EMERGENCY USE AUTHORIZATION (EUA) TEST SUMMARY FOR THE *[LABORATORY NAME – TEST NAME]*

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

The *[test name]* will be performed at the *[laboratory name]* located at *[laboratory address]*, 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 ***[test name]*** is intended for the *in vitro* ***[insert indication(s) from applicable appendix(ces)]***. Testing is limited to ***[laboratory name]*** laboratory located at ***[laboratory address]***, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high-complexity testing.

The ***[test name]*** is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The ***[test name]*** is only for use under the Food and Drug Administration's Emergency Use Authorization.

Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 nucleic acid 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.

[INCLUDE THIS PARAGRAPH IF YOUR INDICATION INCLUDES POOLING:] 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 or 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 reported as presumptive positive or tested individually prior to reporting a result. Individuals included in a pool that returns a positive or invalid result should be treated as a presumptive positive unless or until they receive a negative result when re-tested individually. However, as most individuals in a positive pool will likely receive a negative result

when re-tested individually, they should isolate until receiving a negative result when re-tested individually and should not be cohorted with other individuals who have received a positive or presumptive positive result. Specimens with low viral loads may not be detected with pooled testing due to decreased sensitivity or increased interference from pooled testing.

For serial testing programs, additional confirmatory testing for negative results may be necessary, if there is a high likelihood of COVID-19, such as an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposure to COVID-19 or residing in communities with low prevalence of infection.

1) Special Conditions for Use Statements:

For use under Emergency Use Authorization (EUA) only
For prescription use only
For *in vitro* diagnostic use only

[INCLUDE THIS PARAGRAPH IF YOUR INDICATION INCLUDES HOME COLLECTION:] Testing of specimens self-collected at home is limited to specimens collected with the ***[name of authorized home collection kit with which your test is validated]*** by ***[the patient population authorized in the home collection kit EUA]***.

This test is authorized under the Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing [include link to this letter] for use in [the specific laboratory, that is certified under CLIA and meets requirements to perform high complexity tests, in which it was developed] for [insert indication(s) from applicable appendix(ces)] using the test procedures validated in accordance with the requirements of the Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The [***Test Name***] assay is a reverse transcription polymerase chain reaction (RT -PCR) test. The SARS-CoV-2 primer and probe set(s) is designed to detect RNA from the SARS-CoV-2 ***[genes/regions]*** in anterior nasal swab specimens that were collected from individuals, including individuals without symptoms or other reasons to suspect COVID-19.

[Describe the processes used to perform the test, including, as applicable, 1) nucleic acid extraction, 2) reverse transcription of target RNA to cDNA, 3) PCR amplification of target and internal control, and 4) simultaneous detection of PCR amplicons by fluorescent dye labeled probes. Include key parameters such as input volumes, reverse transcription (RT) time and temperature, PCR cycling parameters including dwell temperature and dwell times.]

INSTRUMENTS USED WITH TEST

Instruments

The [***test name***], a real-time RT-PCR test, is to be used with the [***list extraction kit(s)***] and the [***list RT-PCR Instrument(s)***] and [***RT-PCR Instrument Software***].

Collection Kits (if applicable)

This assay can be used with the **[*list EUA authorized Home Collection Kit(s)*].**

Reagents

The primary reagents used in [***test name***] assay:

Kits and Reagents	Manufacturer	Catalog #

CONTROL MATERTIAL(s) TO BE USED WITH *[test name]:*

[List all control materials used with the test and describe what they are, how they are expected to work, where in the testing process they are used, and the frequency of use. If a control is commercially available, provide supplier's name and catalog number or other identifier; if your device relies on external controls that are manufactured by a third party please note that these controls must also be validated within your analytical and clinical studies.]

Controls that are used with the test include:

a) A "no template" (negative) control is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]***

b) A positive template control is needed to ***[describe need]*** and is used ***[describe use – please specify the concentration of the positive control relative to the LoD of your test (note that ideally the positive control concentration should be such that it is close to the LoD of your test) and also specify frequency of use]***

c) An extraction control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use – please also specify frequency of use]*. Please note that if the no**

template control and positive control, are taken through the entire sample processing procedure, including the extraction, then a separate extraction control is not required.

d) An internal control ***[describe control]*** is needed to ***[describe need]*** and is used ***[describe use]***.

INTERPRETATION OF 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. Appropriate control interpretation criteria and result interpretation criteria are described here. **You must describe if a Ct cutoff is used as part of your testing algorithm and/or if the end user is required to review curves before final result interpretation. Although not typical for molecular-based tests, if the test result involves the use of an algorithm/calculation, for example a ratio value, when determining the final patient test result, include a detailed description and any additional calibration materials that may be required.**

1. **Examination and Interpretation of Control Results**

   [Describe in detail the expected results generated, including acceptance criteria, for all the controls used in test. Describe the measured values (if applicable) for valid and invalid controls and outline the actions to take in the event of an invalid control result.]

2. **Examination and Interpretation of Patient Specimen Results:**

   Assessment of clinical specimen test results must be performed after the controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

   [Describe when clinical specimen test results should be assessed and outline the criteria for test validity. Clearly indicate how to interpret numeric test values (if applicable) as positive or negative for presence of SARS-CoV-2. Indicate if the end user is required to review curves before final result interpretation and, if applicable, how to identify indeterminate/inconclusive/equivocal results. When applicable, we recommend providing a table clearly describing the possible combinations of test result values for each primer/probe set. Describe how they should be combined into a final interpretation of the result for your test. If the test produces an equivocal or indeterminate result, please indicate what follow-up testing/process should be conducted, if applicable.]

   [If your test is indicated for pooling, also include a pooling results interpretation table, indicating how to interpret each possible result, including when samples should be retested individually.]

PERFORMANCE EVALUATION

1) Limit of Detection (LoD) -Analytical Sensitivity:

The LoD for the ***[test name]*** was evaluated and verified using ***[validation material, e.g., SARS-CoV-2 inactivated virus (e.g., heat treated or irradiated)]*** per the validation required by Appendix A of the Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing. Nucleic acid was extracted from the swabs using ***[specify nucleic acid extraction]*** and the reverse transcription RT-PCR was performed using the ***[specify RT-PCR Instrument and, if applicable, interpretive software version]***. Preliminary and Confirmation LoD results are included in the tables below.

[insert table such as:] **Table Example: Preliminary Determination of LoD**

Virus Concentration	Target 1 Ct Value	Target 2 Ct Value	Internal Control Ct Value	# of Replicates

[insert table such as:] **Table Example: LoD Confirmation**

Targets	Target 1	Target 2
Analyte Concentration		
Positives/Total		
% Detected		
Mean Ct		
Mean SD		
CV		

The data confirmed the assay analytical sensitivity is ***[specify LoD represented as genome copies or equivalents/mL]***.

2) Inclusivity (Analytical Reactivity):

An alignment was performed with the oligonucleotide primer and probe sequences of the ***[test name]*** with ***[number of sequences]*** publicly available SARS-CoV-2 sequences (including mutation variants of high prevalence, i.e., B.1.617.2 and sub-lineages at the time of issuance of this letter) from ***[specify sequence data base, e.g., GISAID]*** to demonstrate the predicted inclusivity of the assay.

[Insert summary of results of inclusivity analysis.]

3) Cross-reactivity (Analytical Specificity):

Analytical specificity of the primer/probe combination for ***[test name]*** was evaluated by conducting sequence alignment of the primer/probe sequences of the test with publicly available genome sequences for potential cross-reacting microorganisms. The following organisms were tested with ***[test name]*** primer probe set.

[insert table such as:] **Table Example: Organisms Analyzed for Cross Reactivity**

Organism	Strain	Target 1	Target 2

4) Clinical Evaluation:

Clinical evaluation of the ***[test name]*** was conducted with 30 individual natural positive and 30 negative anterior nasal swab clinical specimens collected from patients suspected of SARS-CoV-2 infection by a healthcare provider in COVID-19 disease endemic region(s). These specimens were ***[prospective, retrospective, or leftover samples]***. Nucleic acid was extracted from the swabs using ***[specify nucleic acid extraction]*** and the reverse transcription RT-PCR was performed using the ***[specify RT-PCR Instrument and, if applicable, interpretive software version]***.

Data is summarized in the Table below:

Table: Summary Performance on individual anterior nasal swab specimens in comparison to an FDA-authorized method for specimens collected from individuals suspected of COVID-19 by a healthcare provider

[Test Name]	**FDA EUA RT-PCR Assay**		**Total**	**% Performance Agreement**	**95% CI**
	Detected	**Not Detected**			
Detected	A	B	A+B	PPA= 100% x A/(A+C)	
Not Detected	C	D	C+D	NPA= 100% x D/(B+D)	
Total	A+C	B+D			

[IF VALIDATION WAS ALSO COMPLETED WITH SPECIMENS COLLECTED FROM INDIVIDUALS WITHOUT SYMPTOMS OR OTHER REASONS TO SUSPECT COVID-19, ALSO INCLUDE THOSE RESULTS:] Clinical evaluation of the ***[test name]*** was conducted with 20 positive and 100 negative specimens collected from individuals without symptoms or other reasons to suspect COVID-19 in COVID-19 disease endemic region(s). These specimens were ***[prospective, retrospective, or leftover samples]***. Nucleic acid was extracted from the swabs using ***[specify nucleic acid extraction]*** and the reverse transcription RT-PCR was performed using the ***[specify RT-PCR Instrument and, if applicable, interpretive software version]***.

Data is summarized in the Table below:

Table: Summary Performance on individual anterior nasal swab specimens in comparison to an FDA-authorized method for specimens collected from individuals without symptoms or other reasons to suspect COVID-19

[Test Name]	**FDA EUA RT-PCR Assay**		**Total**	**% Performance Agreement**	**95% CI**
	Detected	**Not Detected**			
Detected	A	B	A+B	PPA= 100% x A/(A+C)	
Not Detected	C	D	C+D	NPA= 100% x D/(B+D)	
Total	A+C	B+D			

5) **Additional Validation for *[indication provided by appendix(ces) B -K, e.g., Media Pooling up to n=10 with validation option 2]*:**

[For each additional indication, include a section with the required validation and documentation from the applicable appendix.]

LIMITATIONS

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between ***[include collection window dates between MONTH, YEAR AND MONTH, YEAR, and the location(s) of clinical evaluation (Countr(ies)– identify if it was multiple sites in the country or limited locations – if known)]***. The clinical performance of this test has not been established in all circulating variants but is anticipated to be reflective of the variants in circulation at the time and location(s) of the clinical evaluation. As such, 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.
- [IF EVALUATION OF SPECIMENS COLLECTED FROM INDIVIDUALS WITHOUT SYMPTOMS OR OTHER REASONS TO SUSPECT COVID-19 HAVE NOT YET BEEN EVALUATED, INCLUDE THIS STATEMENT:] Clinical performance has been established in specimens collected from subjects suspected of COVID-19 by a healthcare provider. Performance of specimens collected from individuals without symptoms or other reasons to suspect COVID-19 has not been established. A study to determine the performance in individuals without symptoms or other reasons to suspect COVID-19 will be completed.

WARNINGS:

- This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by the laboratory that developed the test and 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 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.