EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE AUDERE HEALTHPULSE@HOME
For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only
For Use by Individuals 16 Years of Age and Older when Self-collected
For Use by Individuals 2 Years of Age or Older when Collected with Adult Assistance

Anterior nasal swabs collected at-home (which includes in a community-based setting) using HealthPulse@home collection kits will be sent to laboratories that have been designated by Audere, consistent with this EUA. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and test the specimens collected with a HealthPulse@home collection kit for COVID-19 using an in vitro diagnostic (IVD) molecular test that is indicated for use with the HealthPulse@home collection kit.

INTENDED USE

The HealthPulse@home collection kit is intended for use by any individual aged 16 years and older (self-collected) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, for collection of anterior nares (nasal) swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider.

Testing is limited to laboratories designated by Audere that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests when such laboratories assemble and use a collection kit that conforms with the HealthPulse@home Emergency Use Authorization (EUA).

Anterior nasal swab specimens collected using HealthPulse@home (i.e., a collection kit that is assembled and conforms with the specifications outlined by HealthPulse@home EUA) can be transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the anterior nasal swabs specimen is maintained in the specimen packaging and suitable for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with HealthPulse@home.

HealthPulse@home is only for use under the Food and Drug Administration's Emergency Use Authorization.

SPECIAL CONDITIONS OF USE STATEMENTS

For In vitro Diagnostic Use
For Prescription Use Only
For Emergency Use Authorization (EUA) Only
For use by individuals 16 years of age and older when self-collected
For use by individuals 2 years of age or older when collected with adult assistance

Audere HealthPulse@home is only authorized for use in conjunction with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with anterior nasal swab specimens collected with collection kits that conform to the HealthPulse@home EUA.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***DEVICE DESCRIPTION:***

Audere HealthPulse@home contains instructions to assemble specimen collection kits with specified components that can be purchased as general purpose laboratory equipment to facilitate the unsupervised self-collection or caregiver collection of anterior nasal swab specimens either on-site or at home, for testing with molecular SARS-CoV-2 tests authorized for use with HealthPulse@home.

The HealthPulse@home conforming specimen collection kit consists of a sterile 3-inch spun polyester swab and a sterile, capped polypropylene collection tube for the anterior nasal collection of a specimen and the subsequent dry transport of the specimen to a CLIA certified laboratory.

Anterior nasal swab specimens are collected from patients for COVID-19 testing based on a clinician's in-person or remote assessment and prescription. HealthPulse@home conforming collection devices are for dry collection of anterior nasal swab specimens.

Authorized laboratories must use the HealthPulse@home conforming collection kit with a molecular test that is authorized for use with HealthPulse@home. Upon contracting with Audere, HealthPulse@home may be used by CLIA-certified laboratories to assemble their own HealthPulse@home conforming specimen collection kits for use with their own molecular test for which they have two options:

1. The laboratory can either use a commercial test, that is authorized for use with HealthPulse@home, or
2. The laboratory can include in the Intended Use of their own molecular SARS-CoV-2 test a claim for home collected samples using a HealthPulse@home conforming home collection kit, by:
    a. Filing their own EUA (for previously unauthorized molecular SARS-CoV-2 tests), or by
    b. Filing an EUA supplement (for previously authorized molecular SARS-CoV-2 tests).

However, the laboratories do not need to file a separate EUA for their HealthPulse@home conforming home collection kit. Instead, authorized laboratories can reference the following validation data from Audere's HealthPulse@home EUA (a RoR will be provided to them by Audere upon contracting) when submitting their own EUA request for a molecular test that has not been previously authorized for use with the HealthPulse@home:

1. The usability study
2. The sample stability study (Except when the laboratory's stability claims exceed the stability claim validated by Audere)

While authorized laboratories must use kits assembled with HealthPulse@home specified components they may define their own branding of the HealthPulse@home conforming collection kit (if desired) per the labels of the collection kit. Authorized laboratories will identify the HealthPulse@home conforming collection kit as being assembled by/for Audere and will use the following components/aspects of HealthPulse@home for their collection device:

- The kit IFU templates in which they may customize the following:
  - Lab branding of the instructions to match the branding of their kit.
  - Lab specific kit registration instructions (including a website for kit registration and activation).
  - Lab specific instructions for returning a kit to the lab on the same day it is collected (e.g., shipping a kit back to a lab or dropping a specimen off at a designated location).
  - Lab specific kit IFU imagery.
  - Lab specific tube labeling.
  - Lab specific packaging and labeling
- The return to lab timing as validated and documented in this EUA.
  - Audere will work with each lab to ensure that the language in the IFU communicates the appropriate time frame for shipping a kit back or dropping it off based on schedules for the chosen carrier or drop-off location. The upper right-hand corner of the IFU template indicates when the kit needs to be dropped off or shipped back. Audere approves all laboratory's specific IFUs.
- An endogenous sample control, such as RNase P, for unobserved collections (unless such requirement is not, or no longer, part of the test's authorization based on data the authorized laboratory provided to FDA).

Authorized laboratories may define their own eligibility/ordering process as well as their own process for results delivery to patients and their HCP. However, a prescription must be issued prior to collection kit ordering and result reporting must include the HCP communicating all test results to the individuals.

Audere will use supplier management controls to ensure that the authorized laboratory meets the requirements of this EUA.

2) ***HOME COLLECTION KIT ORDERING AND PROCESSING***

HealthPulse@home conforming specimen collection kits enable the collection of an anterior nasal swab specimen by an individual that is then transported to a partnering lab for processing.

a) Medical Oversight (Kit Ordering and Eligibility)

Medical oversight of the process is provided by the healthcare provider who is ordering the test. HealthPulse@home conforming specimen collection kits will only be distributed to patients who were previously qualified for SARS-CoV-2 testing. The healthcare professional may directly request (prescribe) a HealthPulse@home conforming specimen collection kit for an individual based on their clinical evaluation of a patient. This clinical evaluation could be, as a result of, but is not limited to, a clinician encounter or part of a public health outreach program (e.g., contact tracing based on a potential exposure, community drive-through collection, etc.). The test may be ordered using an offline process or an online platform that is provided by the participating laboratory. If using an online platform, the lab has the option to use their own website, or a website provided through Audere's partner.

The HealthPulse@home conforming specimen collection kit collects anterior nasal swab specimens which are tested for SARS-CoV-2 and used for the transportation and short-term storage of a specimen en-route to a lab (not using cold-chain storage). Collected specimens will be tested for RNA using SARS-CoV-2 molecular diagnostic assays that have been issued an EUA and are authorized for use with HealthPulse@home.

Test results are returned to the ordering clinician, who is ultimately responsible for releasing results to the patient verbally and/or electronically. Individuals cannot directly order a HealthPulse@home conforming specimen collection kit.

b) Collection Kit Delivery

Upon determination of eligibility for testing, the individual is provided with a HealthPulse@home conforming specimen collection kit, either through pickup from a central location or delivery via a delivery service. Each kit has a unique ID affixed to the kit box. The same unique ID is affixed to the collection tube included in the kit.

c) Kit Registration & Usage Instructions

The individual using the HealthPulse@home conforming specimen collection kit performs the following steps to register their kit and collect the specimen:

- Registers their kit using processes and procedures defined by the lab that are consistent with the HealthPulse@home EUA which enable associating a unique ID on the kit to an individual being tested (e.g., QR-codes)
- Schedules a pickup of their completed collection kit or plans where to drop off their collection kit
- Washes their hands and clears their nose

- Opens the swab
- Performs an anterior nasal collection. Using the same swab, for both nostrils, the individual:
  - Gently inserts the soft tip of the swab until resistance is felt
  - Using medium pressure, rubs the swab slowly in a circular motion around the inside of the nostril four times. The swab tip should be touching the inside wall of the nostril through each rotation.

After the anterior nasal swab specimen is collected:

- The swab is inserted into the collection tube and the tube is sealed
- The individual fills out information on the collection tube label as specified by the lab.
- The tube is placed into the provided bio-specimen transport bag and the bag is sealed
- The individual is instructed to place the bio-specimen transport bag into the original specimen collection kit box, protecting the specimen during transit
- The individual is subsequently instructed to place the box in the provided UN3373 bag for transport if their specimen is being shipped.

d) Kit Return to Lab - Device Shipping

For collection kit return, the individual is instructed to plan how to drop off or ship their specimen to the lab within 24 hours of collecting the specimen. The specimen must reach the lab within 48 hours of collection. The IFU includes instructions optimized to ensure delivery of specimens to the lab within that time frame, with a preference for same day collection and shipment to the lab.

Collected specimens are returned from an individual to a CLIA-certified lab via FedEx or an alternative carrier.

HealthPulse@home was reviewed by the Department of Transportation (DoT) for adherence to shipping requirements for hazardous materials. The kit was found to be acceptable and appropriate for shipping within the United States. Separately, FedEx reviewed the HealthPulse@home return shipping plans and determined the return shipping met their requirements.

e) Specimen Accessioning

Specimens collected using the HealthPulse@home conforming specimen collection kit and received at the clinical laboratory for testing undergo the below accessioning checks prior to acceptance for testing. If one or more of the accessioning checks do not pass, the specimen will not be processed:

- **Incorrect specimen packaging** - sample not returned in the supplied packing materials; sample not in the correct collection/transport tube
- **Missing order** - the patient erroneously received the kit
- **Missing registration** - the patient failed to register the kit per the lab's instructions

- **Invalid collection tube information -** the patient erroneously writes information that should uniquely identify the sample on the collection tube or entirely omits adding the requested information, such as name, DOB, time and date of collection

Delayed return of sample: the sample is not received within the established sample stability claims**.**The accessioning criteria are part of the HealthPulse@home contracts between Audere and the participating laboratory sites.

2) *AUTHORIZED LABORATORIES*

For HealthPulse@home, testing is limited to use of the below assays when authorized for use with HealthPulse@home conforming collection kits used to collect anterior nasal swab specimens, and when performed consistently with the authorized labeling:

- **LumiraDx (EUA202584/S007)**

3) *TEST RESULTS AND INTERPRETATION*

a) Assay Controls to be used with the authorized SARS-CoV-2 IVD molecular test

Accepted specimens are tested using an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with anterior nasal swab specimens collected with the HealthPulse@home conforming collection kit. Controls to be used with COVID-19 molecular tests authorized for use with the HealthPulse@home conforming collection kit depend on the specific test used. The authorized IVD molecular test must be performed according to the authorized instructions for use and must incorporate at a minimum:

1. **Negative Control**: A negative (no template) control is required to eliminate the possibility of sample contamination on the assay run and is used on every extraction or assay plate. If the participating testing site choses to not use this control as a full process control (i.e., laboratories performing molecular tests that employ a separate RNA extraction and purification step would include this control into the extraction step), then the additional Negative Extraction Control (see below) needs to be included in the testing.
2. **Positive Control**: A positive template control is required to verify that the assay run is performing as intended and is used on every assay plate starting at master mix.
3. **Endogenous Internal Control**: Unless the participating laboratory site has provided data to FDA demonstrating a negligible invalid rate that eliminates the need of such control with unobserved self-collected specimens, an endogenous internal control targeting e.g., RNase P RNA is required for home collected samples using HealthPulse@home to verify sample integrity and the presence of nucleic acid in the sample. This also serves as the extraction control for those molecular tests that are employing a separate RNA extraction and purification step, to ensure that samples resulting as negative contain nucleic acid for testing.

4. **Negative Extraction Control (Optional)**: If the participating laboratory performs a molecular test that employs a separate RNA extraction and purification step and chooses to include the negative Control (above) in the extraction step, this control is optional. If the negative Control (above) is only included in the sample processing steps downstream of an RNA extraction step, then this control is mandatory for each extraction run. This control monitors for any cross-contamination that occurs during the extraction process, as well as the extraction reagents and successful RNA extraction.

All controls must generate expected results in order for a test to be considered valid, as outlined in its authorized labeling.

b) INTERPRETATION OF RESULTS

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. COVID-19 test results must be interpreted according to the instructions for use for the authorized IVD. Typically, COVID-19 test results are divided into "positive" (synonyms: reactive, detected), "negative" (synonyms: non-reactive/not detected), and "invalid" (no result), but can also include a result of "indeterminate" (synonym: inconclusive) for samples that do not demonstrate presence of all assay targets. Indeterminate (inconclusive) results generally require additional testing. The test report will then be delivered to both the ordering healthcare provider and the patient/adult caregiver. Patients/adult caregivers will have the opportunity to discuss the test results with a healthcare provider.

PERFORMANCE EVALUATION

1) *DRY SWAB SAMPLE STABILITY STUDY*

Quantigen Biosciences, with support from the Bill & Melinda Gates Foundation and UnitedHealth Group conducted a stability study of an anterior nasal swab sample using dry transport. Results from this study demonstrated that a SARS-CoV-2 positive anterior nasal swab sample in a dry transport tube is stable with overnight or 48-hour (+8 hr) shipping, including a high temperature excursion (12 hr at 40°C, 34 hr at 32°C, 2 hr RT). Dry specimens were also shown to be stable through up to two freeze-thaw cycles. The findings support the stability of dry anterior nasal swab specimens collected using a HealthPulse@home conforming specimen collection kit and was published in L.R. Padgett et al 2021. Quantigen Biosciences has granted a right of reference to their data to any sponsor wishing to pursue an EUA. A summary of the study results is provided below.

a) Summer Profile Specimen Stability Study:

The Summer Profile Specimen Stability Study of the anterior nasal swab specimen

transported in saline or dry was conducted by Quantigen Biosciences, with support from the Gates Foundation and UnitedHealth Group. Quantigen Biosciences has granted a right of reference to any sponsor, wishing to pursue an EUA to leverage their COVID-19 swab stability data for Summer Profile Specimen Stability of anterior nasal swabs in saline, and or dry as part of that sponsor's EUA request.

Briefly, two SARS-CoV-2-positive pools (2xLoD and 10xLoD based on an EUA authorized test) were contrived by combining SARS-CoV-2- negative human/porcine matrix with previously confirmed, high-positive patient specimens. The 2xLoD and 10xLoD pools were added directly to swabs through a procedure that mimics a nasal swabbing action: swabs were submerged into a reservoir of either 2xLoD or 10xLoD mixture and "abraded" against the side of the (Eppendorf style) tube while the viral solution absorbs into the swab (whether foam or polyester). A total of 5 replicates was tested for the un-stored control condition a T0, and 20 and 10 replicates were tested for the 2x LoD and the 10xLoD specimens, respectively, for each stress testing timepoint (T1).

For the "Dry Swab" arm of the experiment, swabs were placed into a sealable tube "dry" (i.e., with no additional media). For the "Wet Saline Swab" arm of the experiment, swabs were placed into 1 mL saline.

Swabs were then incubated at 40℃ for 12 hours, followed by 32℃ for 18 or 42 hours, respectively (see *Table 1* below). Specimens were allowed to equilibrate to room temperature for 2 hours before testing.

Table 1: Sample Stability - Summer Temperature Stress Profile

Temperature	Cycle Period	Cycle Period Hours	Total Time Hours*
40°C	1	12	12
32°C	2	42	54
RT (equilibration before extraction)	3	2	56

Specimens were tested using the EUA authorized test at time 0-, 32-, and 54-hours post-incubation. *Table 2* below summarizes the results from the maximum stress condition (i.e., 40℃ for 12 hours, followed by 32℃ for 42 hours, followed by 2 hours RT equilibration).

Table 2: Stability of Swab Samples Exposed to Summer Temperature Stress (56 Hours)

Swab	Time	Positivity Rate [R_+/R_{tested}]	Concen-tration	N		ORF1ab		S Gene	
				Mean Ct	ΔCt*	Mean Ct	ΔCt*	Mean Ct	ΔCt*
Polyester [DRY]	T0	5/5	2xLoD	32.06	0.63	29.57	0.73	31.69	-1.18
	T1	20/20		31.43		28.84		32.87	
	T0	5/5	10xLoD	29.06	-0.35	26.54	-1.23	27.84	-2.23

	T1	10/10		29.41		27.77		30.07	
Foam [DRY]	T0	5/5	2xLoD	32.3	-0.64	29.95	-0.03	31.93	-3.04
	T1	20/20		32.9		29.95		34.96[#]	
	T0	5/5	10xLoD	29.41	-0.15	27.23	-0.77	28.81	-0.63
	T1	10/10		29.56		27.90		29.44	

*ΔCt=Mean Ct $_{T0}$-Mean Ct $_{T48;}$
[#]2/20 replicates for wet polyester swabs and 7/20 replicates for dry foam swabs were negative for the S target with Ct values that were either negative or above the cutoff.
T=0 unstressed Control; T1= Temperature Stress as detailed in *Table 1*.

The acceptance criteria laid out for the study was a 95% agreement or greater for positive specimens. Both time points met this criteria and supported specimen shipping stability, using a drop box, with over-night or 48-hour shipping.

b) Winter Profile Specimen Stability Study (Dry Swabs)

Multiple studies were performed to assess sample stability upon exposure to winter temperature extremes and freezing cycles. A 10x LoD SARS-CoV-2 positive sample (based on an EUA authorized test) was generated by spiking a matrix (see below) with a confirmed SARS-CoV-2 positive patient sample. Experiment 1 was performed using porcine clinical matrix as a surrogate - similar to the design of the summer stress testing above – and three freeze/thaw cycles were performed per *Table 3* below. Experiment 2 was performed in human clinical matrix using only two freeze/thaw cycles per *Table 3* below.

To create the SARS-CoV-2 positive swabs, the 10 x LoD positive matrix was added directly to cotton swabs through a procedure that mimicked a nasal swabbing action. Each swab was submerged into a single 1.5 mL microcentrifuge tube containing 40 µL (2500 GCEs) of the 10 x LoD mixture and "abraded/circled" five times in a single direction against the tube wall, followed by five times in the opposite direction while the viral solution absorbed into the swab. The inoculated swab was returned to a dry 15 mL conical tube with a screw cap and subjected to several freeze-thaw cycles to simulate the effect of winter transport conditions on SARS-CoV-2 stability.

Table 3: Sample Stability - Winter Temperature Stress Profile

Temperature	Freeze Thaw	Cycle Period Hours	Total Time Hours*
-17°C	1	17	17
RT (25-27°C)		4	21
-20°C	2	20	41
RT (25-27°C)		4	45
-20°C	3	20	65
RT (25-27°C)		4	69

* Cycle periods are sequential. After each cycle period, the "total time hours" increments by the number of hours in the cycle period.

Swabs were eluted in 1 mL of PBS per dry swabs. Swabs were vortexed for 30 seconds with intermittent pulsing and then incubated at room temperature for at least 10 minutes before extraction. SARS-CoV-2 testing was performed using the same EUA authorized test as for the summer temperature stress conditions (above).

At each time point 10 replicates were tested, and delta Ct values (Control – Test) were calculated for each target in the EUA authorized test. Samples were interpreted per result interpretation of the EUA authorized test and results are summarized in *Table 4* below – The MS2 internal control values are not included in *Table 4* and *Table 5*.

Table 4: Stability of 10xLoD Dry Swab Samples in Porcine Matrix Exposed to Winter Temperature Stress

Time	Temp	N		ORF1ab		S Gene	
		Mean Ct	ΔCt	Mean Ct	ΔCt	Mean Ct	ΔCt
T=0	n/a	29.4	n/a	29.4	n/a	30.4	n/a
1 Freeze/Thaw	Control	29.4	-0.1	29.1	-0.1	30.6	0.0
	Test	29.5		29.2		30.6	
2 Freeze/Thaw	Control	29.3	-0.1	29.2	-0.2	30.3	-1.0
	Test	29.4		29.3		31.3	
3 Freeze/Thaw	Control	29.5	-0.1	29.4	-0.5	30.6	-1.1
	Test	29.9		30		31.8	

A second experiment was performed with only 2 freeze thaw cycles per *Table 3* above) but using paired negative clinical matrix (dry anterior nasal swabs) from individual patients to generate the control and test conditions for 10 patient samples. Samples were tested at time 0 and after completion of the two freeze thaw cycles. Additional RNase P testing was performed for this experiment; however, RNase P results are not included in the result table below. This experiment was repeated a second time in almost identical manner with similar results. Results for the SARS-CoV-2 targets are summarized in *Table 5* below.

Table 5: Stability of 10xLoD Dry Swab Samples in Human Matrix Exposed to Winter Temperature Stress

Time	Temp	N		ORF1ab		S Gene	
		Mean Ct	ΔCt	Mean Ct	ΔCt	Mean Ct	ΔCt
Negative swabs stored a 4°C over night before spiking							
T=0	n/a	29.5	n/a	29.5	n/a	30.5	n/a
2 Freeze/Thaw	Control	29.5	-0.3	29.3	-0.6	30.7	-1.1
	Test	29.7		29.9		31.8	
Negative swabs stored a 4°C for 4 hours before spiking							
T=0	n/a	29.8	n/a	29.4	n/a	31.0	n/a

2 Freeze/Thaw	Control	29.7	-0.5	29.7	-0.8	31.0	-0.7
	Test	30.1		30.5		31.6	

In summary, all tested swabs spiked with high SARS-CoV-2 positive clinical sample at 10 x LoD (based on the EUA authorized test) resulted in 100% agreement with expected results indicating that specimens transported under dry, winter conditions (-20 to 4°C) are stable for the detection of SARS-CoV-2 and RNase P for up to 70 hours and including three freeze-thaw cycles. Moreover, swabs stored at 4°C are indistinguishable from those exposed to two freeze-thaw cycles in the detection of SARS-CoV-2 RNA and RNase P RNA. There was no effect of the temperature stress on the detection of SARS-CoV-2. These studies support a claim of 56 hours sample stability under winter temperature fluctuations.

2) ***DRY-SWAB REHYDRATION EQUIVALENCY***

Rehydration of the swab in different volumes of PBS and saline (i.e., 0.7mL and 1mL), are supported by swab equivalence studies performed by Lumira Dx and included by reference. A RoR letter was provided to Audere by Lumira Dx. The equivalency studies were performed as part of the LoD studies using heat-inactivated Severe Acute Respiratory Syndrome Related Coronavirus 2 (SARS-CoV-2) strain 2019nCoV/USAWA1/2020 (ATCC VR1986HK) diluted in clinical matrix. The studies demonstrated similar sensitivity of the Lumira Dx SARS-CoV-2 RNA STAR Complete test with both rehydration volumes as indicated in the table below:

Table 6: LoD Equivalency with 1mL and 0.7mL Rehydration Volume

	Elution Volume	**Processing Instrument**	**LoD Copies/Swab**
Dry Swab	1mL	96-Well	1,875
		348-Well	9,000
	0.7mL	96-Well	1,875
		348-Well	6,000

3) *HUMAN USABILITY STUDIES FOR THE HEALTHPULSE@HOME SELF-COLLECTION KIT FOR COVID-19:*

IRB-reviewed human usability studies were conducted by Audere to confirm proper, unassisted (adults) and assisted (pediatrics) self-collection by individuals and return of their specimen to a lab. After each participant consented to participate in the study, they were sent a HealthPulse@home conforming specimen collection kit. Participants were observed registering the kit, completing a nasal swab specimen collection, arranging to ship the sample to the lab, and preparing the specimen for shipment. After the package was prepared, they were asked to complete a follow-up survey. A study coordinator observed adherence to each step without providing any instructions.

a) Usability Study Results: Adult Population

i. Study Description

The adult study recruited 35 participants from across the mainland United States in actual home-use environments. One participant was unavailable to participate after recruitment, and one participant's kit was not received at the lab.

Over 88% of the participants were assessed as having 'no difficulty' or just a 'little difficulty' completing any single step in the process, meeting study targets. The kit registration process, which required entry of both a registration ID and barcode from the kit packaging, obtained an 88% (29) adherence rate. All other steps received from 91% (30) to 100% (33) adherence rate. Audere will continue to track user success and error rates during usage to identify additional areas for improvement in user instructions and overall user experience.

Each specimen sent back to the lab was tested for RNase P to confirm adequate, unassisted sample collection. The mean Ct value across all lab tested specimens (33) was 26.4, with a median Ct value of 25.0, indicating successful sampling of human biological material.

ii. Demographics

Table 7: Characteristics of Adult Study Population

Characteristics of Adult Study Population		**N = 33**	**Percent**
Gender	Male	16	48%
	Female	17	52%
Age	18-30	10	30.3%
	31-40	9	27.3%
	41-540	6	18.2%
	551-64	4	12.1%
	>=65	4	12.1%

Characteristics of Adult Study Population		N = 33	Percent
Ethnicity	Hispanic or Latino	5	15%
	Other	28	85%
Race	Asian	3	9%
	Black or African American	4	12%
	Other	2	6%
	White or Caucasian	24	73%
Education Level	Grade 12 or GED	3	9.1%
	Some college, no degree	12	36.4%
	Associate degree (~2 years College)	1	3%
	Bachelor's degree (~4 years College)	10	30.3%
	Graduate or professional degree	7	21.2%
Geographic Location (State or District)	AZ	1	3%
	CA	4	12%
	CO	1	3%
	CT	2	6%
	FL	1	3%
	IL	2	6%
	IN	1	3%
	MN	1	3%
	MO	1	3%
	NJ	4	12%
	NV	1	3%
	NY	3	9%
	OH	2	6%
	OR	1	3%
	VA	3	9%
	TX	4	12%
	WA	1	3%

iii. Observational Results:

Table 8: Format of Collection Instructions Used in the Adult Study

Instruction format usage		N = 33	Percent
Instruction format used	Digital	17	76%
	Paper*	1	3%
	Combination	7	21%

*At least one action taken beyond registering using paper instructions.

Table 9: Observer Notes on Adult Self-Collection

Task	Pass (no difficulty or only a little difficulty)	Failure (a lot of difficulty)
Getting started (Correct/Total)	32/33 (97%)	1/33 (3%)
Register kit	29/33 (88%)	4/33 (12%)
Plan for drop-off or pickup	32/33 (97%)	1/33 (3%)
Wash hands (pre)	32/33 (97%)	1/33 (3%)
Open nasal swab	33/33 (100%)	0/33 (0%)
Swab nose	33/33 (100%)	0/33 (0%)
Put swab in tube	33/33 (100%)	0/33 (0%)
Fill out info on tube	33/33 (100%)	0/33 (0%)
Wash hands (post)	33/33 (100%)	0/33 (0%)
Prepare and send kit	32/33 (97%)	1/33 (3%)

Table 10: Ship-Back Option Used in the Adult Study

Ship-back to lab option chosen by participant	N =33
Drop-off*	6 (18%)
Pickup scheduled by phone	0 (0%)
Pickup scheduled online	27 (82%)

*6 participants stated intention to drop-off but there were some moderator interventions due to the day of the week or unusual circumstances (e.g. participant distressed to leave home due to being in a high risk group and concerned about COVID exposure)

Table 11: Ship-Back Duration Adult Study

Ship-back duration (in hours)*	N =33	Pass
24 hours or less	22 (67%)	Yes
25-48 hours	4 (12%)	Yes
49-80 hours	5 (15%)	No
81 hours plus	2 (6%)	No

iv. Sample Accessioning:

All samples could be accepted for testing. Except for one user, the samples were adequately packaged in an outer shipping envelope that was properly sealed inside the biohazard bag and within the rigid outer box; the tubes were closed and the Date of Birth, and collection dates were written on the tubes. One user had to be prompted to use the provided rigid box.

v. Rnase P Results

Table 12: RNase P Results (Ct) of Adult Collected Samples

RNase P Ct value	N=33	Pass
22.5 - 27.0	21 (64%)	Yes
27.1 - 32.0	10 (30%)	Yes
32.1 - 35.5	2 (6%)	No
Mean	26.4	
Median	25.0	
Min	22.5	
Max	35.5	

b) Usability Study Results: Pediatric Population (Aged 3-17)

i. Study Description

The pediatric study recruited 44 participants from across the mainland United States in actual home-use environments. Five participants were unavailable to participate in their session after recruitment, one participant did not appear for their session. The remaining 38 participants all completed the session and successfully returned their test kits to the lab. Most pediatric samples were collected by the adult caregiver (see breakdown in *Table 13* below).

Table 13: Collection Process

Age	n	Gender	Child swabbed self	Swabbed by adult	Total
3-6 yrs	8	M: 6 | F: 2	M: 0 | F: 0	M: 6 | F: 2	8
7-10 yrs	10	M: 6 | F: 4	M: 0 | F: 0	M: 6 | F: 4	10
11-14 yrs	10	M: 7 | F: 3	M: 1 | F: 0	M: 6 | F: 3	10
15-17 yrs	10	M: 6 | F: 4	M: 1 | F: 0	M: 5 | F: 4	10

M=Male, F=Female

The majority of participants were assessed as having 'no difficulty' or just a 'little difficulty' completing each step (89%-100%), including properly swabbing the child's nose (92%, n=35). The step of properly washing hands prior to collection for the child was assessed at 34% (n=25), which did not meet study targets. Mitigations are planned to clarify that anyone touching the supplies (child and/or person swabbing the child) must wash their hands before proceeding. Audere will continue to track user success and error rates during usage to identify additional areas for improvement in user instructions and overall user experience.

Each specimen sent back to the lab was tested for RNase P to confirm adequate, unassisted sample collection. The mean Ct value across all lab tested specimens (38) was 25.1, with a median Ct value of 24.8, indicating successful sampling of human biological material.

ii. Demographics

Table 14: Characteristics of Pediatric Usability Study Population

Characteristics of Pediatric Study Population		N = 38	Percent
Gender	Male	17	45%
	Female	21	55%
Age	3-6	8	21%
	7-10	10	26%
	11-14	10	26%
	15-17	10	26%
Ethnicity	Hispanic or Latino	3	8%
	Other	35	92%
Race	Asian	4	11%
	Black or African American	9	24%
	Other	3	8%

Characteristics of Pediatric Study Population		N = 38	Percent
	White or Caucasian	21	55%
Education Level of parent	Grade 12 or GED	4	11%
	Associate degree	2	5%
	Bachelor's degree	19	50%
	Some college, no degree	6	16%
	Graduate or professional degree	7	18%
Geographic Location (State or District)	AR	1	2.6%
	AZ	3	8%
	CA	6	16%
	FL	1	2.6%
	GA	2	5%
	KS	1	2.6%
	MI	1	2.6%
	MN	1	2.6%
	MO	1	2.6%
	NC	3	8%
	NJ	3	8%
	NY	4	10.5%
	OH	2	5%
	OK	1	2.6%
	PA	1	2.6%
	TX	4	10.5%
	UT	1	2.6%
	WI	2	5%

iii. Observational Results:

Table 15: Format of Collection Instructions Used in the Pediatric Study

Instruction format usage		N = 38	Percent
Instruction format used	Digital	34	89%
	Paper*	1	1%
	Combination	3	8%

*At least one action taken beyond registering using paper instructions.

Table 16: Observer Notes on Pediatric Self-Collection

Task	Pass (no difficulty or only a little difficulty)	Failure (a lot of difficulty)
Getting started	38/38 (100%)	-
Register kit	38/38 (100%)	-
Plan for drop-off or pickup	38/38 (100%)	-
Wash hands (pre)	25/38 (66%)	13/38 (34%)*
Open nasal swab	38/38 (100%)	-
Swab nose	35/38 (92%)**	3 (8%)***
Put swab in tube	38/38 (100%)	-
Fill out info on tube	38/38 (100%)	-
Wash hands (post)	34/38 (89%)	4(11%)
Prepare and send kit	37/38 (97%)	1 (3%)

***Wash hands-pre (A lot of difficulty**): Parent performed swab, but did not wash their hands. In some of these cases the child did wash their hands, but they did not perform the swab. (13)
****Swab nose (A little difficulty)**: swab performed without 4 full rotations (3), swab inserted a bit deeper than needed (2), child pulled away repeatedly (2). Note - some participants had more than one issue listed here - hence the numbers in this note appear larger than in the chart.
*****Swab nose (A lot of difficulty):** Only swabbed one nostril (3)

Table 17: Ship-Back Option Used in the Pediatric Study

Ship-back to lab option chosen by participant	N =38
Drop-off*	11 (29%)
Pickup scheduled by phone	0 (0%)
Pickup scheduled online	27 (71%)

*6 participants stated intention to drop-off but there were some moderator interventions due to the day of the week or unusual circumstances (e.g. participant distressed to leave home due to being in a high risk group and concerned about COVID exposure)

Table 18: Ship-Back Duration Pediatric Study

Ship-back duration (in hours)*	N =38	Pass
24 hours or less	19 (50%)	Yes
25-48 hours	17 (45%)	Yes
49-80 hours	1 (2.5%)	No
81 hours plus	1 (2.5%)*	No

Note: 'Duration defined as the time from the start of the session to when the package arrived at the lab. Samples were tested the same day they arrived at the lab.
*FedEx did not pick-up from the participant's home as scheduled. Participant took extra time to get a new pick-up scheduled, hence the late delivery to the lab.

iv. Sample Accessioning:

All samples could be accepted for testing. All samples were adequately packaged in an outer shipping envelope that was properly sealed inside the biohazard bag and within the rigid outer box; the tubes were closed and the Date of Birth, and collection dates were written on the tubes. One participant's tube arrived at the lab with the swab pointing up. The lab flipped it around and processed it as usual.

v. Rnase P Results

Table 19: RNase P Results (Ct) of Pediatric Samples

RNase P Ct value	N=38	Pass
22.5 - 27.0	32 (84%)	Yes
27.1 - 32.0	6 (16%)	Yes
Mean	25.1	
Median	24.8	
Min	20.1	
Max	30.5	

Warnings:

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