EMERGENCY USE AUTHORIZATION (EUA)
SUMMARY
ECL COVID TEST SYSTEM-1
Empire City Laboratories Inc.

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

For Use by Individuals 18 Years of Age or Older

(The ECL COVID TEST SYSTEM-1 will be performed at the Empire City Laboratories Inc. located at 229 49th Street, Brooklyn, NY 11220, 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. The Laboratory Standard Operating Procedures were reviewed by the FDA under this EUA.)

INTENDED USE

The ECL COVID TEST SYSTEM-1 is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in self-collected (unsupervised) anterior nasal swab specimens at home using the ECL COVID-19 AT HOME COLLECTION KIT, by individuals 18 years of age or older suspected of COVID-19, when determined to be appropriate by a healthcare provider based on the results of an online COVID-19 questionnaire. Specimens collected using the ECL COVID-19 AT HOME COLLECTION KIT are transported at ambient temperature for testing at a laboratory.

Testing is limited to the Empire City Laboratories Inc., located at 229 49th Street, Brooklyn, NY 11220, 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 anterior 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.

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.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The ECL COVID TEST SYSTEM-1 is intended for use by qualified laboratory personnel specifically instructed and trained in molecular testing and in vitro diagnostic procedures. The ECL COVID TEST SYSTEM-1 is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) ***ECL COVID-19 AT HOME COLLECTION KIT***

a) Product Overview/Test Principle:

The ECL COVID-19 AT HOME COLLECTION KIT consists of the following components:

Components	**Quantity**
Viral Transport Tube Containing 3 mL Normal Saline (0.9%) (CitoTest, catalog# 2118-0031)	1
Sterile Polyester Spun Swab (SteriPack, catalog# 60564)	1
Pre-Printed Barcode Label	1
Specimen Collection Instructions	1
Zip-lock Bag (biohazard symbol)	1
Absorbent Pad	1
Pre-Printed Test Requisition Card (patient information card) and Activation Card	1
Cardboard Shipping Box	1
FedEx Bag with FedEx Label (Pre-Printed and Pre-Paid)	1
Shipping Instructions	1

The molecular test to be used with the ECL COVID-19 AT HOME COLLECTION KIT is the EURORealTime SARS-CoV-2 which is a real-time reverse transcription polymerase chain reaction test for the detection of SARS-CoV-2 RNA, performed at the Empire City Laboratories Inc.

b) Medical Oversight and Process:

Patients may request the ECL COVID-19 AT HOME COLLECTION KIT through the ECL online portal (https://www.empirecitylabs.com/covid-19-test-at-home-collection-kit/). The online portal has a series of questions based on the CDC guidelines to assess eligibility of the patients to order the test (https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html).

The answers to the questionnaire are reviewed by a member of the physician network (UDoTest). If the physician approves the test based on the review, a script will be provided to the laboratory. An e-mail would be sent to the patient, letting him/her know that he/she has been approved or not approved for the test. If the patient is approved, he/she would be charged for the physician fee and the kit, and a kit will be mailed out to him/her. If the patient is not approved, he/she would only be charged the fee for the physician.

An approved patient is provided a link in the e-mail directing him/her to a secure patient portal. The patient creates an account with a username and password in the portal and is then able to track the order progress from the laboratory to the home.

Once the kit is received, it must be activated in the online portal before use by entering the activation code provided. The activation code can be found in the activation card included in the kit. The patient is then prompted to record the collection date and time in the online portal. After answering a few New York State Dept of Health mandated questions, the patient submits the information. A message is then automatically sent to the e-mail address on file stating that the information has been received and the kit has been activated.

c) Description of Specimen Collection Steps:

Once ECL COVID-19 AT HOME COLLECTION KIT is activated, the patient follows the specimen collection instructions to collect the specimen. Briefly, patient should apply sanitizer and/or wash and dry hands thoroughly prior to opening the kit and removing the contents. The kit contents are placed on a clean, dry surface. The cap is removed from the collection tube and set aside. The swab is removed from the wrapper, being careful not to touch the soft end of which is the absorbent tip. The absorbent tip of the swab is placed into the nostril. Care is taken so the swab is not inserted more than ¾ of an inch into the nose. The swab is slowly rotated in a circular path against the inside of the nostril at least 4 times for a total of 15 seconds. Any nasal drainage that may be collected on the swab is also collected. The swab is then gently removed. The steps are repeated using the same swab to collect specimen from the other nostril.

After a nasal swab specimen is collected, the swab is placed into the pre-labeled tube with 3 ml normal saline and the shaft is broken by bending at the breakpoint. The cap is screwed onto the tube tightly to prevent leakage. Patient should reapply hand sanitizer and/or wash hands thoroughly after specimen collection.

For device return, the patient places the tube containing the swab in a biohazard bag with absorbent pad. The bag is sealed and placed into the cardboard shipping box. The cardboard shipping box is placed into the FedEx return pack and sealed with adhesive cover slip. The postage paid, pre-addressed FedEx return pack is delivered to a FedEx drop box. It is important to bring the collected specimen to a drop box on the same day it is collected and before the last Express pickup.

A step-by-step detail instruction for specimen collection is provided in the ECL COVID-19 AT HOME COLLECTION KIT. A training video is also available online, both on https://www.empirecitylabs.com/covid-19-test-at-home-collection-kit/ and https://my.wellcom.us/home-test.

d) Inspection of Nasal Swab Specimens at the Empire City Laboratories Inc.

Specimens collected with the ECL COVID-19 AT HOME COLLECTION KIT are received at the Empire City Laboratories and undergo the following accessioning prior to processing as outlined in the ECL COVID-19 AT HOME COLLECTION KIT accessioning standard operating procedure (SOP).

- The packages will be delivered to the accessioning department by FedEx. The logistics dispatcher will fill out the logbook of received packages.
- The specimen handler (accessioning expeditor) will then open the packages and check off that the number of packages and the number of patient specimens received match. He/she will indicate this with a checkmark in the logbook.
- An accessioning expeditor will check each self-collected specimen for the following criteria before these specimens enter the regular laboratory workflow:

  Proper Return of Specimen Packaging:

  - confirm that specimen is present,
  - test requisition is present,
  - the specimen tube is not broken,
  - specimen is not leaking,

  Verification of Patient Information:

  - ensure the patient information on the specimen container matches the information on test requisition

  Specimen Acceptability:

  - ensure specimen volume is sufficient,
  - confirm that the swab is present and properly inserted into the tube
  - acceptable specimen temperature,
  - specimen was received within 2 days from patient shipping date,
  - specimen was received within acceptable stability window after collection
- The accessioning expeditor will accumulate the specimens (a maximum of 60 specimens), place them in a basket and bring them to the accessioners assigned to self-collected specimens.
- Each accessioner is responsible for re-checking each specimen and verifying the information and acceptability. Acceptable specimens received at the clinical laboratory for testing would then follow the same route, with the same acceptance and rejection criteria as our regular specimens.
- If the specimen is not acceptable by the laboratory, the specimen must be accessioned and then rejected using the TNP (test not performed) option, stating the reason for the rejection.
- If the specimen is acceptable by the laboratory, the accessioning department will keep the specimens in a separate rack for the molecular microbiology department. These specimens must first have touch imprint evaluation using the Diff-Quik stain and reviewed before any of these tests can be performed. If the specimen is found to be acellular, the test must be TNP'ed (test not performed) with a comment stating that the specimen was likely improperly

collected. In case of improper collection, a patient is not contacted for collection of another specimen. A new ECL COVID-19 AT HOME COLLECTION KIT may be ordered if the patient chooses to collect another specimen.

e) Partnering Laboratories:

Laboratory	**EUA Assay**	**Lab Testing Capacity (per day or week)**
Empire City Laboratories Inc. 229 49th Street Brooklyn, NY 11220 Phone: 718-840-1661 Fax: 347-296-0591 CLIA #: 33D1057336	EUA201525 EURORealTime SARS-CoV-2 (EUROIMMUN US, Inc.)	Approximately 8000/day

2) *EURORealTime SARS-CoV-2*

The molecular test to be used with the ECL COVID-19 AT HOME COLLECTION KIT is an EUA test (EUA201525), the EURORealTime SARS-CoV-2 (EUROIMMUN US, Inc.) assay, which is a real-time reverse transcription polymerase chain reaction test for the detection of SARS-CoV-2 RNA. The test combines reverse transcription (RT) to convert viral RNA into complementary DNA (cDNA) with PCR amplification and fluorescence-based real-time detection of two defined sections within the ORF1ab- and N-genes of the SARS-CoV-2 genome. Reverse transcription, amplification and detection of SARS-CoV-2 cDNA are carried out by means of SARS-CoV-2-specific primers and probes. An RNA sequence that is unrelated to the SARS-CoV-2 sequence is added to each specimen at the beginning of specimen preparation and is simultaneously amplified with the SARS-CoV-2 specific target sequences to serve as an internal control (IC). This control monitors correct specimen processing and amplification for each specimen and the negative control. The test kit includes a SARS-CoV-2-positive control that is used as an external control in every test run.

INSTRUMENTS USED WITH TEST

EURORealTime SARS-CoV-2 assay is used with the following instruments for RNA extraction/purification followed by PCR amplification:

- Automated nucleic acid extraction and purification: Perkin Elmer JANUS Automated Workstation (Janus 1 and 2) and the chemagic instrument.

- Real-time PCR cycler: The CFX96 Touch (Bio-Rad) software version CFX Maestro 1.1 (4.1.2433.1219), 2.0 (5.0.021.0616).

EQUIPMENT, REAGENTS AND MATERIALS

RNA Extraction kit:

Automated RNA extraction uses one of the following kits:

- Chemagen – Catalog Number: CMG-2017 Prepito Viral DNA-RNA300 Kit (https://chemagen.com/wp-content/uploads/2019/02/CMG-2017-Prepito-Viral-DNA-RNA300-Kit.pdf)
- Chemagen – Catalog Number: CMG-1033 Chemagic Viral DNA/RNA 300 Kit H96

Real-time RT-PCR Test Kit:

Table: Contents of the test kit (MP 2606-####)

Component	0125	0225	0425	0100	0200	1000	Symbol
1. PCR Mix A SARS-CoV-2 (green cap), ready for use	1 x 150 µl	2 x 150 µl	4 x 150 µl	1 x 600 µl	1 x 1.2 ml	5 x 1.2 ml	PCR MIX A
2. PCR Mix B SARS-CoV-2 (yellow cap), ready for use	1 x 150 µl	2 x 150 µl	4 x 150 µl	1 x 600 µl	1 x 1.2 ml	5 x 1.2 ml	PCR MIX B
3. Positive control SARS-CoV-2 (purple cap), ready for use	1 x 400 µl	1 x 400 µl	1 x 400 µl	1 x 400 µl	1 x 400 µl	2 x 400 µl	POS CONTROL
4. RNA internal control (white cap), ready for use	1 x 1.2 ml	1 x 1.2 ml	1 x 1.2 ml	1 x 1.2 ml	1 x 1.8 ml	6 x 1.8 ml	INT CONTROL
5. Instruction for use	1 piece	1 piece	1 piece	1 piece	1 piece	1 piece	-

CONTROLS TO BE USED WITH THE ECL COVID TEST SYSTEM-1

- Human Specimen Control (HSC): Prior to testing with the EURORealTime SARS-CoV-2 assay, each at-home collected anterior nasal specimen (unsupervised) is evaluated for the presence of human nasal epithelial cells. A touch prep onto a glass slide is prepared from each nasal swab. The slides are stained with the Diff-Quik stain and examined under a microscope for presence or absence of nasal epithelial cells. The entirety of each touch prep slide is scanned at 4x objective for presence/absence of any epithelial cells, and 10x and 40x objectives may be used as necessary. A specimen HSC is considered positive if epithelial cells are present and negative if epithelial cells are absent. Only HSC positive specimens are accepted for testing with EURORealTime SARS-CoV-2 assay.

EURORealTime SARS-CoV-2 assay reagents include a positive control and an RNA internal control. To ensure correctness of results, parallel testing (extraction and amplification) of a no template negative control (not included in the test kit) and the positive control of the test kit must be performed in every test run.

- RNA Internal Control (IC): In order to check for potential real-time PCR inhibition or extraction failure the RNA internal control (IC) containing an artificial in vitro transcribed sequence with no homology to any other known sequence is provided with the kit. The IC must be added to each reaction. Without the IC, negative results must be classified as "invalid".

- SARS-CoV-2 Positive Control (PC): In order to monitor the RT-PCR reaction and reagents including the RNA detection a SARS-CoV-2 positive control (PC) is needed. The Positive Control consists of in vitro transcribed RNA fragments containing the target sequences (ORF1ab and N genes of SARS-CoV-2), is provided with the kit, and must be tested in each RT-PCR run. The positive control must be added directly to the PCR reaction and must not be used for extraction. If the PC is omitted or classified as "invalid", all results obtained with this test must be classified as "invalid".

- Negative Control (Not Included): In order to exclude contamination of the test components with amplifiable nucleic acid a negative control must be performed with each batch of extracted specimens, using a nucleic acid-free solution, i.e., water or TE buffer, as the specimen (negative control, NC). If the NC is omitted or classified as "invalid", all results obtained with this test must be evaluated as "invalid".
  It is mandatory to add the IC to the negative control to control the extraction and reverse transcription process of RNA in specimens. Negative controls without amplification signal for the IC are classified as "invalid". If the IC is used as extraction control, EUROIMMUN recommends using the IC also for the negative control already during RNA preparation.

INTERPRETATION OF RESULTS

Prior to testing with the EURORealTime SARS-CoV-2 assay, each specimen is evaluated by HSC touch prep method. If the HSC is negative (no epithelial cells present), the specimen is considered invalid and not acceptable for testing. If the HSC is positive (epithelial cells present), the specimen is acceptable for testing with the EURORealTime SARS-CoV-2 assay.

With EURORealTime SARS-CoV-2 assay, detection of SARS-CoV-2 RNA is performed using two target regions, which are both detected in the same fluorescence channel (FAM).

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted.

Table: Interpretation of Controls

	SARS-CoV-2 FAM	IC VIC	Result
Positive Control	+ ≤ Ct 35	-	Valid
	+ ≤ Ct 35	+	Invalid[1] (contamination)
	-	-/+	Invalid[1]
Negative Control	-	+	Valid
	-	-	Invalid[1] (no or inhibited[2] amplification signal for internal control)
	+	-/+	Invalid[1] (contamination)

[1]If the negative control and/or the positive control show an invalid result all test results are to be evaluated as "invalid".

[2]If the negative control shows no or an inhibited amplification signal for the IC all patient test results are to be evaluated as "invalid".

Examination and Interpretation of Patient Specimen Results:

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted and all patient specimens need to be retested after a root cause has been identified and eliminated. The detection of SARS-CoV-2 RNA is performed using a total of two target regions, which are both detected in the same fluorescence channel (FAM).

Table: Interpretation of patient specimens

	SARS-CoV-2 FAM (≤ Ct 45)*	IC VIC (≤ Ct 45)*	Result Interpretation	Action
Patient Specimen	-	+	SARS-CoV-2 RNA not detected	Report Result
	-	-	**Invalid** (no amplification signal for internal control)	Invalid result, specimen needs to be re-tested from re-extraction or re-collection from patient for test.
	+	-/+	SARS-CoV-2 RNA detected	Report Result

- Positive Results: All specimens with SARS-CoV-2 amplification ≤ Ct 45* are positive.
- Negative Results: All specimens with positive internal control results of ≤45 Ct* but without SARS-CoV-2 amplification ≤ Ct 45* are negative.
- Invalid Results: Specimens without amplification in both the SARS-CoV-2 target AND the internal control are invalid and require retesting starting from extraction.

***General note for evaluation:** Ct-values should never be taken as sole basis for result interpretation. EUROIMMUN recommends repeating the analysis for all specimens showing an ambiguous or atypical curve that does not allow a clear interpretation.

PERFORMANCE EVALUATION

1) **EURORealTime SARS-CoV-2 Analytical and Clinical Performance Evaluation:**

The analytical and clinical performance of the EURORealTime SARS-CoV-2 has been demonstrated by EUROIMMUN US, Inc. in the Emergency Use Authorization (EUA 201525) submission authorized on 06/08/2020. The ECL COVID TEST SYSTEM-1 runs the EURORealTime SARS-CoV-2 per EUROIMMUN's Instructions for Use (IFU) without modifications. EUROIMMUN has granted Empire City Laboratories Inc. right of reference to data in support of using EURORealTime SARS-CoV-2 assay in the ECL COVID TEST SYSTEM-1. The details of the performance of the EURORealTime SARS-CoV-2 can be found here: https://www.fda.gov/media/138761/download.

2) **ECL COVID-19 AT HOME COLLECTION KIT Specimen Stability Studies:**

a) **Summer Profile Specimen Stability Study:**

The Summer Profile Specimen Stability Study of the anterior nasal swab specimen transported in saline was conducted by the Quantigen Biosciences, with support from The Gates Foundation and UnitedHealth Group. Quantigen Biosciences has granted a right of reference to any sponsor, such as Empire City Laboratories Inc., wishing to pursue an EUA to leverage their COVID-19 swab stability data for Summer Profile Specimen Stability of anterior nasal swabs in saline, as part of that sponsor's EUA request.

Briefly, 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 specimens.

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 specimens and the 10 intermediate-positive specimens used with each test condition did not come from individual patients. Rather, for each of the two concentrations, a single preparation of virus + collection media or virus + matrix was prepared, from which technical replicates were prepared.

Swabs were then placed into 1 mL of saline and incubated at 40°C for 12 hours, followed by 32°C for 18 or 42 hours, respectively. Specimens were tested using an EUA authorized assay at time 0, 30, and 54 hours post-incubation (Table). Specimens 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 specimens. Both time points met this criteria and supported specimen shipping stability, using a drop box, with over-night or 48-hour shipping.

Table: Average Ct values for each time point for both specimen dilutions

Swab	Time Point	N	MS2 Internal Control	N Gene	ORF1ab	S Gene
2xLoD swab in Saline	0h	5	23.74	32.23	30.03	31.80
10xLoD swab in Saline	0h	5	23.27	29.46	27.58	28.67
2xLoD swab in Saline	30h	20	26.00	32.69	31.33	34.59
10xLoD swab in Saline	30h	10	26.19	29.54	28.37	28.69
2xLoD swab in Saline	54h	20	25.70	32.03	31.09	32.10
10xLoD swab in Saline	54h	10	26.11	28.73	27.25	25.09

b) Winter Profile Specimen Stability Study:

A winter profile specimen stability study was conducted by Empire City Laboratories to confirm that signal degradation from variable temperatures would not occur during shipping in winter-like conditions. Contrived specimens for this study were prepared by spiking an inactivated virus (AccuPlex SARS-CoV-2 Molecular Controls Kit – Full Genome, catalog# 0505-0159) into 40 remnant SARS-CoV-2 negative patient specimens at concentrations targeting 2x LoD and 5-10x LoD. The remnant patient specimens used for this study included nasal swabs in sterile saline (0.9 % NaCl). A total of 20 replicates at 2x LoD, 10 replicates at 5-10x LoD, and 10 negative specimens were tested using EURORealTime SARS-CoV-2.

This study simulated shipping conditions by cycling the specimens through the following temperature profile:

Temperature	Cycle Period	Cycle Period Hours	Total 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

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

Touch imprints of the nasal swabs was performed at baseline, T = 0 and at T = 56 hours. These touch imprints were Diff-Quik stained and reviewed by a board-certified pathologist for the presence or absence of nasal (respiratory) epithelium. Nasal epithelial cells were identified in 100% of cases at both time points.

Specimens were tested at each timepoint with EURORealTime SARS-CoV-2. The Ct values at each timepoint were compared to the Ct values at time zero (T= 0). All positive specimens remained positive at T= 56 hours after cycling through the winter temperature profile. All positive specimens at T=56 remained within 1 Ct of the baseline, T= 0 result. All negative

specimens remained negative at T=56 hours after cycling through the winter temperature profile. Negative specimens showed 100 % agreement with the baseline, T= 0 results.

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

	T=0 (Baseline)			
	n	**Epithelial Cells Identified (%)**	**Mean Ct**	**Detectable Rate (%)**
Negative	10	100	N/A	0
2x LOD	20	100	37.52	100
10x LOD	10	100	34.62	100

	T=56 hours (Post Stability)			
	n	**Epithelial Cells Identified (%)**	**Mean Ct**	**Detectable Rate (%)**
Negative	10	100	N/A	0
2x LOD	20	100	37.44	100
10x LOD	10	100	34.71	100

Results from the Summer Profile and Winter Profile Specimen Stability Studies demonstrated that positive anterior nasal swab specimens in saline are stable with over-night or 48-hour shipping and the findings support the stability of the ECL COVID-19 AT HOME COLLECTION KIT.

3) Human Usability Study:

A Usability Study was conducted to confirm that patients could follow the instructions included in the ECL COVID-19 AT HOME COLLECTION KIT to appropriately collect, package, and ship a self-collected anterior nasal specimen to Empire City Laboratories for testing. The study was completed in an Empire City Laboratories Patient Service Center.

A total of 30 individuals consented to participate in the study. These participants included individuals representing varying education levels and age ranges. No individual under the age of 18 years was included in this study. Individuals with prior medical or laboratory training as well as prior experience with self-collection were excluded from the study.

Number	**Age**	**Gender**	**Educational Level**
1	48	Male	Associate degree
2	28	Female	College graduate
3	44	Female	College graduate
4	31	Male	High school graduate
5	64	Female	High school graduate
6	76	Female	Did not finish high school
7	46	Female	1 year college
8	20	Female	Attending college
9	35	Male	2 years college
10	34	Male	College graduate
11	24	Male	Almost finished college

12	50	Female	High school graduate
13	31	Female	College graduate
14	48	Male	1 year college
15	69	Male	1 year college
16	18	Male	Almost finished high school
17	24	Female	Associate degree
18	87	Male	High school graduate
19	42	Female	2 years college
20	29	Female	1 year college
21	56	Male	College graduate
22	60	Male	2 years college
23	67	Female	3 years college
24	32	Female	High school graduate
25	36	Female	Did not finish high school
26	40	Male	High school graduate
27	38	Male	High school graduate
28	24	Female	1 year college
29	26	Female	High school graduate
30	36	Male	Graduate degree

These participants were given an ECL COVID-19 AT HOME COLLECTION KIT, which included the specimen collection instructions, test requisition card (patient information card) and activation card, polyester spun swab, viral transport tube containing 3 mL normal saline (0.9 %), biohazard bag containing an absorbent pad, cardboard shipping box, FedEx bag with pre-printed FedEx label and shipping instructions. The participants proceeded to collect anterior nasal specimen following the specimen collection instructions under observation of a medical assistant. After specimen collection, participants packed the specimens to send back to Empire City Laboratories via FedEx following the shipping instructions on the kit. The medical assistant who was the passive observer for this study indicated that all participants correctly performed the entire self-collection process, including the online portions without any issues or prompting. After specimen collection and packing, participants were also asked to critique the kit and its instructions in a usability questionnaire.

Human Usability Study results showed that 100% (30/30) of specimens were received at the Empire City Laboratories within 48 hours of collection and met the accessioning criteria. All participants confirmed the ease of use of the kit and clarity of instructions provided in the ECL COVID-19 AT HOME COLLECTION KIT.

Evaluating Presence of Human Nasal Epithelial Cells by Microscopic Examination of Self-Collected Anterior Nasal Swabs

Specimens collected using the ECL COVID-19 AT HOME COLLECTION KIT in the Human Usability Study were also evaluated for the presence of human nasal epithelial cells. A touch prep onto a glass slide was prepared from each nasal swab specimen. The slides were stained with Diff-Quik stain and examined under a microscope for presence or absence of nasal epithelial cells. The entirety of each touch prep slide was scanned with a 10x objective for presence or absence of any epithelial cells. A 40x objective was used to confirm some of the cell types. A specimen was considered positive if epithelial cells were present and negative if epithelial cells were absent.

All specimens were positive for human nasal epithelial cells by microscopic examination and therefore were deemed acceptable for testing with the ECL COVID TEST SYSTEM-1.

Based on the usability study data and feedback, the ECL COVID-19 AT HOME COLLECTION KIT instructions were understandable, the kit was easy to use, and specimens were successfully self-collected, which has demonstrated the usability that is acceptable to the FDA.

Additional Post-Authorization Additional Requirement:
Empire City Laboratories will submit a report to the FDA (within 30 days of authorization) summarizing any testing performed with the ECL COVID TEST SYSTEM-1 including how many ECL COVID-19 AT HOME COLLECTION KITs were requested and sent for home collection. Empire City Laboratories will also document the number of kits that were disseminated and returned to the laboratory according to the instructions, how many specimens were rejected during accessioning and the reasons for rejection, and the positivity rate of the first ECL COVID-19 AT HOME COLLECTION KIT lot using the EURORealTime SARS-CoV-2 assay.

LIMITATIONS:

• A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.

• This test cannot rule out diseases caused by other bacterial or viral pathogens.

• Specimens must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.

• Results from the ECL COVID TEST SYSTEM-1 should be used as an adjunct to clinical observations and other information available to the physician. The result is only for clinical reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.

• Although the detected target sequences of this test system are in conserved regions of the SARS-CoV-2 genome, rare mutations may lead to negative results.

• Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined.

• The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

• The presence of epithelial cells by microscopy implies that human biological material was collected. It does not necessarily indicate that the specimen is of appropriate quality to enable

detection of SARS-CoV-2. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

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; and

• 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 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 declaration is terminated or authorization is revoked sooner.