EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
FOR THE EMPOWERDX AT-HOME COVID-19 PCR TEST KIT

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

INTENDED USE

The EmpowerDX At-Home COVID-19 PCR Test Kit is intended for use by individuals to self-collect nasal swabs at home, when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire. Specimens collected using the EmpowerDX At-Home COVID-19 PCR Test 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 suitable for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 that is indicated for use with the EmpowerDX At-Home COVID- 19 PCR Test Kit.

Testing is limited to laboratories designated by Clinical Enterprise, Inc. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests. Testing is also limited to molecular diagnostic tests that are indicated for use with the EmpowerDX At-Home COVID-19 PCR Test Kit.

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

SPECIAL CONDITIONS OF USE STATEMENTS

For Emergency Use Authorization (EUA) only
For Prescription Use only
For in vitro diagnostic use
For use by people 18 years of age or older

The EmpowerDX At-Home COVID-19 PCR Test Kit is only authorized for use in conjunction with an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with nasal swab specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The EmpowerDX At-Home COVID-19 PCR Test Kit collection device consists of a designated box containing the following components:

1. user sample collection instructions
2. polyester nasal swab
3. collection tube containing 0.9% buffered saline
4. tube label
5. biohazard bag with absorbent pad
6. FedEx return shipping box/envelope prelabeled with the receiving laboratory delivery address.

The EmpowerDX At-Home COVID-19 PCR Test Kit collection device was reviewed for adherence to the Department of Transportation's shipping requirements for hazardous materials. The kit was found to be acceptable and appropriate for shipping within the United States.

Individuals may request the EmpowerDX At-Home COVID-19 PCR Test Kit collection device by filling out an online COVID-19 questionnaire that is reviewed by a physician and his/her staff EmpowerDX will determine test eligibility and write prescriptions for testing if the requesting individual is eligible based on CDC recommendations for testing prioritization. Following physician authorization, the EmpowerDX At-Home COVID-19 PCR Test Kit will be delivered to the individual.

Nasal swab samples will be collected by the individual following instructions provided with the EmpowerDX At-Home COVID-19 PCR Test Kit. The instructions include kit registration and sample collection steps. The EmpowerDX At-Home COVID-19 PCR Test Kit consists of a polyester tipped swab and a collection tube containing 0.9% buffered saline. The individual using the EmpowerDX At- Home COVID-19 PCR Test Kit to collect nasal swabs specimens performs the following steps to collect the initial specimen: wash and dry hands before beginning, remove swab from envelop, screw off the top of the collection tube, insert tip of swab into one nostril and rotate three times around the inside edge of the nostril, and repeat on second nostril. After the nasal swab specimen is collected, place swab tip down in the collection tube so that swab tip contacts media, wash and dry hands, write date of birth on label and place label on tube, place tube in biohazard bag, and place biohazard bag in the provided box.

For device shipping, the individual must place the box in the provided labeled FedEx envelop and deliver to a FedEx drop box or FedEx location for pick-up the on the day of sample collection. Samples will be shipped ambient directly to the receiving laboratory. Device shipping is priority overnight with Saturday delivery, both to the consumer and back to the laboratory following sample collection.

Upon receipt by the testing laboratory, SOPs will be followed which specify confirmation that shipping time has not exceeded allowable limits. Additional SOPs will be followed by the receiving laboratory for all testing steps for samples collected by the EmpowerDX At-Home COVID-19 PCR Test Kit.

The EmpowerDX At-Home COVID-19 PCR Test Kit collects and stabilizes virus and viral RNA from nasal swab specimens; it can also be used for the transportation and short-term room temperature storage of a sample. The EmpowerDX At-Home COVID-19 PCR Test Kit is a non-invasive alternative for collecting high quality and quantity virus and viral RNA by/from individuals who are suspected of COVID-19 by their healthcare provider for use in molecular COVID-19 diagnostic assays that are authorized for use with the EmpowerDX At-Home COVID-19 PCR Test Kit.

REAGENTS AND MATERIALS

Name	Description	Quantity	Material Supplier
Instructions	Kit registration, sample collection and shipping instructions	1	EmpowerDX
Label	bar-coded label with individuals name and line for addition of date of birth	1	Path-Tec
Nasal Swab	Polyester tipped, plastic shaft nasal swab	1	Path-Tec
Collection tube	Screw-capped collection tube containing 3 mL 0.9% buffered saline solution	1	Path-Tec
Biohazard bag	Sealing (zip-lock) biohazard bag containing an absorbent pad	1	Path-Tec
Box	Cardboard box for material shipping to individual and return of sample to the laboratory	1	Path-Tec
Fedex shipping envelop	Addressed, pre-paid FedEx shipping envelop, UN 3373 Biological Substance Category B labeled	1	FedEx

MEDICAL OVERSIGHT AND PROCESS TO BE USED:

After an individual requests the EmpowerDX At-Home COVID-19 PCR Test Kit collection device by filling out an online COVID-19 questionnaire, the answers to this questionnaire are reviewed by an EmpowerDX physician and his/her staff. The physician will determine test eligibility and write prescriptions for testing if the requesting individual is eligible based on CDC recommendations for testing prioritization. Only patients with either mild symptoms or those with no symptoms but with known exposure, contact with a sick individual, or living in an area with known community spread, will be eligible to receive a kit. Individuals with no symptoms and no known exposures will not be eligible to receive a kit.

Test results are communicated back to individuals that used the EmpowerDX At-Home COVID-19 PCR Test Kit via the EmpowerDX patient portal. An email notification will be sent when the results are ready.

PATIENT INCLUSION/EXCLUSION CRITERIA

Inclusion criteria include:

1. Patients with “mild” symptoms
2. Individuals with no symptoms but with known exposure, contact with a sick individual, or living in an area with known community spread.

Exclusion criteria include:

1. Individuals with no symptoms or known exposures
2. Patients with severe symptoms (which will be directed to seek immediate medical care)

INSPECTION OF SPECIMENS AND VERIFICATION OF OBSERVED SELF-COLLECTION

Specimens received at the clinical laboratory for testing with an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with nasal swab specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit will undergo the full accessioning by the laboratory prior to acceptance for testing, using either a laboratory developed accessioning SOP or the “Self-Collection Specimen Receipt

and Accessioning SOP" available from Clinical Enterprise, Inc. Include reference to the accessioning SOP. Rejection criteria include:

1. Specimens not registered
2. Unlabeled specimens
3. Specimens with missing or incorrect information such as date of birth, date of collection or name
4. Specimens exceeding demonstrated stability timeframes
5. Specimen tubes without a swab present in the tube, discolored or cloudy specimens with or without visible precipitate

CONTROLS TO BE USED WITH THE SARS-COV-2 ASSAY

The following controls (at a minimum) should be included in the in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 RNA that is indicated for use with nasal swab specimens collected with the EmpowerDX At-Home COVID-19 PCR Test Kit:

1. A negative (no template) control is needed to eliminate the possibility of sample contamination and is used on every assay plate. This control is molecular grade, nuclease-free water.
2. A negative extraction control is needed to eliminate the possibility of sample contamination during nucleic acid extraction and is used with every extraction run. This control is known-negative phosphate buffered saline.
3. A positive template control is needed to verify that the assay run is performing as intended and is used on every assay plate
4. 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.

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 and will be reported as "Inconclusive". Patients with "Inconclusive" results will be instructed to collect a second sample if warranted by clinical symptoms or risk. If controls are valid and the rRT-PCR C_T value for SARS-CoV-2 is equal to or below the C_T cutoff, the result will be reported as "Positive". If controls are valid and the rRT-PCR C_T value for SARS-CoV-2 is greater

than the C_T cutoff, the result will be reported as “Negative”. Results will be reported by EmpowerDX to public health agencies as required. The following comment will be provided to the patients with the results:

If your results say “Positive” this means the COVID-19 virus was found in the sample you provided and it is very likely that you are infected with COVID-19. Contact your healthcare provider to interpret and determine how best to care for you based on the test results along with medical history, your symptoms and other factors. You must quarantine to avoid spreading the virus to others. Your healthcare provider will help you determine how long you must remain quarantined.

If your results say “Negative” this means the virus that causes COVID-19 was not found in your sample. A test result that says “Not Detected” for a sample collected while a person has COVID-19 related symptoms usually means that COVID-19 did not cause your symptoms. There may be other causes of your symptoms that require treatment. It is also possible that this result is not correct (it could be a false negative). Follow up with your healthcare provider to interpret and consider the test result together with all other aspects of your personal and medical history, such as symptoms, possible exposures, geographical location of places you have recently traveled, and other factors, in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps you should take.

If your result says "Inconclusive" this means we could not determine whether or not the virus was in the sample you provided. A new sample will need to be collected to determine if you are infected with the COVID-19 virus. It is important to be evaluated by your healthcare provider to address any symptoms and quarantine according to your healthcare provider's recommendation.

PERFORMANCE EVALUATION

1) EmpowerDx Shipping Stability Studies:

The EmpowerDX At-Home COVID-19 PCR Test Kit uses wrapped polyester nasal swabs transported in 0.9% saline and therefore references the COVID-19 swab stability studies conducted by Quantigen Biosciences through the right of reference granted to any sponsor wishing to pursue an 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°C for 12 hours, then 32°C 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 positive samples. Both time points met this criteria and supported sample shipping stability, using a drop box, with over-night or 48-hour shipping.

Average C_T 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	0 h	5	23.74	32.23	30.03	31.80
10xLoD swab in saline	0 h	5	23.27	29.46	27.58	28.67
2xLoD swab in saline	30 h	20	26.00	32.69	31.33	34.59
10xLoD swab in saline	30 h	10	26.19	29.54	28.37	28.69
2xLoD swab in saline	54 h	20	25.70	32.03	31.09	32.10
10xLoD swab in saline	54 h	10	26.11	28.73	27.25	25.09

2) Human Usability Studies for the EmpowerDX At-Home COVID-19 PCR kit

Testing was performed with 30 participants and took place in the actual use environment (participant's home). None of the 30 participants had medical or laboratory training or prior experience with self-collection. The ages and educational levels of the participants varied and is shown in the table below with the results of testing.

The entire workflow was performed by each individual participant and included registration of the kit, sample collection, packaging of the sample, and mailing to the laboratory with pre- prepared FedEx envelope. Sample collection of each participant was observed by remote visual monitoring and no difficulties were noted.

The following criteria were used to assess the sample collection procedure (a summary of results is provided after each criteria in italics):

1. Did participant read the instructions? *30 out of 30 participants indicated they had read the instructions.*
2. Did participant wash their hands before opening the kit? *30 out of 30 participants washed their hands prior to opening the kit.*
3. Did participant open the swab without touching the tip to hands/ surfaces? *30 out of 30 participants opened the swab without touching the tip to hands/surfaces.*
4. Did participant properly collect both nasal swabs? *29 out of 30 participants properly collected both nostrils; one participant properly collected a single nostril.*
5. Did participant place swab in collection tube? *30 out of 30 participants placed the swab in the collection tube with the soft (collection) end contacting the liquid.*
6. Did participant spill any liquid from collection tube? *None of the 30 participants spilled any liquid from the collection tube.*
7. Did participant place vial in biohazard bag? *30 out of 30 participants placed the collection tube in the biohazard bag.*
8. Did participant place biohazard bag in the box? *30 out of 30 participants placed the biohazard bag in the box.*
9. Did participant place box in shipping envelop and seal? *30 out of 30 participants placed the box in the shipping envelop and sealed.*
10. Did any injury occur during the procedure? *None out of 30 participants experienced any injury in the procedure.*
11. Were there any deviations from the instructions? *One out of 30 participants deviated from the instructions (noted above in no. 4 in which a single nostril was collected).*

Laboratory personnel inspected the packaging and samples upon receipt. No packaging errors were noted. Each sample from the 30 participants was acceptable for testing. The following parameters were evaluated during packaging inspection (a summary of results is provided after each criterion in italics):

1. Is the sample tube in the biohazard bag? *30 out of 30 sample tubes were in a biohazard bag*
2. Is the sample tube labeled with name/barcode sticker? *29 out of 30 sample tubes were correctly labeled with the name/barcode sticker; for one sample the barcode sticker was on the tube but did not have a name. Based on the barcode, this participant was contacted to verify the correct name of the participant.*
3. Is the DOB on the name/barcode sticker? *28 out of 30 participants correctly printed their DOB on the name/barcode sticker; for the two stickers that that did not have a DOB, follow-up contact confirmed this information.*
4. Is the biohazard bag sealed? *30 out of 30 biohazard bags were sealed.*
5. Is the absorbent pad in the biohazard bag? *30 out of 30 biohazard bags contained the absorbent pad.*
6. Is a swab present in the tube? *30 out of 30 sample tubes had a swab present.*
7. Is the volume of liquid in the tube 2 - 3 mL? *30 out of 30 sample tubes had 2 – 3 mL of liquid.*
8. Is there evidence of leaking from the tube? *None of the 30 sample tubes showed evidence of leaking in the biohazard bag.*
9. Is the biohazard bag with the tube in the box? *30 out of 30 biohazard bags (containing sample tubes) were in the box.*
10. Is the consent form in the box or external package? *30 out of 30 consent forms were in the box or external packaging.*

The samples were tested for specimen adequacy using a primer/probe set that detects RNAse P gene. Pre-defined acceptance criteria for sample adequacy were RNAse P CT value <40 and MS2 (exogenous internal control) CT value <35. Study participants ranged in age from 19 to 58 years old and in educational level from a high school degree to a doctoral level degree. Results of testing for each of the 30 participants are shown in the following table:

Participant age, educational level and Viracor SARS-CoV-2 rRT-PCR results

Subject ID	**Age (yrs)**	**Education level**	**MS2 CT**	**RNAse P CT**
1	35	BS/BA[1]	26.80	25.35
2	56	BS/BA	26.40	26.10
3	34	MS[3]	26.18	31.83
4	31	BS/BA	26.54	26.15

5	58	MS	26.40	26.65
6	55	Doctoral[4]	26.15	31.42
7	27	Doctoral	26.30	30.55
8	55	MS	27.03	23.58
9	35	BS/BA	26.22	27.12
10	34	MS	26.36	29.25
12	46	MS	26.47	29.29
13	24	HS[5]	26.33	29.36
14	34	MS	26.38	29.39
15	54	MS	26.74	24.37
16	50	BS/BA	26.43	31.89
17	57	BS/BA	26.83	25.23
18	56	BS/BA	27.17	22.56
19	22	BS/BA	26.33	27.28
20	54	Associates[6]	26.41	27.43
21	57	BS/BA	27.16	24.17
22	30	BS/BA	26.59	25.23
23	27	Associates	26.24	28.71
24	35	BS/BA	26.67	23.52
25	31	Associates	27.46	25.30
26	21	Some college	26.23	30.71
27	48	BS/BA	26.50	25.80
28	51	BS/BA	26.54	25.22
29	22	Associates	27.31	21.03
30	19	Some college	26.28	26.48

[1]4 year bachelors level degree
[2]Not detected (negative)
[3]Master's level degree
[4]Doctoral level degree
[5]High school degree
[6]2 year associates level degree

The results from the usability indicate users are able to safely and appropriately collect a nasal swab specimen with sufficient human biological material.

WARNINGS:

- This home-collection kit has not been FDA cleared or approved.
- This home-collection kit has been authorized by FDA under an EUA for use by designated laboratories.
- This home-collection kit has been authorized only for the self-collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- This home-collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the authorization is terminated or revoked sooner.