EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
EVERLYWELL COVID-19 TEST HOME COLLECTION KIT

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

Anterior nasal swab specimens collected at home using the Everlywell COVID-19 Test Home Collection Kit will be sent to laboratories that have been designated by Everlywell, 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 the Everlywell COVID-19 Test Home Collection Kit using an in vitro diagnostic (IVD) molecular test that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit.

INTENDED USE

The Everlywell COVID-19 Test Home Collection Kit is intended for use to collect anterior nasal swab specimens at home from individuals age 18 years or older (self-collected) when determined to be appropriate by a healthcare provider.

Anterior nasal swab specimens collected using the Everlywell COVID-19 Test Home 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 RNA that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit.

Testing is limited to laboratories designated by Everlywell 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 and that run the specimens collected from the Everlywell COVID-19 Test Home Collection Kit on an IVD molecular test that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization.

The Everlywell COVID-19 Test Home Collection Kit is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Everlywell COVID-19 Test Home Collection Kit will be dispensed to patients when indicated based on review by the Physician Wellness Network (PWN) of the information provided through the Everlywell website COVID-19 questionnaire. The PWN will

determine test eligibility and write prescriptions for testing. PWN will also follow up all positive and inconclusive test results by contacting the patients. Negative patients will be notified by email, phone message, and through the website portal.

The Everlywell COVID-19 Test Home Collection Kit is composed of sample registration instructions, sample collection instructions, sample preparation and shipping instructions, nasal swab, saline in a tube, shipping materials, and return labels. Instructions are included in the kit to direct the home users on how to appropriately collect the nasal swab specimen and place it in the saline transport tube, how to properly package the specimen, and how to mail the specimen back to the laboratory using the pre-labeled UPS return envelope (or to otherwise arrange for specimen pick-up via courier). Each Everlywell COVID-19 Test Home Collection Kit is intended to be returned via overnight courier service at ambient conditions on the same day of or the day following sample collection in accordance with the standards as put forth by the CDC and WHO for the transport of suspected COVID-19 samples.

Specimens received at the clinical laboratory for testing will undergo review and accessioning prior to acceptance for testing. See Accessioning SOP for details.

The COVID-19 RT-PCR test will be performed at a High Complexity certified laboratory (Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a using an FDA authorized NAAT test per the Instructions for Use.

REAGENTS AND MATERIALS

Everlywell COVID-19 Test Home Collection Kit

POLY MAILER 7.5 X 10.5
2D BARCODE LABEL
NASAL SWAB (round foam)
TRANSPORT MEDIUM KIT (0.85% saline)
KIT ID STICKERS
RETURN BOX
UN3373 LABEL (pre-applied to return materials)
MEDIUM ALCOHOL PREP PAD
ABSORBENT SHEET
SMALL BIOHAZARD BAG

INNER BOX TRAY 1-3
HELP AND CONTACT NUMBER INSERT
SHIPPING AND PREPARATION INSTRUCTIONS
COLLECTION INSTRUCTIONS
WELCOME PANEL WITH KIT ID
WHITE TRAY
RETURN SHIPPING LABEL

MEDICAL OVERSIGHT AND PROCESS TO BE USED:

Medical oversight of the process is provided by the third-party physician network, PWN Health (PWN). PWN Health designed the health screening questions and implementation algorithm utilized at the point of customer purchase on the digital platform; the prescription for the test is written before the kit is shipped to the patient's home. The process includes an initial triage of severely ill individuals to in-person or emergency care. Before the home-collected sample can be processed at the CLIA lab, PWN generates the lab test requisition for the end-user, if appropriate. After the home-collected sample is processed at the CLIA lab, PWN reviews and approves the test results, and recommends follow-up action and education to the end-user of the Everlywell COVID-19 Test Home Collection Kit.

PWN is an independent company that employs or contracts with physicians licensed in all 50 states, healthcare professionals, and non-clinical patient care coordinators as support staff. All individuals taking the test will receive education and information both before and after the test on symptom monitoring including when to seek in-person or emergency care, isolation precautions, health hygiene, and other critical points to limit the spread of the disease and to optimize outcome. The opportunity to contact a physician/healthcare provider to ask questions and/or to receive other information/education is made available at all points in the process.

INSPECTION OF SPECIMENS:

Applies to specimens received from patients using home collection kit

Specimen received through the Everlywell Home Collection Kit should be checked for the following criteria before entering the work flow:

- **Improper return of sample packaging -** sample not returned in supplied packing materials; sample not returned in biohazard bag; sample not in correct collection/transport device or tube; insufficient volume/ or leak/dry tube
- **Not Registered** - customer did not register kit on EW platform
- **QNS** - customer did not provide enough specimen for processing
- **Missing Information** - customer did not write name, date of birth, or date of collection on the specimen

- **Incorrect Name** - name on the requisition does not match what is written on specimen
- **Invalid Date** - DOB on the requisition does not match what is written on the specimen or the date of collection that is written on specimen is in the future
- **Expired shipping time** – If a specimen is received ≥ 96 hours from the collection date/time, the specimen is rejected
- **Other** - any other error that requires Everlywell review; these are typically rare events, often associated with other extenuating factors.
- **Wrong Lab –** customer mixed up return shipping labels and specimen arrived at the incorrect lab for processing
- **Missing Barcode –** customer received replacement materials at home and forgot to write the Kit ID on the new specimen

CONTROLS TO BE USED WITH THE COVID-19 RT-PCR TEST

1) A negative (no template) control is needed to eliminate the possibility of sample contamination on the assay run and is used on every assay plate. This control is molecular grade, nuclease-free water.

2) A positive template control is needed to verify that the assay run is performing as intended and is used on every assay plate starting at master mix addition at a concentration of 50 copies/uL. The positive template control does not include RNase P target and will result as "undetermined" for that marker.

3) 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 the extraction control to ensure that samples resulting as negative contain nucleic acid for testing.

4) A negative extraction control (optional) is a previously characterized negative patient sample. It serves both as a negative extraction control to monitor for any cross-contamination that occurs during the extraction process, as well as an extraction control to validate extraction reagents and successful RNA extraction.

INTERPRETATION OF RESULTS

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

PWN's protocol provides for real-time communication throughout the testing process, including when the individual is waiting for the test kit, while the individual is waiting for results, and after the result is provided. Educational materials include information on maintaining social distancing or isolation, monitoring for severe symptoms, and seeking care when necessary and adheres to both CDC and HHS

guidelines. Patient care coordinators, other healthcare professionals, and physicians are available at all times throughout this process for questions/concerns.

COVID-19 test results are divided into "Reactive" (positive/detected), "Non-reactive" (negative/not detected), and "Invalid" (no result, indeterminate). PWN makes phone calls and outreach attempts as soon as possible after the result is reported in order to speak to the individual and provide education and additional information.

In the case of positive results:

- Individuals will receive a result reporting call and a letter in the case that they cannot be reached
- Call and outreach attempts will be made promptly from the time of receiving the test results
- Outreach calls provide: result of the test, counseling on the disease and next steps based on immediate symptoms including isolation vs in-person or emergency care, and the opportunity to have a telehealth consult with a physician or trained healthcare provider licensed in the state of where the individual is located
- Results are reported by PWN to public health agencies as required

Additionally, physician or trained healthcare provider consultations are available to anyone who requests one regardless of test result. All individuals have the opportunity to follow up with the Physician or trained healthcare provider with regards to what to watch for, specific symptoms, self- quarantine questions as appropriate, and when to seek care with necessary parameters provided.

PERFORMANCE EVALUATION

1) Everlywell COVID-19 Test Home Collection Kit Sample Stability Studies:

A stability study was conducted by Gravity Diagnostics, LLC, to support stability of nasal swabs, collected in 0.9% saline, for up to 96 hours from time of collection. A right of reference was obtained by Everlywell to leverage the Gravity Diagnostics COVID-19 swab stability data to extend the shipping time for nasal swabs, collected in 0.9% saline, from 48 hours to 96 hours.

The stability study was conducted by subjecting contrived SARS-CoV-2 samples to either a winter shipping temperature profile or summer shipping temperature profile. Following storage at each of these conditions, sample integrity was assessed using an EUA authorized SARS-CoV-2 assay. The results of the EUA authorized SARS-CoV-2 assay indicated that there was no evidence of degradation of target RNA when compared with the control condition. The results of this study have been reviewed by FDA and support the stability of nasal swabs when collected and shipped in 0.9% saline for up to 96 hours from time of collection, year-round.

2) Specimen Collection Validation:

Usability study for adults age 18 and older

For every new test Everlywell launches, pre-release usability testing is conducted where comprehension of the collection experience including online and written instructions is confirmed. In the course of product development, Everlywell conducts ongoing user research. This involves proactive in-depth interviews of customers who have recently completed a test to discuss their experience in an attempt to discover potential improvements. This information is reviewed and used to inform areas where users are confused by language and graphics, and those areas are changed to become more understandable.

Everlywell closely monitors user error rates and sample receipt/accessioning issues for all tests using standardized procedures.

At launch of the Everlywell COVID-19 Test Home Collection Kit, Everlywell monitored the user error rate and implemented a usability assessment to identify and characterize user success with at-home collection of samples. Data tabulated from use of the kit from May 2020 through December 2020 are shown in the following table.

	Total Count	**% of Total**
No. of kits returned to lab for processing	**201,290**	
Total samples identified with no errors	186,832	92.82%
Total samples identified with errors	14,457	7.18%
Errors resolved	13,668	94.54%
Total samples with no errors or resolved errors	**200,500**	**99.60%**
Unresolved error rate	**790**	**0.40%**
Description of Errors		
Not registered	4,314	2.14%
Rejected - Missing Identifiers	276	0.14%
Other	353	0.18%
Improper return of sample packing	4,086	2.03%
Incorrect Name	447	0.22%
Registered - Missing PWN Order	167	0.08%
Wrong Lab	1	0.00%
Invalid Date	1,227	0.61%
Missing Info	2,474	1.23%
Expired Order	169	0.08%
QNS	6	0.003%

In addition, over 19,000 collection kit users completed a survey addressing their experience with the Everlywell COVID-19 Test Home Collection Kit, including questions related to registration, specimen handling and collection, and kit return. Based upon the usability data and user feedback, the Instructions for Use have been refined since initial kit introduction.

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

- 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.