EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE QDX SARS-COV-2 ASSAY

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

(The QDx SARS-CoV-2 Assay will be performed at QDx Pathology Services, located at 20 Jackson Dr, Cranford, NJ 07016, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, and meets requirements to perform high complexity tests as described in the Laboratory Standard Operating Procedures that were reviewed by the FDA under this EUA).

INTENDED USE

The QDx SARS-CoV-2 Assay is a real time RT-PCR assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected at home using the Qdetect home collection kit, or other authorized home-collection kit specified in this EUA's authorized labeling, by individuals (18 years of age or older) suspected of COVID-19 when home collection is determined to be appropriate by a healthcare provider. Specimens collected using Qdetect can be transported at ambient temperature for testing at QDx Pathology Services.

Testing is limited to QDx Pathology Services, located at 20 Jackson Dr, Cranford, NJ 07016 which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, and meets requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient 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. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The QDx SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR assays and *in vitro* diagnostic procedures. The QDx SARS-CoV-2 Assay and the Qdetect are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION

1) Device Description:

The QDx SARS-CoV-2 Assay for use with the QDx Pathology Services' Qdetect collection kit enables the self-collection of a nasal swab specimen by an individual qualified by their healthcare provider as needing SARS-CoV-2 testing. This specimen is then transported to QDx Pathology Services for SARS-CoV-2 testing using the QDx SARS-CoV-2 Assay. The Qdetect kit contains includes the following materials:

Reagent	Manufacturer	Catalog#
Shipping box	Path-Tec	#30472
Self-collection instruction	Qdetect	NA
Swab (Nest Specimen Collection Nylon Flocked Swab 150 mm with 2 breakpoints at 80 mm & 30 mm)	Wuxi Nest Biotechnology	#202003
13mL Specimen Collection Tube with 3ml fill, Sterile, Buffered Saline Solution	Sarstedt	#60.540.386
Specimen biohazard bag with absorbent 6x9	Path-Tec	CZSB09-B 
Gel pack	Black Ice	BLK 6 https://www.polar-tech.com/shop/item/blk%206/refrigerants-black-ice/
Insulated Silver Pouch	Insultote	https://insul.net/product/insultote-pouches/
UN 3373 Pak	Federal Express	#163034

The Qdetect home collection kit 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.

2) Home Collection Kit Ordering, Processing and Testing:

The QDx SARS-CoV-2 Assay is only for patients who have been previously qualified by their healthcare provider as needing SARS-CoV-2 testing based on the provider's medical judgement regarding symptoms, exposure, and risk factors. After a healthcare provider qualifies a patient for testing using the self-collection kit, the healthcare provider will submit an order to QDx

Pathology Services. The order will indicate that the self-collection will be unobserved. QDx Pathology services will then ship the self-collection kit directly to the patient.

The individual using the Qdetect kit will follow the self-collect instructions to appropriately collect the nasal swab specimen, place the swab into the transport tube, properly package the specimen, and mail the specimen back to the laboratory using the pre-labeled FedEx return envelope. The Qdetect kit collects and stabilizes SARS-CoV-2 from nasal swab specimens; it can also be used for the transportation and short-term storage of a sample at room temperature for 48-hours.

Once self-collected nasal swab specimens are received by QDx Pathology Services, they will be tested by laboratory personal using the QDx SARS-CoV-2 Assay, which is performed using the FDA EUA-authorized ChromaCode Inc. HDPCR SARS-CoV-2 Assay. Test results from the QDx SARS-CoV-2 Assay are communicated back to individuals that used the Qdetect via their ordering physician. Negative results may also be obtained by patients by calling QDx Pathology Services. Positive results will not be returned to patients by QDx Pathology Services, and only will be provided by the ordering physician.

PATIENT INCLUSION/EXCLUSION CRITERIA
Only patients who are suspected of COVID-19 by a healthcare provider are eligible to receive the Qdetect self-collection kit.

INSPECTION OF SPECIMENS
QDx Pathology Services has submitted an SOP for Receipt and accessioning of COVID-19 self-collection kits at QDx Pathology Services Laboratory. This protocol is summarized below:

Specimens received through the Qdetect self-collection kit will be checked for the following criteria before entering the workflow:

1. **Physical Damage**. Check the specimen collection container to ensure it is not broken or leaking.
2. **Patient Test Order Form**. If the specimen does not have complete information on the requisition/test order form, the specimen may be rejected. QDx Client Services will attempt to obtain additional information needed from the patient, which will allow acceptance of specimens that lacked required information
3. **Collection Container Labeling**. If the collection container labeling does not match the requisition/order form, and this cannot be resolved by contacting the patient/physician, the sample will be rejected.
4. **Sample Acceptability**. Ensure appropriate sample volume and that patient sample was received within 48-hours of the shipping date.

3) Test Results and Interpretation:

CONTROLS TO BE USED WITH QDX SARS-COV-2 ASSAY
QDx Pathology Services will test the controls used for the ChromaCode Inc. HDPCR SARS-CoV-2 Assay, which include an internal control (RNase P), positive control, negative control, and no template control (NTC). Controls will be used in accordance with the package insert.

The ChromaCode Inc. HDPCR SARS-CoV-2 Assay provides the positive and negative controls with the kit, and the controls are ready-to-use. All controls should yield the expected result; if they do not, the run is invalidated, and patient results cannot be reported.

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. Results are reported as Positive, Presumptive Positive, Negative, or Invalid.

The QDx SARS-CoV-2 Assay will use the result interpretation displayed in the table below:

SARS-CoV-2 N1	SARS-CoV-2 N2	Human RNase P (IC)	Report	Action
Detected	Detected	Passed or Not Assessed	SARS-CoV-2 Positive	Report result to appropriate health authorities and ordering physician.
Detected	Not Detected	Passed or Not Assessed	SARS-CoV-2 Presumptive Positive	Repeat testing of nucleic acid and/or re-extract and repeat HDPCR SARS-CoV-2. If the repeated result remains inconclusive, contact your State Public Health Laboratory or CDC for instructions for transfer of the specimen or further guidance.
Not Detected	Detected	Passed or Not Assessed	SARS-CoV-2 Presumptive Positive	Repeat testing of nucleic acid and/or re-extract and repeat HDPCR SARS-CoV-2. If the repeated result remains inconclusive, contact your State Public Health Laboratory or CDC for instructions for transfer of the specimen or further guidance.
Not Detected	Not Detected	Passed	SARS-CoV-2 Negative	Report result to appropriate health authorities and ordering physician.
Not Detected	Not Detected	Failed	Invalid Results	Repeat test, if second test result is invalid, report as invalid and recommend recollection if patient is still clinically indicated.

Collection Kit Stability:

All components in the Qdetect Home Collection Kit have established expiration dates.
The Black Ice gel pack does not expire. The distribution center applies the shortest expiration date of these items on the label. The label is then applied on the outside of the shipping box.

PERFORMANCE EVALUATION

1) Sample Stability Studies for QDx Pathology Services Qdetect Self-Collection Kit

A specimen stability study was performed to confirm that signal degradation at high temperatures (i.e., summer conditions) or low temperatures (i.e., winter conditions s) would not occur during shipping. For this study, contrived samples were prepared by spiking inactivated virus [ZeptoMetrix SARS-Related Coronavirus 2 (SARS-CoV-2) External Run Controls, CAT# NATSARS (COV2)-ERC] onto swabs at concentrations targeting 2x LoD and 5-10x LoD and placed into saline. For both the summer and winter profile, twenty (20) samples at 2x LoD, 10 samples at 5-10x LoD, and 10 negative samples were evaluated. In addition, to evaluate the worst-case scenario, 10 samples at 2x LoD without the gel pack and insulated pouch were evaluated as part of the summer profile study

These summer profile and winter profile studies simulated shipping conditions that may be encountered during these time periods by cycling the samples through the temperature profiles outlined in the following table:

Summer Profile			
Storage Temperature	**Cycle Period**[1]	**Time at Store Temp (hours)**	**Cumulative Time (hours)**
40°C	1	8	8
Room temp (24°C-25°C)	2	4	12
40°C	3	2	14
30°C	4	36	50
40°C	5	6	56
Winter Profile			
Storage Temperature	**Cycle Period**[1]	**Time at Store Temp (hours)**	**Cumulative Time (hours)**
-10°C	1	8	8
18°C	2	4	12
-10°C	3	2	14
10°C	4	36	50
-10°C	5	6	56

[1] Cycle periods are sequential. After each cycle period, the "total time hours" increments by the number of hours in the cycle period.

Samples were tested at time 0 (i.e., before undergoing the temperature cycling conditions illustrated in the above table) and at the completion of the study (i.e., 56 hours after study initiation) with the QDx SARS-CoV-2 Assay. The Ct values were compared before and 56 hours after cycling in and out of high temperatures. For both the summer and winter conditions, all negative samples remained negative and all positives remained positive, including those without

the gel pack and insulated pouch (worst-case scenario, evaluated only under summer conditions). Additionally, for summer conditions, Ct values were within 1.9 Ct between time 0 and 56-hours for all positive samples. For winter conditions, Ct values within 1.0 Ct between time 0 and 56-hoursfor all positive samples. These results indicate acceptable specimen stability under the evaluated simulated shipping conditions.

2) Human Usability Study for the QDx Pathology Services Qdetect Self-Collection Kit

A usability study was conducted to confirm that patients could follow the instructions included in the Qdetect self-collection instructions to appropriately collect, package, and ship a self-collected nasal specimen to QDx Pathology services. The study was completed in an actual home-use environment.

After providing informed consent, participants were mailed a Qdetect self-collection kit, which included the instructions for use, test requisition form, nasal swab, saline collection container, biohazard bag, transport box, gel pack, an Insulote padded pouch, and a labeled Fedex UN 3373 Pak. The participants proceeded to collect a nasal specimen observed, with no instruction from the observer, in their home environment and then shipped the specimens back to QDx Pathology Laboratory via FedEx following the instructions in the Qdetect self-collection kit. Participants were also asked to fill out a questionnaire that assess their ability to understand the different steps in the instructions for use.

A total of 30 individuals were consented to participate in the study. These participants included individuals representing varying education levels and age ranges. No individuals under the age of 18 were included in this study. Individuals with prior medical or laboratory training as well as prior experience with self-collection were excluded from the study. Of the 30 individuals, all participants returned the kit and questionnaire within the study window. Of these 30, 100% (30/30) returned a specimen that was acceptable for testing according to pre-determined acceptance criteria. The returned specimens were all tested with the QDx SARS-CoV-2 Assay, which detects an internal house-keeping gene RNase P. All specimens yielded strong RNase P signals, indicating successful sampling of human biological material.

***3) QDx SARS-CoV-2 Assay Analytical and Clinical Performance Evaluation*:**

The QDx SARS-CoV-2 Assay is performed on the ChromaCode Inc. HDPCR SARS-CoV-2 Assay using nasal swabs collected with the QDx Qdetect Self-Collection Kit. The analytical and clinical performance of the ChromaCode Inc. HDPCR SARS-CoV-2 Assay has been demonstrated by ChromaCode, Inc. in the Emergency Use Authorization submission authorized on 06/09/20. The details of the performance of the authorized ChromaCode, Inc. HDPCR SARS-CoV-2 Assay 2 can be found here: https://www.fda.gov/media/138786/download. ChromaCode Inc. granted Right of Reference to QDx Pathology Services for ChromaCode Inc.'s authorized HDPCR SARS-CoV-2 Assay.

Warnings:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by QDx Pathology Services located at 20 Jackson Dr, Cranford, NJ 07016, 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;

- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.