EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
Gx HTIQ SARS-CoV-2 Test
(RCA Laboratory Services LLC dba GENETWORx)

For *in vitro* Diagnostic Use
Rx Only
For Use Under Emergency Use Authorization (EUA) Only

The Gx HTIQ SARS-CoV-2 Test will be performed at RCA Laboratory Services LLC dba GENETWORx, located at 4060 Innslake Drive, Glen Allen, VA 23060 and 670 US 1, Iselin, NJ 08830, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet 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 Gx HTIQ SARS-CoV-2 Test is an *in vitro* diagnostic real-time reverse transcription polymerase chain reaction (rRT-PCR) assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in mid-turbinate and anterior nasal swab specimens collected from any individual, including from individuals without symptoms or other reasons to suspect COVID-19, using the NEST collection device when determined to be appropriate by a healthcare provider. Testing is limited to RCA Laboratory Services LLC dba GENETWORx, located at 4060 Innslake Drive, Glen Allen, VA 23060 and 670 US 1, Iselin, NJ 08830, which are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet 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 mid-turbinate and 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 definitive cause of disease. Laboratories within the United States and its territories are required to report all test 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/or epidemiological information.

The Gx HTIQ SARS-CoV-2 Test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR and in vitro diagnostic procedures. The Gx HTIQ SARS-CoV-2 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

Device Description

The Gx HTIQ SARS-COV2 Test is a real time reverse transcription polymerase chain reaction (rRT-PCR) assay intended for the qualitative detection of nucleic acids from the SARS-CoV-2 in mid turbinate (MT) and anterior nasal (AN) swabs collected in NEST collection device from individuals suspected of COVID-19 by their healthcare provider and/or for screening of individuals

without symptoms or other reasons to suspect COVID-19 infection. NEST collection device (Wuxi NEST Biotechnology Co., Ltd; Catalog number 202015) consists of a 5 mL vial with 2.5 mL VTM (Viral Transport Media) and one individually wrapped and sterile nasopharyngeal swab.

Patient specimens are transferred with the Hamilton MicroLab automated systems or manually in Biological Safety Cabinets level 2 (BSC2).

The assay is composed of two principal steps: (1) preparation of RNA from patient specimens on a ThermoFisher KingFisher Flex extraction instrument and (2) one-step reverse transcription and PCR amplification with SARS-CoV-2 specific primers and real-time detection with SARS-CoV-2 specific probe labelled with ROX. The assay targets N1 region of the virus nucleocapsid gene (N1) and is designed for the detection of the SARS-CoV-2.

Amplification and detection are accomplished using BioGX SARs-COV-2 RT-PCR kit on the 768 Array Tape® IntelliQube Real-Time PCR Detection System from LGC. To ensure the absence of non-specific PCR inhibition in a sample, the assay targets human RNase P gene as an internal positive control (IPC). The probe is labelled with FAM. A sample can be interpreted as negative only if the analysis of the RNase P gene indicates that amplification has occurred in the reaction tube and signal from SARS-CoV-2 target reporter dye is more than 40 Ct value. In addition, the assay includes an Internal Amplification Control (IAC) to monitor well-to-well amplification across the entire plate and confirms the integrity of each assay. The IAC is a non-naturally occurring proprietary ssRNA sequence, that is formulated along with corresponding primers and probe into the BioGX X-free Master Mix. The 5' end of its probe is modified with a Quasar (QUA) fluor group. An IAC Ct value of <40 Ct is acceptable.

Description of Test Steps:

1. *Sample transfer*: Patient specimens are transferred with the Hamilton MicroLab automated systems or manually in Biological Safety Cabinets level 2 (BSC2).
2. *Nucleic acid extraction*: using MagMAX Viral/Pathogen II (MVP II) Nucleic Acid Isolation Kit on KingFisher Flex, ThermoFisher. The steps of extraction using MagMax are:
    a. Digestion/lysis of 200 µl sample with Proteinase K and addition of magnetic beads.
    b. Nucleic acids are immobilized by binding to magnetic beads. Proteins and other contaminants are washed out and removed as nucleic acids bound to magnetic beads are purified.
    c. A second wash solution is used to remove residual binding solution.
    d. Nucleic acid is eluted in 75 µL resuspension/elution buffer.
3. *PCR set up and Liquid Handling*: 0.8 µl of viral RNA is dispensed to a 384 or 768 Well Array Tape and the array is sealed automatically.
4. *Amplification and Detection*: RT-PCR is performed on IntelliQube Real-Time automated PCR instrument from LGC using BioGX X-free custom formulation that contains all primes, probes, Master Mix, and enzymes required for SARS-CoV-2 amplification and detection on the 384 or 768 Array. The reaction is a one-step reverse transcription and PCR amplification with SARS-CoV-2 specific primers and real-time detection with SARS-CoV-2 specific probe labelled with ROX. Detection uses IntelliQube features for inline fluorescence detection (excitation range of 480-620 nm).

5. *Data Analysis*: After amplification, the data is exported and analyzed for the presence or absence of the N1 target for the determination of SARS-CoV2 and the RNaseP target for sample adequacy. Intellics software is used for data analysis. Intellics is pre-loaded on each instrument and is accessible to users through a unified web-based interface that allows easy multi-user access.

INSTRUMENTS AND REAGENTS USED WITH THE TEST ASSAY

The Gx HTIQ SARS-COV2 Test is to be used with the following instrument, software, and reagents:

Table 1. Gx HTIQ SARS-COV2 Test Instrument, Software, and Reagents

Name	Vendor	Catalog ID
KingFisher Flex	Thermo Scientific	5400630
BindIT Software for KingFisher	Thermo Scientific	5189009
Hamilton MicroLab Prep	Hamilton	Microlab Prep
IntelliQube Real-time PCR detection system (with IntelliQube software version 1.13.3.0)	LGC-Douglas Scientific	IQ1804
MagMax Viral/Pathogen II Nucleic Acid Isolation kit	Thermo Fisher	A42383
BioGX SARs-COV-2 lyophilized custom Mix*	BioGX	Custom Product Ref # 205-0407
Array Tape and Array Tape Seal	Douglas Scientific	AXIT768-13WP050 AX8591CVRT
CyBio Tips 384/40µL & CyBio Tips 96/40µL	Analytik Jena	OL 3810-25-231 OL 3810-25-431

*Contains polymerase, reverse transcriptase, primers, probes, dNTPs, MgCl2, Internal Amplification Control RNA (IAC), and buffer

CONTROLS

Three external controls are required for each 96 well plate; therefore, each plate contains 93 samples plus one of each of the external controls. Additionally, there is an internal positive control to monitor each well amplification and verification of sample adequacy, and an internal amplification control that monitors well-to-well amplification across the entire plate.

The following further describes the external and internal controls:

a) An external Positive Template Control (PTC) is needed to monitor the entire sample processing procedure, including the extraction and amplification. The PTC is prepared using ZeptoMetrix or Microbiologics inactivated SARS-CoV-2 in negative patient matrix diluted to 3xLoD or positive pooled patient specimens of appropriate Ct value. The PTC is used as one sample for each 93 samples within a 96 well plate. PTC in a range of 26-34 Ct is acceptable.

b) An external Negative Template Control (NTC) is needed to monitor reagent contamination including extraction reagents; the NTC contains only elution buffer without a template; one NTC is required on every 96-well extraction plate. An NTC Ct value of >40 Ct for N and RP are acceptable.

c) Human Template Control (HTC) monitors extraction and amplification processes and reagent contamination for N1 gene/amplicon. It consists of buccal swabs in NEST VTM collected from Medical Technologist volunteers confirmed negative for SARS-CoV-2. It also verifies performance of the RP assay on the plate. It is required on every 96-well extraction plate. An RP Ct value of <40 Ct and N Ct value >40 is acceptable. The HTC must be verified before use in clinical testing.

d) An Internal Amplification Control (IAC) monitors well-to-well amplification across the entire plate and provides monitoring of integrity of each assay. The IAC target and probe are formulated into the BioGX X-free Master Mix and IAC is introduced at the time of assay set-upon the IntelliQube. The IAC is a non-naturally occurring proprietary ssRNA sequence. The 5' end of the internal amplification control probe is modified with a Quasar (QUA) fluor group. An IAC Ct value of <40 Ct is acceptable.

e) An Internal Positive Control (IPC) monitors the extraction, amplification, and detection steps of each specimen and confirms the appropriate collection of the specimens. The human RNaseP (RNase P, RP) gene constitutes the IPC and is tested in every patient sample. The IPC is sensitive to possible inhibitors of SARs-CoV-2 virus detection. All negative samples must be positive for RNaseP and a RP Ct value of <40 Ct is acceptable.

INTERPRETATION OF RESULTS

Assay Controls

Assessment of Gx HTIQ SARS-CoV-2 Test results should be performed after the positive and negative controls have been examined and determined to be valid and acceptable. If the controls are not valid, the patient results cannot be interpreted.

Refer to **Table 2** for Acceptance Criteria for Controls in Gx HTIQ SARS-CoV-2 Test

Table 2. Acceptance Criteria for Controls in Gx HTIQ SARS-CoV-2 Test.

CONTROL NAME	CONTROL ID	Acceptance Criteria		
		N1 (ROX)	RP (FAM)	ssRNA (QUA)
Positive Template Control	PTC	26-34 Ct	< 40 Ct	< 40 Ct
No Template Control	NTC	ND	ND	< 40 Ct
Human Template Control	HTC	ND	< 40 Ct	< 40 Ct

ND=Not Detected

Clinical Specimens

For sample interpretation, the amplification graphs are reviewed prior to releasing results. Refer to **Table 3** for Interpretation of patient sample results for Gx HTIQ SARS-CoV-2 Test.

Table 3. Interpretations of patient sample results

N1	RP	INTERPRETATION	RESULT	Action
< 40	N/A	Sample is positive for SARS-CoV-2	Positive	Report the result
≥ 40	< 40	Sample is negative for SARS-CoV-2	Negative	Report the result
≥ 40	≥ 40	Failure in sample collection or procedure	Invalid	Repeat from extraction

PERFORMANCE EVALUATION

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

A preliminary LoD study for the Gx HTIQ SARS-CoV-2 Test was completed using inactivated SARS-CoV-2 from Microbiologics (Lot # K2009C) at a stock concentration of 4.50E+09 copies/mL, which was serially diluted 1:10 twice followed by 1:3 serial dilutions (13 steps) in a negative Nest VTM patient matrix from Mid-Turbinate (MT) nasal swab collections. Each serial dilution was extracted and amplified in triplicate. The preliminary LoD was defined as the lowest virus concentration at which positivity was observed for all three replicates. The preliminary LoD of SARS-CoV-2 detection from MT swab specimens was determined as 7.62E+02 copies/ml.

Table 4. Preliminary LoD results using Microbiologics material

#	Concentration (cp/mL)	N1 Detected	RP Detected	IAC Detected	Interpretation
1	1.50E+07	3/3	3/3	3/3	Positive
2	5.00E+06	3/3	3/3	3/3	Positive
3	1.67E+06	3/3	3/3	3/3	Positive
4	5.56E+05	3/3	3/3	3/3	Positive
5	1.85E+05	3/3	3/3	3/3	Positive
6	6.17E+04	3/3	3/3	3/3	Positive
7	2.06E+04	3/3	3/3	3/3	Positive
8	6.86E+03	3/3	3/3	3/3	Positive
9	2.29E+03	3/3	3/3	3/3	Positive
10	**7.62E+02**	**3/3**	**3/3**	**3/3**	**Positive**
11	2.54E+02	0/3	3/3	3/3	Negative
12	8.5E+01	0/3	3/3	3/3	Negative
13	2.8E+01	0/3	3/3	3/3	Negative

An LoD confirmation study of the Gx HTIQ SARS-CoV-2 Test was completed by running 20 replicate samples of three dilutions, at 6.859E+03, 2.286E+03, and 7.62E+02 cp/ml of the virus in NEST negative patient matrix along with controls per the assay SOP. The LoD was confirmed to be 6.859E+03 copies/ml.

Table 5. LoD Confirmation Results using Microbiologics inactivated SARS-CoV-2

Concentration (cp/mL)	N1 Detected
6.859E+03	**100% (20/20)**

2.286E+03	80% (16/20)
7.62E+02	45% (14/18)

Similarly, a secondary LoD study for the Gx HTIQ SARS-CoV-2 Test was completed using Zeptometrix (NATtrol, Isolate USA-WA1/2020, Lot # 330338) control reference, which had a specification range of 7.94E+05 to 1.26E+06 copies/mL, and a CoA specification concentration of 8.87E+05 copies/mL. The Zeptometrix material was value assigned using RCA Laboratory Services LLC dba GENETWORx own quantitative PCR measurement against a standard curve prepared with the Microbiologics product, which resulted in a stock concentration of the Zeptometrix product of 3.42E+06 copies/mL.

Table 6. Preliminary LoD results using Zeptometrix material

#	Concentration (cp/mL)	N1 Detected	RP Detected	IAC Detected	Interpretation
1	2.01E+06	3/3	3/3	3/3	Positive
2	6.70E+05	3/3	3/3	3/3	Positive
3	2.23E+05	3/3	3/3	3/3	Positive
4	7.44E+04	3/3	3/3	3/3	Positive
5	2.48E+04	3/3	3/3	3/3	Positive
6	8.27E+03	3/3	3/3	3/3	Positive
7	**2.76E+03**	**3/3**	**3/3**	**3/3**	**Positive**
8	9.19E+02	1/3	3/3	3/3	Negative
9	3.06E+02	0/3	3/3	3/3	Negative
10	1.02E+02	1/3	3/3	3/3	Negative
11	3.4E+01	0/3	3/3	3/3	Negative
12	1.1E+01	1/3	3/3	3/3	Negative

An LoD (for Zeptometrix) confirmation study of the Gx HTIQ SARS-CoV-2 Test was completed by running 20 replicate samples of three dilutions at 4.99E+03, 2.49E+03, and 1.25E+03 cp/ml in NEST negative patient matrix along with controls per the assay SOP. The LoD was confirmed to be 4.99E+03 copies/ml.

Table 7. LoD Confirmation Results for Zeptometrix

Concentration (cp/mL)	N1 Detected
4.99E+03	**95% (19/20)**
2.49E+03	65% (13/20)
1.25E+03	25% (5/20)

The lowest detectable concentration of SARS-CoV-2 at which ≥ 95% of all replicates test positive detected by the Gx HTIQ SARS-CoV-2 Test in nasal swabs collected in NEST viral transport media is 6,859 copies/mL in the case of the Microbiologics material and 4,990 copies/mL in the case of the Zeptometrix material value assigned in house. The Microbiologics material and corresponding LOD value was used in subsequent studies of Inclusivity and Specificity (interferences), while the Zeptometrix material and LOD value was used for the Specimen stability experiments.

2) <u>Inclusivity (Analytical Reactivity):</u>

To mitigate the possibility that currently known emerging, variants and mutations might prove detectable by this assay at less than acceptable limits, the GISAID database for emerging SARS-CoV-2 mutations was reviewed on 10/9/2023 and all commercially available synthetic variants were evaluated. *In silico* analysis indicated that the probe hybridization site is mostly affected, but wet lab assessment of Twist controls that include the most common mutations revealed that the mutations within the probe sequence did not impact the test's performance. One indel was observed. Less frequently observed mutations within primer hybridization sites are single mutations, which are not likely to severely impact the assay.

In the future, any concerns noted as the assay is assessed against any new, or emerging, variants or mutations will be immediately shared with the FDA.

3) **Cross-Reactivity (Analytical Specificity):**

Cross reactivity with microorganisms commonly found in mid-turbinate and anterior nasal swab samples was evaluated via *in silico* analysis using published genome sequences and the sequences of Gx HTIQ SARS-CoV-2 Test's primers and probe. As expected, the only organism that fit the ≥ 80% criterium homology to the assay primers and probe was SARS-CoV-2. In addition, the search found correctly oriented primer pairs in six organisms *Candida albicans, Chlamydia pneumoniae, Haemophilus influenzae, Staphylococcus epidermis, Streptococcus pneumoniae, and Streptococcus pyogenes*; however the lack of probe similarity indicated that they will not cross-react with the SARS-CoV-2 assay.

There were 16 microorganisms identified that may interfere with amplification of SARS-CoV-2 nucleic acid in upper respiratory samples due to having ≥ 80% sequence homology to the assay primers or probe (refer to Table 8) These microorganisms were studied further in Microbial Interference studies.

Table 8. *In silico* cross-reactivity analysis results between primers-probe assay and microorganisms present in upper respiratory samples

Group	Organism	Sequence accession	≥ 80% Homology
Pathogen of interest	SARS-CoV-2	NC_045512.2	Yes
Similar, high priority pathogens	Human coronavirus 229E	AF304460.1	Yes
	Human coronavirus HKU1	NC_006577.2	No
	Human coronavirus NL63	NC_005831.2	No
	Human coronavirus OC43	NC_006213.1	Yes
	SARS-CoV-1	NC_004718.3	Yes
	MERS-coronavirus	NC_019843.3	No
Likely present, high priority pathogens	Adenovirus	KF268207.1	No
	Human metapneumovirus	NC_039199.1	Yes
	Human parainfluenza virus 1	NC_003461.1	No
	Human parainfluenza virus 2	NC_003443.1	No
	Human parainfluenza virus 3	NC_001796.2	No
	Human parainfluenza virus 4a	NC_021928.1	No
	Influenza A	NC_007382.1, NC_007374.1, NC_007381.1, NC_007375.1, NC_007380.1, NC_007376.1, NC_007377.1, NC_007378.1	No

	Influenza B	NC_002205.1, NC_002204.1, NC_002206.1, NC_002210.1, NC_002209.1, NC_002207.1, NC_002211.1, NC_002208.1	No
	Enterovirus 68	NC_038308.1	Yes
	Respiratory syncytial virus	MK733766.1	No
	Bordetella pertussis	CP011448.1	Yes
	Candida albicans	NC_032089.1, NC_032090.1, NC_032091.1, NC_032092.1, NC_032093.1, NC_032094.1, NC_032095.1, NC_032096.1	Yes
	Chlamydia pneumoniae	NC_005043.1	Yes
	Haemophilus influenzae	CP000672.1	Yes
	Legionella pneumophila	NZ_CP015941.1	Yes
	Mycoplasma pneumoniae	NZ_LR214945.1	Yes
	Pseudomonas aeruginosa	CP007224.1	Yes
	Rhinovirus A	NC_038311.1	No
	Rhinovirus B	NC_038312.1	No
	Rhinovirus C	NC_009996.1	No
	Staphylococcus epidermis	NZ_CP035288.1	Yes
	Streptococcus pneumoniae	CP027540.1	Yes
	Streptococcus pyogenes	AE014074.1	Yes
	Streptococcus aureus	CP066093.1	Yes

Organisms in gray shaded boxes were further tested for microbial interference.

4) Microbial Interference:

Sixteen microorganisms from the *in silico* cross-reactivity analysis were found to have ≥ 80% homology to one of the primers or probes in the SARS-CoV-2 primers/probe set (refer to Table 8). A microbial interference study was performed to further evaluate potential interference of these organisms. To evaluate microbial interference, samples in triplicate were prepared by spiking inactivated SARS-CoV-2 at a concentration of 3X LoD and with the potentially interfering microorganism at high concentration in negative swab in Nest matrix. One sample was tested without microorganism to serve as a reference. Results showed that high concentration of microorganisms that are commonly found in respiratory specimens and have ≥80% homology to the SARS-CoV-2 primers or probes do not interfere with the detection of SARS-CoV-2 when present at low concentration.

5) Endogenous/Exogenous Interference Evaluation:

Interference with potentially interfering endogenous and exogenous substances commonly found in upper respiratory samples was evaluated to assess their impact on assay performance. Inactivated SARS-CoV-2 was serially diluted to a concentration of 3X LoD in negative NP swab Nest patient matrix, and the Interfering Substances were spiked into the SARS-CoV-2 sample at the concentrations showed in Table 9. One sample prepared with PBS instead of interfering substance served as a reference. Triplicate samples were prepared. No relevant interferences were detected. Therefore, none of the potentially interfering substances (at the

concentrations tested) affected the detection of SARS-CoV-2 by the Gx HTIQ SARS-CoV-2 Test.

Table 9. Endogenous/Exogenous Interference Study Results

Interference Substance	with SARS-CoV-2 virus	
	RNaseP gene positive/tested	N1 gene positive/tested
Sore Throat Spray (5% v/v)	3/3	3/3
Mouth Wash (5% v/v)	3/3	3/3
Cough Syrup (5% v/v)	3/3	3/3
Nicotine (.03 mg/ml)	3/3	3/3
Toothpaste (.5% v/v)	3/3	3/3
Human Genomic DNA (10ng/uL)	3/3	3/3
Afrin Original Nose Spray (15% v/v)	3/3	3/3
Cough Lozenges (3 mg/mL)	3/3	3/3
Nasacort Allergy 24HR (glucocorticoid) Nasal Spray (10% v/v)	3/3	3/3
Whole Blood (K_2EDTA collection tube) (2.5%)	3/3	3/3
PBS (10% v/v)	3/3	3/3
Mucin (2.5 mg/mL)	3/3	3/3

6) Specimen Stability:

Specimen stability was evaluated to support claims for storage of MT samples in NEST VTM. Specimens were stable for a total of 142 hours including collection (2 hours) and this included shipping under summer and winter conditions (56 hours) and storage at room temperature or refrigerated upon arrival (84 hours).

7) Clinical Evaluation (Symptomatic Patient Group):

The clinical evaluation study was performed on 209 (mid-turbinate and anterior swab) samples from patients suspected of COVID-19 by their healthcare provider. Samples were collected at multiple collections sites served by RCA Laboratory Services LLC dba GENETWORx. Samples (n=201) received for routinary testing between August 3 and August 18, 2023, that

meet inclusion/exclusion criteria were prospectively included in the study without any other pre-selection. The study also included eight positive samples (7 MT and 1 AN) collected between August 29 and September 9, 2023, which were added to increase the number of positive samples and have at least 30 positive samples for each type of swab. Following the clinical testing, all samples were archived by freezing (-70ºC) and once sufficient samples were obtained, the samples were de-identified and tested by the Gx HTIQ SARS-COV2 Test method and the comparator test. R&D personnel conducting the study were blinded as to the production test data to avoid bias and the comparator and candidate tests runs were performed by separate technologists in blind fashion.

The study included 141 anterior nasal and 68 mid-turbinate swab samples collected in NEST device. According to the comparator test, there were 30 AN and 31 MT positive samples for a total of 61 positive samples, including low positive samples, and there were 111 AN and 37 MT negative samples for a total of 148 negative samples. Testing with the Gx HTIQ SARS-COV2 Test resulted in two false negative and one false positive result in the AN specimens and one false negative result in the MT specimens. The three false negative results (two in AN specimen and one in MT specimen) corresponded to the three samples with the lowest positivity tested according to the comparator assay. These samples had Ct values higher than the Ct value observed at the LoD of the comparator assay, indicating viral loads at or below 95% of the LoD of the comparator assay.

The calculated OPA, PPA, and NPA for the combined AN and MT sample set were 98.1%, 95.1%, and 99.3%, respectively and meet the ≥95% agreement criteria (**Table 10).**

Table 10. Clinical Evaluation Summary - Symptomatic

		Comparator Test	
		Positive	**Negative**
Gx HTIQ SARS-COV2 Test	**Positive**	58	1
	Negative	3	147

OPA: 98.1%, 95%CI = 95.2% - 99.3%
PPA: 95.1%, 95%CI = 86.5% - 98.3%
NPA: 99.3%, 95%CI = 96.3% - 99.9%

Clinical Evaluation (Screening of Individuals Without Symptoms or other reasons to suspect COVID-19 Group):

The clinical evaluation for screening of individuals without symptoms or other reasons to suspect COVID-19 was performed on 159 AN and 88 MT nasal samples collected consecutively over several time periods. Samples were tested by the Gx HTIQ SARS-COV2 Test method and the comparator test. There were 61 positive and 186 negative sample results by the comparator test. The Gx HTIQ SARS-CoV-2 test produced one False Positive result and three False Negative results. The OPA, and PPA were demonstrated as ≥95% acceptance criteria and the PPA lower bound of the two-sided 95% confidence interval >76%, meeting acceptance criteria. Additionally, the NPA was ≥98% with its lower bound of the two-sided 95% confidence interval as >95%, showing acceptance criteria were also met (Table 11).

Table 11. Clinical Evaluation Summary - Asymptomatic

		Comparator Test	
		Positive	**Negative**
Gx HTIQ SARS-COV2 Test	**Positive**	58	1
	Negative	3	185
OPA: 98.4%, 95%CI = 96.0%-99.4% PPA: 95.1%, 95%CI = 86.5%-95.1% NPA: 99.5%, 95%CI = 97.0%-99.5%			

Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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.
- Detection of RNase P indicates that human nucleic acid is present and implies that human biological material was collected and successfully extracted and amplified. It does not necessarily indicate that the specimen is of appropriate quality to enable detection of SARS-CoV-2.

WARNINGS

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