

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

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

**Direct to consumer (DTC) home-collected anterior nasal swabs collected from individuals age 18 years and older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) with the Everlywell COVID-19 Test Home Collection Kit DTC 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 to perform high complexity tests and that run the specimens collected from the Everlywell COVID-19 Test Home Collection Kit DTC on an in vitro diagnostic (IVD) molecular test that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit DTC for collection of anterior nasal swab specimens.**

### **INTENDED USE**

The Everlywell COVID-19 Test Home Collection Kit DTC is a direct to consumer product for collecting an anterior nasal swab (nasal) specimen at home from individuals age 18 years and older (self-collected), 16 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) that is sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the Everlywell COVID-19 Test Home Collection Kit DTC and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19.

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.

All test results are delivered to the user via an online portal. Individuals with positive or invalid/indefinite results will be contacted by a healthcare provider. The direct to consumer home collection system is intended to enable users to access information about their COVID-19 infection status that could aid with determining if isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The Everlywell COVID-19 Test Home Collection Kit DTC is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with an authorized test should not be used to start, stop, or change any course of treatment unless advised by a healthcare provider.

The Everlywell COVID-19 Test Home Collection Kit DTC 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 DTC will be available direct to consumer (DTC) without a prescription use consistent with the authorization. When ordering a kit online, individuals must self-certify they are 18 years or older. Individuals are recommended to complete a screening questionnaire when registering the kit. All test results are then delivered to the user via an online portal. Additionally, individuals with positive and invalid results are contacted by a healthcare provider. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, and epidemiologists. The healthcare provider contacting individuals with test results will have prescribing privileges for that individual, should medication be indicated for treatment.

The Everlywell COVID-19 Test Home Collection Kit DTC is composed of sample registration instructions, sample collection instructions, Fact Sheet for Individuals, sample preparation and shipping instructions, anterior 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 DTC 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 DTC

POLY MAILER 7.5 X 10.5
2D BARCODE LABEL
NASAL SWAB (round foam or flocked)
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
FACT SHEET FOR INDIVIDUALS
WELCOME PANEL WITH KIT ID
WHITE TRAY
RETURN SHIPPING LABEL

## INSPECTION OF SPECIMENS:

### **Applies to specimens received from individuals using home collection kit**

Specimen received through the Everlywell COVID-19 Test Home Collection Kit DTC 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  $\geq 96$  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**

Testing is limited to laboratories designated by Everlywell that are certified under CLIA, 42 U.S.C. §263a, and meet the requirements to perform high complexity tests. Testing is limited to laboratories using a rRT-PCR test for the qualitative detection of nucleic acid from SARS-CoV-2 that is authorized for testing individuals without symptoms or other reasons to suspect COVID-19 and has been issued an EUA for use with Home Collection Kits, that includes the Everlywell COVID-19 Test Home Collection Kit DTC. The test should incorporate the following controls:

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

Everlywell currently has a contract with Physicians Wellness Network (PWN). PWN’s protocol provides for real-time communication throughout the testing process, including when the individual (or parent or guardian, as applicable) 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 adhere 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 a positive or invalid result is reported in order to speak to the individual (or parent or guardian, as applicable) 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, quarantine questions as appropriate, and when to seek care with necessary parameters provided.

## **PERFORMANCE EVALUATION**

### ***1) Everlywell COVID-19 Test Home Collection Kit DTC 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.

### **Home Collection Kit Stability:**

#### **Saline Tube (Reagent) Stability**

The saline tubes used in the Everlywell COVID-19 Test Home Collection Kit DTC are sourced from Teknova. The specific product used, catalog # 4S0085, is FDA registered and has an established shelf life of 3 years (1095 days). The product is made in Class 5 hoods, filtered using 0.1 µm filters, and tested for sterility (acceptance criteria for sterility is 0 CFU). Tubes from each lot are tested for pH, conductivity, density, sodium chloride concentration.

## **2) Specimen Collection Validation:**

### **a) 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 (Rx only kit with instructions comparable to the Everlywell COVID-19 Test Home Collection Kit DTC), Everlywell monitored the user error rate and implemented a usability assessment to identify and characterize user success with at-home collection of samples. 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 for the Everlywell COVID-19 Test Home Collection Kit DTC have been refined.

### **b) Usability study for minors age 2-17**

In addition, Everlywell conducted usability testing to assess self-collection involving minors aged 16 and 17 and parent-assisted collection of specimens from individuals 2-15 years of age. The study was conducted to evaluate the ability of individuals of various ages, ethnicities, and education levels to successfully perform home specimen collection. Parents and child participants completed a set of tasks related to various stages of using the kit to collect and return a sample from a minor in/from an at-home environment. Tasks covered the typical end-to-end process following receipt of the kit including online registration, sample collection, and return preparation and shipment to the laboratory. Participants recorded the process using their mobile device or computer camera. Participants received standard instructions provided in the kit and available on the Everlywell commercial site to complete specimen collection and shipping to the laboratory, and no additional interaction or direction from those conducting the study, apart from training related to informed consent, general study steps, and use of video recording, occurred. Objective measures for the study included determination of the proportion of successful scenario completions (i.e. registered kits which ultimately yield valid results) and Ct values for internal sample controls targeting RNase P mRNA. Additionally, observed error types and rates were described. Post-use interviews/email outreach to further assess ease of kit use and instructions was obtained as well.

Evaluated samples from all but one participant tested positive for RNase P (93 of 94), indicating the presence of human nucleic acid. A number of the kits returned from the usability study experienced registration errors or were noted to have been expired upon receipt to the laboratory. Based on the historical data above, however, these errors are considered to be an artifact of the usability study and are not expected to occur with regularity. For the critical collection, packaging, and shipping steps that were observed in the usability study, results were deemed acceptable for participating adults and

minor children aged 2-17 years old. Results tallied from the optional survey conducted after kit use indicated no adverse results were reported and generally indicated success/ease of the collection process. Everlywell will continue to monitor usability of the kit and introduce improvements to the process as warranted. Based on the overall assessment of the usability study and in an effort to align with other home collection kits authorized for specimen collection from minors, the following changes were implemented in the Instructions for Use:

1. Added text to further clarify appropriate distance swab should be inserted during collection and collection method
2. Edited age limit warning/comments to facilitate collection, packaging, and shipment of specimens from minors 2-17 years of age.

#### **WARNINGS:**

- This product has not been FDA cleared or approved, but, has been authorized by FDA under an Emergency Use Authorization (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.
- 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.