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

Home self-collected nasal swabs collected with the Everlywell COVID-19 test home collection kit will be sent to High Complexity Laboratories that have been designated by Everlywell. All laboratories will be certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a and will be using an FDA authorized NAAT test per the Instructions for Use that was reviewed by the FDA under the test EUA and is authorized 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 by individuals to self-collect nasal swab specimens at home, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire. Specimens collected using the Everlywell COVID-19 Test Home Collection Kit can be transported at ambient temperature for testing at a laboratory. SARS-CoV-2 RNA from the nasal swabs specimen is maintained in the specimen packaging and suitable for use in molecular diagnostic testing preformed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that has been issued an EUA for use with Home Collection Kits, that includes the Everlywell COVID-19 Test Home Collection Kit.

Testing is limited to laboratories designated by Everlywell and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Testing is also limited to molecular diagnostic tests that are authorized for use with Home Collection Kits for collection of nasal swab specimens, including the Everlywell COVID-19 Test Home Collection Kit.

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 only be dispensed to patients meeting the inclusion criteria based on the information provided through the Everlywell website COVID-19 questionnaire and reviewed by the Physician Wellness Network (PWN). 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 FedEx or UPS return envelope. Each Everlywell COVID-19 Test Home Collection Kit is intended to be returned via overnight courier service at ambient conditions on the same day or the following day of 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

SELF-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. Before the self-collected sample can be processed at the CLIA lab, PWN generates the lab test requisition for the end-user, if appropriate, based on CDC-approved eligibility criteria. After the self-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, all as outlined below.

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. Patient care coordinators are overseen by multiple layers of clinical and non-clinical professionals. The Clinical Director meets with the team on a weekly basis to discuss quality metrics, address broad clinical issues, and enhance all process elements as necessary. There is a real-time escalation process that provides for a feedback loop and ongoing training. Physicians and healthcare providers are routinely trained on all aspects of care programs and are also monitored for quality, undergoing full credentialing and ongoing certification assessment in states in which they are licensed. The Chief Medical Officer of PWN, working with a team of external advisors and experts, ultimately oversees all aspects of the care program and conducts routine checks on all facets of patient care support.

The PWN COVID-19 care program is highlighted below and described in the Everlywell Patient Screening SOP.

Eligibility assessment hinges on three main characteristics:

1. Symptoms
    - Includes initial triage of severely ill to in-person or emergency care while further segmenting into those with mild/non-limiting symptoms and no symptoms at all
2. Exposure
    - Delineation based on any form of exposure including workplace, etc.
    - Categories include: Known exposure, Sick Contact, Community Spread, and No Known Exposure

3. Medical and Personal History
    - Includes comorbidities and age to stratify for risk
    - Individuals with No Known Exposure and No Symptoms are not currently eligible for a test kit
    - 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 is made available at all points in the process to ask questions and/or to receive other information/education

The performance of the Everlywell COVID-19 Home Collection Kit was established using symptomatic individuals and performance may be different with asymptomatic individuals.

PATIENT INCLUSION/EXCLUSION CRITERIA:
Applies to patients using Everlywell COVID-19 test product for home collection
The criteria below in use as of 8/31/20.
Exclusion:

- Patients with no symptoms and no known exposure risks
- Individuals with severe symptoms (will be directed to seek immediate care)

Inclusion:

- Patients with "mild" symptoms
- Individuals with known exposure, sick contact, or living in area of Community Spread, with no symptoms

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 either in the future or exceeded expiration

- **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:

The stability study described below 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.

Two SARS-CoV-2-positive pools (2xLoD and 10xLoD) were contrived by combining SARS-CoV-2- negative human/porcine matrix with previously confirmed, high-positive patient samples.

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). The 20 low-positive samples and the 10 intermediate-positive samples used with each test condition did *not* come from individual patients. Rather, for each of the two concentrations, a *single* preparation of virus + media or virus + matrix was prepared, from which technical replicates were prepared.

The human/porcine negative matrix swabs were prepared by spiking them into negative porcine nasal mucous using the same procedure described above. Swabs were then placed into 1 mL saline.

Samples were tested using an EUA authorized assay at time 0, 30 hours, and 54 hours post incubation. Samples were held at 40℃ for 12 hours, then 32℃ for 18 or 42 hours, respectively. Samples were allowed to equilibrate to room temperature for 2 hours before testing.

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

Average Ct Values for Each time point for both sample dilutions.

Swab	Time Point	N	Internal Control	Target 1	Target 2	Target 3
2xLoD swab in Saline	0h	5	23.74	32.23	30.03	31.80
10xLoD swab in Saline	0h	5	23.27	29.46	27.58	28.67
2xLoD swab in Saline	30h	20	26.00	32.69	31.33	34.59
10xLoD swab in Saline	30h	10	26.19	29.54	28.37	28.69
2xLoD swab in Saline	54h	20	25.70	32.03	31.09	32.10
10xLoD swab in Saline	54h	10	26.11	28.73	27.25	25.09

2) Self-Collection Validation:

For every new test Everlywell launches, they conduct pre-release usability testing where they confirm comprehension of the collection experience including online and written instructions. In the course of product development, Everlywell conduct 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. They have conducted at least 20 usability studies in the past 12 months with over 150 unique participants. They review and use this information to inform areas where users are confused by language and graphics and change those areas to become more understandable.

Everlywell has four years of experience in developing and implementing instructions for at-home collection and shipping for a variety of sample types, including swab collection for hundreds of thousands of test results. Everlywell closely monitors user error rates and sample receipt/accessioning issues for all tests using standardized procedures. The data below is representative of registered swab collection kits, containing similar instructions as the Everlywell COVID-19 home collection kit, that were returned to lab successfully from Sept 28, 2017 to April 1, 2020:

Kit A = 964/1,016 = 94.8%
Kit B = 5,300/5,608 = 94.5%

At launch of the Everlywell COVID-19 Test Home Collection Kit, Everlywell will implement a usability assessment to identify and characterize user success and error rates with at-home collection of samples which will be shared with the Agency. This will be a

prospective assessment of error rate by type and overall success for samples received at the laboratory to identify potential areas for improvement in user instructions and experience. Specifically, they will evaluate user error rate on an aggregating basis for the first 2-weeks post-launch up to 1,000 samples. At each 100-sample receipt increment, they will calculate error rates (by type and overall) as well as overall success metrics. User error rates will be calculated as an overall error rate (# of total errors over total number of samples received) and for each error rate type (number of specific errors over total number of samples received). User success rate will be calculated as the number of samples received with no errors divided by the total number of samples. Based upon previous experience, Everlywell will use the acceptance criteria of 10% for error rate type and 90% success as thresholds for implementing corrective actions (e.g. modifications to user instructions). Corrective action will be undertaken in the event a specific error rate type exceeds the criterion or if the success rate falls below the user success acceptance criteria.

Conclusion: The Everlywell COVID-19 Test home collection kit has demonstrated sample stability and usability that is acceptable to the FDA.