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Template for Developers of Home Specimen Collection Devices for Use with Molecular Diagnostic Tests [1]

This template provides the Food and Drug Administration's (FDA) current recommendations concerning what data and information should be submitted to FDA in support of a pre-Emergency Use Authorization (EUA) submission/EUA request for prescription use and non-prescription use (often referred to as direct-to-consumer or DTC) molecular diagnostic home collection devices where an individual collects certain clinical sample(s) that are then sent to a clinical laboratory for testing with a molecular diagnostic for SARS-CoV-2 that is authorized for use with the home collection kit. This template does not address over the counter (OTC) tests for fully at-home COVID-19 testing.[2]

As described in the FDA guidance document *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*,[3] FDA is providing recommendations in this and other EUA templates regarding testing that should be performed to ensure appropriate analytical and clinical validity, including descriptions of appropriate comparators, for different types of tests. FDA generally recommends certain validation studies be conducted for a molecular diagnostic test for SARS-CoV-2.

The EUA Templates[4] are intended to help test developers provide recommended validation data and other information to FDA, but alternative approaches can be used. This template reflects FDA's current thinking on the topic, and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should*, means that something is suggested or recommended, but not required. For more information about EUAs in general, please see the FDA Guidance document: *Emergency Use Authorization of Medical Products and Related Authorities*.[5]

Test developers interested in pursuing an EUA may submit a pre-EUA to begin discussions with the FDA or may submit an EUA request to covid19dx@fda.hhs.gov.

FDA recommends that all developers of molecular SARS-CoV-2 tests and collection devices for use with molecular diagnostic tests include the Molecular EUA Template Cover Sheet[6] when submitting their EUA request to covid19dx@fda.hhs.gov to help streamline the routing, triage, and review of EUA requests.

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[1] This template is part of the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) - Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff.

[2] Please refer to the Template for Test Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Home Use, available at: https://www.fda.gov/media/140615/download.

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised

[4] All EUA templates can be found at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#covid19ivdTemplates.

[5] https://www.fda.gov/media/97321/download.

[6] Available at https://www.fda.gov/media/152768/download.

GENERAL INFORMATION ABOUT THIS TEMPLATE

- Text highlighted in yellow ***[Text]*** should be completed by the collection kit developer as applicable to their specific device. Text in **bold** outlines the FDA's additional recommendations for the developers' consideration when completing the suggested information in each section.
- Not all portions of this template may be relevant for all developers/tests. FDA recommends developers complete all portions that are relevant to facilitate a streamlined review.
- This template is intended for home collection kits for anterior nasal swab or saliva samples.
- There are three general options for seeking authorization for an at-home collection kit:
    - Included as part of a single EUA request for a SARS-CoV-2 molecular diagnostic test (i.e., when the same developer is responsible for the home collection kit and molecular diagnostic test and seeks authorization at the same time for the molecular diagnostic test and home collection kit);
    - In multiple EUA requests (e.g., when the developer of the home collection kit is different from the developer(s) of the molecular diagnostic assay(s)); or
    - As a supplemental EUA request to the EUA of a previously authorized molecular diagnostic test to add home collection with a specific home collection kit.
- This template includes part of FDA's current recommendations concerning the data and information that should be submitted to FDA in support of an EUA request for a home collection kit. Please refer to the Molecular Diagnostic Template for Test Developers[7] for FDA's current recommendations concerning what data and information should be submitted to FDA in support of an accompanying molecular diagnostic test for SARS-CoV-2, which may be submitted in the same EUA request as the home collection kit or in a separate EUA request. If submitted as a separate EUA request, FDA recommends including a right of reference from the developer of the home collection kit to allow the data from the home collection kit EUA request to be incorporated by reference in the separate EUA request for a molecular diagnostic test for SARS-CoV-2.
- A developer that has provided data to the FDA may grant a right of reference to other developers, either broadly or to individual developers, to leverage that data. A right of reference provides a developer the ability to rely upon, and otherwise use, existing information in one regulatory submission for the purpose of supporting a different regulatory submission. In these cases, if the data is applicable to the new developer's test, the new developer may not have to repeat that validation for its submission to the FDA or FDA may recommend only a bridging study. Any developer seeking to leverage data regarding another developer's EUA-authorized assay must obtain a right of reference from that developer.

[7] Available at https://www.fda.gov/media/135900/download

- A home collection kit authorized under an EUA is only authorized for emergency use while the EUA is in effect.
- We may update the template as appropriate as we learn more about COVID-19 and gain experience with the EUA process for these kinds of devices.
- FDA recommends distributors of home specimen collection kits contact the Pipeline and Hazardous Materials Safety Administration (PHMSA) within the Department of Transportation (DOT) to confirm their packaging and shipping instructions will ensure users are in compliance with the hazardous materials regulations for shipping medical material. PHMSA can be contacted at HMInfo@dot.gov.

EXAMPLE TEMPLATE:

A. PURPOSE FOR SUBMISSION

Emergency Use Authorization (EUA) request for distribution and/or use of the ***[name of collection kit]*** for the [***collection or collection and stabilization***] of ***[add all claimed sample types, i.e., anterior nasal swabs and/or saliva]*** in ***[add transport media or dry tube]*** to transport viral SARS-CoV-2 RNA, from **[*patients suspected of COVID-19 by a healthcare provider or patients suspected of COVID-19 by a healthcare provider and individuals without signs or other reasons to suspect COVID-19 or individuals with or without signs or other reasons to suspect COVID-19]***. The home collection kit is for use in conjunction with molecular diagnostic testing performed at a clinical laboratory using an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 that is authorized for use with the home collection kit.

B. APPLICANT

[Official name, address, and contact information (including phone number and email address) of applicant and primary correspondent.]

D. PROPRIETARY AND ESTABLISHED NAMES

Proprietary Name - ***[device name (home collection kit name)]***
Established Name - ***[device name (home collection kit name)]***

C. REGULATORY INFORMATION

Approval/Clearance Status:

The ***[device name]*** device is not cleared, approved, or subject to an approved investigational device exemption.

[*If the device has been previously reviewed in an EUA request or p-EUA submission, please provide the submission number.*]

Product Code:

QLW - COVID-19 test home collection kit devices

D. PROPOSED INTENDED USE

1) <u>Intended Use (IU):</u>

The proposed IU will be finalized based on, among other things, the data and recommendations from Public Health authorities at the time of authorization. Example text is provided below.

Example text for a standalone prescription use (Rx only) home collection kit (e.g., where the developer is seeking authorization of the home collection kit independent of a diagnostic test EUA):

The ***[name of collection kit]*** is intended to collect ***[add all claimed sample types, i.e., anterior nasal swabs and/or saliva]*** at home by ***[intended use population, e.g., individuals age 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance)]***, when determined by a healthcare provider to be appropriate.

Samples collected using the ***[name of collection kit]*** are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the ***[add all claimed sample types, i.e., nasal swabs and/or saliva]*** is maintained in the sample packaging and is only for use with a molecular test for the detection of SARS-CoV-2 that is EUA-authorized and indicated for use with the ***[name of collection kit]***.

Testing is limited to laboratories designated by ***[name of test developer]*** and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests and that run the samples collected from the ***[name of collection kit]*** on a molecular diagnostic test that is EUA-authorized and indicated for use with the ***[name of collection kit]***.

The ***[name of collection kit]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

Example text for a prescription use (Rx only) home collection kit and a COVID-19 molecular test in a single EUA request (e.g., where the COVID-19 molecular diagnostic test developer is also manufacturing the home collection kit and requesting an EUA for the combined system or, if the COVID-19 molecular diagnostic test is already authorized, the developer is requesting a revision to their already issued EUA to authorize home sample collection as an option):

The ***[name of the EUA molecular diagnostic test]*** is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test for the qualitative detection of RNARNA from SARS-CoV-2 in ***[name typical respiratory samples collected, e.g., upper and lower respiratory samples such as nasal, nasopharyngeal (NP) or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage (BAL), and NP wash/aspirate or nasal aspirate]*** collected from individuals suspected of COVID-19 by their healthcare provider.

This test is also for use with ***[name samples, i.e., nasal swab or saliva]*** samples collected with the ***[name of home collection kit]*** at home by ***[intended use population, e.g., individuals age 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance)]*** when determined by a healthcare provider to be appropriate.

Testing is limited to ***[specify laboratory/laboratories]*** certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in ***[name sample type, e.g., upper respiratory]*** during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ***[test name]*** is intended for use by ***[include intended user, e.g., qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of RT-PCR and in vitro diagnostic procedures]***. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

Example text for a non-prescription/DTC home collection kit:

The ***[name of DTC home collection kit]*** is a direct-to-consumer product for self-collecting a ***[add all claimed sample types, i.e., nasal swabs and/or saliva]*** sample at home by ***[intended use population, e.g., individuals 18 years or older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance)]*** that will be transported to a laboratory for testing with a molecular diagnostic test for the detection of SARS-CoV-2 that is EUA-authorized and indicated for use with the ***[name of DTC collection kit]*** and is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

Testing is limited to laboratories designated by ***[name of developer]*** and that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests using samples collected with the ***[name of collection kit]*** on a molecular diagnostic test that is EUA-authorized for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19 and indicated for use with the ***[name of collection kit]***.

All test results are delivered to the user via ***[include mechanism via which the individual will receive test results]***. Individuals with positive or invalid/indeterminate 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 ***[name of DTC home collection kit]*** 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 ***[name of DTC home collection kit]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

2) Special Conditions for Use Statements:

For prescription use only **(as applicable)**
For *in vitro* diagnostic use
For Emergency Use Authorization only

E. DEVICE DESCRIPTION

Please provide a device description, as outlined below, modifying the example text as appropriate for your specific collection kit. For new technologies, FDA may request additional detailed information so we can adequately assess the known and potential risks and benefits associated with the device.

1) Collection Kit Description:

[Describe the basic design of the device and the components included in the home collection kit.]

The ***[name of collection kit]*** collects and stabilizes [***virus/viral RNA]*** from ***[add all claimed sample types, i.e., nasal swabs and/or saliva]*** samples***(s)***; it can also be used for the transportation and [***short/long-term room temperature storage***] of a sample. The ***[name of collection kit]*** is a non-invasive alternative for collecting high quality and quantity [***virus/viral RNA]*** by/from individuals ***[insert intended testing population, e.g., who are suspected of COVID-19 by their healthcare provider for use]*** with a molecular diagnostic test for the detection of SARS-CoV-2 that has been issued an EUA and is authorized for use with ***[name of collection kit]***.

The ***[name of collection kit]*** collection kit consists of a ***[e.g., swabs, collection tube containing stabilizing liquid, gel pack, return shipping box/envelope, insulated pack, instructions]***. Upon contacting ***[e.g. clinical sample, saliva cells], [e.g., the stabilizing liquid lyses cellular and nuclear membranes to release and stabilize nucleic acids].***

[Include details of all reagents/materials included in the kit and their function. Include how the components of the collection kit stabilize the sample and protect the virus/viral RNA for shipment.]

2) Home Collection Kit Ordering and Processing:

Individuals may request the ***[name of collection kit]*** collection kit ***[describe how your kit will be sold, online, in retail stores, etc.]*****. For prescription use devices, the**

home collection kit should not be dispensed to the patient before the prescription for the test is written.

[Describe how the sample is collected and then transferred into the collection device. Describe the shipping conditions during transit ((for example, use of a drop box, sample waiting for pick up outside, etc.) and how the transit/shipping time will be tracked. How does the home user know where to send their samples? Are there specific shipping instructions? Please identify the company(ies) shipping samples and if samples will be placed in drop boxes or mailboxes for pickup.]

The individual using the ***[name of collection kit]*** to collect a ***[add all claimed sample types, i.e., nasal swabs and/or saliva]*** sample performs the following steps to collect the sample: ***[describe the steps to collect the sample].***

After a ***[add all claimed sample types, i.e., nasal swabs and/or saliva]*** sample is collected, the ***[e.g., swab is inserted, stabilizing liquid is mixed with the sample]***.

For device shipping, the individual must ***[describe steps and expected timeframe]***.

Prior to acceptance for testing with an IVD molecular test that is EUA-authorized and indicated for use with the ***[name of collection kit]***, samples received at the clinical laboratory must be subjected to the following accessioning procedure ***[describe the sample log in, acceptance and rejection criteria, mechanism for handling rejected samples, etc. Please provide your accessioning Standard Operating Procedure (SOP) for all laboratories to use when accepting samples collected with your home collection kit for testing, before entering them into the workflow.]***

Test results are communicated back to individuals that used the ***[name of collection kit***] via ***[describe the mechanism via which results are returned to individuals that use the home collection kit]*** with a result interpretation table**.**

3) <u>Sample Collection Control:</u>

The accessioning procedure should include a control to ensure that an adequate human sample was collected. This could include using an EUA-authorized test that includes some form of human sample control (e.g., RNaseP) to determine if sufficient sample was collected by the user. Alternatively, the laboratory could run a separate FDA-cleared RT-PCR test in parallel for each sample type that targets a human housekeeping gene. Sample collection visually observed by a healthcare provider through a telemedicine visit, and a method/procedure for the laboratory to confirm this, could also serve as this control. FDA is open to considering alternative methods that assess adequate sample presence and/or quality.

4) <u>Partnering Laboratories:</u>

Fill out the table below to identify all laboratories that samples will be sent to and all tests that will be run with the samples at each laboratory.

Laboratory	EUA Assay	Lab Testing Capacity (per day or week)
[Lab Name Address Phone: CLIA #:]	***[Assay Name and Test Developer, submission # if EUA request submitted, link to EUA if already authorized]***	

Where the developer of the home collection kit is different from the developer of the diagnostic assay, we recommend requesting a letter from the developer of each test permitting FDA to discuss their submission with you.

Additionally, each test developer should submit an EUA or supplemental EUA request for authorization for testing home collected samples collected with *[name of collection kit]*. Please provide a right of reference to each test developer to allow the data validating your home collection kit to be incorporated by reference in the test developer's EUA request.

5) Test Result Reporting:

All test results are to be reported to healthcare providers and relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the *Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests*[8] provided by CDC. Core diagnostic data elements[9] are to be collected for all tests, which have been defined by the Department of Health and Human Services (HHS), along with technical specifications for implementation for lab-based[10] and non-lab-based[11] tests.

F. PRODUCT MANUFACTURING

The ***[name of collection kit]*** has been validated using only the components referenced in this request and will not be changed after authorization without concurrence from the FDA.

1) Overview of Manufacturing and Distribution:

[Please provide information for the collection kit consistent with the recommendations in the Molecular Diagnostic Template for Test Developers.]

[8] Available at https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html *(last accessed on July 7, 2021). Note this website is not controlled by FDA.*
[9] Available at https://www.hhs.gov/coronavirus/testing/covid-19-diagnostic-data-reporting/index.html *(last accessed on July 24, 2021). Note this website is not controlled by FDA.*
[10] Available at https://www.hhs.gov/sites/default/files/hhs-guidance-implementation.pdf *(last accessed on July 24, 2021). Note this website is not controlled by FDA.*
[11] Available at https://www.hhs.gov/sites/default/files/non-lab-based-covid19-test-reporting.pdf *(last accessed on July 24, 2021). Note this website is not controlled by FDA.*

2) ***Components and Other Materials/Information Included with the Home Collection Kit***

Components manufactured by ***[developer's name and FDA registration number (if applicable)]*** and included with the home collection kit include:

[List all components and other materials/information included with your home collection kit, including descriptions, volumes, concentrations, quantities, buffer components, etc. If you plan to use non-traditional sources of swabs or media, please describe your qualification testing and validation procedures.]

Collection media that contain hazardous or irritating materials (such as guanidinium salts) should not be used for home collection unless the collection device has specific safety features to mitigate the risk of patient exposure (such as releasing preservative only when the container lid is closed). ***[Present a detailed assessment of the toxicology profile of the components of your assay and proposed assay labeling that informs users of the risks associated with use of your device, as well as any recommendations for personal protective equipment. Please specify the volumes and concentrations of each reagent included in your test kit.]*** **FDA will conduct an independent risk assessment to determine if the proposed mitigations are appropriate for all collection media and containers.**

The swab type included in the kit should be appropriate for collection of samples from the intended anatomical site (i.e., nasal swab for anterior nasal swab collection) and safe for home collection.

Example: Kit components

Name	Description	Quantity	Material Supplier	Catalog Number

3) ***Reagent Stability:***

[Please provide information consistent with the recommendations in the Molecular Diagnostic Template for Test Developers.]

G. PERFORMANCE EVALUATION

The following recommended validation studies should be performed during your home collection kit development. ***[For each validation study, you should provide a study protocol that includes detailed, step-by-step description of how samples were prepared and how testing was conducted. You should also include the complete study line data from each validation study in an Excel-compatible spreadsheet format for all validation studies.]***

1) ***Home Collection Sample Stability Study Design:***

If your kit will use foam or wrapped polyester nasal swabs transported in 0.9% saline, PBS, or dry tubes, you may reference summer stability studies conducted by Quantigen Biosciences,[12] with support from The Gates Foundation and UnitedHealth Group and do not have to perform your own separate summer stability study for sample transport.

If your kit will use foam or wrapped polyester nasal swabs transported in dry tubes, you may also reference winter stability studies conducted by Quantigen Biosciences, with support from The Gates Foundation and UnitedHealth Group and do not have to perform your own separate winter stability study for sample transport.

If you are shipping a dry swab, you should also provide a rehydration SOP for laboratories to use and provide validation data for the rehydration protocol.

The proposed study design is for validation of home sample collection for nasal swab samples in media (you should test all media you intend to use for shipping), or saliva. Testing should include 20 spiked samples at 2x LoD (low positives) and 10 spiked samples at 5-10x LoD (high positives). We also recommend testing 10 negative samples to monitor for false positives. Spiked swab samples should be generated by spiking virus onto swabs and placing the swab in media, if appropriate. Diluted clinical samples can be used for spiking or you can use clinical samples spiked with inactivated whole virus. Ideally, spiking material should be prepared with clinical matrix that most closely replicates a clinical sample.

Table: Sample Panel

Sample	Replicates	Titer
Low Positive	20	2 times LoD
High Positive	10	5-10 times LoD
Negatives	10	Not applicable
Total	**40**	

The shipping study is designed to simulate the following situations during home sample collection and shipping:

- **Storage of samples before the customer ships the sample**
- **Sample sitting in mailbox or drop box waiting for pick-up**
- **Shipping conditions after pick-up, when the sample is shipped to testing lab**

General Acceptance Criteria:

- **Low Positive Samples: ≥95% agreement with expected results.**
- **High Positive Samples: 100% agreement with expected results.**
- **Negative Samples: 100% agreement with expected results.**

[12] Quantigen Biosciences has granted a right of reference to any sponsor wishing to pursue an EUA to leverage their COVID-19 swab stability data as part of that sponsor's EUA request.

The tables below describe each temperature profile to replicate worst case scenario shipping conditions (for spring/summer and winter) for an 8 hour wait at the customer's house before shipping and then a subsequent 48-hour shipping cycle. If you plan to allow testing of samples that have been shipped by 3-5-day mail, please expand the shipping study times below. If you plan to store samples at the laboratory site after receipt for extended period of times, or at the collection site before shipment, this should also be added to the stability study as additional cycle periods. The complete sample panel in the Table below should be cycled through the temperatures and times below and then tested with a molecular diagnostic test for SARS-CoV-2 that will be used with your collection kit that produces a cycle threshold (Ct) value. FDA expects that the samples not only remain positive, but that the Ct value does not appreciably increase (more than 3 Ct).

Table: Summer Profile *

Temperature	Cycle Period**	Cycle Period Hours	Total Time Hours
40°C	1	8	8
22°C	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56

**Cycle Period refers to the sequential events (e.g. cycling between temperatures for the indicated duration (in hours))

Table: Winter Profile*

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours
-10C	1	8	8
18C	2	4	12
-10C	3	2	14
10C	4	36	50
-10C	5	6	56

*Shipping conditions for cycle periods 2 through 5 are modeled after International Safe Transit Association (ISTA) 7D 2007 shipping standard (48-hour domestic freight transport) where for cycle period 3 and 5 the temperature has been increased from 35°C to 40°C. The cycle period 1 (8 hours) has been included for the time delay between collection of the sample and shipment of the sample. The remaining time (48 hours) covers the domestic shipment within the continental U.S. Cycle periods are sequential with the "cycle period hours" required per cycle listed in the table. After each cycle period, the "total time hours" increments by the number of hours in the cycle period.

2) Usability Study:

FDA recommends that usability studies (for the purpose of this template, usability studies are studies that assess the ability of an intended lay user to follow labeling

instructions for collecting, packaging, and shipping samples under expected use conditions without serious use errors) be completed prior to initiating clinical agreement studies to address potential issues in instructions, packaging, and shipping procedures that could impact clinical agreement assessments. You may contact FDA for feedback on your collection and shipping procedures and quick reference instructions (QRI), when planning these studies. If conducted prior to the clinical agreement study, any use errors identified from this evaluation can be used to modify your instructions and/or procedures prior to starting your clinical studies, where you would then validate the final instructions for use during the clinical performance study(ies).

FDA recommends the following study design to assess usability of instructions for home collection and mailing the sample to a CLIA-certified lab for testing:

- **Testing should include a minimum of 30 participants and take place in an actual use environment or simulated environment. If you plan to include children in your intended use population, your study should include at least 15 children for each intended age group.**
  - **Children 2y-13y (child/adult pairs where parent collects sample from child).**
  - **Children 14-17y (child collects sample with or without assistance from parent).**
- **The entire workflow should be performed by each individual participant using the kit, including kit registration, sample collection, packaging of the sample, and mailing to the laboratory with pre-prepared label.**
- **Collection should be performed using the quick reference instructions only. The development of supplemental on-line instructional materials/videos are encouraged but should not be used during the study.**
- **The participants should be observed (either in person or by remote visual monitoring, such as a video conference) during sample collection and all difficulties should be noted.**
- **After the entire process is completed the user should be given a questionnaire to indicate the ease of use of the kit and sample collection as well as understanding the consequences if steps are not performed correctly. The participant should be able to provide comments if needed.**
- **The laboratory personnel should inspect the packaging and sample upon delivery, following the accessioning procedure, and note all packaging errors and acceptability of the sample for testing.**
- **Participants should include individuals representing varying education levels and ages. Participants with prior medical or laboratory training should be excluded. Ideally, participants who have prior experience with self-collection should be excluded. If you are having difficulty enrolling naïve users, you may enroll some users with self-collection experience, but this information should be captured in your data.**
- **The samples collected during the study should be tested for sample adequacy using a human sample control assay. This could include using an EUA-authorized assay that includes a human sample control (e.g., RNaseP) to**

determine if sufficient sample was collected by the user. Alternatively, the laboratory could run a separate FDA-cleared RT-PCR test for each sample that targets a human housekeeping gene. FDA is open to considering alternative methods that assess adequate sample presence and/or quality.

- **The study should have pre-defined acceptance criteria and a defined strategy to mitigate risk of errors identified in the study (e.g., modifying the instructions).**

  Significant modifications to mitigate observed errors may necessitate additional usability data to ensure the modifications are effective at mitigating the occurrence of errors.

  See the FDA guidance document "*Applying Human Factors and Usability Engineering to Medical Devices*"[13] for additional information about conducting a usability study.

[Please provide FDA with the version of the instructions that was used in the usability study and resulting summary and line data from your usability study.]

3) User Comprehension:

User comprehension studies are intended to objectively assess the intended user's understanding/comprehension of critical elements and concepts in the labeling. FDA recommends performing a study to validate and confirm user comprehension of test results (e.g., positive, invalid, and negative results) and instructions for use. *[You should provide data to verify that users access their test results within a quick time frame (e.g., 24-48 hours).]*

If you do not perform this study, it is a best practice to have a health care professional (HCP) contact patients (phone call or text message) with positive and invalid results.

4) Post Authorization 30 Day Report:

If your home collection kit is authorized, FDA may include a Condition of Authorization in your EUA requiring you to submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using your home collection kit during that timeframe, including how many kits were sent to individuals or patients, how many samples were received, how many samples had to be rejected during accession and the main reasons for rejection, and the positivity rate for samples collected with the authorized self-collection kit. In such cases, this table is provided as a recommended format in which to provide the data, which can be modified to best suit your device, accessioning criteria, and user feedback.

[13] Available at https://www.fda.gov/media/80481/download.

Description	Total # of Samples	% of Total Samples
Number of samples received		
Number of samples that had to be rejected		
• Leaked samples due to damage to container		
• Quantity not sufficient		
• Sample not labeled		
Number of sample that had to be repeated		
Number of Invalid sample		
Self-collection positivity rate		

H. UNMET NEED ADDRESSED BY THE PRODUCT

This section will be completed by FDA.

I. APPROVED/CLEARED ALTERNATIVE PRODUCTS

There is no adequate, approved, and available alternative to the emergency use of the product.

J. BENEFITS AND RISKS:

This section will be completed by FDA.

K. FACT SHEET FOR HEALTHCARE PROVIDERS AND RECIPIENTS:

During review, FDA will make available Fact Sheet templates. See examples for authorized tests and home collection kits on our website.[14]

L. INSTRUCTIONS FOR USE/ PROPOSED LABELING/PACKAGE INSERT:

[You should include Instructions for Use, Box Labels, Vial Labels, and any other proposed labeling for the test and/or home collection kit.]

User Labeling:

[You should submit for review your packaging and directions for your specimen collection kit.] **FDA will review these documents for their ease of use and clarity of**

[14] A list of EUA-authorized tests and collection kits and their accompanying fact sheets are available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

instructions. We recommend all directions be written at a 7th grade reading level or below.

The following should be included on the outer box of a home collection kit:

- **Expiration date (sticker): Based on component of kit with the earliest expiration date**
- **For Emergency Use Authorization (EUA) only**
- **For in vitro diagnostic use**
- **Must be 18+ to use this kit (as applicable)**
- **Storage temperature**
- **Summary of box contents**
- **Items necessary to use the kit: e.g., access to computer/smartphone, internet, email account**
- **Summary of how the kit works.**
- **FDA warnings from EUA letter of authorization:**
    - **Standalone kit:**
        - **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 *[add all claimed sample types, i.e., nasal swabs and/or saliva]* 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.**
    - **Kit/Assay Combination:**
        - **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 detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and**
        - **The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal, Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.**

The FDA recommends providing a link or Quick Response (QR) code to an instructional video for sample collection and packaging/shipping of sample (i.e., requiring users to watch instructional video prior to kit registration).

M. RECORD KEEPING AND REPORTING INFORMATION TO FDA:

As allowed by Section 564(e) of the FD&C Act, FDA may require certain conditions as part of an EUA. FDA generally includes the following record keeping and reporting information requirements in the EUA.

[Test Developer name] will track adverse events and report to FDA under 21 CFR Part 803. A website is available to report adverse events, and this website is referenced through the ***[Test Developer name]*** Product Support website: ***[Include link to Test Developer's Website]***. Each report of an adverse event will be processed according to ***[Test Developer name]***'s Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, ***[Test Developer name]*** will also maintain records of device usage/purchase. ***[Test Developer name]*** will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which ***[Test Developer name]*** becomes aware. ***[Test Developer name]*** will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.