# EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
# RapidRona Self-Collection Kit

For *in vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

**For use by people 18 years of age or older**

**At-home self-collected nasal swabs collected with the RapidRona Self-Collection Kit will be sent to High Complexity Laboratories that have been designated by RapidRona, Inc. 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 run the specimens collected from the RapidRona Self-Collection Kit on an in vitro diagnostic (IVD) molecular test for SARS-CoV-2 that is indicated for use with the RapidRona Self-Collection Kit for self-collection of nasal swab specimens.**

## INTENDED USE

The RapidRona Self-Collection Kit is intended for use by individuals for self-collection of nasal swab specimens at home, when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire.

Specimens collected using the RapidRona Self-Collection Kit are transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the nasal swabs is maintained in the specimen packaging and is only for use in molecular diagnostic testing performed using an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with the RapidRona Self-Collection Kit.

Testing is limited to laboratories designated by RapidRona, Inc., 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 and that run the specimens collected with the RapidRona Self-Collection Kit on an *in vitro* diagnostic (IVD) molecular test that is indicated for use with the RapidRona Self-Collection Kit for self-collection of nasal swabs.

The RapidRona Self-Collection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

## SPECIAL CONDITIONS FOR USE STATEMENTS

For Emergency Use Authorization (EUA) only.
For prescription use only.
For in vitro diagnostic use only.

For use by people 18 years of age or older.

The RapidRona Self-Collection Kit is only authorized for use in conjunction with an *in vitro* diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with this collection device.

**DEVICE DESCRIPTION**

Individuals may create an account and request the RapidRona Self-Collection Kit online (https://www.RapidRona.com). During the ordering process, a COVID-19 questionnaire is filled out. PWNHealth (PWN) will review the questionnaire and patient information, and a requisition will be generated and transmitted to the lab for individuals who are deemed eligible. Eligible individuals will be shipped the collection kit. Those determined ineligible for testing will be notified that testing is not currently available to them. At the time of sampling, the patient will register on line the unique collection kit identifier; the confirmation of sample collection and time will be electronically transmitted to the lab at which the test will be performed and to which the self-collected nasal swab sample will be sent.

The RapidRona Self-Collection Kit is used to collect RNA from nasal swab specimens that have been self-collected (unsupervised) and stabilized during transportation and storage at room temperature for a total of 48 hours from initial sample collection. The RapidRona Self-Collection Kit is a method for collecting viral RNA for use in molecular COVID-19 diagnostic assays indicated for use with the RapidRona Self-Collection Kit.

The RapidRona Self-Collection Kit is composed of a packaged sterile swab, sterile collection tube, transport medium (saline), shipping materials, barcode labels for identification, and printed instructions for use (IFU) that state how to register, collect and ship the sample. Specimens are to be mailed to the laboratory for testing using the pre-labeled return envelope. Each RapidRona Self-Collection Kit is intended to be picked up on the day of specimen collection for return shipment overnight at ambient conditions for next day delivery.

Each laboratory designated by RapidRona, Inc. for receipt of RapidRona Self-Collection Kit specimens shall process samples in accordance with an accessioning SOP that defines the criteria for verification, acceptance and rejection of clinical samples and documentation of results.

Completed test results are reviewed by PWN. If results are positive or indeterminate (i.e., invalid or inconclusive), the PWN care team will attempt to contact those individuals by telephone to deliver and explain test results. Re-testing is recommended for those receiving indeterminate results. Following email notification of result availability, negative test results will be accessed through a secure online portal. All test results are

made available through the portal within 48 hours of specimen shipment to the laboratory.

## REAGENTS AND MATERIALS

The RapidRona Self-Collection Kit consists of the items listed in the table below.

| Component | Description |
|---|---|
| Swab | Sterile polyester tip swab with polypropylene shaft |
| Transport tube | Sterile polypropylene tube |
| Transport medium | 3 mL 0.9% normal saline |
| Sample bag | Biohazard bag with absorbent pad |
| Shipping box | Cardboard box for sample return |
| Envelope | Pre-labeled return envelope |
| Label | Pre-printed barcode label |
| Instructions | Printed pamphlet of sample collection instructions |

## MEDICAL OVERSIGHT AND PROCESS TO BE USED

Medical Oversight of the process is provided by the third-party physician network, PWN. PWN performs review of the COVID-19 questionnaire and, for those individuals meeting eligibility criteria for testing, electronically sends a test requisition, also prompting a collection kit to be sent by RapidRona. Following self-collection of specimens and processing at the designated authorized laboratory, PWN will review and approve test results. A PWN care coordinator or healthcare provider will attempt to call those receiving positive or indeterminate results to explain the result and offer a telehealth consult. If PWN is not able to reach those individuals, PWN will provide email notification of the result availability and will mail a follow-up letter (not including results) to such individuals.

Eligibility for testing is based on reporting of symptoms or potential exposure to COVID-19. Those without symptoms or with no known exposure are not eligible for testing.

## PATIENT INCLUSION/EXCLUSION CRITERIA

Inclusion criteria include:
1. Age ≥ 18 years
2. Patients with symptoms of COVID-19
3. Individuals with no symptoms of COVID-19 but with known exposure such as through the workplace, residence, or contact with a sick/SARS-CoV-2-positive individual

Exclusion criteria include:
1. Individuals with no symptoms or known exposure
2. Patients with emergency warning signs of COVID-19 as they are directed to immediately seek emergency care.

## INSPECTION OF SPECIMENS AT THE TESTING LABORATORY

**Applies to specimens received from patients using home collection kit**
Requisitions are transmitted electronically from PWN to the laboratory designated for specimen processing. Specimens collected using the RapidRona Self-Collection Kit should be checked at the testing laboratory for the following criteria before being entered into the work flow:

- **Missing requisition** - a kit is received but there is no requisition matching its registration number
- **Improper packaging/physical damage** - A sample is received in inappropriate packaging or compromised packaging. Biohazard bag containing one vial with transport medium and one swab is expected.
- **Expired shipping time** - A kit is received ≥48 hours after specimen collection
- **Expired collection kit** - Sample box expiration date has passed

## CONTROLS TO BE USED WITH THE COVID-19 TEST

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

1) A negative (no template) control (NTC) is needed to eliminate the possibility of sample contamination and is used in every extraction run. The NTC consists of nuclease-free water.

2) A positive template control is needed to verify that the assay run is performing as intended and is used in every run.

3) A SARS-CoV-2 negative control is run and consists of a human genomic RNA background. This control will yield a negative result for the SARS-CoV-2 targets and a positive result for RP.

4) An internal control targeting RNase P is needed to verify that nucleic acid is present in every sample and is used for every sample processed. This also serves as an extraction control to ensure that samples resulting as negative contain nucleic acid for testing.

5) A human specimen control (HSC)/extraction control (optional) is used as a nucleic acid extraction procedural control to demonstrate successful recovery of nucleic acid as well as extraction reagent integrity.

## 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 are divided into positive, negative, and indeterminate (invalid or inconclusive).

In the case of positive results:

- Individuals will receive notification of their result. A healthcare professional will attempt to call the patient no less than three times to explain the results. A follow-up letter will be sent in the case that they cannot be reached by phone after multiple attempts.
- Outreach calls provide an explanation of the test result and include the opportunity for a telehealth consult.

In the case of indeterminate results:

- Individuals will receive a result reporting call and a letter in the case that they cannot be reached after multiple phone attempts.
- Outreach calls provide the result of the test and a recommendation to get re-tested.

## PERFORMANCE EVALUATION

### *1) RapidRona Self-Collection Kit Sample Stability Studies:*

The study to assess stability of swabs in saline 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 as part of that sponsor's EUA request. The Quantigen Biosciences study supported 48-hour stability at ambient temperature for swabs transported in saline.

An additional transportation stability study was conducted using negative clinical matrix collected with the RapidRona Self-Collection Kit. Participants enrolled for the usability study (see below) each provided three specimens as negative clinical matrix. Following overnight shipping to the designated, authorized laboratory, one sample from each participant was tested to confirm SARS-CoV-2 negativity, the second sample was spiked at 3 x LoD with heat-inactivated SARS-CoV-2 (BEI Resources, Cat No. NR-52286), and the third sample was spiked with an equal volume of diluent (saline). The spiked samples (positive and negative) were incubated at 40°C for 12 hours and then shipped overnight again for return to the testing site. Upon receipt at the testing site, the two spiked samples from each participant were tested. The study reflects the transportation stability of SARS-CoV-2 genetic material while awaiting courier pick up and subsequent transportation to the partner clinical laboratory. This stability protocol spanned a total of three days.

All unspiked specimens were analyzed for RNase P to confirm the presence of human cellular material as a determinant of adequate sample collection and for SARS-CoV-2 to confirm negativity prior to spiking. All were positive for RNase P with average Ct value

of 27.3 and were initially SARS-CoV-2 negative (Ct cutoff for RP and SARS-CoV-2 targets is 40 cycles). After spiking, incubation, and shipping, all SARS-CoV-2-spiked low positive samples were confirmed as SARS-CoV-2 positive (with average Ct values of 33.4 and 33.8 for the two SARS-CoV-2 targets) and all samples spiked with saline only were again confirmed as SARS-CoV-2 negative. The average RNase P Ct values for the spiked positive and negative samples were 26.1 and 26.0, respectively.

***2) Self-Collection Validation:***

A usability study was conducted to confirm that subjects could follow the instructions included in the RapidRona Self-Collection Kit to appropriately collect, package, and ship a self-collected nasal specimen to the laboratory designated for testing. Following recruitment through social media platforms and email blasts, consented individuals meeting study inclusion criteria were sent a RapidRona Self-Collection Kit and accessed a video conferencing platform where they were observed self-collecting nasal specimens and scheduling specimen shipment of the kit using the provided written instructions and the instructions on the online registration platform. They were monitored, without further instruction or assistance, by a trained observer.

Following collection and shipment, subjects completed a usability survey that assessed their ability to understand the different steps in the instructions for use, with responses reported on a five-point scale. Upon specimen receipt, the testing laboratory checked that the packaging was intact, evaluated specimens according to acceptance/rejection criteria contained in the study design and tested them for the endogenous human RNase P gene. All participants' samples tested positive for RNase P, indicating the presence of human nucleic acid in all cases.

A total of 45 individuals were consented, self-collected a specimen, and completed the usability survey. These participants included individuals representing varying education levels and age ranges.

Results of the summative evaluation and feedback from the usability survey were used to assess risks which were then mitigated through improvements in the user interface, and updates to the collection kit contents, instructions, website, and labelling as appropriate.

**WARNINGS**

- This home collection kit has not been FDA cleared or approved.
- This home collection kit has been authorized by FDA under an EUA for use by authorized laboratories.
- This home collection kit has been authorized only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This home collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices 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. § § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.