EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE LETSGETCHECKED CORONAVIRUS (COVID-19) TEST

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only
For use by people 18 years of age or older

INTENDED USE

The LetsGetChecked Coronavirus (COVID-19) Test is intended for qualitative detection of nucleic acid from the SARS-CoV-2 in nasal swab specimens self-collected by individuals at home, using the LetsGetChecked COVID-19 Home Collection Kit, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire (based on current testing guidelines). Specimens collected using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit can be transported at ambient temperature for testing.

Testing is limited to PrivaPath Labs d.b.a. LGC Labs certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meets the 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 swabs during the acute phase of infection. Positive results 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 positive 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 treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Testing with the LetsGetChecked Coronavirus (COVID-19) Test is intended for use by qualified and trained laboratory personnel specifically instructed and trained in the molecular testing and in vitro diagnostic procedures. The LetsGetChecked Coronavirus

(COVID-19) Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The LetsGetChecked COVID-19 Home Collection Kit enables the self-collection of a nasal swab sample that is then transported to PrivaPath Labs d.b.a. LGC Labs, for RT-PCR testing for SARS-CoV-2 with the LetsGetChecked Coronavirus (COVID-19) Test, when determined by a healthcare provider to be appropriate using a COVID-19 eligibility questionnaire that is based on current testing guidelines. LetsGetChecked will contact all patients receiving positive and invalid test results. Patients with negative test results will be notified by email, phone message and through the website portal.

The LetsGetChecked COVID-19 Home Collection Kit includes a shipping box, pre-labeled return envelope, Instructions for Use, specimen collection materials (nasal swab and transport media tube), and biohazard bag. Each LetsGetChecked COVID-19 Home Collection Kit is intended to be returned via Next Day Air shipping at ambient conditions on the same day of sample collection.

Specimens received at the clinical laboratory for testing will undergo review and accessioning prior to acceptance for testing.

The LetsGetChecked Coronavirus (COVID-19) Test will be performed at the PrivaPath Labs d.b.a. LGC Labs High Complexity certified laboratory (Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a. The PrivaPath Labs d.b.a. LGC Labs uses the Hologic Panther Fusion SARS-CoV-2 assay or the Hologic Aptima SARS-CoV-2 Assay (Panther System) per the Instructions for Use (without modification).

REAGENTS AND MATERIALS

LetsGetChecked Coronavirus (COVID-19) Home Collection Kit

Shipping box
Polymailer with UN3373
Return Label (attached to polymailer)
Specimen biohazard bag with absorbent material
Nasal swab & transport tube with transport media (Hologic Multitest Swab Collection Kit; Cat.: PRD-03546)

MEDICAL OVERSIGHT AND PROCESS TO BE USED:

LetsGetChecked will use an online eligibility questionnaire, based on current CDC testing guidelines (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html) to determine whether a customer is eligible for a COVID-19 test. If a customer is determined to be eligible based on current CDC testing guidelines, a prescription for testing is issued by a LetsGetChecked board certified physician. Only after this step is completed the LetsGetChecked COVID-19 Home Collection Kit can be shipped to the customer's home.

In addition, the LetsGetChecked COVID-19 Home Collection Kit will be provided to members of particular payer and provider programs. LetsGetChecked is currently prioritizing programs which serve healthcare workers (e.g. insurance providers, emergency responder networks, etc.) and essential/critical workers (e.g. logistics and supply chain staff, electric company staff, pharmaceutical production staff). All members must be deemed eligible for the LetsGetChecked Coronavirus (COVID-19) Test, per the CDC guidelines and relevant eligibility questionnaire, before a prescription for testing can be written and a test can be dispatched.

Patient Inclusion/Exclusion Criteria:

These criteria are based on current CDC testing guidelines

Exclusion

- Anyone with severe symptoms
- People of any age with no symptoms
- People under 65 years with mild symptoms and reporting exposure, but no comorbidity
- People under 65 years with mild symptoms and reporting no exposure, and no comorbidity)

Inclusion

- People over 65 years are eligible for a test if they have any mild symptoms (cough, sore throat, muscle aches or body aches, vomiting or diarrhea, change in smell or taste, and shortness of breath), whether or not they report exposure or a comorbidity.
- People under 65 years are eligible if they have a comorbid condition and any mild symptoms (cough, sore throat, muscle aches or body aches, vomiting or diarrhea, change in smell or taste, and shortness of breath).

LGC Labs Accessioning Criteria:

All tests arriving at LGC Labs will be checked for the following deficiencies:

- Viral transport media leaked resulting in no sample for testing
- No swab and/or sample transport tube
- Kit not activated on LetsGetChecked.com (sample held until Customer Care can reach patient and advise on activation)
- Accession date is greater than 48 hours from the return pick-up date for specimens tested with Hologic Panther Fusion SARS-CoV-2 Assay

- Accession date is greater than 88 hours from the return pick-up date for specimens tested with Hologic Aptima SARS-CoV-2 Assay.

CONTROLS TO BE USED WITH THE LETSGETCHECKED COVID-19 HOME COLLECTION KIT

Each patient sample is run with authorized Hologic Panther Fusion SARS-CoV-2 or the Hologic Aptima SARS-CoV-2 Assays with applicable assay controls per manufacturer Instructions for Use, without any modification.

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. The results interpretation algorithm for the LetsGetChecked COVID-19 Home Collection Kit is based on the Hologic Panther Fusion SARS-CoV-2 or Hologic Aptima SARS-CoV-2 Assay. The algorithm is presented in Table 1.

Table 1. Results Interpretation Algorithm.

SARS-CoV-2	Interpretation	Lab Action
Positive	Valid sample	SARS-CoV-2 (+) result is valid and can be released
Negative	Valid sample	SARS-CoV-2 (-) result is valid and can be released
Invalid	Invalid Result. Repeat extraction and rRT-PCR. If the repeated result remains invalid, collect a new specimen from the patient	SARS-CoV-2 result is invalid and sample analysis is repeated

Patients receiving positive and invalid results will be contacted by the Nursing Team. Patients with negative test results will be notified by email, phone message and through the website portal. Patients will be receiving Patient Fact Sheets with their results. Patients with the invalid result will be receiving a second test kit.

In the case of positive results:

- Individuals will receive a phone call from the Nursing Team and results will be released to patient portal
- Results will be reported by LGC Labs to public health agencies as required

PERFORMANCE EVALUATION

1) The LetsGetChecked Coronavirus (COVID-19) Test Sample Stability Studies

Sample stability studies were conducted using a temperature cycle that simulated summer shipping conditions to determine shipping stability for the LetsGetChecked Coronavirus (COVID-19) Test. Human SARS-CoV-2 isolate obtained from BEI Resources, Manassas, VA, was used for creating contrived positive specimens by spiking the negative clinical specimens from 35 donors. Samples were prepared by spiking the virus directly to the sample transport media containing the clinical matrix at 2x LoD (20 samples) and 5x LoD (10 samples). In addition, five negative samples were tested. Swabs were left in the transport media throughout the course of the experiment to mimic clinical samples. The samples were subjected to the following temperature cycling profile: 8 hours at 40°C, 4 hours at 22°C, 2 hours at 40°C, 36 hours at 30°C, and 6 hours at 40°C. The 35 test samples were extracted and assayed with the Hologic Panther Fusion SARS-CoV-2 assay at the final time point of the experiment. The mean Ct values are presented in Table 2.

Table 2. Mean Ct values for the stability study.

	Initial Values (Timepoint Zero)		Endpoint Values (Timepoint 56 Hours)		Detection Rate
	Average Ct		Average Ct		
Sample Name	**ORF1ab**	**IC**	**ORF1ab**	**IC**	
Negatives	N/A	31.3	N/A	31.3	0% (0/5)
2XLoD	30.5	31.4	30.7	31.7	100% (20/20)
5XLoD	29.1	31.6	28.5	31.6	100% (10/10)

The LetsGetChecked Coronavirus (COVID-19) Test Sample Stability Study for specimens tested with Hologic Aptima SARS-CoV-2 Assay

Stability studies were performed by spiking the virus directly to the sample transport media containing the clinical lower nasal swab matrix at LoD (20 samples) and 2.5x LoD (10 samples) and negative samples (5). Swabs were left in the transport media throughout the course of the experiment to mimic clinical samples. The samples were subjected to 55°C, sustained for 6 days and tested every 24 hours. The 35 test samples were extracted and assayed with the Hologic Aptima SARS-CoV-2 assay at the final time point of the experiment.

Acceptance Criteria

- LoD samples: ≥ 95% agreement with expected results.
- 2.5 x LoD: = 100% agreement with expected results.
- Negative samples: = 100% agreement with expected results.

The results from the study support sample shipping stability of 88 hours for specimens tested with Hologic Aptima SARS-CoV-2 assay.

2) Self-Collection Validation

Two usability studies were conducted to assess user interactions with the LetsGetChecked Coronavirus (COVID-19) Test. In the first study, a total of 55 adults completed the study, of which 38% were over 60 years of age, 46% were between 40 - 59 years, and 16% were between 18 - 39 years old; 42% of participants were male and 58% were female. The majority (54/55) of participants produced self-collected nasal swabs that were received by the laboratory in a condition that was considered acceptable for testing. The majority of participants reported that they understood the Instructions provided for sample collection and packaging. Upon the completion of the first study, the Instructions for Sample Collection have been updated and a second usability study was undertaken. It included 33 participants of which 48% were over 60 years of age, 46% were between 40 - 59 years, and 6% were between 18 - 39 years old; 39% of participants were male and 61% were female. The study was conducted at simulated at-home environment and the participants were observed during the sample collection and packing process.

All participants produced self-collected nasal swabs that were received by the laboratory in a condition that was considered acceptable for testing. No deviations from the Instructions for Use were noted by staff observing the sample collection.

All samples tested positive for human RNaseP gene (tested using authorized CDC 2019-Novel Coronavirus (2019-nCoV) kit) indicating that all participants successfully collected human biological material.

In addition to completed studies, PrivaPath Diagnostics, Inc. will submit a report to the FDA (within 30 days) summarizing any testing performed with LetsGetChecked Coronavirus (COVID-19) Test including how many kits were requested and sent for home collection, how many kits were shipped and returned according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate of the first LetsGetChecked COVID-19 Home Collection Kit lot.

Conclusion: The LetsGetChecked Coronavirus (COVID-19) Test has demonstrated sample stability and usability that is acceptable to the FDA.

3) Human Gene Control Evaluation

Among 5,007 consecutive nasal swab samples self-collected using the LetsGetChecked COVID-19 Home Collection kit, 100% of the samples tested were found to contain the RNase P gene (cellularity rate of 100%; 95% CI: 99.9%, 100%). The mean and standard deviation of RNase P gene PCR Ct values were similar among sex, age group, race/ethnicity categories and comorbidities.

4) Analytical and Clinical Performance

The analytical and clinical performance of the Hologic Panther Fusion SARS-CoV-2 and Hologic Aptima SARS-CoV-2 Assays has been demonstrated by Hologic in the Emergency Use Authorization submission authorized on 03/16/2020 and 05/14/2020 respectfully. The details of the performance of the authorized Panther Fusion SARS-CoV-2 Assay and Hologic Aptima SARS-CoV-2 assay can be found here https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas
Hologic granted Right of Reference to PrivaPath Diagnostics, Inc. for Hologic's authorized Panther Fusion SARS-CoV-2 and Aptima 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 authorized laboratories;
- This test has been authorized only for the detection of nucleic acid from SARSCoV-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 diagnostic tests 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.

LIMITATIONS:

- Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly;
- The requirement to run a sample adequacy control for all samples that were self-collected will be waived provided that the following disclosure has been acknowledged by the entity utilizing authorized home collection kits and a statement is included in the test reports for specific patients who self-collected a specimen:

Acknowledgement (Insert Client name) acknowledges it has received the disclosure below: *Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.*

LetsGetChecked Coronavirus (COVID-19) Test

Test Report Limitation

Specimens that are self-collected were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction method and instrument used were the Aptima SARS-CoV-2 Assay extraction and the Hologic Panther respectively. The results are summarized in the following Table.

Table 3. Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Pane l

Reference Materials Provide d by FDA	Spe cimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasal Swab	$7.2x10^2$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected