EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
THE GETMYDNA COVID-19 TEST HOME COLLECTION KIT
For *In vitro* Diagnostic Use
For use under Emergency Use Authorization (EUA) only

A direct to consumer (DTC) product for home self-collection of anterior nasal swabs by individuals 18 or older with the GetMyDNA COVID-19 Test Home Collection Kit. Specimens will be sent to high complexity laboratories that have been designated by GetMyDNA. 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 GetMyDNA COVID-19 Test Home Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the GetMyDNA COVID-19 Test Home Collection Kit for self-collection of anterior nasal swab specimens.

INTENDED USE

The GetMyDNA COVID-19 Test Home Collection Kit is a direct to consumer (DTC) product for self-collection (unobserved) of an anterior nasal swab specimens at home by individuals 18 or older that are sent for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the GetMyDNA COVID-19 Test Home Collection Kit for self-collection of anterior nasal swab specimens, and the IVD is indicated for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19 infection.

Testing is limited to laboratories designated by GetMyDNA 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/indeterminate results additionally 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 self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The GetMyDNA COVID-19 Test Home Collection Kit is for use by adults 18 years and older, to self-collect anterior nasal swab specimens, including for use by such individuals without symptoms or other reasons to suspect COVID-19 infection.

The GetMyDNA COVID-19 Test Home Collection Kit 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 GetMyDNA COVID-19 Test Home 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 in vitro diagnostic use
For use by people 18 years of age or older.

The GetMyDNA COVID-19 Test Home Collection Kit collection device is only authorized for use in conjunction with an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 indicated for use with this collection device for testing any individuals, including individuals without symptoms or other reasons to suspect COVID-19 infection.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The GetMyDNA COVID-19 Test Home Collection Kit is available direct to consumer (DTC) without a prescription online for any individual 18 years and older. The GetMyDNA COVID-19 Test Home Collection Kit is for the self-collection of anterior nasal swab specimens and stabilization of SARS-CoV-2 RNA for shipping to a clinical laboratory. Kits can be purchased online or in physical retail locations. Once the kit has been obtained, individuals will register their kit and complete a screening questionnaire online.

After the anterior nasal swab specimen is collected, the swab is inserted into the transportation liquid (0.9% saline), and the swab shaft is broken off at the score. Upon contacting the medium, the viral particles are stabilized for transportation. For specimen shipping, the individual must place the tube in the biohazard bag. The bag with the specimen is placed within the supplied GetMyDNA box and then placed in the supplied FedEx UN3373 overpack. The individual drops off the package at a FedEx drop box for shipping to a clinical laboratory.

Specimens received at the clinical laboratory for testing with the GetMyDNA COVID-19 Test Home Collection Kit undergo accessioning prior to acceptance for testing. All acceptable samples are processed by the laboratory. All rejected specimens are disposed of and the individual is contacted for potential recollection.

All test results are delivered to the user via an online portal. Additionally, individuals with positive and invalid/inconclusive 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.

REAGENTS AND MATERIALS

GetMyDNA COVID-19 Test Home Collection Kit consists of the items listed in Table 1.

Table 1. Components Included with the GetMyDNA COVID-19 Test Home Collection Kit

Kit Box
Instructions for Use
Prefill 13 mL vial with 3 mL Buffered Saline Solution
OP/Nasal swab, Nylon Flock, Sterile
6" x 9" Bio Bag with Absorbent
Medium alcohol prep pads
Patient Label (Barcoded)
Lab Pak, FedEx, UN3373
Return Service Label - Priority Overnight with Saturday Delivery, FedEx
Fact Sheet for Individuals

PROCESS AND MEDICAL OVERSIGHT

The organization providing medical oversight for the GetMyDNA COVID-19 Test Home Collection Kit is PWNHealth. PWNHealth is an independent healthcare provider network that provides oversight services in connection with the laboratory testing requested. PWN employs or contracts with physicians licensed in all 50 states, healthcare professionals, and non-clinical care coordinators as support staff. PWNHealth and its services are independent from the clinical testing laboratory and GetMyDNA .

1) ***Ordering a Kit***
   Because the GetMyDNA COVID-19 Test Home Collection Kit is DTC, all individuals 18 or older, who request a kit, will receive a kit, regardless of the answers given on the screener i.e., online screening questionnaire (with the exception of selecting an age under 18). The screener is only used for data collection. To place an order for the kit, the individual registers and is prompted to complete a screener.

2) ***Screener***
   The screener is based on CDC published guidelines in conjunction with HHS priority levels and is changed accordingly as updates are presented. The question categories listed below are for data collection use only:
   1) Age - must be 18 years or older. (if an individual selects an age less than 18 they will be ineligible for a kit).
   2) Reason for test - records the work-issued reason (where applicable) for the testing as either (a) PCR recurrent re-test, (b) flagged for check, (c) returning to work after isolation, (d) household contact of employee.

3) Symptoms - Includes initial triage of (a) NO symptoms, (b) MILD symptoms, and (c) SEVERE symptoms.
4) Exposure - delineation based on (a) proximity, (b) testing recommended by HCP, (c) congregate setting, or (d) unexposed.
5) Medical and Personal History – Includes (a) comorbidities, (b) ethnicity, (c) race, and (d) age to stratify for risk.

3) Accessioning and Testing Process

When the online order and screener are submitted through the GetMyDNA website, they are first sent to PWNHealth. At this point the screener is reviewed for age verification and data collection purposes only and the patient portal, where results can be accessed, is created. The information then flows to the CLIA Laboratory, where a test requisition is generated and a unique Specimen ID is assigned to the order. That information is then sent to the fulfillment partner (Path-Tec), who prints a tube label for that order. The label includes the unique identifiers and a unique barcode linked to the individual's Specimen ID. The kit is then shipped to the individual. When the kit is received at the CLIA laboratory, the specimen accessioner scans the tube label barcode and the correct Specimen ID for the order pulls up in their system to accurately accession the sample. The sample is inspected (according to the criteria described below) for integrity, and if acceptable, is processed by an FDA-authorized SARS-CoV-2 molecular assay that is authorized for use with the GetMyDNA COVID-19 Test Home Collection Kit and which also assays for a human endogenous control gene (i.e., RNase P).

4) Process for Results Reporting and Interpretation

Upon results being available, an email is sent, via PWNHealth, to the individual which contains links to patient portal for viewing results. All emails have contact information for both PWNHealth and GetMyDNA for reference. In the case that an individual receives a positive or inconclusive/invalid result, they will be contacted directly by telephone by an HCP from PWNHealth.

This following language is included in all emails to individuals:

If you have questions about this test or your results, you can contact the PWNHealth Care Coordination Team at 315-401-7865, Monday-Sunday, 8 AM to 11 PM Eastern Time, or email covid19@pwnhealth.com. You can also leave a message after hours and a PWNHealth team member will call you back as soon as possible.

INSPECTION OF SPECIMENS

Specimens collected using the GetMyDNA COVID-19 Test Home Collection Kit will be checked for the following criteria before entering the work flow at the High Complexity Laboratory:

- **Physical Damage -** Specimens with physical damage are rejected. Any damage to the tube allowing exposure of the specimen will be cause for rejection.

- **Sufficient Transport medium** – Specimens without transport medium will be rejected.
- **Labeling** - Improperly labeled or shipped specimens that cannot be resolved are rejected. If the name on the tube does not match a corresponding electronic order or test request form, the tube will be rejected.
- **Electronic order -** If the specimen does not have complete information on the electronic order or test request form, the specimen may be rejected. Required information will usually be obtained by Lab customer service personnel, which will allow acceptance of specimens that initially lack all the required information.
    - Specimens holding for incomplete information are considered expired 96 hours after the collection date. These specimens are held at 2-8°C.
- **Expired shipping time -** If a specimen is received > 96 hours from the collection date, the specimen is rejected.

CONTROLS TO BE USED WITH THE EUA SARS-COV-2 MOLECULAR TEST

All test controls should 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 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. 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.

PERFORMANCE EVALUATION

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

A stability study was conducted by Gravity Diagnostics, LLC, to support shipping of nasal swabs, collected in 0.9% saline, for up to 96 hours. A right of reference was obtained by GetMyDNA 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 and 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 shipping of nasal swabs collected in 0.9% saline for up to 96 hours, year-round.

2) GetMyDNA COVID-19 Test Home Collection Kit Self-Collection Validation:

A human usability study was conducted by GetMyDNA for the home-collection and mailing of the sample to Gravity Diagnostics, LLC for testing. The study included 30 participants (age and education ranges are broken down in Table 2). The study was designed to assess each participant's ability to receive a test kit, collect an anterior nasal swab sample, ship the test kit to the clinical lab, and have the lab receive the test kit with no defects. User error rates (by type and overall) were calculated from the 30 samples that were returned to the lab. Error rates were calculated as the number of samples received with errors divided by the total number of samples. The acceptance criterion was an error rate of less than 10% as the threshold before implementing corrective actions.

The results of sample accessioning by Gravity Diagnostics are as follows:

1. Number of samples properly packaged. *28 out of 30 (93%) arrived with complete packaging. Two samples were missing the return box; however, the samples were still intact and therefore accessioned by Gravity Diagnostics.*
2. Number of samples accessioned. *30 out of 30 (100%) samples passed the inspection of specimens criteria and were accessioned by Gravity Diagnostics.*
3. Number of samples properly labeled. *29 out of 30 (97%) samples were properly labeled. One sample was held at 2 - 4°C for 12 to 24 hours and labeling was resolved by customer service.*
4. Number of samples with a matching electronic order. *30 out of 30 (100%) samples had a matching order in Gravity Diagnostic's LIS.*
5. RNase P results. *30 out of 30 (100%) samples had a positive RNase P result, indicating all samples contained human nucleic acid.*

Table 2. Human Usability Study Participant Demographics for Unobserved Self-Collection.

Age Group	Count
18-34	8
35-49	14
50-64	7
65+	1

Education	Count
High School	2
College	17
Greater than College	11

At the conclusion of the patient self-collection portion of the study, a questionnaire was administered to each participant. Answer choices to each question were: "strongly disagree", "disagree", "neutral", "agree", and "strongly agree". Additionally, individuals had an opportunity to return written responses to each question. For the purposes of acceptance criteria, answers "agree" and "strongly agree" are considered positive responses. Scores were calculated as number of positive responses divided by total responses. If any of the survey questions received < 90% positive response rate, a mitigation was formulated to address that particular failure point. Seven of the 27 survey questions did not meet the ≥ 90% success threshold. GetMyDNA formulated mitigations and revised their instructions for use based on the results of this study.

Additionally, GetMyDNA produced an instructional video (https://getmydna.com/instructions) based on the results of the participant survey. The revised instructions for use and instructional video been reviewed by FDA and appear to be acceptable.

GetMyDNA will conduct a usability assessment to identify and characterize user error rates, specifically pertaining to kit registration. This assessment will evaluate registration error rates for the first month, post-authorization. User error rate will be calculated as the number of samples with errors divided by the total number of samples for each metric associated with kit registration. GetMyDNA 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 criterion. Specifically, GetMyDNA will track errors associated with:

1) Mislabeled samples (i.e., does not match the registration)
2) Unreadable labels
3) Order processing errors associated with the website (pre-registration)
4) Calls to the help line/emails associated with kit registration

3) Kit stability:

Saline Tube (Reagent) Stability

The pre-filled saline tubes used in the GetMyDNA COVID-19 Test Home Collection Kit are manufactured at Sarstedt. Each batch of product is quality controlled before release into saleable inventory and is sterile according to Sarstedt manufacturing specifications and ISO 11137: "Sterilization of Health Care Products Package". The manufacturer is providing the product with dating not beyond one year. The expiration date of GetMyDNA COVID-19 Test Home Collection Kit will correspond with the kit component that has the earliest expiration date, which will likely be the saline.

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.
- 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.