EMERGENCY USE AUTHORIZATION (EUA) TEST SUMMARY FOR THE *Helix Diagnostics – SARS nCoV-2019 Multiplexed Assay*

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

The *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* is an LDT that will be performed at the *Helix Diagnostics* located at *6620 Highland Rd. Waterford, MI 48327*, 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 *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* is intended for the *in vitro* qualitative detection of RNA from SARS-CoV-2 in individual human anterior nasal swab samples collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week.

Testing is limited to ***Helix Diagnostics*** laboratory located at ***6620 Highland Rd. Waterford, MI 48327***, 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 *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* 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 *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* 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.

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

This test is authorized under the Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing (https://www.fda.gov/media/154111/download) for use in Helix Diagnostics, that is certified under CLIA and meets requirements to perform high complexity tests, in which it was developed for qualitative detection of RNA from SARS-CoV-2 in individual human anterior nasal swab samples collected by a healthcare provider (HCP) or self-collected under the supervision of an HCP from individuals, including individuals without symptoms or other reasons to suspect COVID-19, when tested at least once per week 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 *Helix Diagnostics SARS nCoV-2019 Multiplexed 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 SARS-CoV-2 in anterior nasal swab specimens that were collected from individuals, including individuals without symptoms or other reasons to suspect COVID-19.

Nucleic acids are isolated and purified from anterior nasal swabs using a nucleic acid extraction system. The purified nucleic acid is reverse transcribed into cDNA and amplified in one step by combining purified nucleic acid with the CoViPLEXm master mix. In the process, the probe anneals to a specific N1 and N2 target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades the probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle for each target for 45 cycles using Fam to detect the N1 gene, VIC to detect the N2 gene, and Rox to detect RNASE P.

INSTRUMENTS USED WITH TEST

Instruments

The *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay***,** a real-time RT-PCR test, is to be used with the Applied Biosystems MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit on ThermoFisher KingFisher Flex instrumentation, and the Applied Biosystems QuantStudio7 Pro

and QuantStudio 5 instrumentation with the QuantStudio Design and Analysis ver. 2.4 Software.

Reagents

The primary reagents used in *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* :

Kits and Reagents	Manufacturer	Catalog #
2X InhibiTaq Multiplex qPCR MasterMix	Empirical Bioscience	ITMP-MM-100-PC
RTScript™ , 200U/uL	Empirical Bioscience	RT-200-PC
Diluted Primer/Probe Mix	Empirical Bioscience	CPPM-100uL-PC

Sample Type	Expiration
Swab Media	5 days or 120 hours

Panel/Test	Acceptable Specimen Types
SARS CoV-2	VTM (See "Acceptable VTM Types"), Amies Media

VTM Tube	Top Color	Tube Volume	Media Color
Remel MicroTest	Orange	5 mL	Orange
Puritan Unitranz	Red	2.5 mL	Red
NEST VTM	Yellow	5 mL or 2.5 mL	Red
Beaver Biomedical Viral Transport Media	Red	5 mL	Clear
NEST Saliva Tube	White	5 mL	Blue
Lingen Disposable Virus Sampling Kits	Red	5 mL	Clear
MANTACC Viral Transport Kits	Red	5 mL	Red
Ardent Biomed Disposable Sampling Tubes	White	5 mL	Clear
PrimeStore-MTM	Clear	2.5 mL	Clear
RMBIO VTM	Red	5 mL	Clear
CITOTEST VTM	White	5 mL	Orange

CONTROL MATERTIAL(s) TO BE USED WITH *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay**:***

Controls that are used with the test include:

a) A "no template" (negative) control is needed to detect contamination in both the extraction and the assay plating process. A no template control is included in the extraction process and run through plating and analysis. Amplification of this extraction control from any of the three targets tested indicates contamination on the plate and the entire plate is re-extracted and rerun.

b) A positive template control is needed to determine the viability of the run to show potential positive patients. Two positive template controls are used in the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay*, a previously tested positive patient control and a positive plasmid control. The positive patient control is used as both a positive patient control and an RT control. The positive plasmid control is a 2x LoD concentration and is included at the assay step.

c) A negative patient control is needed to determine the possibility of potential negative patients on the run. A previously tested patient is included in every qPCR run to ensure the patient's RNaseP results are legitimate.

d) An extraction control is needed to determine that the extraction of patient samples was completed successfully and is multiplexed in with every sample's results. This serves as both an extraction control and an internal control. RNaseP is a constitutively expressed sequence in human epithelial cells, this target is run to show that nucleic acid extraction was successful and that each patient's N1 and N2 results are legitimate.

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.

Examination and Interpretation of Control Results

The following result evaluation rules apply to the controls of every nCoV-2019 plate run:

- No Template Control (NTC)
  - Expected result: No amplification of any target
  - If amplification is <40 for any target, all elution plates must be re-plated
- Patient Negative
  - Expected result: Amplification of RNase P, no amplification of N1 or N2
  - If there is no RNase P amplification for any patient, the plate must be re-plated
  - If N1 and/or N2 amplification is present, the entire 384-well plate must be re-plated
- CoVi Positive Control
  - Expected Result: Amplification of RNase P, N1, and N2
  - If no amplification, or amplification is ≥ 37.5, refer to the Patient Positive Control as an alternate positive control for the assay.
- Patient Positive Control
  - Expected Result: Amplification of RNase P, N1, and N2
  - If there is no amplification of RNase P in the Patient Positive Control
    - Samples that are strongly positive for both N1 and N2 (Ct values 40 or absent) –

are acceptable and should be reported as positive

- If there is no amplification of N1 or N2 in the Patient Positive Control, the entire plate must be repeated.

- Review the Extraction NTC of each elution plate that has been plated on the 384-well plate. The well location of the NTC for each elution plate can be found on the Elution Plate Maps or the extraction workflow for each respective elution plate.
  - Expected Result: No amplification of any target
  - If RNase P amplification is observed at a Ct value <40 all samples from that elution plate must be re-extracted.
  - If N1 or N2 amplification is observed at a Ct value <40, all samples from that elution plate must be re-extracted.

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.

Every patient's curve resulting from the qPCR process is checked by a member of the molecular staff. Samples that are <37.5 Ct for N1 and N2 are considered positive. Samples with Ct values between 37.5 ≤ Ct < 40 are pulled for re-extraction to confirm suspicious results. If the re-extraction is consistent with the first run, the sample is sent out as "indeterminate." Samples that have a Ct above 40 for N1 and N2 are considered negative. Samples that do not show amplification of N1 or N2 are considered negative. Suspicious looking curves or potential false positive results are re-extracted and rerun. Samples that do not show amplification for RNaseP are re-extracted and rerun. Please see the below chart for the result evaluation rules.

Result Interpretation.

N1 (Ct)	N2 (Ct)	Reported Result
< 37.5	< 37.5	**Positive**
≥ 37.5, < 40	≥ 37.5, < 40	**Indeterminate**
≥ 40	≥ 40	**Negative**
< 37.5	≥ 37.5, < 40	Re-extract then **Positive** if concordant
	≥ 40	Re-extract then **Positive** if concordant
≥ 37.5, < 40	< 37.5	Re-extract then **Indeterminate** if concordant
≥ 40		Re-extract then **Indeterminate** if concordant
≥ 37.5, < 40	< 37.5	Re-extract then **Indeterminate** if concordant
	≥ 40	Re-extract then **Indeterminate** if concordant
< 37.5	≥ 37.5, < 40	Re-extract then **Positive** if concordant
≥ 40		Re-extract then **Indeterminate** if concordant

Rnase P (Ct)	Reported Result
< 40	**Valid**
≥ 40	**Invalid***

*** NOTE: Samples that are strongly positive for both N1 and N2 but have weak/no amplification for RNase P are acceptable and should be reported as positive**

PERFORMANCE EVALUATION

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

The LoD for the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* was evaluated and verified using ***ATCC VR-1986HK Heat inactivated nCoV-2019 Virus*** 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 Applied Biosystems MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit and the reverse transcription RT-PCR was performed using the ***QuantStudio7 Pro or QuantStudio5 Real-time PCR Machine with the QuantStudio Design and Analysis software ver. 2.4***. Preliminary and Confirmation LoD results are included in the tables below.

Preliminary Determination of LoD

Virus Concentration	Target 1 Ct Value	Target 2 Ct Value	Internal Control Ct Value	# of Replicates
10 copies/uL	34.89	34.03	34.15	20
5 copies/uL	35.90	34.97	35.55	20
2 copies/uL	37.35	36.68	36.85	20
1 copy/uL	38.60	38.20	38.53	20

LoD Confirmation:

Targets	Target 1	Target 2
Analyte Concentration	2 copies/uL	2 copies/uL
Positives/Total	19/20	20/20
% Detected	95%	95%
Mean Ct	37.35	36.68
Mean SD	0.80	1.01
CV	2.1%	2.8%

The data confirmed the assay analytical sensitivity is ***2 copies/uL***.

2) Inclusivity (Analytical Reactivity):

An alignment was performed with the oligonucleotide primer and probe sequences of the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* with 831,910 Global Genome Sequences and 295,775 U.S. 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 GISAID to demonstrate the predicted inclusivity of the assay.

Note: These are the same primer/probe sequences used in the CDC SARS CoV-2 assay.

Primer/ Probe	N2 Forward			N2 Probe			N2 Reverse	
Location	4	8	16	7	10	13	4	13
Mismatch Nucleotide	C>T	C>T	G>T	T>C	C>T	C>T	C>A	G>A
Mismatch Number (Global)	1010	1723	2362	1051	13621	1583	2004	959
Mismatch Frequency % (Global)	0.12	0.21	0.28	0.13	1.64	0.19	0.24	0.12
Mismatch Number (US)	285	873	231	1018	8997	569	1273	377
Mismatch Frequency % (US)	0.1	0.3	0.08	0.34	3.04	0.19	0.43	0.13

Primer/Probe	N1 forward				N1 reverse	N1 probe							
Location (5'>3')	4	5	9	14	15	2	3	4	5	13	18	22	24
Mismatch Nucleotide	C>T	C>T	A>G	G>T	G>T	C>T	C>T	C>T	C>T	G>T	G>T	A>G	C>T
Mismatch No. (Global)	909	1,175	3,247	2092	440	2073	12899	1958	2387	699	859	753	397
Mismatch Frequency % (Global)	0.11	0.14	0.39	0.7	0.05	0.03	1.55	0.24	0.29	13	0.1	0.091	0.05
Mismatch No. (US)	131	526	1024	520	425	193	10915	1163	1107	147	373	716	310
Mismatch Frequency % (US)	0.04	0.18	0.35	0.18	0.14	0.07	3.69	0.39	0.37	0.08	0.13	0.24	0.11

Helix Diagnostics SARS nCoV-2019 Multiplexed Assay

Oligo Name	Target	Sequence
N1 Forward	Nucleocapsid N1 gene SARS-Cov-2	GAC CCC AAA ATC AGC GAA AT
N1 Reverse	Nucleocapsid N1 gene SARS-Cov-2	TCT GGT TAC TGC CAG TTG AAT CTG
N1 Probe	Nucleocapsid N1 gene SARS-Cov-2	ACC CCG CAT TAC GTT TGG TGG ACC
N2 Forward	Nucleocapsid N2 gene SARS-Cov-2	TTA CAA ACA TTG GCC GCA AA
N2 Reverse	Nucleocapsid N2 gene SARS-Cov-2	GCG CGA CAT TCC GAA GAA
N2 Probe	Nucleocapsid N2 gene SARS-Cov-2	ACA ATT TGC CCC CAG CGC TTC AG

RPP Forward	Ribonuclease P gene	AGA TTT GGA CCT GCG AGC G
RPP Reverse	Ribonuclease P gene	GAG CGG CTG TCT CCA CAA GT
RPP Probe	Ribonuclease P gene	TTC TGA CCT GAA GGC TCT GCG CG

3) Cross-reactivity (Analytical Specificity):

Analytical specificity of the primer/probe combination for *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* 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 *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* primer probe set.

Pathogen	Strain	Target 1	Target 2
Coronavirus	**HKU1**	**Negative**	**Negative**
Coronavirus	**NL63**	**Negative**	**Negative**
Coronavirus	**OC43**	**Negative**	**Negative**
Coronavirus	**229E**	**Negative**	**Negative**
Influenza A	**H1-2009**	**Negative**	**Negative**
Influenza A	**A/H3**	**Negative**	**Negative**
Influenza B	**-**	**Negative**	**Negative**
Parainfluenza 3	**-**	**Negative**	**Negative**
Rhinovirus	**-**	**Negative**	**Negative**
RSVA/B	**-**	**Negative**	**Negative**

4) Accuracy

Accuracy was determined by testing 40 samples in triplicate consisting of 20 contrived Positive samples made from Puritan transport media at a 2X LOD and 20 negatives. Acceptable concordance will be 95%. Concordance was found to be 100%. See the table below for concordance results.

Sample (2x LoD)	Replicate 1	Replicate 2	Replicate 3	Replicate 1	Replicate 2	Replicate 3
Target	N1 (Ct)	N1 (Ct)	N1 (Ct)	N2 (Ct)	N2 (Ct)	N2 (Ct)
Sample 1	35.41	34.87	35.41	34.81	35.09	35.68

Sample 2	35.51	36.04	35.65	35.09	35.07	35.58
Sample 3	34.97	35.21	35.52	35.65	35.05	34.89
Sample 4	35.89	34.92	35.78	35.73	35.28	34.72
Sample 5	35.67	35.41	35.98	37.27	35.38	35.89
Sample 6	36.36	35.52	35.68	36.52	35.06	34.1
Sample 7	35.57	34.84	35.81	34.93	35.12	35.45
Sample 8	35.5	36.72	34.92	34.88	35.62	34.83
Sample 9	35.52	34.52	35.2	35.35	34.38	35.29
Sample 10	35.69	35.59	35.54	35.46	35.57	35.99
Sample 11	35.65	35.31	35.29	35.17	34.95	36.37
Sample 12	35.18	35.44	36.25	35.05	35.16	36.32
Sample 13	35.14	35.42	35.41	34.92	35.07	34.55
Sample 14	36.79	35.97	34.91	35.67	34.84	35.62
Sample 15	35.26	36.82	35.7	35.07	36.49	35.21
Sample 16	35.11	35.59	35.99	35.11	35.46	35.72
Sample 17	36.6	36.78	36.72	35.67	35.39	35.85
Sample 18	35.96	35.6	35.14	35.7	35.91	35.66
Sample 19	35.8	35.47	36.02	35.04	36.12	35.3
Sample 20	35.43	35.97	36.66	36.52	36.13	35.65

5) Precision (Reproducibility)

The precision of the assay was determined through repeating 5 replicates of samples at near-LoD concentrations on 4 occasions over the span of 4 days. A set of specimens were run on day 1, 8 hours apart and on day 4, 8 hours apart. The assay was determined to be reproducible at the 2 copy/uL level. The table below shows the results.

Copy Number	Day 1-1	Day 1-2	Day 4-1	Day 4-2
1 copy/uL	3/5 Positive	5/5 Positive	3/5 Positive	4/5 Positive
2 copies/uL	5/5 Positive	5/5 Positive	5/5 Positive	5/5 Positive
5 copies/uL	5/5 Positive	5/5 Positive	5/5 Positive	5/5 Positive

6) Clinical Evaluation:

Clinical evaluation of the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* was conducted with 20 individual natural positive and 20 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). This study was performed using retrospective samples.

Based on the most recent communication dated 1/28/2022, the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* was not within the scope of the FDA LDT submission guidelines for further review due to a lack of the minimum volume of correlated clinical samples. Clinical evaluation of the *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* was further conducted with 70 clinical anterior nasal swab specimens collected from patients suspected of SARS-CoV-2 infection by a healthcare provider in COVID-19 disease endemic region(s). Nucleic acid was extracted from all specimens using the Applied Biosystems MagMAX™ Viral/Pathogen Nucleic Acid Isolation Kit and reverse transcription Real-time-PCR was performed using Applied Biosystems QuantStudio 7 Pro and Design and Analysis Software. Clinical results yielded 31 positive for SARS-CoV-2 and 39 negative for SARS-CoV-2.

These same 70 clinical anterior nasal swab specimens were subsequently run on the FDA EUA-approved Abbott Alinity m instrument and results were compared. This evaluation yielded 100% concordance between *Helix Diagnostics SARS nCoV-2019 Multiplexed Assay* and the FDA EUA-approved Abbott Alinity m.

Data for the correlation study with the FDA EUA-approved Abbott Alinity m 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.

Result	***Helix Diagnostics SARS nCoV-2019 Multiplexed Assay***	**Abbott Alinity m**		**Total**	**% Performance Agreement**	**Concordance**
	Total	**Detected**	**Not Detected**			
Positve	31	31	0	31	PPA= 31/31	100%
Negative	39	0	39	39	NPA= 39/39	100%

As our original clinical correlation was performed much earlier in the pandemic, we feel that these new patient correlation points address a few issues; 1) the additional correlation data would put the Helix Diagnostics assay within scope of the minimum requirement of 30 positive and 30 negative samples correlated with an FDA EUA authorized assay and, 2) is more current with the multiple variants now present within the population. Please see the table below for the additional

patient correlation data required.

EUA Sample ID	Clinical Information Response	*Helix Diagnostics SARS nCoV-2019 Multiplexed Assay*				*Abbott Alinity m*	
		Raw Data			Result Interpretation	Raw Data	Result Interpretation
		N1 (Ct)	N2 (Ct)	RNase P (Ct)		CN	
EUA 01	Anterior Nasal Swab	25.46	28.66	25.73	Positive	26.78	Positive
EUA 02	Anterior Nasal Swab	32.08	32.59	26.43	Positive	26.55	Positive
EUA 03	Anterior Nasal Swab	36.29	36.21	24.23	Positive	34.88	Positive
EUA 04	Anterior Nasal Swab	33.06	31.94	27.18	Positive	27.98	Positive
EUA 05	Anterior Nasal Swab	23.93	23.55	25.34	Positive	17.79	Positive
EUA 06	Anterior Nasal Swab	29.76	29.43	28.94	Positive	19.70	Positive
EUA 07	Anterior Nasal Swab	31.20	30.70	25.38	Positive	25.60	Positive
EUA 08	Anterior Nasal Swab	25.11	24.52	25.67	Positive	19.49	Positive
EUA 09	Anterior Nasal Swab	29.33	29.15	25.69	Positive	23.87	Positive
EUA 10	Anterior Nasal Swab	23.62	22.72	27.46	Positive	17.78	Positive
EUA 11	Anterior Nasal Swab	26.81	26.57	21.43	Positive	25.75	Positive
EUA 12	Anterior Nasal Swab	23.61	23.66	25.06	Positive	17.87	Positive
EUA 13	Anterior Nasal Swab	24.56	25.00	24.43	Positive	19.43	Positive
EUA 14	Anterior Nasal Swab	19.40	19.97	24.16	Positive	15.00	Positive
EUA 15	Anterior Nasal Swab	25.71	25.75	28.01	Positive	19.63	Positive
EUA 16	Anterior Nasal Swab	24.51	24.77	27.82	Positive	16.83	Positive
EUA 17	Anterior Nasal Swab	22.72	22.72	25.41	Positive	18.66	Positive
EUA 18	Anterior Nasal Swab	25.97	25.61	32.72	Positive	18.44	Positive
EUA 19	Anterior Nasal Swab	31.29	31.32	25.90	Positive	25.47	Positive
EUA 20	Anterior Nasal Swab	24.10	23.94	26.11	Positive	20.90	Positive
EUA 21	Anterior Nasal Swab	21.38	21.51	25.93	Positive	17.33	Positive
EUA 22	Anterior Nasal Swab	23.82	23.05	29.60	Positive	16.89	Positive
EUA 23	Anterior Nasal Swab	19.97	18.96	24.15	Positive	14.52	Positive
EUA 24	Anterior Nasal Swab	35.38	36.14	24.23	Positive	30.35	Positive
EUA 25	Anterior Nasal Swab	26.28	24.82	27.97	Positive	21.24	Positive
EUA 26	Anterior Nasal Swab	25.59	26.05	30.32	Positive	21.68	Positive
EUA 27	Anterior Nasal Swab	20.25	20.16	24.13	Positive	16.90	Positive
EUA 28	Anterior Nasal Swab	26.35	26.73	25.76	Positive	22.97	Positive
EUA 29	Anterior Nasal Swab	36.93	36.42	26.61	Positive	34.92	Positive
EUA 30	Anterior Nasal Swab	22.10	21.79	24.73	Positive	18.43	Positive
EUA 31	Anterior Nasal Swab	32.28	32.00	25.44	Positive	29.08	Positive
EUA 32	Anterior Nasal Swab	Undetermined	Undetermined	28.45	Negative	Not Detected	Negative
EUA 33	Anterior Nasal Swab	Undetermined	Undetermined	29.05	Negative	Not Detected	Negative
EUA 34	Anterior Nasal Swab	Undetermined	Undetermined	30.75	Negative	Not Detected	Negative
EUA 35	Anterior Nasal Swab	Undetermined	Undetermined	32.47	Negative	Not Detected	Negative

EUA 36	Anterior Nasal Swab	Undetermined	Undetermined	30.60	Negative	Not Detected	Negative
EUA 37	Anterior Nasal Swab	Undetermined	Undetermined	31.75	Negative	Not Detected	Negative
EUA 38	Anterior Nasal Swab	Undetermined	Undetermined	29.12	Negative	Not Detected	Negative
EUA 39	Anterior Nasal Swab	Undetermined	Undetermined	28.90	Negative	Not Detected	Negative
EUA 40	Anterior Nasal Swab	Undetermined	Undetermined	27.70	Negative	Not Detected	Negative
EUA 41	Anterior Nasal Swab	Undetermined	Undetermined	28.14	Negative	Not Detected	Negative
EUA 42	Anterior Nasal Swab	Undetermined	Undetermined	31.06	Negative	Not Detected	Negative
EUA 43	Anterior Nasal Swab	Undetermined	Undetermined	31.29	Negative	Not Detected	Negative
EUA 44	Anterior Nasal Swab	Undetermined	Undetermined	29.54	Negative	Not Detected	Negative
EUA 45	Anterior Nasal Swab	Undetermined	Undetermined	28.77	Negative	Not Detected	Negative
EUA 46	Anterior Nasal Swab	Undetermined	Undetermined	29.10	Negative	Not Detected	Negative
EUA 47	Anterior Nasal Swab	Undetermined	Undetermined	28.64	Negative	Not Detected	Negative
EUA 48	Anterior Nasal Swab	Undetermined	Undetermined	27.50	Negative	Not Detected	Negative
EUA 49	Anterior Nasal Swab	Undetermined	Undetermined	28.41	Negative	Not Detected	Negative
EUA 50	Anterior Nasal Swab	Undetermined	Undetermined	30.10	Negative	Not Detected	Negative
EUA 51	Anterior Nasal Swab	Undetermined	Undetermined	30.76	Negative	Not Detected	Negative
EUA 52	Anterior Nasal Swab	Undetermined	Undetermined	32.78	Negative	Not Detected	Negative
EUA 53	Anterior Nasal Swab	Undetermined	Undetermined	27.69	Negative	Not Detected	Negative
EUA 54	Anterior Nasal Swab	Undetermined	Undetermined	27.53	Negative	Not Detected	Negative
EUA 55	Anterior Nasal Swab	Undetermined	Undetermined	27.64	Negative	Not Detected	Negative
EUA 56	Anterior Nasal Swab	Undetermined	Undetermined	26.74	Negative	Not Detected	Negative
EUA 57	Anterior Nasal Swab	Undetermined	Undetermined	30.24	Negative	Not Detected	Negative
EUA 58	Anterior Nasal Swab	Undetermined	Undetermined	31.73	Negative	Not Detected	Negative
EUA 59	Anterior Nasal Swab	Undetermined	Undetermined	30.67	Negative	Not Detected	Negative
EUA 60	Anterior Nasal Swab	Undetermined	Undetermined	28.02	Negative	Not Detected	Negative
EUA 61	Anterior Nasal Swab	Undetermined	Undetermined	29.33	Negative	Not Detected	Negative
EUA 62	Anterior Nasal Swab	Undetermined	Undetermined	27.62	Negative	Not Detected	Negative
EUA 63	Anterior Nasal Swab	Undetermined	Undetermined	25.60	Negative	Not Detected	Negative
EUA 64	Anterior Nasal Swab	Undetermined	Undetermined	27.60	Negative	Not Detected	Negative
EUA 65	Anterior Nasal Swab	Undetermined	Undetermined	28.85	Negative	Not Detected	Negative
EUA 66	Anterior Nasal Swab	Undetermined	Undetermined	27.96	Negative	Not Detected	Negative
EUA 67	Anterior Nasal Swab	Undetermined	Undetermined	30.38	Negative	Not Detected	Negative
EUA 68	Anterior Nasal Swab	Undetermined	Undetermined	32.63	Negative	Not Detected	Negative
EUA 69	Anterior Nasal Swab	Undetermined	Undetermined	27.02	Negative	Not Detected	Negative
EUA 70	Anterior Nasal Swab	Undetermined	Undetermined	26.57	Negative	Not Detected	Negative

LIMITATIONS

- The initial performance of this test was established based on the evaluation of a limited number of clinical specimens collected between 10/4/2020 and 10/6/2020 and were collected from various collection sites throughout the state of Michigan within the United States. 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.

- 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.