high satisfaction), n (%)			
ASQ average score of 4 to 7 (indicating neutral or strong dissatisfaction), n (%)			

Table 4. The After-Scenario Questionnaire (ASQ) Scale Items, Overall and by SARS-CoV-2 Test Outcome

Individual items from the ASQ	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
ASQ1. *Overall I am satisfied with the ease of completing the tasks in this scenario.*			
Response category, n (%)			
1. *Strongly Agree*			
2			
3			
4			
5			
6			
7. *Strongly Disagree*			

Not Applicable			
Missing			
ASQ2. *Overall I am satisfied with the amount of time it took to complete the tasks in this scenario.*			
Response category, n (%)			
1. *Strongly Agree*			
2			
3			
4			
5			
6			
7. *Strongly Disagree*			
Not Applicable			
Missing			
ASQ3. *Overall, I am satisfied with the support information (online help, messages, documentation) when completing the tasks.*			
Response category, n (%)			
1. *Strongly Agree*			
2			
3			
4			
5			
6			
7. *Strongly Disagree*			
Not Applicable			
Missing			

Table 5. Total Correct Answers to Instructions for Use (IFU) Comprehension Questions, Overall and by SARS-CoV-2 Test Result

Total number of comprehension questions answered correctly	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
N			
Mean			
Standard Deviation			
Median			
Inter quartile range			

Table 6. Correct vs Incorrect Answers to Instructions for Use (IFU) Comprehension Questions, Overall and by SARS-CoV-2 Test Result

Comprehension Questions Answered Correctly	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result

Zero correct (all incorrect), n (%)			
One correct (two incorrect), n (%)			
Two correct (one incorrect), n (%)			
Three correct (none incorrect), n (%)			

Table 7. Instructions for Use (IFU) Comprehension Questions, Overall and by SARS-CoV-2 Test Outcome

IFU Comprehension Questions	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
Q1. *After collecting a nasal swab, when should a person ship it to the lab?*			
Correct response, n (%)			
Incorrect response, n (%)			
Q2. *After collecting a nasal swab, when should a person ship it to the lab?*			
Correct response, n (%)			
Incorrect response, n (%)			
Q3. *What could happen to your nasal swab sample if you do not follow the steps in the IFU?*			
Correct response, n (%)			
Incorrect response, n (%)			

Table 8. Total of 26 Tasks Not Completed, Overall and by SARS-CoV-2 Test Outcome

Total number of tasks not completed	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
Number of subjects for whom observer marked all tasks as observed			
Total number of tasks not completed			
Mean			
Standard Deviation			
Median			
Inter quartile range			
Total tasks not completed, n (%)			
0			
1-5			
6-10			
11-15			
16-20			
21-26			

Table 9. Total of 15 Critical Tasks Not Completed, Overall and by SARS-CoV-2 Test Outcome

Total number of critical tasks not completed	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
Number of subjects for whom observer marked all tasks as observed			
Total number of tasks not completed			
Mean			
Standard Deviation			
Median			
Inter quartile range			
Total tasks not completed, n (%)			
0			
1-5			
6-10			
11-15			

Table 10. Observed Problems Using SARS-CoV-2 Test Specimen Collection Materials, by User Task

Critical task	User Task	Yes – Completed, no issues, n (%)	Yes w/ issues – Completed with issues or unexpected effort, n (%)	No – Did not complete or required assistance, n (%)	N/A - not applicable, n (%)
	Section: Before you collect				
Yes	1.1 Read these 2 pages of instructions completely				
	1.2 Wash your hands with soap and water. Dry your hands with a clean towel.				
	1.3 Put all collection materials on a clean dry surface. Refer to page 2 for kit contents.				
	Section: Collect your nasal swab sample				
Yes	2.1 Using blue or black ink, write your name, date of birth, and date and time of collection on the Collection Tube Label.				
Yes	2.2 Set label aside				
	2.3 Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart.				
	2.4 Be careful to only touch the swab handle, not the swab tip				
Yes	2.5 While holding the swab, remove cap from tube.				
	2.6 Be careful to not spill liquid.				
	2.7 Do not drink liquid.				
	2.8 Set cap aside.				

Yes	2.9 Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle inside the nose 4 times.				
Yes	2.10 Repeat in other nostril.				
Yes	2.11 Remove swab from nostril and place in collection tube liquid.				
Yes	2.12 Swirl in tube for 10 seconds.				
Yes	2.13 Press the tip of the swab against the side of the tube to squeeze liquid from swab.				
	2.14 Discard swab into your waste.				
Yes	2.15 Put the cap back on the tube.				
Yes	2.16 Securely tighten so liquid does not leak.				
Yes	2.17 Using the completed label from Step 1, place middle of label on tube, wrap label ends around tube, stick label ends together.				
	2.18 Wash and dry your hands again.				
Yes	2.19 Put your tube in the bag with the absorbent pad.				
	2.20 Seal the bag.				
	Section: Ship your kit back to the lab				
	3.1 Fold the bubble wrap around sealed biohazard bag.				
Yes	3.2 Place bubble wrapped biohazard bag into shipping box.				
Yes	3.3 Remove paper backing from tape, fold box flaps closed, press to seal box closed.				

Table 11. [redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]			

Table 12. [redacted]

[redacted]	[redacted]	[redacted]	[redacted]
[redacted]			
[redacted]			
[redacted]			

Table 13. [redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
[redacted]				
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[redacted]				
[redacted]				
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[redacted]				
[redacted]				
[redacted]				
[redacted]				

Table 14. Demographic and Subject Characteristics, Overall and by SARS-CoV-2 Test Outcome

	Overall	Valid SARS-CoV-2 Test Result	Invalid SARS-CoV-2 Test Result
Age, mean (SD)			
Age category, n (%)			
< 18			
18 to 30			
31 to 45			
46 to 65			
> 65			
Gender assigned at birth, n (%)			
Female			
Male			
Hispanic Ethnicity, n (%)			
Hispanic or Latino			
Not Hispanic or Latino			
Unknown			
Race, n (%) (subjects may report more than one option)			
American Indian or Alaska Native			
Asian			
Black or African-American			

Native Hawaiian or other Pacific Islander			
White			
Unknown			
Education, n (%)			
No high school			
Some high school			
High school degree only			
College degree			
Advanced degree			
Medical or laboratory training, n (%)			
Yes			
No			
Prior experience with COVID-19 specimen self-collection, n (%)			
Yes			
No			
Previously had COVID-19 testing, n (%)			
Yes			
No			
Instructions for Use, n (%)			
Completed			
Discontinued			

APPENDIX III
Figure Descriptions

Figures will not be pre-specified for this study. Figures may be produced post-hoc at the request of the Clinical and Regulatory team.

APPENDIX IV
Listing Descriptions

Listing 1. Observation for Problems, Task 1.1 ***Read these 2 pages of instructions completely.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 2. Observation for Problems, Task 1.2 ***Wash your hands with soap and water. Dry your hands with a clean towel.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 3. Observation for Problems, Task 1.3 ***Put all collection materials on a clean dry surface. Refer to page 2 for kit contents.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 4. Observation for Problems, Task 2.1 ***Using blue or black ink, write your name, date of birth, and date and time of collection on the Collection Tube Label.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 5. Observation for Problems, *Task 2.2 Set label aside.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 6. Observation for Problems, Task 2.3 *Remove the nasal swab from the wrapper by pulling the two ends of the wrapper apart.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 7. Observation for Problems, Task 2.4 *Be careful to only touch the swab handle, not the swab tip.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 8. Observation for Problems, Task 2.5 *While holding the swab, remove cap from tube.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 9. Observation for Problems, Task 2.6 *Be careful to not spill liquid.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 10. Observation for Problems, Task 2.7 *Do not drink liquid.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 11. Observation for Problems, Task 2.8 *Set cap aside.*

Subject ID	Critical Task ('Yes';	Age Group (<18, 18-30, 31-	Education (No HS, some HS,	Test Result	Completed Task? Yes, Y with issues,	Observer Feedback

	otherwise NP*)	45, 46-65, >65)	HS, college, advanced)		No, N/A	
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 12. Observation for Problems, Task 2.9 ***Gently insert the entire soft tip of the swab into one nostril until you feel a bit of resistance and rub it in a circle inside the nose 4 times.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 13. Observation for Problems, Task 2.10 ***Repeat in other nostril.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 14. Observation for Problems, Task 2.11 ***Remove swab from nostril and place in collection tube liquid.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					

02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 15. Observation for Problems, Task 2.12 *Swirl in tube for 10 seconds.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 16. Observation for Problems, Task 2.13 *Press the tip of the swab against the side of the tube to squeeze liquid from swab.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 17. Observation for Problems, Task 2.14 *Discard swab into your waste.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 18. Observation for Problems, Task 2.15 *Put the cap back on the tube.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 19. Observation for Problems, Task 2.16 *Securely tighten so liquid does not leak.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 20. Observation for Problems, Task 2.17 *Using the completed label from Step 1, place middle of label on tube, wrap label ends around tube, stick label ends together.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 21. Observation for Problems, Task 2.18 *Wash and dry your hands again.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 22. Observation for Problems, Task 2.19 *Put your tube in the bag with the absorbent pad.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 23. Observation for Problems, Task 2.20 *Seal the bag.*

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 24. Observation for Problems, Task 3.1 *Fold the bubble wrap around sealed biohazard bag.*

Subject ID	Critical Task ('Yes';	Age Group	Education (No HS, some HS,	Test Result	Completed Task? Yes,	Observer Feedback

	otherwise NP*)	(<18, 18-30, 31-45, 46-65, >65)	HS, college, advanced)		Y with issues, No, N/A	
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 25. Observation for Problems, Task 3.2 ***Place bubble wrapped biohazard bag into shipping box.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 26. Observation for Problems, Task 3.3 ***Remove paper backing from tape, fold box flaps closed, press to seal box closed.***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Completed Task? Yes, Y with issues, No, N/A	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 27. Instructions for Use (IFU) Comprehension, Q1. ***After collecting a nasal swab, when should a person ship it to the lab?***

Subject ID	Critical Task ('Yes';	Age Group (<18, 18-30, 31-	Education (No HS, some HS,	Test Result	Accuracy of Subject Response	Observer Feedback

	otherwise NP*)	45, 46-65, >65)	HS, college, advanced)		(Correct, Incorrect)	
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 28. Instructions for Use (IFU) Comprehension, Q2. ***After collecting a nasal swab, when should a person ship it to the lab?***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Accuracy of Subject Response (Correct, Incorrect)	Observer Feedback
01	Yes					
02	Yes					
03	Yes					
…						

* NP = Task not pre-specified as critical.

Listing 29. Instructions for Use (IFU) Comprehension, Q3. ***What could happen to your nasal swab sample if you do not follow the steps in the IFU?***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Accuracy of Subject Response (Correct, Incorrect)	Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 30. General Questions to Subject by Observer, Q1. ***What information in the instruction for use is confusing?***

Subject ID	Critical Task ('Yes';	Age Group (<18, 18-30, 31-	Education (No HS, some HS,	Test Result		Observer Feedback

	otherwise NP*)	45, 46-65, >65)	HS, college, advanced)			
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 31. General Questions to Subject by Observer, Q2. ***Is there anything we could do to make it easier to collect a nasal swab sample using these materials?***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result		Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 32. Subject Written Feedback, ***Q1. What, if any, steps did you have trouble completing?***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result		Observer Feedback
01	NP					
02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 33. Subject Written Feedback, ***Q2. Do you have suggestions for improving the collection instructions?***

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result		Observer Feedback
01	NP					

02	NP					
03	NP					
…						

* NP = Task not pre-specified as critical.

Listing 34. Listing of Adverse Events, Serious Adverse Events, and Deviations (if any are reported)

Subject ID	Critical Task ('Yes'; otherwise NP*)	Age Group (<18, 18-30, 31-45, 46-65, >65)	Education (No HS, some HS, HS, college, advanced)	Test Result	Description of Adverse Event, Serious Adverse Event, and any deviations (or "None Reported")
01	NP				
02	NP				
03	NP				
…					

* NP = Task not pre-specified as critical.