EXACT SCIENCES

Usability Study of Home Collection and Mailing with SARS-CoV-2 Test Specimen Collection Materials (2020-06)

Study Title:	Usability Study of Home Collection and Mailing with SARS-CoV-2 Test Specimen Collection Materials (2020-06)
Study Number:	2020-06
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Study Sponsor:	Exact Sciences Laboratories 145 E. Badger Road Madison, WI 53719
Sponsor Contact:	[redacted]

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1 LIST OF ABBREVIATIONS

Abbreviation	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
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
RT-PCR	Reverse transcription polymerase chain reaction
SAE	Serious Adverse Event
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2 (see also 2019-nCoV)

2 PROTOCOL SYNOPSIS

Primary Objective:	Determine the usability of the SARS-CoV-2 Specimen Collection Materials for at-home collection and mailing of sample to the testing laboratory
Study Design:	Prospective observational human factors usability study
Population:	Subjects of varying education levels, age, and health status Subjects are considered enrolled when they provide written informed consent. Approximately 30 subjects are targeted for enrollment.
Primary Endpoint:	The primary endpoint is the percent of samples from the fully enrolled cohort to return a valid SARS-CoV-2 test result (positive, not detected, or inconclusive). The target is 80% as an acceptable rate of success given the first-time task completion for minimally trained users.
Study Duration:	The study will be complete when approximately 30 self-collected nasal swab samples have corresponding SARS-CoV-2 test results (positive, not detected, inconclusive, invalid, or unable to be processed). Subject participation is up to one day from enrollment to completion.
Study Procedures:	Subjects will be observed while following the Instructions for Use (IFU) for the SARS-CoV-2 Specimen Collection Materials in a setting that simulates a home environment. Subjects will take the After-Scenario Questionnaire (ASQ) to measure ease of use. Subjects will have the opportunity to provide written feedback on their experience. Subjects will be asked questions about their comprehension of the IFU by the observer.

The specimens collected by the subject will be tested in the laboratory for SARS-CoV-2. Subjects will remain blinded to the results of the study sample.

Subject data will be collected and provided to the Sponsor.

3 BACKGROUND / RATIONALE

3.1 SARS-CoV-2 Testing in the United States

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 Food and Drug Administration (FDA) has given Emergency Use Authorization (EUA) for select Real-Time RT-PCR Diagnostic Panels that detect RNA specific to SARS-CoV-2. This study will use the Exact Sciences Laboratories (ESL) SARS-CoV-2 (N gene detection) Test [redacted]

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 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] The use of the nasal swab that meets CDC recommendations has advantages, including avoiding the supply issues for specialized sample collection devices, such as the nasopharyngeal swab. Sample collection is also easier with a nasal swab. While the supply shortages could be transient, the collection methods of washes and aspirates potentially increase the risk of exposure for healthcare workers.[2]

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

3.2 Usability of the SARS-CoV-2 Test Specimen Collection Materials

The SARS-CoV-2 Specimen Collection Materials (**Section 6**) allow for self-collection of a nasal swab specimen and return to a testing laboratory, which will enable at home collection. The Materials include Instructions for Use (IFU), which are a straightforward, step-by-step guide. The usability of the IFU is a critical factor in the success of at-home testing and is the focus of this clinical study. An IFU with a high completion rate that provides samples with sufficient quality and quantity of specimen for SARS-CoV-2 testing is necessary.

4 OBJECTIVES AND ENDPOINTS

4.1 Objectives

4.1.1 Primary Objective

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.

4.1.2 Secondary Objective

The secondary objectives of this study are to evaluate perceived usability of the IFU as well as comprehension by the subject, identify problems (e.g., use errors, delays, close calls) that occur while following the IFU, evaluate root causes of problems, and develop strategies to mitigate those risks going forward.

4.2 Endpoints

4.2.1 Primary Endpoint

The primary endpoint is the percent of samples from the fully enrolled cohort to return a valid SARS-CoV-2 test result (positive, not detected, or inconclusive). The target is 80% as an acceptable rate of success given the first-time task completion for minimally trained users.

4.3 Other Pre-Specified Analyses

Other pre-specified analyses include

- characterization of subjects' self-reported ease of use of the Specimen Collection Materials,
- acceptable answers on general comprehension of the IFU,
- observer-reported problems associated with following the IFU,
- [redacted]
- [redacted]
- evaluation of root causes of problems associated with user tasks, including but not limited to critical tasks, to develop risk mitigation strategies.

5 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.

Subjects with a range of education levels and ages but without medical, laboratory, or COVID-19 specimen self-collection experience will be recruited. Subject participation is up to one day from enrollment to completion. The specimens collected by the subjects will be tested in the laboratory for SARS-CoV-2. Subjects will remain blinded to the test results. The study will be considered complete when approximately 30 self-collected nasal swab samples have corresponding SARS-CoV-2 test results (positive, not detected, inconclusive, invalid, or unable to be processed).

6 STUDY MATERIALS

6.1 SARS-CoV-2 Specimen Collection Materials

The SARS-CoV-2 Specimen Collection Materials is a single-use convenience kit comprised of a sterile individually wrapped nasal swab (polyester tip with plastic handle) and a 2 ml transport tube with 0.9% saline transport medium, packaged together in a single container not intended to be unwrapped or unsealed before it is used by the end user, an individual undergoing testing for COVID-19. A biohazard bag, absorbent pad, and UN3373-labelled shipping container are also provided. Instructions for Use (IFU) are also provided (**Appendix 2.0**). The SARS-CoV-2 Specimen Collection Materials is for use outside of a clinical setting.

6.2 Critical Tasks for the SARS-CoV-2 Specimen Collection Materials

A Use-Related Failure Modes Effect Analysis (FMEA) approach was used to determine potential hazards and their associated risks during use of the SARS-CoV-2 Specimen Collection Materials. For each activity, the following high-level questions were asked:

- Do users correctly collect nasal swab samples?
- Do users correctly prepare samples for shipment?
- Do other aspects of use of the SARS-CoV-2 Specimen Collection Materials impact the receipt of usable nasal swab samples at ESL?
- How easy or difficult is it to understand and use the IFU in the SARS-CoV-2 Specimen Collection Materials to perform tasks?

The activities in the workflow described in the IFU were used to determine tasks to be evaluated in this usability study. Each task was then assigned a rating of “critical” or “essential,” based on a human factors risk assessment done at Exact Sciences. Critical and essential tasks are defined as follows.

- Critical tasks are those in which use errors or failure to complete would have a negative clinical impact, such as inaccurate or delayed test results.
    - Failure to successfully complete a critical task results in a use error or performance failure.
- Essential tasks represent behaviors that are important to the overall use of the SARS-CoV-2 Specimen Collection Materials but do not pose an immediate risk to the user.

- Failure to successfully complete an essential task will be recorded as a use error but will not necessarily result in a performance failure.

While only the critical tasks identified for the SARS-CoV-2 Specimen Collection Materials are listed **(Table 2),** all user interactions will be observed and subsequently evaluated in the Other Pre-specified Analyses. Most outcomes related to problems with critical tasks result in no specimen or no/delayed test results, which are low risk to patients. Additional low risk outcomes are the return of invalid or false inconclusive test results. These outcomes would result in potential recollection of sample for a retest. There is a possibility for false negatives, which would be a medium risk, but this outcome is not anticipated as a negative test result in this SARS-CoV-2 test still requires signal from the control human RNase P signal. The more probable outcome for use errors involving loss or degradation of RNA is an invalid test result, which would be a result of impacting all RNA in a sample as opposed to only viral RNA for a false negative.

Specimen Collection Tasks	Potential Use Errors	Outcomes	Level of Risk to Patient	Test Method
Read these 2 pages of instructions completely	User cannot read the IFU User does not understand the IFU	No specimen obtained	Low	Simulated use
Plan your collection time	User does not plan time well and misses shipping time. User does not arrange for same day shipment. User takes package to other shipping vendor or a UPS drop box	No test result Lost sample Unusable sample	Low	IFU comprehension questions
Prepare the tube label	User does not label sample with first and last name and date of birth User does not include time and date of collection	No test result Delayed test result	Low	Simulated use
Remove tube cap	User spills most or all of liquid.	No test result	Low	Simulated use
Swab nose	User does not swab each nostril and/or enough times User does not rub the swab long enough	Invalid test result False inconclusive result	Low	Simulated use
		False negative test result	Medium	

Add swab to tube. Remove swab from tube.	User does not swirl the swab long enough User does not press liquid out of swab	Invalid test result False inconclusive test result	Low	Simulated use
		False negative result	Medium	
Replace tube cap.	User does not close the sample tube tightly and contents leak during shipment.	No test result	Low	Simulated use
Place label on tube	User does not put label on tube	No test result	Low	Simulated use
Place bubble wrapped bag in box	User does not pack tube in shipping box	No test result	Low	Simulated use
Store sample in sealed box away from direct heat and sunlight until shipment.	User leaves sample in heat or sunlight.	Invalid test result	Low	IFU comprehension questions
		False negative test result	Medium	
Ship package by UPS	User misses shipping pick-up User does not arrange for same day shipment User takes package to other shipping vendor or a UPS drop box	No test result Lost sample Unusable sample	Low	IFU comprehension questions

Table 2: Critical tasks identified as having potential to harm users or delay in treatment or diagnosis for users of the SARS-CoV-2 Specimen Collection Materials.

7 SUBJECT SELECTION AND WITHDRAWAL

Each subject must meet all the following inclusion criteria and none of the exclusion criteria to participate in this study.

7.1 Inclusion Criteria

1. Ability to provide informed consent

7.2 Exclusion Criteria

1. Prior medical or laboratory training
2. Prior experience with COVID-19 specimen self-collection
3. Prior SARS-CoV-2 testing

7.3 Subject Withdrawal

Subjects may be withdrawn from the study by any of the following mechanisms:

- Voluntary withdrawal of participation by the subject at any time during the study.
- Determination by the Investigator that it is in the best interest of the subject.
- Determination by the Sponsor it is in the best interest of the subject or study.
- Determination by review that the subject does not meet eligibility criteria.

All data available from enrollment to subject withdrawal will be collected. Data for the study visit will be collected for subjects who discontinue participation but who do not withdraw consent.

8 STUDY PROCEDURES

8.1 Overview

Subjects who provide informed consent will be observed while following the IFU for the SARS-CoV-2 Specimen Collection Materials in a setting that simulates a large surface area, such as a kitchen or bathroom counter or a tabletop. The room will include common items such as hand sanitizer, pens, pencils, paper towels, and a wastebasket. In the event a sink is not available, a large bowl labeled “SINK” will be provided next to the hand sanitizer. Subjects will also 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 will be an employee of Exact Sciences.

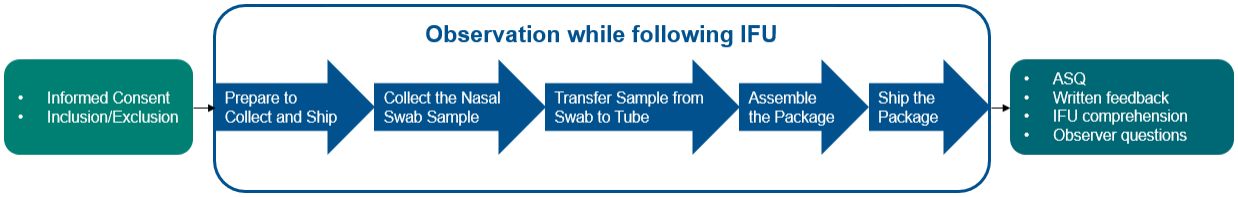

Figure 1: Overview of study procedures.

8.2 Enrollment

Inclusion and exclusion criteria will be reviewed. After subjects have provided written informed consent, demographic information will be obtained, and subject eligibility will be confirmed.

Enrollment and the use of the device may occur on the same day.

8.3 Observation for Problems Using SARS-CoV-2 Test Specimen Collection Materials

The subject will be provided with the SARS-CoV-2 Specimen Collection Materials that include the IFU. An observer will watch the subject perform the tasks in the IFU without providing input or assistance. The observer will record the following information by IFU task:

- Completed

- Completed with use errors, close calls

- Did not complete
- Free form observational notes

8.4 Subject Experience with SARS-CoV-2 Specimen Collection Materials

Subjects will take a survey called the After-Scenario Questionnaire (ASQ) to evaluate perceived ease of use.[3-5]

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

Figure 2: After-Scenario Questionnaire (ASQ)

Subjects will have the opportunity to provide written feedback on their experience.

Subjects will be asked questions about their experience by the observer, including their comprehension of the IFU (e.g., shipping instructions). Follow up questions to the subject by the observer may be needed to clarify areas of misunderstanding about the IFU.

Finally, the observer will ask questions to help identify the root causes of tasks observed as not completed or completed with use errors or close calls during the simulation of the IFU.

8.5 SARS-CoV-2 Testing of Subject Samples

For the IFU to be successful for at home testing, valid test results must result from self-collected sample. Valid SARS-CoV-2 test results are positive, not detected, and inconclusive (**Table 1**). In addition, the following will be determined.

- [redacted]

8.6 Data Collection

Subject data will be collected on Case Report Forms (CRFs) as subject and observer reported surveys and provided to the Sponsor.

8.6.1 Subject Reported Data

- Name
- Date of birth
- Demographics
- Responses to exclusion criteria
- Usability survey (ASQ)
- Written feedback on following the IFU
- Responses to IFU comprehension questions
- Responses to questions about IFU close calls or tasks not completed, documented by the observer

8.6.2 Observer Reported Data

- Checklist based on workflow steps to record completion, completion with difficulty (e.g., use errors or close calls), and did not complete
- Written notes for each task
- Subject-reported answers to questions on IFU comprehension and issues following the IFU

8.6.3 Lab and Test-Related Data

- Qualitative results for the SARS-CoV-2 test
- [redacted]
- [redacted]

8.7 End of Study

Subjects' participation will be considered completed following completion of the survey, forms, and potential interview with the observer or at the point of early termination as described in Section 7.3.

8.8 Sample Retention

Samples may not be used in their entirety. Samples may be retained for purposes such as additional testing in this or alternative SARS-CoV-2 tests. Information from this additional testing may be used to inform study questions around laboratory QA processes or test improvement. Unused sample will be destroyed after 1 year or earlier.

9 DATA ANALYSIS AND STATISTICAL METHODS

9.1 Sample Size Determination

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 will be made to enroll subjects of varying age and educational status.

9.2 Analysis of Primary Endpoint

The primary endpoint is the percent of samples from the fully enrolled cohort to return a valid SARS-CoV-2 test result (positive, not detected, or inconclusive). The target is 80% as an acceptable rate of success given the first-time task completion for minimally trained users.

9.3 Other Pre-Specified Analyses

Other pre-specified analyses include a characterization of subjects' self-reported ease of use with the Specimen Collection Materials Instructions for Use (IFU), acceptable answers on general comprehension of the IFU, observer-reported problems associated with following the IFU, [redacted] and evaluation of root causes of problems associated with user tasks, including but not limited to critical tasks. All analyses will be descriptive in nature. Frequency and percentage will be calculated for categorical measures and mean, standard deviation, median, and interquartile range will be calculated for continuous measures.

The subject's self-reported satisfaction and ease of using the IFU will be assessed using the After-Scenario Questionnaire (ASQ).[3, 4] 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). The frequency and percentage of each response to all questions will be presented, along with the mean, standard deviation, median, and interquartile range of the overall score. In addition, 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) will be presented. An average of 3.5 or lower on the overall ASQ score will be considered acceptable self-reported user satisfaction.

The frequency and percentage of correct vs. incorrect responses from the subject on questions around shipping and invalid tests consequences will be presented.

The frequency and percentage of individual problems observed (by an external observer) with the Specimen Collection Materials IFU will be presented, along with the distribution of total number of problems overall and total number of problems on critical tasks (**Section 6.2**).

[redacted]

A qualitative evaluation of results from the user reported data, external observer feedback on user interactions, and laboratory testing will be conducted to assess the root cause of problems and evaluate mitigating solutions, e.g., whether specific parts of the IFU should be modified.

9.4 Analytic Cohort

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

Demographic and subject disposition characteristics will be described using frequency and percentage for categorical measures and mean, standard deviation, median, and interquartile range for continuous measures.

9.5 Stopping Rule

This study is expected to run through its conclusion without premature termination.

9.6 Bias Considerations

Subjects who participate in this study may not be wholly representative of those who would use a home collection kit for SARS-Cov-2 testing. Subjects with a range of education levels and ages but without medical, laboratory, or self-collection experience will be recruited. There are no other known bias considerations in this study design.

9.7 Handling of Missing Data

Missing data will not be imputed.

Per the published scoring guidelines for the ASQ, the overall score is calculated by taking the average of the non-missing items.

All analyses will be described in the study Statistical Analysis Plan, which will supersede the methodology presented in the Study Protocol. Any deviations in the Statistical Analysis Plan will be recorded along with their rationale in the final study report, as appropriate.

10 ADVERSE EVENT REPORTING

10.1 Definition of Adverse Events

An adverse event (AE) is any unfavorable or unintended sign, symptom, or disease temporally associated with the use of an investigational product or protocol-imposed intervention, regardless of attribution. All observed or volunteered adverse events regardless of suspected causal relationship to the investigational product(s) will be reported as described in the following sections.

Potential side effects from routine nasal swabbing, including, but not limited to, acute epistaxis (nosebleed), sneezing, nasal redness, are not required to be reported to the Sponsor as adverse events.

10.2 Reporting Period

Adverse events collection begins at enrollment and ends after completion of the sample collection. Adverse events will only be recorded for events that occur during or are believed to be associated with the nasal swab sample collection procedures. All AEs will be reported on the adverse event page(s) of the CRF.

10.3 Serious Adverse Events

Serious adverse events are not expected for this study. In the event of an SAE, the event will be reported to the IRB per IRB standard operating procedure.

11 QUALITY CONTROL AND QUALITY ASSURANCE

The study site may be subject to review by the (IRB)/Ethics Committee (EC), and/or to quality assurance audits performed by Exact Sciences.

12 DATA HANDLING AND RECORD KEEPING

All references to the Sponsor in this section include all designees e.g., Contract Research Organizations or Consultants acting on behalf of the Sponsor.

12.1 Protocol Deviations

The site should make all efforts not to deviate from any of the study procedures or requirements as described in this protocol, except where necessary to eliminate immediate risks to the subject(s).

Any deviations from this protocol must be notified to the Sponsor and documented properly. Protocol deviations must also be reported to the IRB per IRB policy.

12.2 Case Report Forms (CRFs)

As used in this protocol, the term Case Report Form (CRF) should be understood to refer to either a paper form or an electronic data record or both, depending on the data collection method used in this study.

A CRF is required and should be completed for each enrolled subject. The completed original CRFs are the sole property of Exact Sciences and should not be made available in any form to third parties, except for authorized representatives of Exact Sciences or appropriate regulatory authorities, without written permission from Exact Sciences.

12.3 Records Retention

The ICH E6(R2) Good Clinical Practice: Consolidated Guidance defines source documents as, "Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial)."

The Sponsor agrees to keep records, including the identity of all participating subjects, all original signed informed consent forms, copies of all CRFs, and adequate documentation of relevant correspondence (e.g., letters, meeting minutes, telephone calls reports). The Sponsor shall maintain study records for a period of 2 years after the latter of the following three dates: the date on which the investigation is terminated or completed, the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol, or date provided in applicable national law.

13 ETHICS

13.1 Risk Analysis

13.1.1 Risk to the subject

The risk to study subjects is minimal and are related to the use of the nasal swab collection materials. The nasal swab could cause mild discomfort or a short-term impact such as a nosebleed. While the saline in the collection tube could spill, the liquid is safe and of small volume.

13.1.2 Benefit to Subject

There are no benefits to the subjects enrolled in this study.

13.2 Institutional Review Board (IRB) / Ethics Committee (EC)

It is the responsibility of the Investigator to have prospective approval of the study protocol, protocol amendments, informed consent forms, and other relevant documents, e.g., recruitment advertisements, if applicable, from the IRB. All correspondence with the IRB/EC should be retained in the Investigator File. Copies of IRB approvals should be forwarded to Exact Sciences or designee.

13.3 Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects (Council for International Organizations of Medical Sciences 2002), the Declaration of Helsinki (World Medical Association), and applicable local regulatory requirements and laws.

13.4 Subject Information and Consent

All parties will ensure protection of subject personal data and will not include subject names on any Sponsor forms, reports, publications, or in any other disclosures, except where required by laws. In case of data transfer, Exact Sciences will maintain high standards of confidentiality and protection of subject personal data. Subject name, contact information, and informed consent will be retained by Exact Sciences Clinical Affairs in a secure, limited access location, for the purpose of conducting and oversight of the clinical study. Subject protected health information, including name and date of birth, may be shared on a limited basis with Exact Sciences staff responsible for conducting data collection and analysis activities.

The informed consent form must be in compliance with ICH GCP, local regulatory requirements, and legal requirements. The informed consent form used in this study, and any changes made during the study, must be prospectively approved by both the IRB/EC and Exact Sciences before use.

The Investigator must ensure that each study subject, or his/her legally acceptable representative, is fully informed about the nature and objectives of the study and possible risks associated with participation. The Investigator, or a person designated by the Investigator, will obtain written informed consent from each subject or the subject's legally acceptable representative before any study-specific activity is performed. The Investigator will retain the original of each subject's signed consent form.

14 DEFINITION OF END STUDY

End of Study is defined when the enrollment target of approximately 30 subjects has been achieved and all samples have been collected, processed, and tested.

15 SPONSOR DISCONTINUATION CRITERIA

Premature termination of this study may occur because of a regulatory authority decision, change in opinion of the IRB, or at the discretion of Exact Sciences.

16 REFERENCES

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.
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4. Lewis, J.R., *Psychometric evaluation of an after-scenario questionnaire for computer usability studies: The ASQ.* ACM SIGCHI Bulletin, 1991. **23**: p. 78-81.
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APPENDIX 1.0 – SCHEDULE OF ACTIVITIES

Activity	Observed Sample Collection
Informed Consent[1]	X
Subject Completed Demographics and Exclusion Criteria	X
Use of SARS-CoV-2 Specimen Collection Materials while under observation	X
Complete the After-Scenario Questionnaire (ASQ)	X
Answer observer questions about comprehension of IFU and observations	X

Footnotes for Schedule of Activities

1. Informed Consent must occur prior to undergoing any study specific procedures

APPENDIX 2.0 – IFU FROM SARS-CoV-2 TEST SPECIMEN COLLECTION MATERIALS

IFU from the SARS-CoV-2 Test Specimen Collection Materials are provided as a supplement to the clinical study protocol.

APPENDIX 3.0 – FORMS FOR DATA TO BE COLLECTED

Subject Demographics

- Education level
  - No high school
  - Some high school
  - High school
  - College degree
  - Advanced degree
- Date of birth
- Race/ethnicity
- Gender

Inclusion/Exclusion Criteria Form

- Participants with prior medical or laboratory training should be excluded.
- Participants who have prior experience with self-collection should be excluded.
- Participants who have previous SARS-CoV-2 testing should be excluded.

Subject ease of use survey

- After–Scenario Questionnaire (ASQ)

Other subject-reported data

- Survey for written comments
  - What, if any, steps did you have trouble completing?
  - Do you have suggestions for improving the collection instructions?
- Questions to evaluate comprehension of the IFU
  - Follow up by observer if necessary
- Subject-specific questions about not completed tasks and tasks completed with use errors or close during observation

Observer

- Observer Script
- Checklist based on tasks in the SARS-CoV-2 Specimen Collection Materials which documents the following outcomes with free fields for observational notes:
  - Completed
  - Completed with use errors, close calls
  - Did not complete