

EMERGENCY USE AUTHORIZATION (EUA) SUMMARY

RapidRona Self-Collection Kit

For *in vitro* Diagnostic Use

Rx Only

For use under Emergency Use Authorization (EUA) only

At-home self-collected anterior nasal swabs collected with the RapidRona Self-Collection Kit will be sent to High Complexity Laboratories that have been designated by Diversified Medical Healthcare. 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 anterior nasal swab specimens.

INTENDED USE

The RapidRona Self-Collection Kit is intended for use by any individual age 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, for collection of anterior nasal swab specimens at home when determined to be appropriate by a healthcare provider.

Anterior nasal swab 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 anterior nasal swab specimens 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 Diversified Medical Healthcare, 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. Testing is also limited to molecular diagnostic tests that are indicated for use with the RapidRona Self-Collection Kit for collection of anterior nasal swabs when used consistent with its authorization.

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 individuals age 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance)

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 anterior nasal swab sample will be sent.

The RapidRona Self-Collection Kit is used to collect RNA from anterior 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 containing 3 mL of 0.9% 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 Diversified Medical Healthcare 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 containing 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/shipping instructions

Expiration dating of the RapidRona Self-Collection Kit will be based on the assigned expiration date of the component with the shortest shelf-life, as defined by the material supplier.

MEDICAL OVERSIGHT PROCESS

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 Diversified Medical Healthcare. 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.

PATIENT INCLUSION/EXCLUSION CRITERIA

Inclusion criteria:

Age 18 years or older (self-collected), 14 years and older (self-collected under adult supervision) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19.

Exclusion criteria:

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 workflow:

- **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 endogenous internal control (e.g., targeting RNase P RNA) is needed to verify sample integrity and the presence of detectable nucleic acid unless data have been submitted to FDA which demonstrate that the *in vitro* diagnostic test for use with the RapidRona Self-Collection Kit has a negligible rate of invalid results that eliminates the need for such a control with specimens that are collected without supervision. The endogenous internal control also serves as an extraction control for those molecular tests that use a separate RNA extraction and purification step, to ensure process integrity and that samples resulting as SARS-CoV-2 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) *Specimen Shipping Stability:*

Diversified Medical Healthcare has obtained a Right of Reference to shipping stability data generated using the DoINeedaCOVID-19Test.com Self-Collection Kit under EUA210247 that support transport and storage of anterior nasal swab specimens in 0.9% normal saline for up to 48 hours at ambient temperature. The format and composition of the two collection kits is similar and therefore it was determined to be appropriate to apply the same shipping stability claims to the RapidRona Self-Collection Kit.

2) *Self-Collection Validation:*

Specimen Collection from Adults

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.

Specimen Collection from Minors

Diversified Medical Healthcare has obtained a Right of Reference to usability data generated using the DoINeedaCOVID-19Test.com Self-Collection Kit under EUA210247 that demonstrated the ease-of-use of the kit for collection of anterior nasal swab specimens from minors (aged 14 years and older under adult supervision or 2 years and older with adult assistance). The format and Instructions For Use of the two collection kits are similar and therefore it was determined to be acceptable to refer to these usability data to support the collection of specimens from minors using the RapidRona Self-Collection Kit.

3) Specimen Collection from Individuals without Symptoms:

Diversified Medical Healthcare has obtained a Right of Reference to performance data generated using the DoINeedaCOVID-19Test.com Self-Collection Kit under EUA210247 to support use of the kit for collection of specimens from individuals without symptoms or reasons to suspect COVID-19. The format and Instructions For Use of the DoINeedaCOVID-19Test.com Self-Collection Kit and the RapidRona Self-Collection Kit are similar. Furthermore, the RapidRona Self-Collection Kit is only authorized for use with *in vitro* diagnostic tests for the detection of SARS-CoV-2 that are authorized for use with the RapidRona Self-Collection Kit, which includes the PMLS SARS-CoV-2 Assay authorized under EUA210247. Therefore, it was determined to be acceptable to refer to performance data generated using the DoINeedaCOVID-19Test.com Self-Collection Kit under to support the Intended Use of the RapidRona Self-Collection Kit.

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 home 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

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- 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 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.