EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
Clear Dx SARS-CoV-2 WGS v3.0 Test
(Labcorp)

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

The Clear Dx SARS-CoV-2 WGS v3.0 Test will be performed at laboratories designated by Labcorp that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests as described in the Clear Dx SARS-CoV-2 WGS v3.0 Test Standard Operating Procedure that was reviewed by the FDA under this EUA.

INTENDED USE

The Clear Dx SARS-CoV-2 WGS v3.0 Test is a next generation sequencing (NGS) test on the MinION sequencer from Oxford Nanopore Technologies (ONT) intended for the identification and differentiation of SARS-CoV-2 Phylogenetic Assignment of Named Global Outbreak (PANGO) lineages, when clinically indicated, from individuals with a positive SARS-CoV-2-diagnostic test result. Testing is limited to laboratories designated by Labcorp that are certified under Clinical Laboratory Improvements Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The Clear Dx SARS-CoV-2 WGS v3.0 Test is intended to be used in conjunction with patient history and other diagnostic information, when clinically indicated, i.e., in situations where results may aid in determining appropriate clinical management. Results of this test are intended to be interpreted by the ordering health care professional. The test is not intended for use as an aid in the primary diagnosis of infection with SARS-CoV-2 or to confirm the presence of SARS-CoV-2 infection, and it is not intended for identification of specific SARS-CoV-2 genomic mutations. Results should not be used as the sole basis for treatment or other patient management decisions.

The Clear Dx SARS-CoV-2 WGS v3.0 Test is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the operation of the Clear Dx system, the MinION sequencer and next generation sequencing workflows, as well as in vitro diagnostic procedures. The Clear Dx SARS-CoV-2 WGS v3.0 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Clear Dx SARS-CoV-2 WGS v3.0 Test is a GridION Nanopore based whole genome sequencing assay used for the determination of PANGO lineage from extracted RNA of SARS-CoV-2 diagnostic test positive samples. This test is run on the Clear Dx system and can process up to 28 patient samples in a run.

Total nucleic acid extract from residual SARS-CoV-2-positive samples from individuals with a positive SARS-CoV-2 diagnostic test result is used with The Clear Dx SARS-CoV-2 WGS v3.0

Test. Two hundred (200) uL of each specimen is extracted using either the KingFisher Flex (Thermo Fisher) or the MagNA Pure 24 system (Roche Molecular). Residual nucleic acid extract can be stored at -20°C for up to 33 days through up to 2 freeze-thaw cycles.

The Clear Dx system (illustrated in Figure 1) uses a Hamilton STAR robotic platform for automation of liquid handling and includes all the required ancillary equipment, such as thermocyclers, barcode reader, and magnet block, needed for the test. The system also houses the GridION Nanopore sequencer developed by Oxford Nanopore Technologies (ONT).

Figure 1. Clear Dx System

The testing procedure is automated and only requires the user to set up the liquid handling deck with extracted RNA, reagents and consumables and start the program. On the Clear Dx system, the extracted RNA for each of the samples is converted to cDNA in independent reverse transcription reactions. The synthesized cDNA is then amplified in multiplexed PCR reactions to generate twenty-nine tiled amplicons, each of approximately 1,200 bp in length, that covers nearly 99.4% of the SARS-CoV-2 genome. Two PCRs are performed for each SARS-CoV-2 positive patient sample to be sequenced with one reaction containing 15 different primer sets and a second reaction containing 14 different primer sets. After PCR, the two amplicon pools are combined, and a Solid Phase Reversible Immobilization (SPRI) bead-based cleanup is performed to remove the excess primers and any short amplification products.

Fragmentation is performed with a transposon complex that cuts the PCR amplicons and attaches a barcoded sequence. Following this step, the barcoded amplicons from all the samples are pooled together and cleaned up through another SPRI bead process. After this step, the ONT sequencing adapters are ligated to all the barcoded amplicons and then sequenced on the GridION sequencer.

Raw sequence data are uploaded directly to the Clear Labs servers for quality control, alignment to the Wuhan reference genome, and creation of a single consensus FASTA file containing the sequence of each individual sample. When a nucleotide is called in the consensus sequence it must have at least 30 reads covering that base pair. The pipeline uses two different variant callers, Medaka (v1.0.3) and Longshot (v0.4.1), use a Neural Network and hidden Markov model respectively. The pipeline also resolved any discrepancy between the two variant callers prior to incorporating the nucleotide into the consensus sequence. Bases or regions that could not be accurately sequenced are represented by N's. After this, the FASTA files (along with raw FASTQ sequence files and intermediate files) are downloaded to Labcorp's servers by users in the Center for Bioinformatics. The SARS-CoV-2 percent genome coverage are calculated for each sample. The lineages for individual samples are then assigned using the consensus sequence as input to the PANGOLIN v4.2 analysis package. Lineage results are released for samples with at least 90% genome coverage.

INSTRUMENTS USED WITH THE TEST

The reagents, materials, instruments, and software required in order to perform the Clear Dx SARS-CoV-2 WGS v3.0 Test are presented in Table 1.

Table 1. Reagent, Material, Instrument and Software Requirements

Reagents

REAGENT	**VENDOR**	**CATALOG #**
MagMAX Viral/Pathogen Nucleic Acid Isolation kit	Fisher Scientific	A48383
MagNA Pure 24 system Nucleic Acid Isolation kit	Roche Molecular	07658036001
Clear Dx WGS SARS-CoV-2 Reagent Kit 1 v3.0	Clear Labs	800018
Clear Dx WGS SARS-CoV-2 Reagent Kit 2 v3.0	Clear Labs	800009
Clear Dx WGS SARS-CoV-2 Reagent Kit 3 v3.0	Clear Labs	800010
Clear Dx WGS SARS-CoV-2 Index Plate v3.0	Clear Labs	800019
100% absolute ethanol	VWR	EM-4455S
Nuclease free-water	Fisher Scientific	PRP1195
Material	**Vendor**	**Catalog #**
MinION Flow Cell	Oxford Nanopore Technologies	820005
Reagent Plates	Hamilton Robotics	11-0006
Sample Plate	Hamilton Robotics	11-0033
Hamilton lid cover	Hamilton Robotics	11-0009
50 µL CO-RE Filter Tips	Hamilton Robotics	11-0018
300 µL CO-RE Filter Tips	Hamilton Robotics	11-0010

Materials

MATERIAL	VENDOR	CATALOG #
MinION Flow Cell	Oxford Nanopore Technologies	820005
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Instruments

EQUIPMENT	VENDOR	CATALOG #
Clear Dx System: 1. Hamilton STAR robotic workstation 2. Hamilton On-Deck Thermal Cycler 3. Two Oxford Nanopore MinION Sequencers 4. ALPAQUA Magnum FLX on deck magnet	Clear Labs	51160-02
C1008-B Microcentrifuge	Cole-Parmer	X-17701-11
Vortex Genie-2	Stellar Scientific	SI-0236
KingFisher Flex	Thermo Fisher	5400630
MagNA Pure 24 system	Roche Molecular	07290519001

Software

SOFTWARE NAME	DEVELOPER	VERSION
Covid analysis post-processing pipeline for Clear Labs samples	Labcorp	v1.0.0
Nextclade	NextStrain project	V2.11.0
Pangolin	COVID-19 Genomics UK Consortium	v4.2
Clear Dx System Software	Clear Labs	Venus 4 version software
Command Line Interface (CLI)	Clear Labs	v1.0.7

Designated laboratories will receive an FDA accepted instrument qualification protocol included as part of Clear Dx SARS-CoV-2 WGS v3.0 Test Standard Operating Procedure (SOP) and will be directed to execute the protocol prior to testing clinical samples. Designated laboratories must follow the authorized SOP, which includes the instrument qualification protocol, as per the letter of authorization.

CONTROLS TO BE USED WITH THE TEST

1. **External Positive Control:** A positive assay control is needed to verify that the assay is performing as intended. This provides certainty of extraction, reverse transcription reaction, robotic liquid handling operations, stability of assay reagents, proper operation of other ancillary instrumentation such as thermocycler, magnets, etc. on the automation platform and the bioinformatics pipeline and reporting software. The ZeptoMetrix NATtrol SARS-CoV-2 Stock External Quality Control (Catalog #: NATSARS(COV2)-St) is used as positive control. This control consists of purified, intact SARS-CoV-2, Isolate USA-WA1/2020, at a concentration of 1,000,000 copies/mL. Extracted nucleic acids from 200 μL of this control will be used in the Clear Dx SARS-CoV-2 WGS v3.0 Test. The control is not part of the assay kit and will be acquired separately by each Labcorp lab performing the testing. One positive control is included per 14 patient specimens tested.

2. **External Negative Control:** An external non-template control (NTC) is needed to verify the absence of viral template contamination in all reagents of all steps of the workflow to monitor false positive signals. This will be accomplished by the use of molecular biology-grade water as a negative specimen, alongside other clinical specimens input in the extraction step. One negative control is included per 14 specimens tested.

3. **Other Control:** Lineage identification results are only released for samples with at least 90% genome coverage.

INTERPRETATON OF RESULTS

All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Expected results are detailed in Table 2.

1) **Positive Control:** After sequencing, the lineage designation of a given plate's positive control will be compared to the known lineage designation of the positive control. A positive control sample will be considered a failure if its assay determined lineage differs from its known lineage or if the positive control sequencing results do not achieve ≥90% of the maximum attainable genome sequence coverage.
2) **Negative Control:** After sequencing, the overall genome coverage is calculated for the NTC samples. A NTC sample will be considered a failure if it has an overall genome coverage >10%.

Table 2. Expected Results for the Clear Dx SARS-CoV-2 WGS v3.0 Test External Controls

External Control Type	Passing Criteria	Action For Control Failure
Positive	Assay determined lineage designation is concordant with known lineage designation and ≥90% of the maximum attainable genome sequence coverage is achieved	The 14 patient specimens associated with the failed positive external control will be re-analyzed starting from extraction a maximum of two additional times. If a particular specimen's residual volume is depleted and cannot be re-analyzed, the sample will be reported as "Quantity Not Sufficient for Repeat".
Negative	Overall genome coverage ≤10%	The 14 patient specimens associated with the failed negative external control are re-analyzed starting from extraction a maximum of two additional times. If a particular specimen's residual volume is depleted and cannot be re-analyzed, the sample will be reported as "Quantity Not Sufficient for Repeat".

Examination and Interpretation of Patient Sample Results:

Assessment of Clear Dx SARS-CoV-2 WGS v3.0 Test results are performed after external control analysis. The genome coverage is calculated for each patient sample. Lineage results are released for samples with >90% genome coverage. The interpretation and reporting of clinical specimens are summarized in Table 3.

Table 3. Result Interpretation for Patient Samples

Sample Level QC results	External Controls results	PangoLearn Output	Action
Pass	Pass	Lineage call	Report results to sender and appropriate public health authorities.
Pass	Pass	None	The specimen is re-analyzed starting from extraction one additional time. If the sample does not pass again, then it is reported as "Failed" * If no residual specimen volume remains for retesting, the sample will be reported as "Quantity Not Sufficient for Repeat"**
Pass	Fail	Not Applicable	The 14 patient specimens associated with the failed external control are re-analyzed starting from extraction a maximum of

Sample Level QC results	External Controls results	PangoLearn Output	Action
			two additional times. If a sample does not pass after two new attempts, then it is reported as "Failed" * If a particular specimen's residual volume is depleted and cannot be re-analyzed, the sample is reported as "Quantity Not Sufficient for Repeat".**
Fail	Pass	Not Applicable	The 14 patient specimens associated with the failed external control are re-analyzed starting from extraction a maximum of two additional times. If a sample does not pass after two new attempts, then it is reported as "Failed"* If a particular specimen's residual volume is depleted and cannot be re-analyzed, the sample is reported as "Quantity Not Sufficient for Repeat".**
Fail	Fail	Not Applicable	The 14 patient specimens associated with the failed external control are re-analyzed starting from extraction a maximum of two additional times. If a sample does not pass after two new attempts, then it is reported as "Failed"* If a particular specimen's residual volume is depleted and cannot be re-analyzed, the sample is reported as "Quantity Not Sufficient for Repeat"**

* Failed samples will be reported as: "No lineage was able to be determined. SARS-CoV-2 virus detected, but genome sequencing was unsuccessful. No lineage information can be reported."

** Samples with no remaining volume left are reported as: "Repeat analysis of this specimen is required to establish valid results. However, the quantity of specimen remaining is insufficient to repeat."

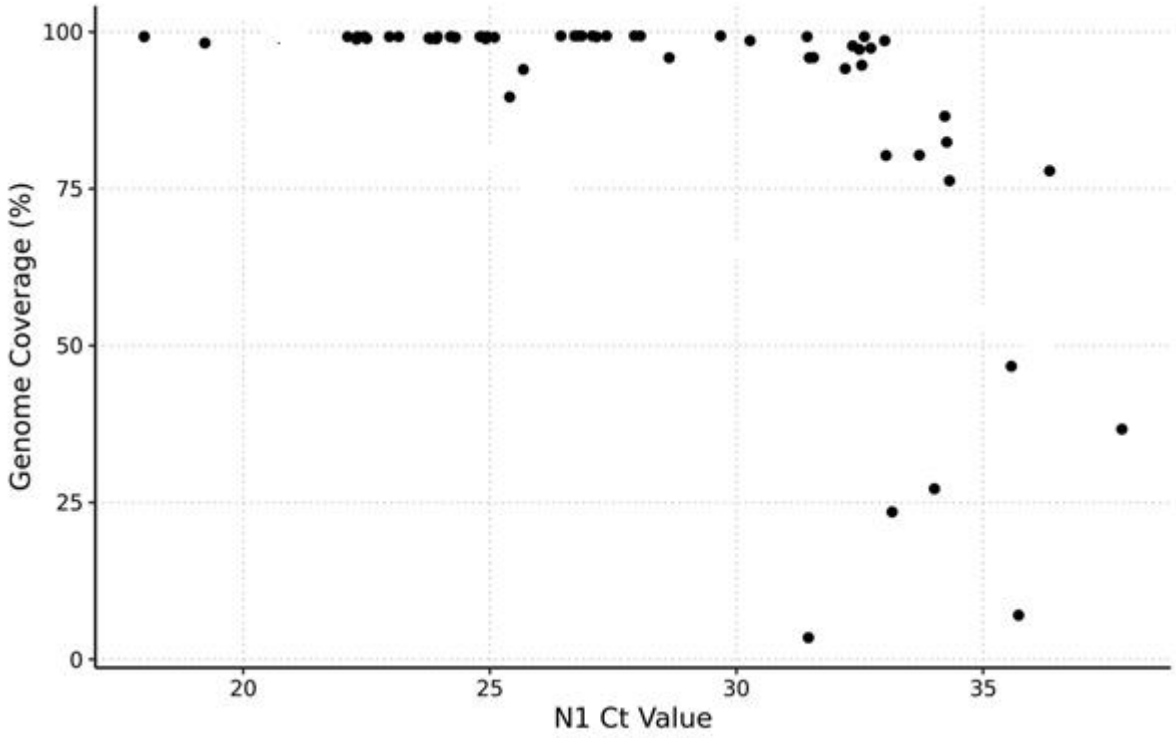
PERFORMANCE EVALUATION

1. Device Tolerance:

Labcorp COVID-19 RT-PCR Positive Samples:

61 patient specimens which tested positive for SARS-CoV-2 by the EUA authorized Labcorp COVID-19 RT-PCR Test were extracted using the Thermo Fisher KingFisher Flex system and then tested with the Clear Dx SARS-CoV-2 WGS v3.0 Test. Genome coverage of these samples are graphed against the N1 CT value in Figure 2.

Figure 2. Genome Coverage Versus Labcorp COVID-19 RT-PCR Ct Value



Out of the 38 specimens with N1 Ct value ≤ 30, 37 specimens (97.37%, 95%CI: 86.51% - 99.53%) have ≥90% genome coverage. The one specimen not meeting this criterion had 89.6% genome coverage with N1 Ct value of 25.4. Of the 23 specimens with N1 Ct values >30, 12 (52.17%, 95%CI: 32.96% - 70.76%) returned genome coverage above 90%.

Labcorp COVID-19 RT-PCR Seasonal RT-PCR Samples:

Eight (8) patient samples with Labcorp COVID-19 RT-PCR N1 Ct values between 24 and 31 were separately tested in triplicate using the Labcorp Seasonal Respiratory Virus RT-PCR Test. Passing-Bablok regression determined that a Labcorp COVID-19 RT-PCR Test N1 Ct value of 30 is equivalent to a N Ct value of 28 of the Labcorp COVID-19 RT-PCR Seasonal RT-PCR Test. Similar level of device tolerance is expected for Labcorp COVID-19 RT-PCR Seasonal RT-PCR Samples with N Ct values ≤ 28 as of Labcorp COVID-19 RT-PCR samples with N1 Ct values ≤ 30.

Hologic Aptima SARS-CoV-2 Assay Positive Samples:

27 randomly selected patient specimens which tested positive for SARS-CoV-2 by the EUA authorized Hologic Aptima SARS-CoV-2 Assay were tested with the Clear Dx SARS-CoV-2 WGS v3.0 Test. 22 of the 27 (81.48%, 95%CI: 63.3% - 91.82%) specimens tested returned genome coverage above 90%.

2. Precision (Repeatability): Intra-Assay

Intra-assay precision was assessed by testing eight (8) Labcorp COVID-19 RT-PCR Test positive patient specimens extracted using the Thermo Fisher KingFisher Flex system. Seven (7) of the patient specimen eluates were tested in triplicate and one (1) patient specimen eluate was tested in duplicate on the same run. The lineages of the eight (8) samples tested were previously determined using the Labcorp VirSeq SARS-CoV-2 NGS Test (EUA220054). All eight specimens returned lineage calls that were 100% concordant across the replicates with all replicates having at least 98.84% genome coverage and an average read depth >1,200.

3. Precision (Reproducibility): Inter-Assay

Inter-assay reproducibility was assessed by testing eleven (11) Labcorp COVID-19 RT-PCR Test positive patient specimens extracted using the Thermo Fisher KingFisher Flex system. Eight patient specimens were tested over 3 runs and 3 patient specimens were tested over 2 runs. The lineages of the eleven (11) specimens tested were previously determined using the Labcorp VirSeq SARS-CoV-2 NGS Test (EUA220054). All 11 specimens returned lineage calls that were 100% concordant across the replicates with all replicates having at least 98.24% genome coverage and an average read depth >700.

4. Sample Stability (Freeze-Thaw)

Stability of patient samples under recommended storage conditions was assessed in the sample stability study. After Nucleic Acid Amplification (NAA) diagnostic testing with Labcorp COVID-19 RT-PCR Test, extracted nucleic acid was shipped on dry ice to the testing laboratory and stored at -20°C before sequencing.

11 unique samples were defrosted and sequenced using the Clear Dx SARS-CoV-2 WGS v3.0 Test (T=0). Samples were refrozen and after 12 days of storage at -20°C, 8 of the samples were defrosted and sequenced. These samples were refrozen and after a total of 33 days of storage at -20°C, all 11 of the samples were defrosted and sequenced.

Repeat testing of RNA samples over the course of 33 days resulted in 11 out of 11 samples producing identical lineage results across three separate test days. Additionally, all samples have genome coverage of >90% and minimum read depth of 733. The result of the study supports the stability of the Clear Dx SARS-CoV-2 WGS v3.0 Test for up to 2 freeze-thaw cycles when samples are stored at -20°C for up to 33 days.

5. Concordance

Thirty (30) positive individual patient specimens tested with the Labcorp COVID-19 RT-PCR Test were extracted using the Thermo Fisher KingFisher Flex system and sequenced using both Clear Dx SARS-CoV-2 WGS v3.0 Test and the Labcorp VirSeq SARS-CoV-2 NGS Test (EUA220054). Results were assessed by determining the concordance of pangolin lineage calls across the two platforms (Table 4). The lineage results were 100% concordant.

Table 4. Comparison of PANGO Lineage Designation between Clear Dx SARS-CoV-2 WGS v3.0 Test and Labcorp VirSeq SARS-Cov-2 NGS Test

Samples Tested	Reportable Result	Concordant Reportable Result	Reportable Result Concordant %
30	30	30	100%

6. Reference Sample Testing

Heat-inactivated SARS-CoV-2 samples from B.1.1.7 (VR-3326HK), Hong Kong/VM20001061, Italy-INMI1, Delta and Omicron lineages characterized by ATCC, were used in this evaluation. Each lineage stock was diluted using negative nasal swab samples in saline prior to extraction using the Thermo Fisher KingFisher Flex system. Sequencing error associated with the Clear Dx SARS-CoV-2 WGS v3.0 Test was evaluated by comparing all mutations identified in the consensus sequences produced by the Clear Dx SARS-CoV-2 WGS v3.0 Test analysis pipeline to the published ATCC reference sequences. The results are shown in the following table:

Table 5. Number of Nucleotide Mismatch between ATCC reference sequences and Clear Dx SARS-CoV-2 WGS v3.0 Test generated sequences

ATCC strain	# Mutation Observed in Reference Sequence (Reference Mutation)	# Reference Mutation Identified in the ClearDx Consensus Sequence	#Additional Mutation Identified in the Virseq Consensus Sequence	Nucleotide sequenced	Percent (%) of Mismatch Between Clear Dx SARS-CoV-2 WGS v3.0 Test Consensus Sequence and Reference Genome
Hong Kong	11	9	0	29,686	0.0067%
Italy-INMI1	3	3	0	29,683	0.0000%
B.1.1.7	36	36	1	29,692	0.0034%
Delta	31	31	0	29,700	0.0000%
Omicron	57	57	0	28,364	0.0000%
Total	**138**	**136**	**1**	**147,125**	0.002%

Overall, an average of 0.002 % sequence differences were observed between the reference sequence and the consensus sequence produced by Clear Dx SARS-CoV-2 WGS v3.0 Test.

7. Extraction Equivalence Study

Diluted replicates of the same positive material used for reference sample testing and 3 additional clinical sample tested in triplicates were used in the extraction equivalence study of MagNA Pure 24 extraction system. After extraction with the Roche MagNA Pure 24 system, samples were tested with the Clear Dx SARS-CoV-2 WGS v3.0 Test. The lineage call for the Roche MagNA Pure extracted samples were compared to the KingFisher Flex extracted samples. The results are summarized in Table 6. The lineages calls were 100% concordant for both extraction systems.

Table. 6 Sequence and Lineage Level Concordance when using the Roche Magna Pure 24 Extraction System

Sample ID	# Concordant Lineage / # Samples Tested
Hong Kong	1/1
Italy-INMI1	1/1
B.1.1.7	1/1
Delta	1/1
Omicron	1/1
Other	9/9

8. Simulation Study

A simulation study was conducted to assess the performance of the Clear Dx SARS-CoV-2 WGS v3.0 Test to identify samples with PANGO Lineages not tested in the concordance and analytical studies.

A sequencing error model that simulates how sequencing error and ambiguous nucleotide are randomly introduced by the Clear Dx SARS-CoV-2 WGS v3.0 Test into the sequenced genome, was estimated based on the sequencing result of 20 positive control samples and 87 clinical samples. The model estimated that the Clear Dx SARS-CoV-2 WGS v3.0 Test on average have an alternate allele fraction of 2.8% at any given genomic position.

Variant of Concern/Variant of Interest Simulation

Three datasets were used in the simulation study. Dataset 1 consists of 500 historical reference sequences downloaded from GISAID (https://www.gisaid.org/) at random. Dataset 2 consists of UshER defining single nucleotide variations (SNVs) for 158 lineages newly designated in pango-designation v1.19 release. Dataset 3 consists of 5 replicates of 9 selected VOCs: B.1.1.7, P.1, B.1.617.2, BA.1, BA.2, BA.4, BA.5, BQ.1, XBB.1.5. The sequencing error model was used to introduce sequencing errors into each of the dataset. Dataset 1 and 2 was simulated at a target depth of coverage of 75X and 100X. Dataset 3 was simulated at a target depth of coverage at 25X, 50X, 75X, 100X, 150X, 200X and 300X.The PANGO Lineages of these simulated sequences are identified

with the lineage identification software (PANGOLIN v4.2) used in the Clear Dx SARS-CoV-2 WGS v3.0 Test. The lineage identification results of each simulated sequence were compared to the known PANGO Lineage Designation of the reference sequence used to produce the simulated sequence. The concordance results of simulated sequences with genome coverage of 90% - 92.5%, 92.5% - 95% and > 95% are shown in the following table:

Table 7. *In silico* performance of Clear Dx SARS-CoV-2 WGS v3.0 Test

Genome Coverage	#Sequences Tested	# Concordant Sequences	% Concordant Sequences (95% CI)
90% - 92.5%	449	431	95.99% (93.75% - 97.45%)
92.5% - 95%	232	225	96.98% (93.90% - 98.53%)
>95%	638	632	99.05% (97.96% - 99.56%)

WARNINGS AND PRECAUTIONS

• For *in vitro* diagnostic use.

• For use under FDA Emergency Use Authorization (EUA) only.

• For prescription use only.

• This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

• This product has been authorized only for the identification of SARS-CoV-2 PANGO Lineages, not for any other viruses or pathogens.

• This product has been authorized only for the identification of PANGO lineage of positive individuals with a positive SARS-CoV-2-diagnostic test result.

• 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.

• All specimens should be handled in accordance with Biosafety Level 2 practices as described in the CDC/NIH Publication, Biosafety in Microbiological and Biomedical Laboratories or other equivalent guidelines.

• Always wear gloves when performing this procedure and treat all specimens and used devices as potentially infectious.

LIMITATIONS

1. Use of the Clear Dx SARS-CoV-2 WGS v3.0 Test is limited to laboratory personnel specifically instructed and trained in the operation of the Clear Dx system, the MinION sequencer and Next Generation Sequencing workflows, as well as in vitro diagnostic procedures.
2. Performance, including invalid rate, has only been assessed with samples positive by Labcorp's COVID-19 RT-PCR TEST and Hologic's Aptima SARS-CoV-2 Assay. Positive specimens from other EUA and FDA-cleared molecular assays have not been evaluated.
3. RFU values of Hologic Aptima SARS-CoV-2 identified positive samples does not correlate with viral load and should not be used to assess the risk of obtaining an invalid result by the Clear Dx SARS-CoV-2 WGS v3.0.
4. The performance of this test was established based on the evaluation of a limited number of clinical specimens. The 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.
5. This test does not identify specific SARS-CoV-2 mutations.
6. This test was not specifically evaluated for use in conjunction with any specific mAb or antiviral product.
7. Invalid results do not preclude presence of specific SARS-CoV-2 PANGO Lineage and should not be used as the sole basis for patient management decisions.
8. PANGO Lineage results from this test should not be used as the sole basis for patient management decisions.
9. Invalid result can occur for samples with greater than 90% genome coverage.
10. Use of this assay is limited to testing residual nucleic acid extracts of diagnostic test SARS-CoV-2 positive samples as a reflexed test.
11. Lineage determination result is specific to the version of PANGO software used at time of testing and may very when PANGO software is updated.