

**EMERGENCY USE AUTHORIZATION (EUA) SUMMARY  
TEST YOURSELF DC AT-HOME COVID-19 COLLECTION KIT  
(DC HEALTH)**

For *in vitro* Diagnostic Use

For Use Under Emergency Use Authorization (EUA) Only

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

**(Direct to consumer (DTC) anterior nasal swab specimens collected at home by individuals age 18 years and older (self-collected), 14 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) using the Test Yourself DC At-Home COVID-19 Collection Kit will be sent for testing with Labcorp’s COVID-19 RT-PCR Test at the Center for Esoteric Testing in Burlington, NC which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.)**

**INTENDED USE**

The Test Yourself DC At-Home COVID-19 Collection Kit is a direct-to-consumer product for collection of anterior nasal swab specimens at home by individuals age 18 years and 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 testing with Labcorp’s COVID-19 RT-PCR Test.

Anterior nasal swab specimens collected with the Test Yourself DC At-Home COVID-19 Collection Kit are also authorized to be tested with Labcorp’s COVID-19 RT-PCR Test, for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples, using a matrix pooling strategy (i.e., group pooling strategy), containing up to five individual upper respiratory swab specimens (nasopharyngeal, mid-turbinate, anterior nasal or oropharyngeal swabs collected using individual vials containing transport media) per pool and 25 specimens per matrix. Negative results from pooled testing should not be treated as definitive and may need follow up testing if inconsistent with an individual’s signs and symptoms. Specimens included in pools where the positive sample cannot be identified using the matrix must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Anterior nasal swab specimens collected with the Test Yourself DC At-Home COVID-19 Collection Kit are authorized to be tested with Labcorp’s COVID-19 RT-PCR Test. Testing is limited to the Center for Esoteric Testing in Burlington, NC which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests.

All test results are delivered to the user via an online DC Health patient information system as well as via email (and text message, if opted in). The direct-to-consumer home collection system is intended to enable users to access information about their COVID-19 status that could aid with determining if self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with medical history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The Test Yourself DC At-Home COVID-19 Collection Kit with Labcorp's COVID-19 RT-PCR Test is not a substitute for visits to a healthcare provider. The information provided by this kit when combined with Labcorp's COVID-19 RT-PCR Test should not be used to start, stop, or change any course of treatment unless advised by your healthcare provider.

Testing with Labcorp's COVID-19 RT-PCR Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Test Yourself DC At-Home COVID-19 Collection Kit with Labcorp's COVID-19 RT-PCR Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

### **SPECIAL CONDITIONS OF USE STATEMENTS**

For use under Emergency Use Authorization (EUA) only.

For *in vitro* diagnostic use.

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

The Test Yourself DC At-Home COVID-19 Collection Kit is only authorized for use in conjunction with Labcorp's COVID-19 RT-PCR Test.

### **DEVICE DESCRIPTION AND TEST PRINCIPLE**

The Test Yourself DC At-Home COVID-19 Collection Kit will be available direct to consumer (DTC) without a prescription for any individual 18 and older. The Test Yourself DC At-Home COVID-19 Collection Kit will be available at select public facilities such as libraries and recreation centers, where kits are stored indoors at room temperature.

Anterior nasal swabs collected with the Test Yourself DC At-Home COVID-19 Collection Kit are to be tested with Labcorp's COVID-19 RT-PCR Test, a real-time reverse transcription polymerase chain reaction (rRT-PCR) test.

The instructions for use for the Test Yourself DC At-Home COVID-19 Collection Kit directs individuals to register themselves via the DC Health online portal. After specimen collection, the specimen is delivered to a designated DC Health drop-box. On the same day of collection, specimens in drop-boxes are picked up by a local courier for transport to DC Health for accessioning. The following are rejection criteria used by DC Health:

- Improper return of sample packaging, including the swab tip not residing in the saline liquid.
- Kit is expired.
- Not registered – user did not register kit on the DC Health Test Yourself platform.
- Expired return timeframe – if specimen is received on a day other than the registration date
- Incorrect specimen collection kit used (not the Test Yourself DC At-Home COVID-19 Collection Kit).

If specimens are determined unacceptable for testing, individuals are notified by text that a new specimen should be collected.

After specimens are determined acceptable for testing by DC Health, they are transported to Labcorp where they undergo additional accessioning according to Labcorp's at-home/DTC accessioning protocol. Specimens are then tested with the authorized Labcorp COVID-19 RT-PCR Test.

DC Health provides all test results (e.g., positive, negative, invalid, etc.) by email (and text message, if opted in), in addition to uploading the result to the DC Health online portal.

The Test Yourself DC At-Home COVID-19 Collection Kit contains the same components as the authorized Pixel by Labcorp COVID-19 Test Home Collection Kit, which is authorized for testing with Labcorp's COVID-19 RT-PCR Test. Specifically, the saline collection tube and anterior nasal swab are identical, while the collection instructions are nearly identical except for minor modifications to the kit registration questionnaire and sample drop-off procedures.

Labcorp has provided a right of reference to DC Health for validation data for the Pixel by Labcorp COVID-19 Test Home Collection Kit (EUA203057) and Labcorp's COVID-19 RT-PCR Test (EUA200011).

For more information on the device description, please refer to the EUA Summaries for EUA203057 and EUA200011, respectively.

## **PERFORMANCE EVALUATION**

Due to extensive similarities between the Test Yourself DC At-Home COVID-19 Collection Kit and the authorized Pixel by Labcorp COVID-19 Test Home Collection Kit, usability and sample stability studies from the Pixel by Labcorp COVID-19 Test Home Collection Kit (EUA203057) were used to support the Test Yourself DC At-Home COVID-19 Collection Kit. All other performance studies are described in the EUA Summary for the authorized Labcorp COVID-19 RT-PCR test (EUA200011).

## **WARNINGS**

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by the authorized laboratory.
- This product has been authorized only for the 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 in vitro diagnostics 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.