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

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

Direct to consumer product for collection of anterior nasal swab specimens by individuals using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit for testing with the LetsGetChecked Coronavirus (COVID-19) Test that will be performed at the LetsGetChecked, Inc. laboratory (PrivaPath Labs d.b.a. LetsGetChecked Labs), 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.

INTENDED USE

The LetsGetChecked Coronavirus (COVID-19) Test is a direct to consumer product for testing of anterior nasal swab specimens collected at home using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit by any individuals, age 18 years and older (self-collected), 12 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19. Specimens collected using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit can be transported at ambient temperature for testing. Testing is limited to the LetsGetChecked, Inc. laboratory (PrivaPath Labs d.b.a. LetsGetChecked Labs) 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.

The LetsGetChecked Coronavirus (COVID-19) Test is also indicated for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled samples containing up to 5 anterior nasal swab specimens per pool that were collected in individual vials containing transport media using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit from any individual (age 2 years and older), including individuals without symptoms or other reasons to suspect COVID-19.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swabs during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with medical history and other diagnostic information is necessary to determine 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 sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result and if results are necessary for patient management, then the patient should be considered for individual testing. Specimens included in pools with a positive or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.

Negative test results from specimens collected with the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit are delivered to the user via email, phone message and through an online portal. Individuals with positive and invalid 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 LetsGetChecked Coronavirus (COVID-19) Test is not a substitute for visits to a healthcare provider. The information provided by this kit should not be used to start, stop, or change any course of treatment unless advised by healthcare provider.

Testing with the LetsGetChecked Coronavirus (COVID-19) Test is intended for use by qualified laboratory personnel specifically instructed and trained in 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 Coronavirus (COVID-19) Home Collection Kit is a direct to consumer product for testing of anterior nasal swab specimens collected at home using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit by any individuals, age 18 years and older (self-collected), 12 years and older (self-collected under adult supervision), or 2 years and older (collected with adult assistance) including individuals without symptoms or other reasons to suspect COVID-19.

The LetsGetChecked Coronavirus (COVID-19) Home Collection Kit enables the at-home collection of an anterior nasal swab sample that is then transported to PrivaPath Labs d.b.a. LetsGetChecked Labs, for TMA testing for SARS-CoV-2 with the LetsGetChecked Coronavirus (COVID-19) Test without prescription. The LetsGetChecked Coronavirus (COVID-19) Home Collection Kit may be available direct to consumer (DTC) without a prescription at a physical retail location and online direct to consumer. Activation can only be completed by an adult. When a minor is using the kit, it is activated in a sub-account of the adult. Customers cannot create a sub-account for an infant (<2years). LetsGetChecked HCP will contact all individuals receiving positive and invalid test results. Individuals with negative test results will be notified by email, phone message and through the website portal. For purposes of this EUA, a healthcare provider includes any healthcare professional with prescribing abilities including, but not limited to, physicians, nurses, pharmacists, and laboratory directors. The healthcare provider contacting individuals with test results will have prescribing privileges for that individual, should medication be indicated for treatment.

The LetsGetChecked Coronavirus (COVID-19) Home Collection Kit includes a shipping box, pre-labelled return envelope, Home Collection Instructions, specimen collection materials (anterior nasal swab and transport media tube), and biohazard bag. Each LetsGetChecked Coronavirus (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 assay is validated for up to 5 sample pooling and pooling is carried out in accordance with the Hologic Aptima SARS-CoV-2 Assay EUA: Appendix A. If the percent positivity rate is less than 5%, the maximum pool size validated, (n=5), is selected to maximize the efficiency of specimen pooling. If the percent positivity rate increases the pooling size is adjusted per Appendix A.

If the pool is positive or invalid, then each of the constituent samples is re-tested as a separate individual specimen. If the pool is negative, then each constituent sample is reported as negative.

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

REAGENTS AND MATERIALS

LetsGetChecked Coronavirus (COVID-19) Home Collection Kit

Table 1. Components Included in the 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; Hologic Direct Load Tube Collection Kit; Cat.: PRD-06997)
Home Collection Instructions
Factsheet for individuals
Box sleeve

LetsGetChecked Labs Accessioning Criteria:

All tests arriving at LetsGetChecked 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 individual and advise on activation)
- Accession date is greater than 88 hours from the return pick-up date and time (no more than 96 hours from specimen collection time).

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

Each individual sample is run with authorized Hologic Aptima SARS-CoV-2 Assay with applicable assay controls per manufacturer Instructions for Use for individual samples or sample pools containing up to five samples.

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. The results interpretation algorithm for the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit is based on the Hologic Aptima SARS-CoV-2 Assay. The algorithm is presented in Table 2.

Table 2. Results Interpretation Algorithm, individual samples

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 analysis. If the repeated result remains invalid, collect a new specimen from the individual	SARS-CoV-2 result is invalid and sample analysis is repeated

Table 3. Results Interpretation Algorithm, pooled samples

SARS-CoV-2	Interpretation	Lab Action
Positive pool	Valid sample	Pooled samples are analysed individually, all individual samples testing positive are reported as positive.
Negative pool	Valid sample	Negative result is valid and can be released, all samples in pool are reported as negative.
Invalid	Invalid Result. Repeat extraction and analysis. If the repeated result remains invalid, collect a new specimen from the individual	Pooled samples are analysed individually. If retest is invalid a new sample is requested.

Individuals with negative test results will be notified by email, phone message and through the website portal.
Individuals with invalid result will receive a phone call from the Nursing Team and provided with 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 online portal. Individual Fact Sheets are included in the box with home collection kit.

All results will be reported by LetsGetChecked Labs to public health agencies as required.

PERFORMANCE EVALUATION

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

Summer conditions: Stability studies were performed by spiking the SARS-CoV-2 isolate (Cat#NR-52286) obtained from BEI Resources, Manassas, VA 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. The positive and negative samples met the following acceptance criteria up to day 5 of testing.

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.

Winter conditions: Stability studies were performed by spiking the SARS-CoV-2 isolate (Cat#NR-52286) obtained from BEI Resources, Manassas, VA directly to the sample transport media containing the clinical nasal swab matrix at 2x LoD (20 samples) and 5x LoD (10 samples) and negative samples (5). All samples were analyzed on day 0 and then put into a -20°C freezer. All samples were removed daily and allowed to thaw completely. Each day one set of samples was tested and disposed of, while the rest were put back into the freezer until the next day. This was continued through 5 days of freeze-thaw cycles. The study showed 100% agreement with expected results for all samples at time points tested.

The results from the summer and winter shipping stability studies support sample shipping stability of 88 hours (96 hours from specimen collection) for specimens tested with Hologic Aptima SARS-CoV-2 Assay.

2) Home Collection Media (reagent) Shelf Life

The shelf life of the home collection media was evaluated by the manufacturer of the collection media, Hologic. Hologic provided supporting data for FDA review and granted Right of Reference to the data to LetsGetChecked Inc.

3) Self-Collection Validation

Adults age 18 years and older

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 anterior 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, LetsGetChecked submitted 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 Coronavirus (COVID-19) Home Collection Kit lot.

Children ages 2-17 years old

Usability studies were conducted to evaluate home collection instructions for the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit among 16 adolescents (12 – 17 years) self-collecting an anterior nasal swab sample under the guidance and supervision of an adult (≥ 18 years), and 33 adults (≥ 18 years) collecting an anterior nasal swab sample from a child (2 –11 years). Sample collection was performed from the participant's home and observed by the study coordinator using online video conferencing. Participants followed the home collection instructions provided with the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit. Afterwards, participants completed a post-sample collection questionnaire to assess the ease of use of the sample collection kit and the adequacy of the kit instructions.

100% (15/15) adolescents were analyzed for the presence of the RNaseP gene and 100% of the adolescent samples analyzed tested positive for the presence of the RNaseP gene. 29/32 (91%) child samples were analyzed for the presence of the RNaseP gene (3 samples were rejected due to delay in sample processing). 100% of child samples analyzed tested positive for the presence of the RNaseP

gene. None of the samples were rejected due to incorrect sample collection, packing, or insufficient identification information.

Upon the completion of the first studies, the home collection instructions have been updated and a second usability study was undertaken. For this study, 16 adults (≥ 18 years) collected an anterior nasal swab sample from a child (2 – 11 years) following revised instructions. Sample collection was performed from the participant's home and observed by the study coordinator using online video conferencing. Afterwards, participants completed a post-sample collection questionnaire to assess the ease of use of the sample collection kit and the adequacy of the kit instructions. 100% (16/16) children produced nasal swab samples that were received by the laboratory in a condition that was considered acceptable for testing. RNaseP gene was detected in 100% of samples tested (16/16 child samples were tested) to indicate adequate nasal sampling.

4) Human Gene Control Evaluation

Among 5,007 consecutive nasal swab samples self-collected using the LetsGetChecked Coronavirus (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.

5) Analytical and Clinical Performance

The analytical and clinical performance of the Hologic Aptima SARS-CoV-2 Assay has been demonstrated by Hologic in the Emergency Use Authorization submission authorized on 05/14/2020. The details of the performance of the authorized 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/in-vitro-diagnostics-euas
Hologic granted Right of Reference to LetsGetChecked for Hologic's authorized Aptima SARS-CoV-2 Assay.

6) Assay Performance in Asymptomatic Individuals

The performance of the LetsGetChecked Coronavirus (COVID-19) Test was determined by comparing assay results to a highly sensitive FDA authorized molecular assay. 120 consecutive negative and 35 consecutive positive nasal swab samples collected from individuals without symptoms of COVID-19 were analyzed. The results are presented in Table 3.

Table 4. Performance of the LetsGetChecked Coronavirus (COVID-19) Test in Asymptomatic Individuals.

	FDA authorized molecular assay		
LetsGetChecked Coronavirus (COVID-19) Test	Positive	Negative	**Total**
Positive	33	1	34*
Negative	0	120	120
Total	33	121	154

*A single sample tested positive using the LetsGetChecked Coronavirus (COVID-19) Test and gave an invalid result with the comparator test. Since the sample was exhausted it was not available for retesting, per protocol, and the sample was therefore excluded from analysis.

Positive Percent Agreement (PPA): 100% (95% CI: 89.6%, 100%)
Negative Percent Agreement (NPA): 99.2% (95% CI: 95.5%, 99.9%)

7) Validation of Pooling

The LetsGetChecked Coronavirus (COVID-19) Test uses the Hologic Aptima SARS-CoV-2 Assay and anterior nasal swab samples. The Hologic Aptima SARS-CoV-2 Assay has been authorized for detection of nucleic acids from SARS-CoV-2 in pooled samples containing up to five anterior nasal swabs collected using individual vials containing transport media. The details of the performance of the authorized 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/in-vitro-diagnostics-euas
Hologic granted Right of Reference to LetsGetChecked for Hologic's authorized Hologic Aptima SARS-CoV-2 Assay.

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 5. Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen 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

WARNINGS:

- For in vitro diagnostic use.
- For emergency use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- 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.

LIMITATIONS:

- 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.
- Performance with specimens collected from individuals 18 years and older by an adult in the home has not been evaluated.
- Samples should only be pooled when testing demand exceeds laboratory capacity and/or when testing reagents are in short supply.
- Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.
- Specimens that are collected at home will not be tested with an internal control to confirm that the specimen was properly collected. Specimens collected at home 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 collected at home 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 individuals who collected a specimen at home:

Acknowledgement

(Insert Client name) acknowledges it has received the disclosure below:

Specimens that are collected at home will not be tested with an internal control to confirm that the specimen was properly collected. Specimens collected at home from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Test Report Limitation

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