EMERGENCY USE AUTHORIZATION (EUA) SUMMARY FOR THE Ambry COVID-19 RT-PCR TEST

For *in vitro* Diagnostic Use
Rx Only
For 18 years of age or older
For Use Under Emergency Use Authorization (EUA) Only

The Ambry COVID-19 RT-PCR Test will be performed at Ambry Genetics Laboratory located at 7 Argonaut Aliso Viejo, CA 92656 that 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 Ambry COVID-19 RT-PCR Test is a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device from individuals suspected of COVID-19 by their healthcare provider due to symptoms. This test is also for use with saliva specimens that are self-collected unsupervised at home by individuals 18 years of age or older using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit, when determined to be appropriate by a healthcare provider based on results of a COVID-19 questionnaire. Saliva specimens collected at home or in healthcare setting can be transported at ambient temperature to the laboratory for testing.

Testing is limited to Ambry Genetics Laboratory located at 7 Argonaut Aliso Viejo, CA 92656, which is certified under 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 saliva 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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

The Ambry COVID-19 RT-PCR Test is intended for use by qualified laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures. The Ambry COVID-19 RT-PCR Test and the Ambry COVID-19 RT-PCR Test Saliva Collection Kit are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1. Device Description

The Ambry COVID-19 RT-PCR Test is for use in detection of SARS-CoV-2 RNA in saliva from patients suspected of COVID-19 that is collected either in a healthcare setting using the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device, or unsupervised at home using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit when determined to be appropriate by a healthcare provider.

The Ambry COVID-19 RT-PCR Test Saliva Collection Kit comprises the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device (consisting of a saliva collection tube with detachable funnel, the lid of which contains a small sealed reservoir containing a specimen stabilizing liquid, and a tube cap), a specimen biohazard bag with an absorbent pad, the kit carboard box, a specimen tube label, a shipping package/envelope with return shipping label and instructions for specimen collection and shipment (**Table 1**). Use of the Ambry COVID-19 RT-PCR Test Saliva Collection Kit is restricted to patients 18 years of age or older.

Specimens that are self-collected using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit will be shipped in a manner compliant with the International Air Transport Authority (IATA) regulations (Dangerous Goods Regulations, 3.6.2.2.2.2; Category B Infectious Substances). The Specimen stabilizing liquid used in the Ambry COVID-19 RT-PCR Test Saliva Collection Kit contains a substance that inactivates SARS-CoV-2 and might be a human health hazard if it accidentally comes in contact with eyes or skin. Appropriate cautionary and advisory statements were added in the user instructions to mitigate that risk.

In a healthcare setting, saliva samples are collected under the supervision of a healthcare provider according to the instructions provided by the manufacturer of the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device.

The Ambry COVID-19 RT-PCR Test utilizes the TaqPath COVID-19 Combo Kit (ThermoFisher) with a modified result interpretation algorithm.

Table-1: Components of the Ambry COVID-19 RT-PCR Test Saliva Collection Kit

Name	Description	Quantity	Material Supplier	GBF Part Number
Kit box barcode (Pre-affixed to Kit)	Barcode used to Register Kit in Ambry's Portal	1	GBF Inc.	SL-AMB-COVID-SALIVA (2x1 Label)
Ambry-branded shipping instructions	Instructions for proper packaging and return mailing to Ambry's facilities	1	Ambry Genetics	IS-AMB-SALIVA-CFC
Ambry-branded saliva tube label	Specimen label required under CLIA	1	Ambry Genetics	LABEL-AMB-PATIENT
Bio-specimen bag with absorbent pad	Secondary container with absorbent pad to contain spills during shipping	1	GBF Inc.	BAG-6X9-BH/ABS

Cardboard Specimen Return Box	Ambry Genetics branded carboard box as rigid outer containment for specimen shipment	1	GBF Inc.	KB-AMB-CARE-0389
Generic UN3373 return mailer bag	Shipping requirement for COVID diagnostic specimens	1	GBF Inc.	RS-AMB-FX-1LB-NDP-S-CA-C
Fedex return service label	Ambry pre-paid return service label	1	FedEx	RS-AMB-FX-1LB-NDP-S-CA-C
Saliva collection device DNA Genotek OM-505/OME-505	OMNIgene·ORAL-505 saliva collection device	1	DNA Genotek	CM-DEVICE-AMB-OM-505
Instructions for Use of the Saliva Collection Device	Instructions for use provided inside the Saliva Collection device packaging from DNA Genotek.	1	DNA Genotek	[CM-DEVICE-AMB-OM-505] *

*[] Denotes that this item is a sub-component of the part number referenced within brackets

2. Collection Device Stability:

DNA Genotek has granted Ambry Genetics a right of reference to information contained in the appropriate Device Master File which includes the OMNIgene·ORAL OM-505/OME-505 saliva collection device formulation, engineering drawings and packaging.

3. Ambry COVID-19 RT-PCR Test Saliva Collection Kit Ordering

Individuals that suspect exposure to SARS-CoV-2 or who are experiencing symptoms of COVID-19 and who are seeking an at home collection kit must register in the online Care for COVID portal and affirm their exposure and health status through response to a symptomology checklist that aligns with the guidance set forth by the United States Centers for Disease Control and Prevention (CDC) for test prioritization. Should the individual be categorized as at-risk through their responses online, the healthcare provider will issue a prescription for the test and a saliva collection kit is then dispensed to the patient or mailed to the patient's home. Under no circumstance will a collection kit be provided to an individual without a prescription.

4. Ambry COVID-19 RT-PCR Test Saliva Collection Kit Use

Upon receiving the kit by mail, the user must read the package insert carefully and thoroughly before beginning the sample collection. The collection and shipping instructions provide a step-by-step guide for kit registration, collection, repackaging, and shipping. Each saliva collection tube comes with a unique barcode. Individuals collecting samples will register their kit at the Ambry web portal (https://www.ambrygen.com/covidkit) and then follow the step-by-step instructions to self-collect their saliva specimen, repackage, and drop the package at the nearest FedEx drop box for return to Ambry Genetics Laboratory for testing.

Test results are communicated back to the healthcare provider via the Ambry Genetics portal. The ordering healthcare provider will also contact patients for follow up, as appropriate.

5. Laboratory Processing (Registration and accessioning of the samples):

Specimens collected with the Ambry COVID-19 RT-PCR Test Saliva Collection Kit that are received at the clinical laboratory (7 Argonaut Aliso Viejo, CA 92656) for testing with the Ambry COVID-19 RT-PCR Test undergo the following accessioning process prior to acceptance for testing: 1) log of receipt into Ambry's laboratory information management system (LIMS), 2) visual examination of the kit and specimen collection device to verify that the specimen volume is adequate and the specimen has not been compromised, 3) verification that the kit was properly registered, and 4) assignment of an Ambry Genetics accession number for specimen tracking in the laboratory. Specimens that appear to be compromised (e.g., leaking tubes, broken tubes, dry tubes, etc.) are rejected from downstream processing and a notification is provided through the Ambry Genetics portal. Specimen in transit for more than 56 hours or received after 5 days (kept at room temperature) from collection will be rejected.

6. Specimen Collection Control

In order to verify whether a patient has provided an adequate volume of saliva in the OMNIgene·ORAL OM-505/OME-505 collection device, visual inspection is conducted to ensure the specimen meets minimum volume requirements. The OMNIgene·ORAL OM-505/OME-505 saliva collection device has a 1mL fill line indicated on the tube and specified in the instructions for use. Furthermore, the specimen collection funnel lid contains 1.1 mL of specimen lysis and preservation buffer, of which about 0.9 mL is released into the collection tube upon closure of the funnel lid. Collection tubes are inspected for the presence of adequate volume (above the fill line) as part of the accessioning process. Additionally, saliva specimen transfer on the liquid handlers at Ambry Genetics utilizes capacitance-based liquid level detection to ensure that at least 1.5 mL of specimen is present prior to transfer for nucleic acid extraction. Samples that have inadequate fill-volume will be rejected and a new specimen may be requested.

7. REAGENTS AND MATERIALS

a. RNA Extraction.

i. Reagents/materials required

Table-2:

Reagent/ Material	Stock Concentration	Source	Ref. Number
Ethanol	100%	Thermo Fisher	BP2818-500
MagMAX DNA/RNA Binding Beads	N/A	Thermo Fisher	A42362
MagMAX Elution Buffer	N/A	Thermo Fisher	A42364
MagMAX Proteinase K	N/A	Thermo Fisher	A42363
MagMAX Viral/Pathogen Binding Solution	N/A	Thermo Fisher	A42359
MagMAX Viral/Pathogen Wash Solution	N/A	Thermo Fisher	A42360

Reagent/ Material	Stock Concentration	Source	Ref. Number
Nuclease-Free Water (not DEPC-Treated)	N/A	Thermo Fisher	AM9932

ii. Equipment/supplies required

Table-3:

Equipment/ Supplies	Source	Ref. Number
100 mL reagent trough	Tecan	10613048
1000 µL filtered Wide Bore LiHa DiTis	Tecan	30115239
1000 µL filtered LiHa DiTis	Tecan	30000631
50 µL filtered LiHa DiTis	Tecan	30032114
96 Deep-Well KingFisher plate	Thermo Fisher	95040450
96 Deep-Well KingFisher tip comb	Thermo Fisher	97002534
96-well KingFisher standard plate	Thermo Fisher	97002540
96-well metal plate holder	Ehrmann Engineering	Custom Part
96-well Framestar Break-away plate	Brooks Life Sciences	4ti-1000/C
Centrifuge	Eppendorf	022625004
KingFisher Flex	Thermo Fisher	5400630
MicroAmp Adhesive Film	Thermo Fisher	4306311
Archiving Stopper	Sarstedt Inc	65-647-020
Tecan Freedom EVO 100 LiHa	Tecan	N/A
Tecan Freedom EVO 75 RoMa	Tecan	N/A
Tube Carrier, 16mm, 16-Position	Tecan	10613003
Zebra GK420T Desktop Barcode Printer	Zebra	H-2526

b. Ambry COVID-19 RT-PCR Test

i. Reagents/materials required

Table-4:

Reagent/ Material	Stock Concentration	Source	Ref. Number
Nuclease-Free Water (not DEPC-Treated)	N/A	Thermo Fisher	AM9932
TaqPath COVID-19 Combo Kit, 1000 Rxns	N/A	Thermo Fisher	A47814
1 X 10ML TaqPath 1STEP Master Mix NO ROX	N/A	Thermo Fisher	A28523

ii. Equipment/supplies required

Table-5:

Equipment/Supplies	Source	Ref. Number
100 µL filtered MCA DiTis	Tecan	30038613
150 µL filtered MCA DiTis	Tecan	30038618

Equipment/Supplies	Source	Ref. Number
300 mL reagent trough	Agilent	201244-100
96 Deep-Well KingFisher plate	Thermo Fisher	95040450
96-well metal plate holder	Ehrmann Engineering	Custom Part
MicroAmp Clear Adhesive Film, 100 Pc	Thermo Fisher	4306311
NS RNase-Free Tubes 1.5ml, 250 Tubes	Thermo Fisher	AM12450
96-well MicroAmp Fast Optical plates	Thermo Fisher	4346907
Applied Biosystems 7500 Fast Dx	Thermo Fisher	4406985
Magnum FLX Magnet Plate	Alpaqua	A0004000
MicroAmp Optical Adhesive film	Thermo Fisher	4311971
Tecan Freedom EVO 100 MCA	Tecan	N/A

8. CONTROLS

The Ambry COVID-19 RT-PCR Test is performed using the assay controls supplied with the TaqPath COVID-19 Combo Kit. An exogenous Internal Control (MS2) is added to each sample and negative control prior to nucleic acid extraction to monitor specimen processing and nucleic acid amplification/detection. The Internal Control must be detected in all samples/controls that are negative for SARS-CoV-2 in order for a negative test result to be reported.

The positive control, which does not undergo extraction, should have clear amplification of ORF1ab, N gene, and S gene and no amplification of MS2. The negative control should show amplification of only MS2.

9. INTERPRETATION OF RESULTS

All assay controls for Ambry COVID-19 RT-PCR Test must be evaluated and found to meet the specified acceptance criteria prior to interpretation of patient results. If the controls are not valid, patient results cannot be interpreted. Any samples that are reported invalid on an initial run need to be retested beginning with extraction. If the result from the rerun remains the same, the result is reported as Invalid, collecting a new specimen is considered.

Table-6: Interpretation algorithm of Ambry COVID-19 RT-PCR Test

		ORF1ab	*N gene*	*S gene*	MS2	Status	Result	Action
Potential Outcome 1	Software Output	NEG	NEG	NEG	NEG	INVALID	NA#!	Repeat test by re-extracting the original sample and repeating the RT-PCR. If the repeat result remains invalid, consider collecting a new specimen.
	Ct Value	Ct > 37	Ct > 37	Ct > 37	Ct > 32			
	Ct Value	POS Ct ≤ 37; NEG Ct > 37	POS Ct ≤ 37; NEG Ct > 37	POS Ct ≤ 37; NEG Ct > 37	POS Ct ≤ 32; NEG Ct > 32			
Potential Outcome 2	Software Output	NEG	NEG	NEG	POS	VALID	SARS-CoV-2 Not Detected	Report results to the healthcare provider and appropriate public health authorities. Consider testing for other respiratory viruses.
	Ct Value	Ct > 37	Ct > 37	Ct > 37	Ct ≤ 32			
Potential Outcome 3	Software Output	One or more SARS-CoV-2 target = POS*			POS or NEG	VALID	Positive SARS-CoV-2	Report results to the healthcare provider and appropriate public health authorities.
	Ct Value	POS Ct ≤ 37; NEG Ct > 37			POS Ct ≤ 32; NEG Ct > 37			

*Denotes modified result interpretation algorithm for saliva specimens compared with original instructions for use provided by Thermo Fisher TaqPath COVID-19 Combo Kit. NA

Result may not be available due to erroneous sample extraction.

! The result output may also be indicated as "NA" because the same sample name (Sample ID) was assigned to multiple wells in the instrument software. Mitigation: In the **Samples** pane of the **Home** screen, review all samples with a status of **INVALID**. If there are duplicate sample names in the instrument software, correct the sample names, for EDS files change the experiment name, save the file with a new file name, then import the corrected file into the interpretive software.

10. PERFORMANCE EVALUATION

1) Limit of Detection (LoD) for Saliva specimen- Analytical Sensitivity:

Estimation of the LoD

The Ambry COVID-19 RT-PCR Test LoD (concentration at which ≥95% of replicates produce a positive result) was determined by testing a dilution series comprised of heat-inactivated virus spiked into COVID-19 negative saliva at different concentrations. Five independent dilutions at each virus concentration (ATCC VR-1986HK) were prepared and run through the Ambry COVID-19 RT-PCR Test. The estimated LoD was determined to be 100 copies per mL of saliva.

Table 7. LoD Estimation for Ambry COVID-19 RT-PCR Test		
Viral Copies/mL	Positive	Not Detected
5	3	2
10	1	4
50	4	1
100	5	0
200	5	0
400	5	0
0 (Negative Control)	0	5

Confirmation of the LoD

The estimated LoD was confirmed by testing an additional 20 replicates at 100 copies/mL of saliva. Nineteen of the 20 replicates (95%) produced the expected positive results. The LoD for the Ambry COVID-19 RT-PCR Test was therefore confirmed to be 100 copies/mL of saliva.

2) Specimen Stability

The Ambry COVID-19 RT-PCR Test Saliva Collection Kit uses the FDA-authorized DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device (EUA202641) that was shown to stabilize SARS-CoV-2 RNA in saliva specimens during transport and storage in accordance with the OMNIgene device labeling.

3) Analytical Specificity (Inclusivity and Cross-reactivity):

The Ambry COVID-19 RT-PCR Test uses the primers and probes from Thermo Fisher TaqPath Combo kit. Ambry Genetics has obtained a Right of Reference from Thermo Fisher to information contained in the EUA submissions for the TaqPath COVID-19 Combo Kit (EUA200010 and supplements), including *in silico* inclusivity and cross-reactivity data.

4) Clinical Validation (Study with paired saliva and NP swab specimen):

Saliva is an atypical specimen type for detecting COVID-19 RNA from suspected individuals. Ambry Genetics conducted a clinical study in which paired saliva and nasopharyngeal (NP) swab samples were collected from 65 patients at three sites. Saliva specimens were self-collected under the supervision of a healthcare provider using the DNA Geneotek OMNIgene·ORAL OM-505/OME-505 saliva collection device who also collected the paired NP swabs during the same healthcare visit. The NP swabs in PrimeStore molecular transport medium (Longhorn Vaccines and Diagnostics) and the saliva specimens were transported to the testing laboratory at ambient temperature within 72 hours of collection. The NP swab specimens were tested using an FDA-authorized RT-PCR assay according to the instructions for use. The saliva specimens were tested utilizing the Ambry COVID-19 RT-PCR Test and associated result interpretation algorithm outlined in Table 6. The summary of the paired specimen study is given in the Table 8.

Table 8: Summary of the paired specimen study

		Nasopharyngeal swab		
		Positive	**Negative**	**Total**
Saliva	**Positive**	**30**	**0**	**30**
	Negative	**1**	**34**	**35**
	Total	**31**	**34**	**65**
Positive Agreement		**96.8% (30/31); 95% CI* (83.8,99.4)**		
Negative Agreement		**100% (34/34); 95% CI (89.8, 100.0)**		

*CI: 95% score confidence interval

This result of this study shows 96.8% (30/31) positive percent agreement (PPA) and 100% (34/34) negative percent agreement (NPA) between paired NP and saliva specimens.

5) Human Usability Study

Ambry Genetics conducted a usability study with 30 participants in order to evaluate the ease of use of the Ambry COVID-19 RT-PCR Test Saliva Collection Kit. The study measured the following outcomes: usability (in Likert scale format), user comprehension, observations made by study staff, packaging error frequencies, and sufficiency of specimen collected for testing purposes.

Inclusion/Exclusion criteria for study participants:

- Participants must be 18 years of age or older
- Participants must not have prior experience with self-collected saliva specimen collection devices.
- Participants must have no prior medical or laboratory training experience.

Upon enrollment into the usability study, the Ambry COVID-19 RT-PCR Test Saliva Collection Kit was sent via FedEx to the participants' homes. The participant and the observer then scheduled a time to meet virtually (via tools like WebEx, Zoom, FaceTime, etc.) or in-person with appropriate personal protective equipment and precautions taken.

Upon initiation of the virtual or live session, the participant performed the following under observation:

1. Read saliva self-collection instructions
2. Collected saliva specimen
3. Wrote Participant ID number on the label
4. Affixed the label to the specimen tube
5. Completed the "Questionnaire for Saliva Sample Self-Collection" form.
6. Packaged kit and questionnaire form for shipment back to the laboratory
7. Contacted FedEx for pick up or delivered the FedEx bag to a drop-off location within 24 hours of specimen collection.

During the virtual or live session, the study staff observer completed the "Questionnaire for Saliva Sample Self-Collection: Observer" form and was not allowed to intervene in any of the collection activities.

Upon receipt in the laboratory, the saliva specimens were accessioned and anonymized to record date and time of receipt in the facility.

Results Summary:
In summary, all 30 participants (age ranges from 18 to 65+ years old) collected the samples correctly, including provision of adequate specimen volume, capping the specimen tube, placement in the biohazard bag and packaging for shipment. Most participants (83%; 25/30) answered all five user comprehension questions correctly and 93% (28/30) stated the instructions were easy to find and understand.

However, 77% of participants (23/30) made suggestions on how the Instruction for Use could be improved.

Based on the feedback from the usability study, and to align to other FDA-authorized saliva home collection kits that use the DNA Genotek OMNIgene·ORAL OM-505/OME-505 saliva collection device, Ambry made the following changes in the instructions for use (IFU):

1. Increased font size,
2. Added pictures of the saliva collection kit box and each component for sample collection and shipping,
3. Added an illustration outlining how to place the label on the saliva collection device,
4. Modified the re-packaging instructions to eliminate the need to place the collection device back inside the smaller plastic box (original packaging for the DNA Genotek saliva collection device),
5. Removed the step for adding an extra bar code label on the collection tube as the collection tube comes with a barcode,
6. Added and bolded instruction to “discard the funnel” after unscrewing the funnel from the collection tube,
7. Added an additional hand washing step,
8. Added a Warning regarding exposure to the stabilizing liquid,
9. Added the appropriate storage conditions for the saliva collection kit,
10. Added appropriate regulatory information,
11. Removed “FedEx pickup” option from the shipping instruction,
12. Moved important steps about reading the instructions thoroughly and preparation for sample collection to the beginning of the IFU

To assess the impact from the modifications made to the IFU, Ambry Genetics performed a pilot beta test with its internal employees. The Accessioning Manager aggregated data to de-identify employee names and summarized sample acceptance upon receipt as assessed by the general accessioning staff as shown in Table 9. Participants were not asked to respond to a questionnaire as a part of this pilot. Results confirmed that the modifications to the instructions for use made as an output of the initial usability study had no negative impact on individuals’ ability to successfully package their specimen and arrange for shipment back to the laboratory.

Table 9: Age Groups and Success Rates of Internal Pilot Study			
Age group	**Count of Accessions**	**Acceptable Specimen**	**Unacceptable Specimen**
18 - 25	6	6/6 100%	0
26 - 40	31	31/31 100%	0
41 - 64	20	20/20 100%	0
Grand Total	**57**	**57/57 100%**	0

In addition to making these changes, Ambry Genetics will conduct a post-authorization human usability survey to monitor the rejection rate for samples collected at-home using the Ambry COVID-19 RT-PCR Test Saliva Collection Kit to determine whether the changes in the IFU were effective. The study will evaluate packaging error frequency, as well as failures in sample identification and assess the adequacy of specimen collection. Ambry Genetics will provide a report to the FDA from their observations on the first 500 self-collected samples within 60 days post authorization.

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 used was Thermo Fisher MagMAX Viral/Pathogen Nucleic Acid Isolation Kit on KingFisher Flex. Amplification was carried out on the Applied Biosystems 7500 Fast Dx RT-PCR Instrument. The results are summarized in the following Table.

Table 10: 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	Saliva	$0.6x10^3$ NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL: RNA NAAT detectable units/mL
N/A: Not Applicable
ND: Not Detected

LIMITATIONS:

- Testing of saliva specimens is limited to patients with symptoms of COVID-19.
- Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.
- 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.

WARNINGS

- For Emergency Use Authorization (EUA) only.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- For *in vitro* diagnostic use.
- For prescription use.
- 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.
- 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 diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.