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

Direct to consumer (DTC) home self-collected anterior nasal swabs collected by individuals 18 years or older (unobserved) with the EmpowerDX COVID-19 Home Collection Kit DTC will be sent to High Complexity Laboratories that have been designated by Clinical Enterprise, Inc. 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 EmpowerDX COVID-19 Home Collection Kit DTC on an in vitro diagnostic (IVD) molecular test that is indicated for use with the EmpowerDX COVID-19 Home Collection Kit DTC for self-collection of anterior nasal swab specimens.

INTENDED USE

The EmpowerDX COVID-19 Home Collection Kit DTC is a direct to consumer (DTC) product for self-collecting (unobserved) an individual anterior nasal swab (nasal) specimen by individuals 18 years or older at home and sending that specimen for testing with an in vitro diagnostic (IVD) molecular test that is indicated for use with the EmpowerDX COVID-19 Home Collection Kit DTC 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.

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 the requirements to perform high complexity tests.

All test results are delivered to the user via an online portal. Individuals with positive or inconclusive 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 self-isolation or quarantine is appropriate and to assist with healthcare decisions after discussion with a healthcare provider.

The EmpowerDX COVID-19 Home Collection Kit DTC 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.

The EmpowerDX COVID-19 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 your healthcare provider.

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

DEVICE DESCRIPTION AND TEST PRINCIPLE

The EmpowerDX COVID-19 Home Collection Kit DTC will be available direct to consumer (DTC) without a prescription for any individual 18 years and older. When ordering a kit online, individuals must verify they are 18 years or older. Individuals are recommended to complete a screening questionnaire when registering their 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 (HCP) via phone. The HCP will be an employee of Clinical Enterprise, Inc. or a contracted HCP with prescribing privileges in the state of residency of the tested individual. 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 EmpowerDX COVID-19 Home Collection Kit DTC is composed of sample registration, collection and shipping instructions, Fact Sheet for Individuals, anterior nasal swab, collection tube, collection tube label and shipping materials. 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 return envelope. Each EmpowerDX COVID-19 Home Collection Kit DTC 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.

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 nucleic acid amplification test (NAAT) test per the Instructions for Use.

REAGENTS AND MATERIALS

Contents of EmpowerDX COVID-19 Home Collection Kit DTC

Name	Description	Quantity	Material Supplier
Instructions	Kit registration, sample collection and shipping instructions	1	EmpowerDX
Fact Sheet for Individuals	Fact Sheet for Individuals	1	EmpowerDX
Label	bar-coded label with individuals name and line for addition of date of birth	1	Path-Tec
Anterior nasal swab	Polyester tipped, plastic shaft anterior 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 envelope	Addressed, pre-paid FedEx shipping envelope, UN 3373 Biological Substance Category B labeled	1	FedEx

INSPECTION OF SPECIMENS:

Applies to specimens received from individuals using home collection kit

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 anterior nasal swab specimens collected with the EmpowerDX COVID-19 Home Collection Kit DTC will undergo the full accessioning by the laboratory prior to acceptance for testing, using the “Self-Collection Specimen Receipt and 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 anterior nasal swab specimens collected with the EmpowerDX COVID-19 Home Collection Kit DTC:

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 individual results. If the controls are not valid, the individual results cannot be interpreted and will be reported as “Inconclusive”. 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 individuals 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 SARS-CoV-2. 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.

A healthcare professional will contact all individuals that receive “Positive” results by phone.

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.

A healthcare professional will contact all individuals that receive “Inconclusive” results by phone.

PERFORMANCE EVALUATION

1) EmpowerDx Shipping Stability Studies:

Summer Profile

The EmpowerDX COVID-19 Home Collection Kit DTC uses wrapped polyester anterior nasal swabs transported in 0.9% saline and therefore references the COVID-19 swab summer profile 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 anterior 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 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

Winter Profile

Winter temperature stability assessment conditions

Cycle period	Temperature	Cycle period time (hrs)	Elapsed time (hrs)
1	-10˚C	8	8
2	18˚C	4	12
3	-10˚C	2	14
4	10˚C	36	50
5	-10˚C	6	56

For this study, contrived samples were prepared by spiking an inactivated, residual, de-identified SARS-CoV-2 positive clinical sample at concentrations of 2xLOD and 8xLOD into nasal swab matrix collected with the EmpowerDx nasal swab kit by healthy volunteers. Twenty samples at 2xLOD, 10 samples at 8xLOD, and 10 negative (un-spiked) samples were prepared for this study and subjected to the sequential time and temperature variations shown above. Matched time 0 controls (negative, 2xLOD, and 8xLOD) were prepared simultaneously and tested using the Viracor SARS-CoV-2 EUA authorized RT-PCR assay immediately following preparation. Following the final cycle (-10˚C, 6 hr), samples were allowed to equilibrate to room temperature before testing with the Viracor SARS-CoV-2 EUA authorized RT-PCR assay. Results are summarized in the table below. All un-spiked samples did not return a C_T value (i.e. "Not detected" or negative). All samples spiked at 2xLOD and 8xLOD returned a C_T value and were positive for SARS-CoV-2 ("Detected", $C_T \leq 38$).

Control and winter temperature stability panel SARS-CoV-2 RT-PCR results

	Control (time 0)			Post-winter temperature cycling		
Sample set	**No. pos/ no. tested**	**Mean C_T**	**C_T SD**	**No. pos/ no. tested**	**Mean C_T**	**C_T SD**
Negative	0/5	N.D.[1]	N.A.[2]	0/10	N.D.	N.A.
2xLOD	5/5	35.44	0.97	20/20	34.75	0.82
8xLOD	5/5	33.08	0.39	10/10	32.51	0.37

[1]N.D., Not detected
[2]N.A., Not applicable

Agreement with expected and control results was 100% for low positive samples, 100% for high positive samples and 100% for negative samples. The mean C_T shift for low positive samples was -0.69 cycles and for high positive samples was -0.57 cycles relative to time 0 control values.

These results indicate acceptable specimen stability under the evaluated simulated winter shipping conditions.

Performance criteria were met for summer and winter shipping stability studies indicating acceptable specimen stability under the evaluated simulated summer and winter shipping conditions.

2) Home Collection Kit Stability

Saline Tube (Reagent) Stability

The saline tubes used in the EmpowerDX Home Collection COVID-19 Kit DTC are sourced from Azer Scientific, Inc. and are manufactured in accordance with ISO 13485:2016, ISO 9001:2015 and 21 CFR 820. Vials are filled in a clean room environment using sterilized vials and caps and then post sterilized using steam sterilization at 115°C for thirty (30) minutes. Each lot is release tested for pH and sterility and results documented in accordance with standard operating procedures. Product stability is verified by retesting the solution at its expiration, which is 12 months from date of production.

3) Human Usability Studies

Human usability studies were performed with the EmpowerDX At-Home COVID-19 PCR Kit (Rx). The EmpowerDX Home Collection COVID-19 Kit DTC uses the same instructions for collecting and returning the sample as the EmpowerDX At-Home COVID-19 PCR Kit (Rx). Therefore, an additional usability study was not required.

The results of the human usability study performed with the EmpowerDX At-Home COVID-19 PCR Kit (Rx) are summarized below.

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 criterion 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 anterior 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 envelope and seal? *30 out of 30 participants placed the box in the shipping envelope 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 C_T	RNAse P C_T
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 18 years of age and older are able to safely and appropriately collect a anterior nasal swab specimen with sufficient human biological material.

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. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.