

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY  
FOR THE AUDERE HEALTHPULSE@HOME FUSION**

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 Fusion 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 Fusion collection kit for COVID-19 using an in vitro diagnostic (IVD) molecular test that is indicated for use with the HealthPulse@home Fusion collection kit.**

**INTENDED USE**

The HealthPulse@home Fusion 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 Fusion Emergency Use Authorization (EUA).

Anterior nasal swab specimens collected using HealthPulse@home Fusion (i.e., a collection kit that is assembled and conforms with the specifications outlined by HealthPulse@home Fusion 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 Fusion.

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

## **SPECIAL CONDITIONS OF USE STATEMENTS**

For Emergency Use Authorization (EUA) Only

For Prescription Use Only

For In vitro Diagnostic Use

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

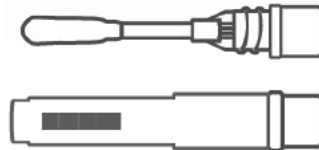
Audere HealthPulse@home Fusion is only authorized for use in conjunction with in vitro diagnostic (IVD) molecular tests for the detection of SARS-CoV-2 RNA that are indicated for use with anterior nasal swab specimens collected with collection kits that conform to the HealthPulse@home Fusion EUA.

## **DEVICE DESCRIPTION AND TEST PRINCIPLE**

### **1) DEVICE DESCRIPTION:**

Audere's HealthPulse@home Fusion solution 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 the HealthPulse@home Fusion.

The HealthPulse@home Fusion conforming specimen collection kit consists of a sterile, spun polyester swab integrated into the lid of a sterile sampling tube (see Figure 1 below) and used for the anterior nares collection of a specimen and the subsequent dry transport of the specimen to a CLIA certified laboratory.



*Figure 1: Swab Design. The swab is integrated into a tube lid that replaces the lid on the unused tube.*

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

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

EUA Summary: Audere HealthPulse@home Fusion  
April 26, 2022

1. The lab can either use a commercial test, such as Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test, that is authorized for use with HealthPulse@home Fusion, or
2. The lab can include in the Intended Use of their own molecular SARS-CoV-2 test a claim for samples collected at home using a HealthPulse@home Fusion conforming home collection kit, by:
  - a. Filing their own EUA (for previously unauthorized SARS-CoV-2 molecular tests), or by
  - b. Filing an EUA supplement (for previously authorized molecular SARS-CoV-2 tests).

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

1. Usability studies
2. Sample stability studies (Except when the laboratory's stability claims exceed the stability claim validated by Quantigen as sample stability is covered under the general RoR from Quantigen).

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

- 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 Fusion 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 Fusion 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 Fusion 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 Fusion 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 Fusion.

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 Fusion conforming specimen collection kit.

***b) Collection Kit Delivery***

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

***c) Kit Registration & Usage Instructions***

The individual using the HealthPulse@home Fusion 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 Fusion 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 Fusion 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 Fusion return shipping plans and determined the return shipping met their requirements.**

*e) Specimen Accessioning*

Specimens collected using the HealthPulse@home Fusion 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 Fusion contracts between Audere and the participating laboratory sites.

*f) Swab Rehydration Process*

HealthPulse@home Fusion conforming specimen collection kits leverage dry transport of the anterior nasal swab specimens, as validated by Quantigen [see L.R. Padgett et al 2021]. Therefore, labs using HealthPulse@home Fusion conforming specimen collection kits must rehydrate the dry anterior nasal swabs in advance of performing Sars-CoV-2 and internal control testing (e.g., RNase P). The labs must adhere to the following swab rehydration processes per licensing agreements with Audere for use of HealthPulse@home Fusion:

***Direct Lysis Buffer***

Dry swabs are rehydrated in 400 µL Direct Lysis Buffer using the automated sample preparation instruments using the Nexar platform (see EUA for LGC Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test)

Authorized laboratories using dry transport in their HealthPulse@home Fusion conforming collection kits must use this swab rehydration process per the licensing agreement with Audere (SOP embedded below).

## 2) **AUTHORIZED LABORATORIES**

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

- **LGC Biosearch Technologies SARS-CoV-2 ultra-high-throughput End-Point RT-PCR Test (BT-SCV2-UHTP-EP; EUA210561)**

## 3) **TEST RESULTS AND INTERPRETATION**

### a) **Assay Controls to be Used with the Authorized SARS-CoV-2 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 Fusion conforming collection kit. Controls to be used with COVID-19 molecular tests authorized for use with the HealthPulse@home Fusion 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 chooses 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 Fusion 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**

The following performance data were generated for HealthPulse@home conforming collection kit previously authorized (under EUA210353) and are applicable also to the HealthPulse@home Fusion conforming collection devices since the instructions did not significantly change.

**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. Quantigen Biosciences has granted a right of reference to their data to any sponsor wishing to pursue an EUA. The study did not observe effects of high or low temperature stress on the detection of SARS-CoV-2. The findings support the stability of dry anterior nasal swab specimens collected using a HealthPulse@home Fusion conforming specimen collection kit [and was published in L.R. Padgett et al 2021](#).

Results from this study demonstrated that a SARS-CoV-2 positive anterior nasal swab sample in a dry transport tube is stable under the following conditions:

- high (summer) temperature excursion (12 hr at 40°C, 34 hr at 32°C, 2 hr RT) up to 56 hours
- low (winter) conditions (-20 to 4°C) for up to 70 hours, including three freeze-thaw cycles.
- 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.

The results support a dry swab stability of 56 hours including 2 freeze thaw cycles.



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

IRB-reviewed human usability studies were conducted by Audere previously to support authorization for the HealthPulse@home Collection Kit authorized under EUA210353.

The studies confirmed proper, unassisted (adults) and assisted (pediatrics) self-collection by individuals and return of their specimen to a lab. Please refer to the detailed Usability study data in the EUA summary of EUA210353.

**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.